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ASTRALIS LTD  
Form 10KSB  
March 30, 2004

U.S. SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-KSB

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES  
EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2003

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE  
ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 000-30997

ASTRALIS LTD.

(Name of small business issuer in its charter)

DELAWARE

(State or other jurisdiction of  
Incorporation or organization)

84-1508866

(I.R.S. Employer  
Identification No.)

75 PASSAIC AVENUE, FAIRFIELD, NEW JERSEY  
(Address of principal executive offices)

07004  
(Zip Code)

ISSUER'S TELEPHONE NUMBER  
(973) 227-7168

SECURITIES REGISTERED UNDER SECTION 12(B) OF THE EXCHANGE ACT:  
NONE

SECURITIES REGISTERED UNDER SECTION 12(G) OF THE EXCHANGE ACT:  
COMMON STOCK, \$.0001 PAR VALUE  
(Title of class)

Check whether the issuer (1) filed all reports required to be filed by  
Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such  
shorter period that the registrant was required to file such reports), and (2)  
has been subject to such filing requirements for the past 90 days. Yes  No

Check whether disclosure of delinquent filers in response to Item 405  
of Regulation S-B is not contained in this form, and no disclosure will be  
contained, to the best of registrant's knowledge, in definitive proxy or  
information statements incorporated by reference in Part III of this Form 10-KSB  
or any amendment to this Form 10-KSB.

State issuer's revenues for its most recent fiscal year. --

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The aggregate market value of the voting and non-voting common equity held by non-affiliates as of March 26, 2004, was approximately \$31,533,399.

As of March 26, 2004, there were 72,998,055 shares of the registrant's common stock outstanding.

Transitional Small Business Disclosure Format (check one):

Yes  No

### PART I

#### ITEM 1. DESCRIPTION OF BUSINESS

##### GENERAL

We are a development-stage biotechnology company primarily engaged in research and development of treatments for immune system disorders and skin diseases. Our current activities focus on the development of a product candidate named Psoraxine (R) for the treatment of the skin disease psoriasis. Currently, we are engaged in ongoing research and development of Psoraxine. We are also engaged in research on the possible development of the technology underlying Psoraxine for the treatment of other indications, such as eczema, seborrheic dermatitis and psoriatic arthritis.

We were originally incorporated under the laws of the State of Colorado in 1999 under the name Hercules Development Group, Inc. We subsequently changed our name to Astralis Pharmaceuticals Ltd. and, in November 2001, reincorporated under the laws of the State of Delaware under our present name. Our main office is located at 75 Passaic Avenue, Fairfield, New Jersey 07004.

##### PSORIASIS

Psoriasis is a chronic inflammatory skin disorder of currently unknown origins that generally lasts a lifetime and for which there is presently no known cure. Researchers believe that psoriasis may be caused by the immune system sending faulty signals that affect the growth cycle of skin cells. As a result, skin cells accumulate on the surface of the body faster than normal. In people without psoriasis, skin cells mature and are shed approximately every 28 days. In psoriatic skin, the skin cells mature over a period of approximately three to six days.

The symptoms of psoriasis include scaly skin and inflammation occurring on a cyclical basis, with periods of remission and relapse. There are five types of psoriasis. The most common form, appearing in approximately 80% of individuals suffering from the disease, is plaque psoriasis. The other forms are guttate, inverse, erythrodermic and pustular psoriasis. Psoriasis typically does not prevent individuals with the condition from functioning normally. However, the pain, discomfort and emotional effects may be extensive.

##### MARKET OPPORTUNITY

According to the National Psoriasis Foundation, psoriasis affects approximately 2.1% of the United States population, or more than 4.5 million people in the United States. Psoriasis also affects approximately 1% to 3% of the world's population. Approximately 150,000 to 260,000 new cases of psoriasis are diagnosed each year. In addition, each year approximately 350 people in the United States die due to complications caused by psoriasis. Primarily, such

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complications occur in relation to severe, extensive forms of psoriasis such as erythrodermic or pustular psoriasis, where large areas of skin are shed. Because the skin plays an important role in regulating body temperature and serving as a barrier to infection, when a person's skin is severely compromised, secondary infections may occur. These serious forms of psoriasis may also cause complicating factors, such as fluid loss and strain on the circulatory system.

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The National Psoriasis Foundation also indicates that between 10% and 30% of people who have psoriasis will also develop psoriatic arthritis, which is similar to rheumatoid arthritis, but generally milder. Psoriatic arthritis causes inflammation and stiffness in the soft tissue around joints, and frequently affects the fingers and toes. Psoriatic arthritis may also affect other areas of the body such as the wrists, neck, lower back, knees and ankles.

Psoriasis is a chronic illness that, in many cases, requires continuous treatment. Patients with psoriasis often pay for costly medications and face ongoing visits with physicians. Severe cases may require periods of hospitalization. The National Psoriasis Foundation estimates that the costs of treating psoriasis may exceed \$3.0 billion annually.

### PSORAXINE

Psoraxine was developed by Dr. Jose Antonio O'Daly, our chairman of the board and president of research and development. In 1991, Dr. O'Daly was conducting trials for a vaccine for leishmaniasis in Caracas, Venezuela. One patient involved in the leishmaniasis vaccine trials, who also suffered from psoriasis for 12 years, experienced complete remission of psoriasis after receiving the vaccine. As a result of this discovery, Dr. O'Daly focused his efforts on developing a product for the treatment of psoriasis. From 1992 through 2001, Dr. O'Daly developed Psoraxine, an improved version of the original product that is an immunotherapeutic agent presented in liquid form and packed in 0.5 miligram ampules for intra-muscular injection. Dr. O'Daly tested the original product that was a precursor of Psoraxine in approximately 2,900 patients in several clinical trials in Venezuela. The results from the studies provided evidence of remission of psoriasis lesions as a result of treatment with the product. In addition, individuals in the studies did not present severe side effects as a result of treatment. In one clinical study, of the 2,770 patients, 648, or 28%, experienced complete remission of psoriasis. In addition, almost half of the patients experienced psoriasis reduction of between 70% to 99% as measured by the Psoriasis Area and Severity Index ("PASI"). Additional studies yielded average PASI reductions of between 73% and 92%.

Dr. O'Daly moved to the United States in 2002 and licensed Psoraxine to us. We made capital investments to our research and development facility of approximately \$500,000 in 2002 and we filed an Investigational New Drug application with the FDA for Psoraxine in March 2003. On August 4, 2003 the FDA allowed us to commence our Phase I clinical trials for Psoraxine.

The purpose of Phase I studies is to test the safety of a drug. We have completed our Phase I studies, which involved the administration by intramuscular injection of a single dose of 50, 150 or 300 micrograms of Psoraxine or a placebo in a controlled setting to groups of psoriatic patients. We spent approximately \$130,000 on our Phase I studies in 2003 and anticipate spending an additional \$150,000 on Phase I studies in 2004. We have commenced Phase II studies. The purpose of Phase II studies is to test the safety and efficacy of a drug. We anticipate that it will take at least one year to complete the Phase II studies at a cost of not less than \$2,500,000. For the year ended December 31, 2003, we incurred \$4,045,673 in research and development

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expenses, including \$1,721,788 related to SkyePharma. For the year ended December 31, 2002, we incurred \$7,761,542 in research and development expenses, including \$6,834,399 related to SkyePharma.

### CURRENT PSORIASIS THERAPIES

The topical treatment for psoriasis has been based on the use of emollients, keratolytic agents, coal tar, anthralin, corticosteroids of medium to strong potency and calcipotriene. UVB phototherapy has been used in the treatment of moderate cases of psoriasis. For severe cases, systemic treatments include methotextrate, cyclosporine and oral retinoids. Each of these treatments has variable efficacy, with side effects and cosmetic problems in addition to the failure to prevent frequent relapses.

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### COMPETITION AND PSORIASIS TREATMENTS IN DEVELOPMENT

The pharmaceutical and biotechnology industries are intensely competitive. Many companies, including biotechnology, chemical and pharmaceutical companies, are actively engaged in activities similar to ours, including research and development of drugs for the treatment of the same disease as Psoraxine. The FDA has approved Amevive, manufactured by Biogen, and Raptiva, manufactured by Genentech/Xoma, for the treatment of moderate-to-severe chronic plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. If we succeed in obtaining FDA approval of Psoraxine, Amevive and Raptiva may compete directly with our product. In addition to Biogen and Genentech/Xoma, our competitors may include Amgen/Wyeth-Ayest, Centocor, Abbott Laboratories and Novartis. Many of these companies have substantially greater financial and other resources, larger research and development staffs, and more extensive marketing and manufacturing organizations than we have. In addition, some of these companies have considerable experience in preclinical testing, clinical trials and other regulatory approval procedures. There are also academic institutions, governmental agencies and other research organizations that are conducting research in areas in which we are working. They may also market commercial products, either on their own or through collaborative efforts.

We expect to encounter significant competition for any of the pharmaceutical products we develop. Companies that complete clinical trials, obtain required regulatory approvals and commence commercial sales of their products before their competitors may achieve a significant competitive advantage.

Developments by others may render our product obsolete or noncompetitive. We will face intense competition from other companies for collaborative arrangements with pharmaceutical and biotechnology companies, for establishing relationships with academic and research institutions and for licenses to additional technologies. These competitors may succeed in developing technologies or products that are more effective than Psoraxine.

### GOVERNMENT REGULATION

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and

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promotion of our potential products.

The process required by the FDA before our product candidate, Psoraxine, may be marketed in the United States generally involves the following:

- o preclinical laboratory and animal tests;
- o submission of an Investigational New Drug application, which must become effective before clinical trials may begin;

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- o adequate and well controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use; and
- o FDA approval of a new drug application or biologics license application.

The testing and approval process requires substantial time, effort and financial resources, and there can be no assurance that any approvals for Psoraxine or any other potential products will be granted on a timely basis, if at all.

Prior to commencing clinical trials, which are typically conducted in three sequential phases, a company must submit an Investigational New Drug application to the FDA. In March 2003, we filed our Investigational New Drug application for Psoraxine with the FDA. The Investigational New Drug application automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the trial. In such a case, the Investigational New Drug sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. In August 2003, the FDA informed us that we could commence our clinical trials of Psoraxine. We have completed Phase I clinical trials and have commenced Phase II clinical trials.

We may not successfully complete the three phases of testing of Psoraxine within any specific time period, if at all. Furthermore, the FDA or an institutional review board or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The results of product development, pre-clinical studies and clinical studies are submitted to the FDA as part of a new drug application or biologics license application. The FDA may deny a new drug application or biologics license application if the applicable regulatory criteria are not satisfied or may require additional clinical data. Even if such data is submitted, the FDA may ultimately decide that the new drug application or biologics license application does not satisfy the criteria for approval. Once issued, the FDA may withdraw product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches market. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Satisfaction of FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or indication. Government regulation may delay or prevent

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marketing of potential products or new indications for a considerable period of time and impose costly procedures upon our activities. Success in early stage clinical trials does not assure success in later stage clinical trials.

Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations which could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, the approval may be significantly limited to specific indications and dosages. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delays in obtaining, or failures to obtain, additional regulatory approvals for any of our product candidates would have a material adverse effect on our business.

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Any products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with good manufacturing practices, which impose certain procedural and documentation requirements upon us and any third party manufacturers we may utilize. We cannot be certain that our present or future suppliers will be able to comply with the good manufacturing practices, regulations and other FDA regulatory requirements.

Outside the United States, our ability to market a product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within the European Union, registration procedures are available to companies wishing to market a product in more than one EU Member State. If the regulatory authority is satisfied that adequate evidence of safety, quality and efficacy has been presented, a marketing authorization will be granted. This foreign regulatory approval process involves all of the risks associated with FDA clearance. To date, we have obtained regulatory approval for clinical testing of Psoraxine in Venezuela, but we have not obtained final regulatory approval for commercial distribution of Psoraxine in Venezuela because we do not have manufacturing facilities in that country and such facilities are required by regulatory authorities in Venezuela before granting commercial approval for a proposed drug.

### INTELLECTUAL PROPERTY

In January 2004 the United States Patent and Trademark Office ("PTO") issued a patent to Dr. Jose O'Daly for the "Compositions and Methods for the Treatment and Clinical Remission of Psoriasis." Under the terms of a license agreement and assignment of license agreement, we have the exclusive right and license to use and exploit this patent. Dr. O'Daly will continue to maintain ownership rights with respect to the patent and patent application. However, Dr. O'Daly has granted us a perpetual, royalty free license to his patent under the agreements, which will terminate only upon the expiration of the patent, or upon the commencement of a bankruptcy or insolvency proceeding involving our company or upon our dissolution or liquidation.

In March 2002, Akiva LLC, an entity controlled by Dr. O'Daly, also

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filed an application to obtain patent protection internationally under the Patent Cooperation Treaty. In addition, in August 2003, Akiva LLC filed patent applications in the European Union, Australia, Brazil, Canada, Mexico and Japan. We have rights to these applications, which are currently pending, pursuant to the license and assignment of license agreements described above.

In January 2004, Dr.O'Daly filed a patent application with the PTO focusing on the mechanism of action of Psoraxine, expanding the claims to include medical indications other than psoriasis, such as Atopic Dermatitis, Psoriatic Arthritis and Rheumatoid Arthritis. In addition, the patent elaborates further on the mechanism of action of Leishmania extracts, which are believed to induce T-cell activation. In January 2004, Dr. O'Daly also filed a second patent relating to a culture medium for parasitic organisms, which is part of our technology platform. Dr. O'Daly has assigned to us the rights in the patent applications. Also, in January 2004, the PTO granted us a federal trademark registration for the mark Psoraxine.

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### AGREEMENTS WITH SKYEPHARMA

We entered into a Purchase Agreement dated as of December 10, 2001 with SkyePharma PLC ("SkyePharma") pursuant to which SkyePharma purchased an aggregate of 2,000,000 shares of our Series A Convertible Preferred Stock, par value \$.001 per share ("Series A Preferred Stock"), for an aggregate purchase price of \$20.0 million. On January 20, 2004, pursuant to an Omnibus Conversion Agreement dated January 12, 2004 between us and SkyePharma, SkyePharma converted all of its outstanding shares of Series A Preferred Stock into 25,000,000 shares of common stock at a conversion price of \$0.80 per share. As a result of its conversion, SkyePharma beneficially owns 34.52% of our common stock.

On January 20, 2004, we and SkyePharma entered into a Call Option Agreement pursuant to which we received the right to repurchase some or all of 12,500,000 shares of our common stock from SkyePharma at a premium to the conversion price. The call option will be exercisable by us for a period commencing upon our achievement of a certain milestone event and ending on January 20, 2007.

On January 20, 2004, we, SkyePharma and other stockholders who are parties to a Stockholders Agreement dated December 10, 2001, entered into an amendment to the Stockholders Agreement to provide for, among other things, the termination of the agreement on the later of (1) January 20, 2007 or (2) the date on which SkyePharma no longer beneficially owns 20% of our outstanding common stock. The amended Stockholders Agreement provides that each party thereto will vote all shares held by such parties for one director designated by Mike Ajnsztajn, one director designated by Jose O'Daly, one director designated by Gaston Liebhaber, one director designated by Gina Tedesco, one director designated by SkyePharma and two independent directors. In addition, SkyePharma is required to vote its shares of our common stock in favor of certain enumerated transactions, where those transactions have been approved by our board of directors and all of the independent directors. These transactions include (i) the amendment of our certificate of incorporation solely to increase authorized capital stock, (ii) the adoption or amendment of an employee benefit plan applicable to all employees, (iii) the issuance of additional securities for cash and (iv) the sale of all of our outstanding capital stock, sale of all or substantially all of our assets or merger with another entity provided that SkyePharma will receive the same consideration for its shares as other holders of common stock and will be able to participate in the transaction on the same terms as Messrs. O'Daly, Ajnsztajn and Liebhaber and Ms. Tedesco and the total

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consideration for the transaction is greater than \$135 million.

We also entered into two agreements concerning the formulation and development of our initial injectable product candidate, Psoraxine, with SkyePharma. Under the terms of the Technology Access Option Agreement, dated December 10, 2001, we paid to SkyePharma a \$5 million fee for the option to acquire a license for DepoFoam and other relevant drug delivery technologies owned by SkyePharma. Under the terms of the Technology Access Option Agreement, if we exercise our option, we must pay a royalty of 5% of net sales of all products manufactured or sold that use or exploit the drug delivery technologies that we license from SkyePharma. In addition, if we exercise our option, SkyePharma retains the right during the term of the Technology Access Option Agreement to undertake the manufacture of all of our products that incorporate or utilize the drug delivery technologies. The option we received under the Technology Access Option Agreement expires on December 10, 2008. The Technology Access Option Agreement may be terminated by either party if (i) the other party commits any irreparable breach of the agreement, (ii) the other party commits any remediable breach and fails to remedy such breach within sixty days of service of notice of the breach, (iii) a court makes an administration order with respect to the other party or any composition in satisfaction of the debts of, or scheme of arrangement of the affairs of, the other party, or (iv) the other party becomes insolvent, has a receiver appointed over any of its assets, enters into any composition with creditors generally or has an order made or resolution passed for it to be wound up. SkyePharma has the right of first negotiation to acquire the worldwide marketing rights to Psoraxine.

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In addition, we entered into a Service Agreement, dated December 10, 2001, pursuant to which SkyePharma will provide us with development, manufacturing, pre-clinical and clinical development services in consideration of \$11 million of which \$3 million was paid in 2001 with the remaining \$8 million paid primarily during 2002 for second generation Psoraxine. The Service Agreement terminated on December 31, 2002. We have entered into an Amendment to the Service Agreement with SkyePharma, effective as of January 1, 2003, to extend the term of the Service Agreement and modify the services to be provided by SkyePharma such that SkyePharma will continue to provide certain services to us through December 31, 2004 in consideration for payments made during 2002. In addition, the amendment sets forth milestones expected to be reached during the 24 month period following January 1, 2003.

### OTHER RESEARCH AND DEVELOPMENT EFFORTS

In addition to our development of Psoraxine for the treatment of psoriasis, we are researching its possible application for the treatment of other conditions, such as eczema, seborrheic dermatitis and psoriatic arthritis. We are also developing a second product for the treatment of leishmaniasis. Since leishmaniasis is not prevalent in the United States, we intend to market this product primarily in other countries. We have not named this product yet and we do not have any approvals from, nor has any application been filed with, the FDA or any foreign governmental regulatory authority for this product. Currently, we do not have any collaborators for this product. However, our Technology Access Option Agreement permits us to use the technology we may license from SkyePharma for our leishmaniasis treatment. We are also engaged in preliminary research of a treatment for transplant rejection.

### EMPLOYEES AND CONSULTANTS

As of December 31, 2003, we employed nine full-time employees, including four scientists and a laboratory technician. We also have 14 consultants. We have no part-time employees. None of our employees are covered

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by a collective bargaining agreement and we believe that our employee relations are good.

### FORWARD-LOOKING STATEMENTS

This annual report on Form 10-KSB contains many forward-looking statements that involve substantial risks and uncertainties. You can identify these statements by forward-looking words such as "may", "will", "expect", "anticipate", "believe", "estimate", and "continue" or similar words. You should read statements that contain these words carefully because they discuss our future expectations, contain projections of our future operating results or of our financial condition or state other "forward-looking" information.

We believe that it is important to communicate our future expectations to our investors. However, we may be unable to accurately predict or control events in the future. The factors listed in the sections captioned "Risk Factors" and "Management's Discussion and Analysis or Plan of Operation", as well as any other cautionary language in this annual report, provide examples of risks, uncertainties and events that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. Before you invest in our common stock, you should be aware that the occurrence of the events described in the "Risk Factors" section, the "Management's Discussion and Analysis or Plan of Operation" section and elsewhere in this annual report could seriously harm our business.

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### RISK FACTORS

WE HAVE NO SALES; WE WILL NOT HAVE SALES IN THE FORESEEABLE FUTURE; WE ARE IN AN EARLY STAGE OF DEVELOPMENT AND WE MAY NEVER SELL PRODUCTS OR BECOME PROFITABLE.

We commenced our current operations in 2001 and such operations remain in an early stage of development. We have no products approved for sale and therefore, no means to generate revenue. We have not commercialized any products, had no revenues and had incurred a net loss of \$29,664,789 as of December 31, 2003 which has increased to date. We expect that substantial losses will continue for the foreseeable future. In order to obtain revenue from the sales of our product candidate, Psoraxine, we must successfully develop, test, obtain regulatory approval for, manufacture, market and eventually sell such product candidate. Our expenses have consisted principally of costs incurred in research and development and from general and administrative costs associated with our operations. We expect our expenses to increase and to continue to incur operating losses for the next several years as we continue our research and development efforts for Psoraxine and any subsequent product candidates. Commercialization of any of our products will take a significant amount of time and successful commercialization may not occur at all. As a result, we may never become profitable.

WE WILL NEED TO OBTAIN ADDITIONAL FUNDS TO SUPPORT OUR FUTURE OPERATION EXPENSES. OUR AUDITORS HAVE EXPRESSED UNCERTAINTY REGARDING OUR ABILITY TO CONTINUE AS A GOING CONCERN.

Based on our current plans, we believe that we currently have sufficient funds to meet our operating expenses and capital requirements through approximately the second quarter of 2005. We will need additional funds to continue our operations following that period. Furthermore, substantial additional funds will be needed in order to fund our continued efforts to obtain

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FDA approval of Psoraxine. No assurance can be given that we will be able to obtain financing, or successfully sell assets or stock, or, even if such transactions are possible, that they will be on terms reasonable to us or that they will enable us to satisfy our cash requirements. In addition, raising additional funds by selling additional shares of our capital stock will dilute the ownership interest of our stockholders. If we do not obtain additional funds, we will likely be required to eliminate programs, delay development of our products, alter our business plans, or in the extreme situation, cease operations.

As a result of our losses and the matters described in the preceding paragraph, the Independent Auditors' Report on our financial statements includes a paragraph indicating doubt about our ability to continue as a going concern. The financial statements that accompany this report do not include any adjustments that might be necessary if we are unable to continue as a going concern.

WE MAY NOT BE SUCCESSFUL IN THE DEVELOPMENT AND COMMERCIALIZATION OF PRODUCTS.

We may not develop products that prove to be safe and effective, that meet applicable regulatory standards or that we can manufacture at reasonable costs or market successfully. Successful products will require significant development and investment, including testing, to demonstrate their safety and efficacy prior to their commercialization. We have not proven our ability to develop and commercialize products. We must conduct a substantial amount of additional research and development before any regulatory authority will approve our initial product candidate, Psoraxine. Our research and development and clinical trials may not confirm the safety and efficacy of our products, in which case regulatory authorities may not approve them. In addition, even if we successfully complete our research and development efforts, Psoraxine may not perform in the manner we anticipate, and may not be accepted for use by the public.

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SUBSTANTIAL ADDITIONAL FUNDS AND EFFORT WILL BE NECESSARY FOR FURTHER DEVELOPMENT AND COMMERCIALIZATION OF PSORAXINE.

Our initial product candidate, Psoraxine, will require the commitment of substantial resources to move it towards commercialization. Before obtaining regulatory approvals for the commercial sale of Psoraxine, we must demonstrate the safety and efficacy of our product candidate through preclinical testing and clinical trials. Conducting clinical trials involves a lengthy, expensive and uncertain process. Completion of clinical trials may take several years or more. The length of time generally varies substantially according to the type, complexity, novelty and intended use of the product. If we or the U.S. Food and Drug Administration believe that our clinical trials expose participating patients to unacceptable health risks, we may suspend such trials. We may encounter problems in our studies which will cause us or the FDA to delay or suspend the studies. Some of the factors that may delay our commencement and rate of completion of clinical trials include:

- o ineffectiveness of the study compound, or perceptions by physicians that the compound will not successfully treat a particular indication;
- o inability to manufacture sufficient quantities of compounds for use in clinical trials;

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- o failure of the FDA to approve our clinical trial protocols;
- o slower than expected rate of patient recruitment;
- o unforeseen safety issues; or
- o government or regulatory delays.

The failure of future clinical trials may harm our business, financial condition and results of operations.

OUR POTENTIAL THERAPEUTIC PRODUCTS FACE A LENGTHY AND UNCERTAIN REGULATORY PROCESS. IF WE DO NOT OBTAIN REGULATORY APPROVAL OF OUR POTENTIAL PRODUCTS, WE WILL NOT BE ABLE TO COMMERCIALIZE THESE PRODUCTS.

The FDA must approve any therapeutic product before it can be marketed in the United States. Before we obtain FDA approval of a new drug application or biologics license application, the product must undergo extensive testing, including animal and human clinical trials, which can take many years and requires substantial expenditure. Data obtained from such testing may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. In addition, changes in regulatory policy for product approval during the period of product development and regulatory agency review of each submitted new drug application may cause delays or rejections. We must devote a substantial amount of time and resources in the regulatory process in order to obtain regulatory approval of our initial product candidate, Psoraxine.

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Because our initial product candidate, Psoraxine, involves the application of new technologies and may be used upon new therapeutic approaches, government regulatory authorities may subject this product to more rigorous review and may grant regulatory approvals more slowly for this product than for products using more conventional technologies. We have not received approval from the FDA to market or commercialize Psoraxine. The regulatory agencies of foreign governments must also approve any therapeutic product we may develop before the product can be sold in those countries. To date, although we have obtained regulatory approval for clinical testing of Psoraxine in Venezuela, we have not sought, nor have we obtained, regulatory approval for the commercialization of Psoraxine in Venezuela because, among other things, we do not have manufacturing facilities in that country and such facilities are required by regulatory authorities in Venezuela before granting commercial approval for a proposed drug.

Even after investing significant time and resources, we may not obtain regulatory approval for our product. If we do not receive regulatory approval, we cannot sell the product. Even if we receive regulatory approval, this approval may place limitations on the indicated uses for which we can market the product. Further, after granting regulatory approval, regulatory authorities subject a marketed product and its manufacturer to continual review, and discovery of previously unknown problems with a product or manufacturer may result in restrictions on the product, manufacturer and manufacturing facility, including withdrawal of the product from the market. In certain countries, regulatory agencies also set or approve prices.

EVEN IF PRODUCT CANDIDATES EMERGE SUCCESSFULLY FROM CLINICAL TRIALS, WE MAY NOT BE ABLE TO SUCCESSFULLY MANUFACTURE, MARKET AND SELL THEM.

We have not completed clinical trials of Psoraxine. If Psoraxine emerges successfully from clinical trials, we will either commercialize products

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resulting from our proprietary programs directly or through licensing arrangements with other companies. We have no experience in manufacturing and marketing, and we currently do not have the resources or capability to manufacture, market or sell our products on a commercial scale. In order to commercialize Psoraxine directly, we would need to develop or obtain through outsourcing arrangements the capability to manufacture, market and sell products. We have an agreement with SkyePharma PLC ("SkyePharma") under which SkyePharma will provide development, pre-clinical and clinical development services for Psoraxine until December 31, 2004. However, we do not currently have a written agreement covering any period after December 31, 2004 and we may not be able to enter into such an agreement on commercially reasonable terms, or at all. In addition, we currently do not have any agreements for the marketing or sale of any of our products and we may not be able to enter into such agreements on commercially reasonable terms, or at all.

WE LICENSE AND DO NOT OWN OUR INTELLECTUAL PROPERTY. ANY INABILITY TO PROTECT OUR PROPRIETARY TECHNOLOGIES ADEQUATELY COULD HARM OUR COMPETITIVE POSITION.

We license, and do not own, the intellectual property rights to Psoraxine. Dr. Jose Antonio O'Daly is the owner of the patent for Psoraxine. Under the terms of a license agreement and assignment of license agreement, we have the right to use any patent issued pursuant to Dr. O'Daly's patent application. We also have rights to other patents filed by Dr. O'Daly under the terms of our employment agreement with him. Our success will depend in part on our ability to obtain patents and maintain adequate protection of other intellectual property for our technologies and products in the United States and other countries. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate our competitive advantage. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these foreign countries.

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The patent positions of biotechnology companies, including our patent positions, involve complex legal and factual questions and, therefore, validity and enforceability cannot be predicted with certainty. Patents may be challenged, deemed unenforceable, invalidated or circumvented. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that we cover our proprietary technologies with valid and enforceable patents or we effectively maintain such proprietary technologies as trade secrets. We will apply for patents covering both our technologies and product candidates as we deem appropriate. However, we may fail to apply for patents on important technologies or products in a timely fashion, or at all, and in any event, the applications we do file may be challenged and may not result in issued patents. Any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative technologies or design around our patented technologies. In addition, others may challenge or invalidate our patents, or our patents may fail to provide us with any competitive advantages. If we encounter challenges to the use or validity of any of our patents, resulting in litigation or administrative proceedings, we would incur substantial costs and the diversion of management in defending the patent. In addition, we do not control the patent prosecution of technology that we license from others. Accordingly, we cannot exercise the same degree of control over this intellectual property as we would over technology we own.

We rely upon trade secrets protection for our confidential and

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proprietary information. We have taken measures to protect our proprietary information. These measures may not provide adequate protection for our trade secrets or other proprietary information. We seek to protect our proprietary information by entering into confidentiality agreements with employees, collaborators and consultants. Nevertheless, employees, collaborators or consultants may still disclose our proprietary information, and we may not be able to meaningfully protect our trade secrets. In addition, others may independently develop substantially equivalent proprietary information or techniques or otherwise gain access to our trade secrets.

MANY POTENTIAL COMPETITORS WHICH HAVE GREATER RESOURCES AND EXPERIENCE THAN WE DO MAY DEVELOP PRODUCTS AND TECHNOLOGIES THAT COULD MAKE OURS OBSOLETE.

Companies in the biotechnology industry face rapid technological change in a rapidly evolving field. Our future success will depend on our ability to maintain a competitive position with respect to technological advances. Rapid technological development by others may result in our products and technologies becoming obsolete.

We face, and will continue to face, intense competition from organizations such as large biotechnology and pharmaceutical companies, as well as academic and research institutions and government agencies. Our competitors may include Biogen, Genentech/Xoma, Abbott Laboratories and Novartis. These organizations may develop technologies that provide superior alternatives to our technologies. Further, our competitors may be more effective at implementing their technologies to develop commercial products.

Any products that we develop through our technologies will compete in multiple, highly competitive markets. Many of the organizations competing with us in the markets for such products have greater capital resources, research and development and marketing staffs, facilities and capabilities, and greater experience in obtaining regulatory approvals, product manufacturing and marketing. Accordingly, our competitors may be able to develop technologies and products more easily, which would render our technologies and products obsolete and noncompetitive.

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IF WE LOSE OUR KEY PERSONNEL OR FAIL TO ATTRACT AND RETAIN ADDITIONAL PERSONNEL, WE MAY BE UNABLE TO DISCOVER AND DEVELOP OUR PRODUCTS.

We depend on the services of Dr. Jose Antonio O'Daly, the loss of whose services would adversely impact the achievement of our objectives. Our key personnel have no prior experience managing a start-up biotechnology company. We do not currently have sufficient executive management personnel to execute our business plan fully. In addition, recruiting and retaining qualified scientific personnel to perform future research and development work will be critical to our success. Although we believe we can successfully attract and retain qualified personnel, we face intense competition for experienced scientists. Failure to attract and retain skilled personnel would prevent us from pursuing collaborations and developing our products and core technologies to the extent otherwise possible.

Our planned activities will require additional expertise. These activities will require the addition of new personnel, including management, and the development of additional expertise by existing management personnel. The inability to acquire or develop this expertise could impair the growth, if any, of our business.

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IF WE FACE CLAIMS IN CLINICAL TRIALS OF A DRUG CANDIDATE, THESE CLAIMS WILL DIVERT OUR MANAGEMENT'S TIME AND WE WILL INCUR LITIGATION COSTS.

We face an inherent business risk of clinical trial liability claims in the event that the use or misuse of Psoraxine results in personal injury or death. We may experience clinical trial liability claims if our drug candidates are misused or cause harm before regulatory authorities approve them for marketing. Although, we currently maintain clinical liability insurance coverage, it may not sufficiently cover any claims made against us and may not be available in the future on acceptable terms, if at all. Any claims against us, regardless of their merit, could strain our financial resources in addition to consuming the time and attention of our management. Law suits for any injuries caused by our products may result in liabilities that exceed our total assets.

SOME OF OUR EXISTING STOCKHOLDERS CAN EXERT CONTROL OVER US AND MAY NOT MAKE DECISIONS THAT FURTHER THE BEST INTERESTS OF ALL STOCKHOLDERS.

Our officers, directors and principal stockholders (greater than 5% stockholders) together control approximately 71.69% of our outstanding common stock. As a result, these stockholders, if they act individually or together, may exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. Furthermore, the interests of this concentration of ownership may not always coincide with our interests or the interests of other stockholders and accordingly, they could cause us to enter into transactions or agreements which we would not otherwise consider. In addition, this concentration of ownership may delay or prevent a merger or acquisition resulting in a change in control of us and might affect the market price of our common stock, even when such a change in control may be in the best interest of all stockholders.

### ITEM 2. DESCRIPTION OF PROPERTY

We lease our executive offices and research laboratory located at 75 Passaic Avenue, Fairfield, New Jersey 07004. The yearly rent for such office and laboratory space is \$77,500.

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### ITEM 3. LEGAL PROCEEDINGS

Neither we, nor any of our properties, are presently a party to any material legal proceeding, nor, to our knowledge, is any such proceeding threatened against us or any of our properties.

### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

No matters were submitted for a vote of our shareholders during the fourth quarter of fiscal 2003.

## PART II

### ITEM 5. MARKET FOR COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND SMALL BUSINESS ISSUER PURCHASES OF EQUITY SECURITIES

#### MARKET INFORMATION

Our common stock is traded on the Over-the-Counter Bulletin Board ("OTC

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Bulletin Board") under the symbol ASTR. The following table sets forth, for the periods indicated, the range of high and low bid quotations for shares of our common stock as quoted on the OTC Bulletin Board. The reported bid quotations reflect inter-dealer prices, without retail markup, markdown or commissions, and may not necessarily represent actual transactions.

|                | High    | Low     |
|----------------|---------|---------|
| 2002           |         |         |
| First Quarter  | \$ 2.75 | \$ 1.50 |
| Second Quarter | \$ 3.35 | \$ 0.91 |
| Third Quarter  | \$ 1.06 | \$ 0.32 |
| Fourth Quarter | \$ 0.66 | \$ 0.22 |

2003

|                |         |         |
|----------------|---------|---------|
| First Quarter  | \$ 0.72 | \$ 0.34 |
| Second Quarter | \$ 1.01 | \$ 0.40 |
| Third Quarter  | \$ 1.41 | \$ 0.36 |
| Fourth Quarter | \$ 0.87 | \$ 0.42 |

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### HOLDERS OF COMMON STOCK

As of March 12, 2004, there were approximately 2,385 holders of record of our common stock.

### DIVIDENDS

We have never paid or declared a cash dividend on our common stock. We intend, for the foreseeable future, to retain all future earnings for use in our business. The amount of dividends we pay in the future, if any, will be at the discretion of our Board of Directors and will depend upon our earnings, capital requirements, financial condition and other relevant factors.

### RECENT SALES OF UNREGISTERED SECURITIES

On January 20, 2004 and February 19, 2004, we sold to accredited investors units consisting of an aggregate of 10,459,866 shares of common stock and warrants to purchase 10,459,866 shares of common stock for an aggregate purchase price of approximately \$5.23 million. In connection with this transaction, Fabien Pictet and his assignees received a consulting fee of \$261,496, warrants to purchase 418,394 shares of our common stock at \$0.50 per share and warrants to purchase 418,394 shares of our common stock at \$0.73 per share. We relied on the exemption from registration with the Securities and Exchange Commission provided under Section 4(2) of the Securities Act of 1933 and Rule 506 of Regulation D under the Securities Act of 1933.

On January 10, 2002, Messrs. Ajnsztajn, O'Daly and Liebhaber transferred, respectively, 175,000, 275,000 and 50,000 shares of our common stock owned by them to Manuel Tarabay for consulting services rendered by Mr. Tarabay in connection with their efforts to raise capital for our company. Messrs. Ajnsztajn, O'Daly and Liebhaber relied on the exemption from registration afforded by Section 4(2) of the Securities Act of 1933.

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We entered into a Purchase Agreement dated as of December 10, 2001 with SkyePharma PLC, a company incorporated under the laws of England and Wales. Pursuant to the Purchase Agreement, SkyePharma purchased, during a thirteen month period ending January 31, 2003, 2,000,000 shares of our Series A Convertible Preferred Stock, par value \$.001 per share, at a purchase price of \$10.00 per share, or an aggregate purchase price of \$20.0 million. We relied on the exemption from registration with the Securities and Exchange Commission provided under Section 4(2) and Rule 506 of Regulation D under the Securities Act of 1933.

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During November of 2001, we completed a private placement offering pursuant to which we sold an aggregate of 2,076,179 shares of our common stock and issued warrants to purchase an aggregate of 415,237 shares of our common stock, at an exercise price of \$4.00 per share, for an aggregate purchase price of \$3,321,887. We relied on the exemption from registration with the Securities and Exchange Commission provided under Section 4(2) of the Securities Act of 1933 and Rule 506 of Regulation D under the Securities Act of 1933.

On November 13, 2001, pursuant to the Contribution Agreement, dated as of September 10, 2001, by and among us and the members of Astralis, LLC, a New Jersey limited liability company, the members of Astralis, LLC transferred all of their respective membership interests in Astralis, LLC to us in exchange for 28,000,000 shares of our common stock and 6,300,000 warrants to purchase common stock at an exercise price of \$1.60 per share. Pursuant to the Contribution Agreement, we cancelled 23,800,000 of the 23,820,000 shares of common stock owned by Mr. Shai Stern who served as our Chief Executive Officer and sole director until his resignation, pursuant to the Contribution Agreement, on November 13, 2001. We relied on the exemption from registration afforded by Section 4(2) of the Securities Act of 1933.

During October of 2001, we issued a promissory note of \$50,000 to Michael Garnick. The promissory note had a maturity date of November 13, 2001. We also issued to the lender 12,000 shares of common stock. The promissory note was repaid out of the proceeds of the private placement. We relied on the exemption from registration afforded by Section 4(2) of the Securities Act of 1933.

On September 1, 2001, Richard Genovese, David Stevenson, Grizzly Consulting Ltd., Wolver Limited and Logarithmic, Inc. purchased units from Astralis, LLC consisting of an aggregate of 2,700,000 membership interests in Astralis, LLC and 6,300,000 options to purchase additional membership interests for a purchase price of \$1.60 per membership interest. The aggregate purchase price for such units was \$1,350,000. Pursuant to the Contribution Agreement, on November 13, 2001 the units were exchanged for an aggregate of 2,700,000 shares of common stock and 6,300,000 warrants to purchase common stock at an exercise price of \$1.60 per share. Astralis, LLC relied on the exemption from registration with the Securities and Exchange Commission provided under Section 3(b) of the Securities Act of 1933 and Rule 505 of Regulation D under the Securities Act of 1933.

During April of 2001, we issued warrants to purchase 75,000 share of our common stock at an exercise price of \$1.75 per share in connection with a loan. We relied on the exemption from registration afforded by Section 4(2) of the Securities Act of 1933.

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During the period from March 15 through April 26, 2000, we issued and sold an aggregate of 750,000 shares (7,500,000 shares post stock dividend) of common stock to a total of fifty persons, all of whom are residents of the State of Colorado, for cash consideration totaling \$75,000. We made the sales in reliance upon the exemption from registration with the U.S. Securities and Exchange Commission provided under Section 3(b) of the Securities Act of 1933 and Rule 504 of Regulation D under the Securities Act of 1933, and via registration by qualification with the Colorado Division of Securities under Section 11-51-304 of the Colorado Uniform Securities Act. Our Application for Registration by Qualification became effective with the Colorado Division of Securities on March 15, 2000.

### ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

The following discussion of our financial condition and plan of operation should be read in conjunction with our financial statements and the related notes included elsewhere in this annual report on Form 10-KSB. This annual report contains certain statements of a forward-looking nature relating to future events or our future financial performance. We caution prospective investors that such statements involve risks and uncertainties, and that actual events or results may differ materially. In evaluating such statements, prospective investors should specifically consider the various factors identified in this annual report, including the matters set forth under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We disclaim any obligation to update information contained in any forward-looking statement.

#### OVERVIEW

We are a development stage biotechnology company engaged primarily in the research and development of treatments for immune system disorders and skin diseases. Our initial product candidate, Psoraxine, is a protein extract used for the treatment of the skin disease psoriasis.

Currently, we are engaged in the following activities to further our development efforts of our initial product candidate:

- o Ongoing research and development of Psoraxine; and
- o Development of the technology underlying Psoraxine for the treatment of indications other than psoriasis, such as eczema, seborrheic dermatitis and psoriatic arthritis.

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FISCAL YEAR ENDED DECEMBER 31, 2003 COMPARED TO FISCAL YEAR ENDED DECEMBER 31, 2002

FOR FISCAL YEAR ENDED DECEMBER 31, 2003:

In January 2003, pursuant to a Purchase Agreement dated as of December 10, 2001, we sold 250,000 shares of our Series A Convertible Preferred Stock to SkyePharma for an aggregate purchase price of \$2,500,000. We received proceeds of \$2,480,000 after we netted out from the proceeds \$20,000 due to SkyePharma in connection with the Service Agreement.

During the fiscal year ended December 31, 2003, we received \$825,000 outstanding under subscription notes. In April 2003, we entered into an Amended Investor Relation Agreement with a stockholder who had outstanding subscription

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notes. In exchange for services rendered, we reduced the outstanding amount by \$36,000. In 2004, the stockholder will provide services valued at \$24,000 in lieu of payment of the outstanding subscription receivable balance.

For the fiscal year ended December 31, 2003, we had no revenue from operations and incurred operating expenses of \$5,362,081 which consisted primarily of:

- o Research and development costs of \$4,045,673, including \$1,007,500 that we incurred in connection with services provided by SkyePharma under our Service Agreement with them and amortization of approximately \$714,288 under our technology option license which is being amortized over a seven year period.
- o General and administrative costs of approximately \$1,290,346, including professional fees and our general corporate expenditures.

As a result, during the fiscal year ended December 31, 2003, we incurred a net loss of \$5,080,427.

In December 2003, we received \$221,636 in cash from the sale of a portion of our tax related net operating losses ("NOLS") under the State of New Jersey's Technology Business Tax Certificate Transfer Program. The program is an initiative passed by the New Jersey State legislature that allows qualified technology and biotechnology businesses in New Jersey to sell unused amounts of NOLS and defined research and development tax credits for cash.

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2002:

In 2002, we sold to SkyePharma pursuant to the Purchase Agreement dated as of December 10, 2001, an aggregate of 750,000 shares of our Series A Convertible Preferred Stock for an aggregate purchase price of \$7,500,000. We received net proceeds of approximately \$5,505,000 from this placement after we netted out from the proceeds \$1,995,000 due to SkyePharma for services they provided under our Service Agreement with them which were treated as an expense at the time of payment.

For the fiscal year ended December 31, 2002, we had no revenue and incurred operating expenses of \$9,151,521 which consisted primarily of:

- o Research and development costs of \$7,761,542, including \$5,985,000 that was paid to SkyePharma for services provided under our Service Agreement with them and amortization of approximately \$714,288 under our technology option license which is being amortized over a seven year period.

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- o General and administrative costs of approximately \$1,374,251, including professional fees and our general corporate expenditures.

We also had a non-cash preferred stock dividend in April of 2002 in the amount of \$270,000. The April 30, 2002 sale of convertible preferred stock to SkyePharma had a conversion rate to our common stock which was lower than the market price of our common stock on that date. Therefore, under the requirements of Emerging Issues Task Force No. 98-5 "Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios", the issuance of this preferred stock with a beneficial conversion feature resulted in a preferred stock dividend.

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We recorded an additional preferred stock dividend in December 2002 in the amount of \$9,078,750. The contingent beneficial conversion feature arose because of the reset of the conversion price of our preferred stock on December 10, 2002 from \$2.50 per share of preferred stock to \$1.60 per share. EITF No. 98-5 and EITF No. 00-27 "Application of Issue No. 98-5 to Certain Convertible Instruments" required that we record this preferred stock dividend.

As a result, during the fiscal year ended December 31, 2002, we incurred a net loss of \$18,388,998.

In March 2003, we amended our Service Agreement with SkyePharma, effective as of January 1, 2003, to extend the term of the agreement and modify the services to be provided by SkyePharma. The amended service agreement provides that, in consideration for payments we previously made to SkyePharma, it will continue to provide services to us through December 31, 2004. Consequently, as of December 31, 2002, we recorded a prepaid expense in the amount of \$1,995,000 which was a portion of what we paid to SkyePharma during 2002 in connection with the Service Agreement. This prepaid amount will be incurred during the remaining period of the amended service agreement.

### THE NEXT TWELVE MONTHS

At December 31, 2003 we had cash balances of \$10,660 and marketable securities of \$1,374,174.

On January 20, 2004 we closed a private placement from which we received gross proceeds of approximately \$4.08 million. The transaction consisted of the sale to accredited investors of units consisting of 8,159,964 shares of common stock and warrants to purchase 8,159,964 shares of common stock. Concurrently with this transaction, SkyePharma converted all of its outstanding shares of Series A Preferred Stock into 25,000,000 shares of common stock at a reduced conversion price of \$0.80 per share. SkyePharma has agreed that 12,500,000 shares of the common stock issued upon conversion of the Series A Preferred Stock will be subject to a right of repurchase by us under certain circumstances at a premium to the conversion price. In connection with this transaction and in accordance with Statement of Financial Auditing Standard 84, "Induced Conversions of Convertible Debt, an Amendment of APB Opinion No. 26" we will record a non-cash preferred stock dividend in January 2004 amounting to \$10,750,000.

On February 19, 2004, we held a second closing for the private placement from which we received gross proceeds of approximately \$1.15 million. The transaction consisted of the sale to accredited investors of units consisting of 2,299,902 shares of common stock and warrants to purchase 2,299,902 shares of common stock.

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Based on our current operating plan, we anticipate conducting the following activities and using our cash over the course of the next twelve months as follows:

- o Our primary focus is to further our development efforts of our initial product candidate, Psoraxine. We have commenced Phase II clinical trials and expect to pay approximately \$2,450,000 to third parties in connection with these activities.
- o We intend to implement our business plan and facilitate the operations of our company. We will spend approximately \$807,500 to pay management

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salaries and salaries of employees, a portion of which is treated as research and development expense.

- o We also expect to expend approximately \$900,000 for our public relations, general administrative and working capital requirements.

We will need to raise additional funds to continue our operations for the period following the second quarter of 2005. Furthermore, substantial additional funds will be needed in order to fund our continued efforts to obtain FDA approval of Psoraxine. No assurance can be given that we will be able to obtain financing, or successfully sell assets or stock, or, even if such transactions are possible, that they will be on terms reasonable to us or that they will enable us to satisfy our cash requirements. In addition, raising additional funds by selling additional shares of our capital stock will dilute the ownership interest of our stockholders. If we do not obtain additional funds, we will likely be required to eliminate programs, delay development of our products, or in the extreme situation, cease operations.

### ITEM 7. FINANCIAL STATEMENTS

The financial statements required by this Item 7 begin at page F-1 of this annual report.

### ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

### ITEM 8A. CONTROLS AND PROCEDURES

#### (A) EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES.

Based on their evaluation as of the end of the period covered by this Annual Report on Form 10-KSB, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-14(c) and 15d-14(c) under the Securities Exchange Act of 1934 (the "Exchange Act")) are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

#### (B) CHANGES IN INTERNAL CONTROLS.

There were no significant changes in our internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

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## PART III

### ITEM 9. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT; COMPLIANCE WITH SECTION 16(A) OF THE EXCHANGE ACT.

#### DIRECTORS AND EXECUTIVE OFFICERS

The names, ages and positions of our current directors and executive officers are as follows:

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| Name                         | Age | Position  |
|------------------------------|-----|---|
| Jose Antonio O'Daly, MD, PhD | 62  | Chairman of the Board of Directors; President of Research and Development |
| Mike Ajnsztajn               | 39  | Chief Executive Officer; Director   |
| Gaston Liebhaber             | 69  | Director of International Affairs; Director                               |
| Gina Tedesco                 | 40  | Chief Financial Officer; Director   |
| Michael Ashton               | 58  | Director  |
| Steven Fulda                 | 71  | Director  |
| Fabien Pictet                | 45  | Director  |

With the exception of Mr. Ajnsztajn and Ms. Tedesco who are husband and wife, and Mr. Liebhaber who is Mr. Ajnsztajn's uncle, there are no familial relationships among our directors and/or officers. Directors hold office until the next annual meeting of our stockholders or until their respective successors have been elected and qualified. Officers serve at the pleasure of the Board of Directors.

JOSE ANTONIO O'DALY, MD, PHD. Dr. O'Daly has served as our Chairman of the Board of Directors and President of Research and Development since November 13, 2001. Dr. O'Daly is the sole founder of Center for Research and Treatment for Psoriasis in Caracas, Venezuela and has served as its president since 1998. From 1972 to 1998, Dr. O'Daly served as Director and Head of Research of the Microbiology Center of the Venezuelan Institute of Scientific Investigations. Dr. O'Daly attended the Central University of Venezuela, Caracas receiving his Doctorate of Medical Sciences in 1968. In 1971, Dr. O'Daly earned a Doctorate of Philosophy from the Johns Hopkins University in Baltimore, Maryland. Dr. O'Daly is an honorary member of the Venezuelan Medical Academy.

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MIKE AJNSZTAJN. Mr. Ajnsztajn has served as our Chief Executive Officer and as a director since November 13, 2001. From 1986 to 1992, Mr. Ajnsztajn worked for Rhone Poulenc as both an Export Manager for the Far East based in France, and as the Marketing Director in China. From 1992 to 2001, Mr. Ajnsztajn was the president of Blowtex, a Brazilian condom manufacturer. Mr. Ajnsztajn is also co-founder of Opus International, a New Jersey based import/export company that distributes hospital examination gloves and raw materials for the latex industry. Opus International also provides business-consulting services.

GASTON LIEBHABER. Mr. Liebhaber has served as our Director of International Affairs since November 13, 2001 and as a director since January 31, 2002. Mr. Liebhaber has 35 years of experience in the pharmaceutical industry. Mr. Liebhaber founded Fundafarmacia in Caracas, Venezuela, a non-profit organization that distributes medicine, at discounted prices, to the poor and homeless. Since 1982, Mr. Liebhaber has served as the Managing Director of Latin America of Sankyo Pharmaceutical. Since 1987, Mr. Liebhaber also has served on the Board of Directors of the Venezuelan Association of Pharmaceutical Companies.

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GINA TEDESCO. Ms. Tedesco has served as our Chief Financial Officer since November 13, 2001 and as a director since January 31, 2002. Ms. Tedesco is a co-founder of Opus International and has served as its President since 1997. Ms. Tedesco has extensive experience in the pharmaceutical industry and in finance and business planning. From 1989 to 1996, Ms. Tedesco held various positions with Rhone Poulenc ranging from controller for the European pharmaceutical subsidiaries to Director of Finance and Investor Relations for a Brazilian subsidiary. Ms. Tedesco earned a MBA from George Washington University in International Business.

MICHAEL ASHTON. Mr. Ashton has served as one of our directors since January 31, 2002. Since 1977, Mr. Ashton has been employed by SkyePharma PLC, a London based drug delivery technology provider. Since 1999, Mr. Ashton has served as the Chief Executive Officer of SkyePharma PLC. Mr. Ashton is a member of the board of directors of Transition Inc. Mr. Ashton has thirty years of experience in the pharmaceutical industry. Mr. Ashton has a Bachelor of Pharmacy Degree from Sydney University and a MBA Degree from Rutgers University.

STEVEN FULDA. Mr. Fulda has served as one of our directors and a member of our audit committee since February 6, 2002. Since 1989, Mr. Fulda has served as Managing Director of Fulda Business Planners. Mr. Fulda has forty years of management and consulting experience including business strategy, planning, development and financing. Since 1992, Mr. Fulda has been an Adjunct Professor of Entrepreneurship and Director of the Small Business Institute at Fairleigh Dickinson University. Mr. Fulda holds a Master's Degree in Quantitative Business Analysis from New York University and a Master's Degree in Systems Engineering from Bell Laboratories' New York University Graduate Program.

FABIEN PICTET. Mr. Pictet has served as one of our directors and a member of our audit committee since February 6, 2002. Since 1998, Mr. Pictet has served as Chairman of Fabien Pictet and Partners, a London based firm which invests in the emerging markets arena. Mr. Pictet has twenty years of experience in investing in emerging markets. During his eleven year tenure with Pictet and Cie, from 1986 to 1997, Mr. Pictet held various positions ranging from Manager responsible for U.S. equity investments to Partner responsible for all of the firm's institutional activities in Geneva, Zurich and London. Mr. Pictet has a Master's Degree in International Management from American Graduate School of International Management and a Bachelor's Degree in Economics from the University of San Francisco.

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### ADVISORS

#### SCIENTIFIC ADVISORY BOARD

JAMES LEYDEN, MD. Dr. Leyden has served as the Chairman of our Medical Advisory Board since November 31, 2001. Dr. Leyden has been a Professor of Dermatology at the Hospital of the University of Pennsylvania in Philadelphia since 1983. He has served on the boards of many of the nation's key dermatological committees, including those of the American Academy of Dermatology and the Dermatology Foundation. Dr. Leyden has also served as a consultant to the U.S. Food and Drug Administration and the Federal Trade Commission, and to drug regulation agencies in England, Germany and Austria. Dr. Leyden has also assisted in the development, testing and commercialization of Accutane, Bactroban, Nizoral, Cleocin, Benzamycin, Benzaclin, Minocin and the use of bicarbonate to control body odor. Dr. Leyden has a Bachelor's Degree from Saint Joseph's College and a MD for the University of Pennsylvania School of Medicine.

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GERALD KRUEGER, MD. Dr. Krueger has served on our Medical Advisory Board since December 2, 2003. Dr. Krueger is a professor of dermatology at the University of Utah School of Medicine. Dr. Krueger consults for the U.S. Food and Drug Administration on psoriasis and serves on the executive committee of the Dermatology Foundation. In addition, he recently completed a ten year term as chairman of the Medical Advisory Board of the National Psoriasis Foundation. Dr. Krueger has been elected into the Alpha Omega Honor Society of Medicine. He has received the Taub International Award for psoriasis research, the American Skin Association Award for psoriasis research and the National Psoriasis Foundation's Lifetime Achievement Award and Founders Award.

Our Scientific Advisory Board does not hold any formal meetings. However, management consults with the Scientific Advisory Board from time to time.

### MARKETING ADVISOR

BRUCE EPSTEIN. Mr. Epstein has served as our Marketing Affairs Advisor since November 13, 2001. Since 2000, Mr. Epstein has served as the General Manager of Noesis Healthcare Interactions, a full-service healthcare communications company managing a creative and support staff focused on the marketing and advertising of multiple pharmaceutical brands with leading pharmaceutical companies. Mr. Epstein specializes in strategic planning and tactical implementation of pharmaceutical products. From 1996 to 2000, Mr. Epstein worked at Klemtner Advertising, the healthcare division of Saatchi and Saatchi. From 1986 to 1996, Mr. Epstein worked for Roche Laboratories, a Swiss pharmaceutical company with a U.S. division based in Nutley, New Jersey. Mr. Epstein obtained a MBA from New York University, Stern School of Business, and a Registered Pharmacist Degree from Rutgers, College of Pharmacy.

### CODE OF ETHICS

We have adopted a Code of Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer, controller and any other person performing similar functions. We intend to satisfy the disclosure requirement under Item 10 of Form 8-K regarding an amendment to, or waiver from, a provision of our Code of Ethics by posting such information on our website, [www.astralisltd.com](http://www.astralisltd.com).

### AUDIT COMMITTEE FINANCIAL EXPERT

The Board of Directors has determined that Steven Fulda is an "audit committee financial expert" as defined by the Securities and Exchange Commission. As corporate division manager of one of two business planning divisions of AT&T, Mr. Fulda was responsible for the creation and development of business plans for five AT&T subsidiaries. Each business plan included a financial plan incorporating past performance and future expectations of the subsidiary, as well as actual and pro forma financial statements. Mr. Fulda collaborated daily with the controller and treasury department of AT&T. In addition, Mr. Fulda has served as an adjunct professor at Fairleigh Dickinson University in the College of Business, teaching courses related to management and business planning, including detailed financial planning.

### SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Securities Exchange Act of 1934, as amended,

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requires our executive officers and directors and persons who own more than 10% of our common stock ("Reporting Persons") to file reports of ownership and changes in ownership with the SEC. Reporting Persons are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file.

Based solely on our review of the copies of such forms received or written representations from Reporting Persons, we believe that with respect to the fiscal year ended December 31, 2003, all the Reporting Persons complied with all applicable filing requirements except that Fabien Pictet failed to timely file Forms 4.

### ITEM 10. EXECUTIVE COMPENSATION.

The following table sets forth certain information regarding compensation paid by us and our predecessors during each of the last three fiscal years to our Chief Executive Officer and any other executive officer who received compensation greater than \$100,000 during any of the last three fiscal years.

SUMMARY COMPENSATION TABLE

| NAME AND PRINCIPAL POSITION   | YEAR | ANNUAL COMPENSATION<br>SALARY (\$) | OTHER ANNUAL<br>COMPENSATION |
|---|------|------------------------------------|------------------------------|
| Mike Ajnsztajn,<br>Chief Executive Officer (1)  | 2003 | 154,375                            | 4,613 (3)                    |
|   | 2002 | 150,000                            | 4,613                        |
|   | 2001 | 81,164                             | --                           |
| Jose Antonio O'Daly,<br>Chairman of the Board of Directors and<br>President of Research and Development (2) | 2003 | 158,750                            | 73,740 (4)                   |
|   | 2002 | 150,000                            | 56,671                       |
|   | 2001 | 63,500                             | --                           |

-----  
(1) Mr. Ajnsztajn became our Chief Executive Officer on November 13, 2001.

(2) Dr. O'Daly became one of our employees on July 1, 2002. Prior to July 1, 2002, Dr. O'Daly provided services as a consultant to the company.

(3) For the fiscal year ended December 31, 2003, this amount includes \$4,613 in health insurance premiums paid by us for Mr. Ajnsztajn's benefit.

(4) For the fiscal year ended December 31, 2003, this amount includes \$9,929 in health insurance premiums paid by us for Dr. O'Daly's benefit, an automobile allowance of \$6,317, \$37,494 for a furnished apartment and \$20,000 for tax payments.

### 2001 STOCK OPTION PLAN

Our 2001 Stock Option Plan ("2001 Plan") was unanimously adopted by the

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Board of Directors on November 1, 2001 and approved by our stockholders at a special meeting held on November 1, 2001. The 2001 Plan provides for the issuance of 5,000,000 shares of common stock underlying stock options available for grant thereunder. The purpose of the 2001 Plan is to provide additional incentive to our directors, officers, employees and consultants who are primarily responsible for our management and growth. Each option will be designated at the time of grant as either an incentive stock option (an "ISO") or as a non-qualified stock option (a "NQSO"). As of December 31, 2003, options to purchase 365,000 shares of common stock have been granted under the 2001 Plan.

The 2001 Plan will be administered by our Board of Directors, or by any committee that we may in the future form and to which the Board of Directors may delegate the authority to perform such functions (in either case, the "Administrator").

Every person who at the date of grant of an option is an employee of ours or any affiliate of ours is eligible to receive NQSOs or ISOs under the 2001 Plan. Every person who at the date of grant is a consultant to, or non-employee director of, ours or any affiliate of ours is eligible to receive NQSOs under the 2001 Plan.

The exercise price of a NQSO will be not less than 85% of the fair market value of the stock subject to the option on the date of grant. To the extent required by applicable laws, rules and regulations, the exercise price of a NQSO granted to any person who owns, directly or by attribution under the Code (currently Section 424(d)), stock possessing more than 10% of the total combined voting power of all classes of our stock or stock of any of our affiliates (a "10% Shareholder") will not be less than 110% of the fair market value of the stock covered by the option at the time the option is granted. The exercise price of an ISO will be determined in accordance with the applicable provisions of the Code and will not be less than the fair market value of the stock covered by the option at the time the option is granted. The exercise price of an ISO granted to any 10% Shareholder will not be less than 110% of the fair market value of the stock covered by the option at the time the option is granted.

The Administrator, in its sole discretion, will fix the term of each option, provided that the maximum term of an option will be ten years. ISOs granted to a 10% Shareholder will expire not more than five years after the date of grant. The 2001 Plan provides for the earlier expiration of options in the event of certain terminations of employment of the holder.

Options may be granted and exercised under the 2001 Plan only after there has been compliance with all applicable federal and state securities laws. The 2001 Plan will terminate within ten years from the date of its adoption by the Board of Directors.

If for any reason other than death or permanent and total disability, an optionee ceases to be employed by us or any of our affiliates (such event being called a "Termination"), options held at the date of Termination (to the extent then exercisable) may be exercised in whole or in part at any time within three months of the date of such Termination, or such other period of not less than thirty days after the date of such Termination as is specified in the Option Agreement or by amendment thereof (but in no event after the expiration date of the option (the "Expiration Date")); provided, however, that if such exercise of the option would result in liability for the optionee under Section 16(b) of the Exchange Act, then such three-month period automatically will be extended until the tenth day following the last date upon which optionee has any liability under Section 16(b) (but in no event after the Expiration Date).

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The Board of Directors may at any time amend, alter, suspend or discontinue the 2001 Plan. Without the consent of an optionee, no amendment, alteration, suspension or discontinuance may adversely affect outstanding options except to conform the 2001 Plan and ISOs granted under the 2001 Plan to the requirements of federal or other tax laws relating to ISOs. No amendment, alteration, suspension or discontinuance will require shareholder approval unless (i) shareholder approval is required to preserve incentive stock option treatment for federal income tax purposes or (ii) the Board of Directors otherwise concludes that shareholder approval is advisable.

### COMPENSATION OF DIRECTORS

Our directors do not receive compensation pursuant to any standard arrangement for their services as directors. We reimburse all outside directors for travel and lodging expenses related to scheduled Board meetings. During the fiscal year ended December 31, 2003, we paid \$1,000 to each outside director for each Board meeting attended and paid an additional \$4,500 to the chairman of the audit committee.

### EMPLOYMENT AGREEMENTS

Pursuant to an Employment Agreement dated December 10, 2001, Dr. O'Daly receives a salary of \$150,000 per year for his services as Chairman of the Board and President of Research and Development. The agreement has a term of three years and requires Dr. O'Daly to refrain from competing with us for a period of one year following termination of his employment. The agreement does not contain any change of control provisions. None of our other executive officers receive compensation pursuant to any standard arrangement for their services as executive officers.

### ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth the names and beneficial ownership of our common stock owned as of March 26, 2004, by (i) each of our directors, (ii) each person named in the Summary Compensation Table, (iii) all our directors and executive officers as a group, and, to the best of our knowledge, (iv) all holders of 5% or more of the outstanding shares of our common stock. Unless otherwise noted, the address of all the individuals and entities named below is care of Astralis Ltd. at 75 Passaic Avenue, Fairfield, NJ 07004.

| NAME AND ADDRESS            | NUMBER OF SHARES OF COMMON STOCK<br>BENEFICIALLY OWNED (1) | PERCENTAGE OF<br>COMMON STOCK |
|-----------------------------|--|-------------------------------|
| Dr. Jose Antonio O'Daly (2) | 13,640,000   | 18.69                         |
| Mike Ajnsztajn (2) (3)      | 8,680,000  | 11.89                         |
| Gina Tedesco (2) (3)        | 8,680,000  | 11.89                         |
| Gaston Liebhaber (2)        | 2,480,000  | 3.40                          |
| Michael Ashton (4)          | 25,220,000   | 34.54                         |

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|   |            |       |
|---|------------|-------|
| Fabien Pictet (5)   | 3,542,000  | 4.85  |
| Steven Fulda (6)  | 29,700     |       |
| SkyePharma PLC (2) (7)<br>105 Piccadilly<br>London W1J 7NJ<br>England | 25,220,000 | 34.54 |
| All Officers and Directors<br>as a Group                              | 53,591,700 | 71.69 |

-----  
\* Less than 1%

(1) Beneficial ownership is determined in accordance with Rule 13d-3(a) of the Securities Exchange Act of 1934 and generally includes voting or investment power with respect to securities. Except as indicated by footnotes and subject to community property laws, where applicable, the person named above has sole voting and investment power with respect to all shares of the common stock shown as beneficially owned by him. The beneficial ownership percentage is based on 72,998,055 shares of our common stock outstanding as of March 26, 2004.

(2) Under the terms of Amendment No. 1 to the Stockholders' Agreement dated as of January 20, 2004 by and among SkyePharma, Jose O'Daly, Mike Ajnsztajn, Gaston Liebhaber, Gina Tedesco and us, the parties agreed to vote all shares held by such parties for (i) one director designated by Mike Ajnsztajn, (ii) one director designated by Jose O'Daly, (iii) one director designated by Gaston Liebhaber, (iv) one director designated by Gina Tedesco, (v) one director designated by SkyePharma and (vi) two independent director. No party to the agreement has the right to dispose (or direct the disposition of) any shares of common stock held by any of the other parties to the agreement. Accordingly, each party disclaims beneficial ownership of the shares held by the other parties.

(3) Ms. Tedesco, our Chief Financial Officer, may be deemed to be the beneficial owner of the 8,680,000 shares of common stock owned as of March 26, 2004 by her husband, Mike Ajnsztajn. Ms. Tedesco disclaims beneficial ownership of such shares.

(4) Includes 25,200,000 shares of common stock beneficially owned by SkyePharma and warrants to purchase 20,000 shares of common stock beneficially owned by SkyePharma. Mr. Ashton is Chief Executive Officer of SkyePharma. Under the terms of a Call Option Agreement dated January 20, 2004, we have the right to repurchase some or all of 12,500,000 shares of our common stock from SkyePharma. The call option will be exercisable by us for a period commencing upon our achievement of a certain milestone event and ending on January 20, 2007.

(5) Includes 1,260,000 shares of common stock owned by FPP Emerging Hedge Fund and warrants to purchase an aggregate of 1,176,000 shares of common stock owned by FPP Emerging Hedge Fund. Includes 390,000 shares of common stock and warrants to purchase 500,000 shares of common stock owned by Perly International Ltd. Also includes 180,000 shares of common stock owned by Pictet Private Equity Investors and warrants to purchase 36,000 shares held by Pictet Private Equity

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Investors.

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(6) Includes 4,700 shares of common stock owned as of March 26, 2004 by Mr. Fulda's spouse. Mr. Fulda disclaims beneficial ownership of such shares. Also includes options to purchase 25,000 shares of common stock.

(7) Includes 25,200,000 shares of common stock and warrants to purchase 20,000 shares of common stock held by SkyePharma PLC. Michael Ashton, Chief Executive Officer of SkyePharma and a member of our Board of Directors, exercises voting control over the shares held by SkyePharma. Under the terms of a Call Option Agreement dated January 20, 2004, we have the right to repurchase some or all of 12,500,000 shares of our common stock from SkyePharma. The call option will be exercisable by us for a period commencing upon our achievement of a certain milestone event and ending on January 20, 2007.

The following table provides information with respect to the equity securities that are authorized for issuance under our compensation plans as of December 31, 2003:

| EQUITY COMPENSATION PLAN INFORMATION                       |  |  |  |
|--|--|--|--|
|  | Number of securities to be issued upon exercise of outstanding options, warrants and rights<br>(a) | Weighted-average exercise price of outstanding options, warrants and rights<br>(b) | Number of securities remaining available for issuance under compensation plans (excluding securities reflected in the table) |
| Equity compensation plans approved by security holders     | 365,000  | \$0.45-\$2.74  | 4,635,000  |
| Equity compensation plans not approved by security holders | --   | --   | --   |
| <b>Total</b>   | <b>365,000</b>   | <b>\$0.45-\$2.74</b>   | <b>4,635,000</b>   |

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

GENERAL

Centro Para La Investigacion y Tratamiento De La Psoriasis, a research entity owned by Helen O'Daly, the spouse of Dr. Jose Antonio O'Daly, provided assistance in the research and development of Psoraxine in Venezuela commencing in November 2001 and terminating in May 2002. We paid approximately \$275,000 to CITP for the services it provided.

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In connection with private placements of units consisting of common stock and warrants that occurred in 2004, Fabien Pictet and his assigns received a consulting fee of \$261,496, warrants to purchase 418,394 shares of our common stock at \$0.50 per share and warrants to purchase 418,394 shares of our common stock at \$0.73 per share. Upon exercise of the warrants issued in the private placement, we will pay a cash commission equal to 5% of the amounts raised through the exercise of the warrants.

### RELATIONSHIP WITH SKYEPHARMA

We entered into a Purchase Agreement dated as of December 10, 2001 with SkyePharma PLC (SkyePharma) pursuant to which SkyePharma purchased an aggregate of 2,000,000 shares of our Series A Convertible Preferred Stock, par value \$.001 per share ("Series A Preferred Stock"), for an aggregate purchase price of \$20.0 million. On January 20, 2004, pursuant to an Omnibus Conversion Agreement dated January 12, 2004 between us and SkyePharma, SkyePharma converted all of its outstanding shares of Series A Preferred Stock into 25,000,000 shares of our common stock at a conversion price of \$0.80 per share. As a result of its conversion, SkyePharma beneficially owns 34.54% of our common stock on a fully diluted basis.

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On January 20, 2004, we and SkyePharma entered into a Call Option Agreement pursuant to which we received the right to repurchase some or all of 12,500,000 shares of our common stock from SkyePharma at a premium to the conversion price. The call option will be exercisable by us upon our achievement of a certain milestone event and ending on January 20, 2007.

On January 20, 2004, we, SkyePharma and other stockholders who are parties to the Stockholders Agreement dated December 10, 2001, entered into an amendment of the Stockholders Agreement to provide for, among other things, the termination of the agreement on the later of (1) January 20, 2007 or (2) the date on which SkyePharma no longer beneficially owns 20% of our outstanding common stock. The amended Stockholders Agreement requires the parties to agree to vote all shares held by such parties for one director designated by Mike Ajnsztajn, one director designated by Jose O'Daly, one director designated by Gaston Liebhaber, one director designated by Gina Tedesco, one director designated by SkyePharma and two independent directors. In addition, SkyePharma is required to vote its shares of our common stock in favor of certain enumerated transactions, where those transactions have been approved by our board of directors and all of the independent directors.

On December 10, 2001, we entered into a Technology Access Option Agreement and a Service Agreement with SkyePharma. Also, effective as of January 1, 2003, we entered into an Amendment to the Service Agreement with SkyePharma. These agreements were described under "Description of Business -- Agreements with SkyePharma."

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### ITEM 13. EXHIBITS AND REPORTS ON FORM 8-K.

#### (A) EXHIBITS

EXHIBIT NUMBER

DESCRIPTION

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|           |  |
|-----------|--|
| -----     | -----  |
| 3.1       | Certificate of Incorporation of Astralis Ltd.  |
| 3.2 *     | Bylaws of Astralis Ltd.  |
| 10.1 *    | Agreement and Plan of Merger   |
| 10.2 #    | Contribution Agreement dated September 10, 2001  |
| 10.3 ##   | Purchase Agreement dated December 10, 2001   |
| 10.4 ##   | Stockholder Agreement dated December 10, 2001  |
| 10.5 +    | 2001 Stock Option Plan   |
| 10.6 **   | Sub-Lease Agreement  |
| 10.7 **   | License Agreement dated April 26, 2001 between Jose Antonio O'Daly   |
| 10.8 **   | Assignment of License  |
| 10.9 **   | Form of Warrant  |
| 10.10 ++  | Agreement for Services dated December 10, 2001 between SkyePharma  |
| 10.11 ++  | Technology Access Option Agreement dated December 10, 2001 by and<br>Inc., SkyePharma Holding AG and Astralis Ltd.   |
| 10.12 ### | Employment Agreement dated December 10, 2001, between Dr. Jose Ant<br>Astralis Ltd.  |
| 10.13 ### | Amendment #1 to Agreement for Services dated March 18, 2003 betwee<br>and Astralis Ltd.  |
| 10.14     | Omnibus Conversion Agreement dated January 12, 2004 between Astral<br>SkyePharma PLC   |
| 10.15     | Call Option Agreement dated January 20, 2004 between Astralis Ltd.   |
| 10.16     | Amendment No. 1 to Stockholders Agreement dated January 20, 2004 b<br>Astralis Ltd., SkyePharma PLC, Jose Antonio O'Daly, Mike Ajnsztajn<br>and Gina Tedesco |
| 14.1      | Code of Ethics for CEO and Senior Financial Officers   |
| 31.1      | Certification by the Chief Executive Officer pursuant to Section 3<br>Sarbanes-Oxley Act of 2002   |
| 31.2      | Certification by the Chief Financial Officer pursuant to Section 3<br>Sarbanes-Oxley Act of 2002   |
| 32.1      | Certification pursuant to Section 906 of the Sarbanes-Oxley Act of   |
| -----     |  |

\* Previously filed with the Securities and Exchange Commission as an Exhibit to the Preliminary Proxy Statement for Astralis Pharmaceuticals Ltd. on November 16, 2001.

# Previously filed with the Securities and Exchange Commission as an Exhibit to

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the Current Report on Form 8-K for Astralis Pharmaceuticals Ltd. on November 14, 2001.

## Previously filed with the Securities and Exchange Commission as an Exhibit to the Current Report on Form 8-K for Astralis Ltd. on December 14, 2001.

### Previously filed with the Securities and Exchange Commission as an Exhibit to the Annual Report on Form 10-KSB on March 31, 2003.

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+ Previously filed with the Securities and Exchange Commission as an Exhibit to the Preliminary Proxy Statement for Hercules Development Group Inc. on October 4, 2001.

\*\* Previously filed with the Securities and Exchange Commission as an Exhibit to the Registration Statement on Form SB-2 for Astralis Ltd. on March 14, 2002.

++ Previously filed with the Securities and Exchange Commission as an Exhibit to the Amendment to the Registration Statement on Form SB-2 for Astralis Ltd. on July 23, 2002.

### (B) REPORTS ON FORM 8-K

On November 17, 2003, we filed a current report on Form 8-K reporting our results of operations and financial condition for the quarter ended September 30, 2003 in a press release dated November 14, 2003.

### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following disclosure presents fees billed for professional services rendered by L J Soldinger Associates LLC, our independent auditors, for 2003 and 2002.

#### AUDIT FEES

The aggregate fees billed for professional services in connection with the audit of our annual financial statements, and the reviews of our quarterly financial statements and audit services provided in connection with regulatory filings, were approximately \$140,000 and \$141,000 for 2003 and 2002, respectively.

#### AUDIT-RELATED FEES

There were no audit-related fees provided by our independent auditor in 2003. Audit-related fees for fiscal 2002 totaled \$11,000, which represents fees billed primarily for assurance and related services in connection with business combinations and consultations concerning financial accounting and reporting standards reasonably related to the performance of the audit or reviews of our financial statements.

#### TAX FEES

There were no tax related services provided by our independent auditors in 2003 or 2002.

#### ALL OTHER FEES

There were no other services provided by our independent auditors in 2003 or 2002

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### PRE-APPROVAL OF AUDIT AND PERMISSIBLE NON-AUDIT SERVICES

The Audit Committee pre-approves all audit and permissible non-audit services provided by the independent auditors. These services may include audit services, audit-related services, tax services and other services. The Audit Committee has adopted a policy for the pre-approval of services provided by the independent auditors. Under the policy, pre-approval is generally provided for up to one year and any pre-approval is detailed as to the particular service or category of services and is subject to a specific budget. In addition, the Audit Committee may pre-approve particular services on a case-by-case basis. For each proposed service, the independent auditor is required to provide detailed back-up documentation at the time of approval. All audit and permissible non-audit services provided by L J Soldinger Associates LLC to us for 2003 and 2002 were approved by the Audit Committee.

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### SIGNATURES

In accordance with Section 13 and 15(d) of the Securities Exchange Act of 1934, the Registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ASTRALIS LTD.  
(Registrant)

By: /s/ Mike Ajnsztajn

-----  
Mike Ajnsztajn  
Chief Executive Officer

In accordance with the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons in the capacities and on the dates indicated.

| Signature<br>-----  | Title<br>-----   | Date<br>----   |
|---|--|----------------|
| /s/ Jose Antonio O'Daly<br>-----<br>Dr. Jose Antonio O'Daly | Chairman of the Board  | March 29, 2004 |
| /s/ Mike Ajnsztajn<br>-----<br>Mike Ajnsztajn               | Chief Executive Officer and<br>Director<br>(principal executive officer)                   | March 29, 2004 |
| /s/ Gina Tedesco<br>-----<br>Gina Tedesco                   | Chief Financial Officer and<br>Director<br>(principal financial and<br>accounting officer) | March 29, 2004 |
| /s/ Steven Fulda  | Director   | March 26, 2004 |

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-----  
Steven Fulda

/s/ Gaston Liebhaber

Director

March 29, 2004

-----  
Gaston Liebhaber

/s/ Fabien Pictet

Director

March 29, 2004

-----  
Fabien Pictet

/s/ Michael Ashton

Director

March 26, 2004

-----  
Michael Ashton

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ASTRALIS LTD.  
(A DEVELOPMENT STAGE ENTITY)

INDEX TO THE FINANCIAL STATEMENTS

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| Statements of Stockholders' Equity | F-5          |
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| Notes to Financial Statements      | F-12         |

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INDEPENDENT AUDITORS' REPORT

Board of Directors and Shareholders  
Astralis Ltd.  
Fairfield, New Jersey

We have audited the accompanying balance sheets of Astralis Ltd. (a development

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stage entity) as of December 31, 2003 and 2002, and the related statements of operations, stockholders' equity, and cash flows for the years then ended and the period March 12, 2001 (date of inception) through December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with auditing standards generally accepted in the United States of America. 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 statements presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Astralis Ltd. as of December 31, 2003 and 2002, and the results of operations, changes in stockholders' equity and its cash flows for the years then ended and the period March 12, 2001 (date of inception) through December 31, 2003 in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the financial statements, the Company has incurred net losses since inception. Also, the Company does not have sufficient funds to execute its business plan. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans regarding those matters are also described in Note 3. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

L J SOLDINGER ASSOCIATES

Deer Park, Illinois  
March 2, 2004

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ASTRALIS LTD.  
(A DEVELOPMENT STAGE ENTITY)  
Balance Sheets

ASSETS

Current Assets

Cash and cash equivalents  
Marketable securities

-----  
2003  
-----  
\$ 10,  
1,374,

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|   |           |
|---|-----------|
| Interest receivable (net of allowance for doubtful accounts of \$16,088)  | 1,007,    |
| Prepaid expense - related party   | 84,       |
| Prepaid expenses  | 87,       |
| Supplies  | -----     |
| Total Current Assets  | 2,564,    |
| Intangible Assets, Net - Related Party  | 3,511,    |
| Other Intangible Assets, Net  | 94,       |
| Property and Equipment, Net   | 293,      |
| Deposits  | 29,       |
|   | -----     |
|   | \$ 6,493, |
|   | =====     |
| LIABILITIES AND STOCKHOLDERS' EQUITY  |           |
| Current Liabilities   |           |
| Accounts payable and accrued expenses   | \$ 279,   |
|   | -----     |
| Total Current Liabilities   | 279,      |
|   | -----     |
| Commitments and Contingencies   |           |
| Stockholders' Equity  |           |
| Convertible preferred stock, Series A, \$.001 par value; 3,000,000 shares authorized at 2003 and 2002; 2,000,000 and 1,750,000 issued and outstanding at 2003 and 2002, respectively<br>(liquidation preference - \$22,122,600 at 2003) | 2,        |
| Common stock; \$.0001 par value; 150,000,000 shares authorized at 2003; 37,538,189 issued and outstanding at 2003 and 2002  | 3,        |
| Additional paid-in capital  | 35,929,   |
| Deferred compensation   | (4,       |
| Common stock subscriptions receivable   | (24,      |
| Accumulated other comprehensive loss  | (27,      |
| Deficit accumulated in the development stage  | (29,664,  |
|   | -----     |
| Total Stockholders' Equity  | 6,214,    |
|   | -----     |
|   | \$ 6,493, |
|   | =====     |

See independent auditors' report and the accompanying notes to financial statements.

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ASTRALIS LTD.  
(A DEVELOPMENT STAGE ENTITY)  
Statements of Operations

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|  | Year Ended December 31, |                 | March         |
|--|-------------------------|-----------------|---------------|
|  | 2003                    | 2002            | (Ince<br>Dece |
| Revenues                                 | \$ --                   | \$ --           | \$            |
| Operating Expenses                       |                         |                 |               |
| Research and development - related party | 1,721,788               | 6,834,399       | 11            |
| Research and development                 | 2,323,885               | 927,143         | 3             |
| Depreciation and amortization            | 26,062                  | 15,728          |               |
| General and administrative               | 1,290,346               | 1,374,251       | 3             |
|  | -----                   | -----           | -----         |
| Total Operating Expenses                 | 5,362,081               | 9,151,521       | 18            |
|  | -----                   | -----           | -----         |
| Loss From Operations                     | (5,362,081)             | (9,151,521)     | (18           |
| Investment Income                        | 60,018                  | 111,273         |               |
|  | -----                   | -----           | -----         |
| Loss before income tax benefit           | (5,302,063)             | (9,040,248)     | (18           |
| Income tax benefit                       | 221,636                 | --              |               |
|  | -----                   | -----           | -----         |
| Net Loss                                 | (5,080,427)             | (9,040,248)     | (18           |
| Preferred Stock Dividends                | --                      | (9,348,750)     | (11           |
|  | -----                   | -----           | -----         |
| Net Loss to Common Stockholders          | \$ (5,080,427)          | \$ (18,388,998) | \$ (29        |
|  | =====                   | =====           | =====         |
| Basic and Diluted Loss per Common Share  | \$ (0.14)               | \$ (0.49)       |               |
|  | =====                   | =====           |               |
| Basic and Diluted Weighted Average       |                         |                 |               |
| Common Shares Outstanding                | 37,538,189              | 37,541,339      |               |
|  | =====                   | =====           |               |

See independent auditors' report and the accompanying notes to financial statements.

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ASTRALIS LTD.  
(A DEVELOPMENT STAGE ENTITY)  
Statements of Stockholders' Equity

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|   | Preferred Stock |          | Common     |
|---|-----------------|----------|------------|
|   | Shares          | Amount   | Shares     |
| Balances, March 12, 2001<br>(Date of Inception)   | --              | \$ --    | --         |
| Members' capital contributions, 3/15/2001   | --              | --       | 25,300,000 |
| Capital contributions received,<br>3/1 - 8/13/2001  | --              | --       | --         |
| Members' contributed services,<br>3/15 - 6/30/2001  | --              | --       | --         |
| Members' capital contributions, 9/1/2001  | --              | --       | 2,700,000  |
| Warrants to purchase 6,300,000<br>shares of common stock at \$1.60 per share<br>issued in private placement                           | --              | --       | --         |
| Common stock issuable for consulting<br>services, 9/1/2001; 500,000 shares  | --              | --       | --         |
| Common stock issued in private<br>placement net of issuance costs,<br>11/13/2001; 2,076,179 shares at<br>\$1.60 per share             | --              | --       | 2,076,179  |
| Warrants to purchase 415,237 shares<br>of common stock at \$4.00 per share<br>issued in private placement, 11/13/2001                 | --              | --       | --         |
| Net assets and liabilities acquired<br>in merger with Hercules  | --              | --       | 7,512,000  |
| Preferred stock issued, net of<br>issuance costs, 12/10/2001; 1,000,000<br>shares at \$10.00 per share                                | 1,000,000       | 1,000    | --         |
| Preferred stock dividend, 12/10/2001  | --              | --       | --         |
| Options to purchase 200,000 shares of<br>common stock at \$1.77 (based on<br>valuation) issued for legal<br>services, 12/31/2001      | --              | --       | --         |
| Options to purchase 100,000 shares of<br>common stock at \$1.77 (based on<br>valuation) issued for consulting<br>services, 12/31/2001 | --              | --       | --         |
| Amortization of deferred compensation   | --              | --       | --         |
| Net loss  | --              | --       | --         |
| Balance, December 31, 2001  | 1,000,000       | \$ 1,000 | 37,588,179 |

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ASTRALIS LTD.  
(A DEVELOPMENT STAGE ENTITY)  
Statements of Stockholders' Equity

|   | Subscription<br>Receivable<br>----- | Deferred<br>Compensation<br>----- | Accumulated<br>Other<br>Comprehensive<br>Loss<br>----- | Deficit<br>Accumulated<br>During the<br>Development<br>Stage<br>----- |
|---|-------------------------------------|-----------------------------------|--|---|
| Balances, March 12, 2001<br>(Date of Inception)   | \$ --                               | \$ --                             | \$ --  | \$ --   |
| Members' capital contributions, 3/15/2001   | (33,183)                            | --                                | --   | --  |
| Capital contributions received,<br>3/1 - 8/13/2001  | 33,183                              | --                                | --   | --  |
| Members' contributed services,<br>3/15 - 6/30/2001  | --                                  | --                                | --   | --  |
| Members' capital contributions, 9/1/2001  | (1,350,000)                         | --                                | --   | --  |
| Warrants to purchase 6,300,000 shares of<br>common stock at \$1.60 per share issued<br>in private placement                   | --                                  | --                                | --   | --  |
| Common stock issuable for consulting<br>services, 9/1/2001; 500,000 shares  | --                                  | --                                | --   | --  |
| Common stock issued in private placement<br>net of issuance costs, 11/13/2001;<br>2,076,179 shares at \$1.60 per share        | --                                  | --                                | --   | --  |
| Warrants to purchase 415,237 shares of<br>common stock at \$4.00 per share issued<br>in private placement, 11/13/2001         | --                                  | --                                | --   | --  |
| Net assets and liabilities acquired in<br>merger with Hercules  | --                                  | --                                | --   | --  |
| Preferred stock issued, net of issuance<br>costs, 12/10/2001; 1,000,000 shares<br>at \$10.00 per share                        | --                                  | --                                | --   | --  |
| Preferred stock dividend, 12/10/2001  | --                                  | --                                | --   | (2,120,000)   |
| Options to purchase 200,000 shares of<br>common stock at \$1.77 (based on valuation)<br>issued for legal services, 12/31/2001 | --                                  | (354,000)                         | --   | --  |

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|  |                |              |       |               |
|--|----------------|--------------|-------|---------------|
| Options to purchase 100,000 shares of common stock at \$1.77 (based on valuation) issued for consulting services, 12/31/2001 | --             | (177,000)    | --    | --            |
| Amortization of deferred compensation  | --             | 132,750      | --    | --            |
| Net loss   | --             | --           | --    | (4,075,36)    |
| Balance, December 31, 2001   | \$ (1,350,000) | \$ (398,250) | \$ -- | \$ (6,195,36) |

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See independent auditors' report and the accompanying notes to financial statements.

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ASTRALIS LTD.  
(A DEVELOPMENT STAGE ENTITY)  
Statements of Stockholders' Equity

|  | Preferred Stock |          | Comm       |
|--|-----------------|----------|------------|
|  | Shares          | Amount   | Shares     |
| Balances Brought Forward   | 1,000,000       | \$ 1,000 | 37,588,179 |
| Oversubscription of common stock issued in private placement, 11/13/2001; 49,990 shares cancelled at \$1.60 per share, 1/24/2002 | --              | --       | (49,990)   |
| Preferred stock issue, net of issuance costs, 1/31/2002; 250,000 shares at \$10.00 per share                                     | 250,000         | 250      | --         |
| Preferred stock issue, net of issuance costs, 4/30/2002; 250,000 shares at \$10.00 per share                                     | 250,000         | 250      | --         |
| Preferred stock dividend, April 30, 2002   | --              | --       | --         |
| Preferred stock issue, net of issuance costs, 7/31/2002; 250,000 shares at \$10.00 per share                                     | 250,000         | 250      | --         |
| Collection of subscription receivable  | --              | --       | --         |
| Options issued for consulting services, 9/10/2002; 15,000 options at \$0.38 per option, based on valuation                       | --              | --       | --         |
| Preferred stock dividend, 12/10/2002   | --              | --       | --         |
| Amortization of deferred compensation  | --              | --       | --         |
| Fair value adjustment on deferred compensation   | --              | --       | --         |

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COMPREHENSIVE LOSS

|   |           |          |            |
|---|-----------|----------|------------|
| Net loss  | --        | --       | --         |
| Other comprehensive loss:                               |           |          |            |
| Unrealized gain (loss) on available-for-sale securities | --        | --       | --         |
| Total Comprehensive Loss                                | -----     | -----    | -----      |
| Balance, December 31, 2002                              | 1,750,000 | \$ 1,750 | 37,538,189 |
|   | =====     | =====    | =====      |

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ASTRALIS LTD.  
(A DEVELOPMENT STAGE ENTITY)  
Statements of Stockholders' Equity

|   | Subscription<br>Receivable | Deferred<br>Compensation | Accumulated<br>Other<br>Comprehensive<br>Loss | Deficit<br>Accumula<br>During<br>Developm<br>Stage |
|---|----------------------------|--------------------------|---|--|
|   | -----                      | -----                    | -----   | -----  |
| Balances Brought Forward  | \$ (1,350,000)             | \$ (398,250)             | \$ --   | \$ (6,195,   |
| Oversubscription of common<br>stock issued in private placement,<br>11/13/2001; 49,990 shares cancelled<br>at \$1.60 per share, 1/24/2002 | --                         | --                       | --  |  |
| Preferred stock issue, net of<br>issuance costs, 1/31/2002; 250,000<br>shares at \$10.00 per share  | --                         | --                       | --  |  |
| Preferred stock issue, net of<br>issuance costs, 4/30/2002;<br>250,000 shares at \$10.00 per share  | --                         | --                       | --  |  |
| Preferred stock dividend, April 30, 2002  | --                         | --                       | --  | (270,  |
| Preferred stock issue, net of<br>issuance costs, 7/31/2002; 250,000<br>shares at \$10.00 per share  | --                         | --                       | --  |  |
| Collection of subscription receivable   | 465,000                    | --                       | --  |  |
| Options issued for consulting services,<br>9/10/2002; 15,000 options at \$0.38 per<br>option, based on valuation                          | --                         | (5,700)                  | --  |  |

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|  |              |             |             |             |
|--|--------------|-------------|-------------|-------------|
| Preferred stock dividend, 12/10/2002             | --           | --          | --          | (9,078,     |
| Amortization of deferred compensation            | --           | 34,254      | --          |             |
| Fair value adjustment on deferred compensation   | --           | 357,532     | --          |             |
| COMPREHENSIVE LOSS                               |              |             |             |             |
| Net loss   | --           | --          | --          | (9,040,     |
| Other comprehensive loss:                        |              |             |             |             |
| Unrealized loss on available-for-sale securities | --           | --          | (15,181)    |             |
|  | -----        | -----       | -----       | -----       |
| Total Comprehensive Loss                         |              |             |             |             |
| Balance, December 31, 2002                       | \$ (885,000) | \$ (12,164) | \$ (15,181) | \$ (24,584, |
|  | =====        | =====       | =====       | =====       |

See independent auditors' report and the accompanying notes to financial statements.

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ASTRALIS LTD.  
(A DEVELOPMENT STAGE ENTITY)  
Statements of Stockholders' Equity

|   | Preferred Stock |          | Common     |
|---|-----------------|----------|------------|
|   | Shares          | Amount   | Shares     |
|   | -----           | -----    | -----      |
| Balances Brought Forward  | 1,750,000       | \$ 1,750 | 37,538,189 |
| Preferred stock issue, net of issuance costs,<br>1/31/2003; 250,000 shares at \$10.00 per share | 250,000         | 250      | --         |
| Collection of subscription receivable   | --              | --       | --         |
| Reduction of subscription receivable,<br>in lieu of payment for services                        | --              | --       | --         |
| Amortization of deferred compensation   | --              | --       | --         |
| Fair value adjustment on deferred compensation  | --              | --       | --         |
| Offering cost for January 2004 private placement  | --              | --       | --         |
| COMPREHENSIVE LOSS  |                 |          |            |

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|   |           |          |            |
|---|-----------|----------|------------|
| Net loss  | --        | --       | --         |
| Other comprehensive loss:                               |           |          |            |
| Unrealized gain (loss) on available-for-sale securities | --        | --       | --         |
|   | -----     | -----    | -----      |
| Total Comprehensive Loss                                |           |          |            |
| Balance, December 31, 2003                              | 2,000,000 | \$ 2,000 | 37,538,189 |
|   | =====     | =====    | =====      |

See independent auditors' report and the accompanying notes to financial statements.

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ASTRALIS LTD.  
(A DEVELOPMENT STAGE ENTITY)  
Statements of Stockholders' Equity

|  | Subscription<br>Receivable | Deferred<br>Compensation | Accumulated<br>Other<br>Comprehensive<br>Loss | Deficit<br>Accumulated<br>During the<br>Development<br>Stage |
|--|----------------------------|--------------------------|---|--|
|  | -----                      | -----                    | -----   | -----  |
| Balances Brought Forward   | \$ (885,000)               | \$ (12,164)              | \$ (15,181)                                   | \$ (24,584,362)  |
| Preferred stock issue, net of<br>issuance costs, 1/31/2003; 250,000<br>shares at \$10.00 per share | --                         | --                       | --  | --   |
| Collection of subscription receivable  | 825,000                    | --                       | --  | --   |
| Reduction of subscription receivable,<br>in lieu of payment for services                           | 36,000                     | --                       | --  | --   |
| Amortization of deferred compensation  | --                         | 25,663                   | --  | --   |
| Fair value adjustment on deferred<br>compensation  | --                         | (18,321)                 | --  | --   |
| Offering cost for January 2004,<br>private placement   | --                         | --                       | --  | --   |
| COMPREHENSIVE LOSS   |                            |                          |   |  |
| Net loss   | --                         | --                       | --  | (5,080,427)  |
| Other comprehensive loss:  |                            |                          |   |  |
| Unrealized gain (loss) on<br>available-for-sale Securities, net                                    | --                         | --                       | (12,517)                                      | --   |
|  | -----                      | -----                    | -----   | -----  |

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Total Comprehensive Loss

|                            |             |            |             |                 |
|----------------------------|-------------|------------|-------------|-----------------|
| Balance, December 31, 2003 | \$ (24,000) | \$ (4,822) | \$ (27,698) | \$ (29,664,789) |
|                            | =====       | =====      | =====       | =====           |

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ASTRALIS LTD.  
(A DEVELOPMENT STAGE ENTITY)  
Statements of Cash Flows

|   | Year Ended Decem |       |
|---|------------------|-------|
|   | -----            |       |
|   | 2003             |       |
|   | -----            |       |
| Cash Flows from Operating Activities  |                  |       |
| Net loss  | \$ (5,080,427)   | \$    |
| Adjustments to reconcile net loss to net cash used in operating activities                          |                  |       |
| Depreciation and amortization   | 847,754          |       |
| Amortization of net premium paid on investments   | 5,737            |       |
| Dividend income reinvested  | (72,308)         |       |
| Members' contributed salaries   | --               |       |
| Research and development service fee netted against proceeds received from preferred stock issuance | 20,000           |       |
| Operating expenses paid by related parties on behalf of Company                                     | --               |       |
| Amortization of deferred compensation   | 25,663           |       |
| Investor relation fees netted against subscription receivable                                       | 36,000           |       |
| Compensatory common stock   | --               |       |
| Loss on sale of available-for-sale securities   | 23,759           |       |
| Changes in assets and liabilities   |                  |       |
| Prepaid expenses  | 975,847          |       |
| Interest receivable   | 5,891            |       |
| Supplies  | (56,798)         |       |
| Deposits  | --               |       |
| Accounts payable and accrued expenses   | (1,169)          |       |
|   | -----            | ----- |
| Net Cash Used in Operating Activities   | (3,270,051)      |       |
|   | -----            | ----- |
| Cash Flows from Investing Activities  |                  |       |
| Purchases of available-for-sale securities  | (1,919,734)      |       |
| Proceeds from sale of available-for-sale securities   | 1,783,032        |       |
| Expenditures related to patent  | (36,267)         |       |
| Purchases of property and equipment   | (60,910)         |       |
|   | -----            | ----- |
| Net Cash Used in Investing Activities   | (233,879)        |       |
|   | -----            | ----- |

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|   |           |
|---|-----------|
| Cash Flows from Financing Activities                            |           |
| Repurchase of common stock                                      | --        |
| Collection of subscription receivable                           | 825,000   |
| Issuance of common stock, net of offering and transaction costs | --        |
| Issuance of preferred stock                                     | 2,480,000 |
| Private placement offering costs                                | (17,603)  |
|   | -----     |
| Net Cash Provided by Financing Activities                       | 3,287,397 |
|   | -----     |
| Net Increase (Decrease) in Cash and Cash Equivalents            | (216,533) |
| Cash and Cash Equivalents, Beginning of Period                  | 227,193   |
|   | -----     |
| Cash and Cash Equivalents, End of Period                        | \$ 10,660 |
|   | =====     |

See independent auditors' report and the accompanying notes to financial statements.

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ASTRALIS LTD.  
(A DEVELOPMENT STAGE ENTITY)  
Notes to Financial Statements

### NOTE 1 - DESCRIPTION OF BUSINESS

#### Nature of Operations

Astralis, Ltd. (the "Company") is an emerging stage biotechnology company, based in New Jersey and incorporated under the laws of the State of Delaware, which primarily engages in research and development of treatments for immune system disorders and skin diseases. The Company is currently developing two products. Psoraxine(R), administered by intramuscular injection, is a protein based therapy for the treatment of psoriasis. The Company's second product is for the treatment of leishmaniasis. The Company is also engaged in research on the possible development of the technology underlying Psoraxine(R) for the treatment of other indications, such as eczema, and psoriatic arthritis.

### NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### Basis of Presentation

The Company's financial statements are prepared on the accrual basis of accounting in accordance with United States generally accepted accounting principles ("US GAAP").

#### Development Stage Enterprise

The Company is a Development Stage Enterprise, as defined in Statement of Financial Accounting Standards No. 7 "Accounting and Reporting for Development Stage Enterprises" ("SFAS No. 7"). Under SFAS No. 7, certain additional financial information is required to be included in the financial statements for the period from inception of the Company to the current balance sheet date.

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Since the inception of the Company, management has been in the process of performing research and development activities, fulfilling FDA requirements in order to enter human clinical trials in the US with Psoraxine(R), initiating Phase I clinical studies and the raising of capital through private placement stock offerings.

### Use of Estimates

The preparation of financial statements in conformity with US GAAP 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.

### Cash and Cash Equivalents

Cash and cash equivalents include cash on hand and investments in money market funds. The Company considers all highly liquid instruments with an original maturity of 90 days or less at the time of purchase to be cash equivalents.

### Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash deposits at financial institutions. To mitigate this risk, the Company places its cash deposits only with high credit quality institutions.

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ASTRALIS LTD.  
(A DEVELOPMENT STAGE ENTITY)  
Notes to Financial Statements

### NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

#### Property and Equipment

Furniture and equipment are recorded at cost, less accumulated depreciation computed on a straight-line basis over the estimated useful lives of the respective assets. Depreciation is computed using a four-year life for computer and office equipment, three to four years for lab equipment, five-year for automobile, seven-year for furniture and fixtures and three-year for leasehold improvements.

#### Income Taxes

Income taxes are recorded in the period in which the related transactions are recognized in the financial statements, net of the valuation allowances, which have been recorded against deferred tax assets. Deferred tax assets and liabilities are recorded for the expected future tax consequences of temporary differences between the tax basis and the financial reporting of assets and liabilities. Net deferred tax assets and liabilities, relating primarily to federal and state net operating loss carryforwards and research and development credits that have been deferred for tax purposes have also been recorded. A valuation reserve has been recorded to offset a portion of the deferred tax

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benefit (except for amount realized through the sale of a portion of the Company's New Jersey net operating loss) because management has determined it is more likely than not that the deferred tax assets will not be realized. See Note 7.

### Fair Value of Financial Instruments

The Company's financial instruments, including cash and cash equivalents, accounts payable and accrued expenses, are carried at cost, which approximates fair value.

### Stock-Based Compensation Arrangements

The Company applies the intrinsic value method of accounting prescribed by Accounting Principles Board Opinion No. 25, "Accounting For Stock Issued To Employees," and related interpretations, in accounting for its stock-based grants to employees and directors. Under the intrinsic value method of accounting, compensation expense is recorded on the date of grant only if the current market price of the underlying stock exceeds the exercise price. The Company applies the disclosure provisions specified in SFAS No. 148, "Accounting For Stock Based Compensation - Transition and Disclosure - an Amendment of SFAS 123." The Company applies SFAS No. 123, "Accounting for Stock-Based Compensation," in accounting for stock-based grants to non-employees.

The following table illustrates the effect on net loss and earnings per share if the Company had applied the fair value recognition provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation," to stock-based compensation.

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ASTRALIS LTD.  
(A DEVELOPMENT STAGE ENTITY)  
Notes to Financial Statements

#### NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

|   | Year Ended     |
|---|----------------|
|   | 2003           |
| Net loss, as reported   | \$ (5,080,427) |
| Add:  |                |
| Stock-based compensation expense included in reported net loss determined under APB No. 25, net of related tax effects              | --             |
| Deduct:   |                |
| Total stock-based director compensation expense determined under fair-value-based method for all awards, net of related tax effects | 11,589         |
|   | -----          |
| Pro forma net loss  | \$ (5,092,016) |
|   | =====          |
| Loss per share:   |                |
| Basic - as reported   | \$ (0.14)      |

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Basic - pro forma

\$ (0.14)

These pro forma amounts may not be representative of future disclosures since the estimated fair value of stock options is amortized to expense over the vesting period and additional options may be issued in future years. The estimated fair value of each option granted was calculated using the Black-Scholes option-pricing model. The following summarizes the weighted average of the assumptions used in the model.

|                               | 2003   | 2002  |
|-------------------------------|--------|-------|
|                               | ----   | ----  |
| Risk free rate                | 2.1%   | --    |
| Expected years until exercise | 3.0    | --    |
| Expected stock volatility     | 100.0% | --    |
| Dividend yield                | --     | --    |
|                               | =====  | ===== |

## Loss Per Share

Loss per common share is calculated in accordance with Statement of Financial Accounting Standards No. 128, Earnings Per Share ("FAS 128"). Basic loss per common share is computed based upon the weighted average number of shares of common stock outstanding for the period and excludes any potential dilution. Shares associated with stock options, warrants and convertible preferred stock are not included because their inclusion would be antidilutive (i.e., reduce the net loss per share).

The common shares potentially issuable arising from these instruments, which were outstanding during the periods presented in the financial statements, consisted of:

|                             | 2003         | 2002         |
|-----------------------------|--------------|--------------|
|                             | -----        | -----        |
| Options                     | \$ 365,000   | \$ 315,000   |
| Warrants                    | 6,780,237    | 6,780,237    |
| Convertible preferred stock | 12,500,000   | 10,937,500   |
|                             | -----        | -----        |
|                             | \$19,645,237 | \$18,032,737 |
|                             | =====        | =====        |

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ASTRALIS LTD.  
(A DEVELOPMENT STAGE ENTITY)  
Notes to Financial Statements

## NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

### Segment Information

The Company has determined it has one reportable operating segment as defined by Statement of Financial Accounting Standards No. 131, "Disclosures about Segments of an Enterprise and Related Information."

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### Research and Development Costs

The cost of research, development and product improvement expenditures, which includes depreciation of the Company's laboratory and amortization of the technology access option, are charged to expense as they are incurred. Research, development and product improvement costs included in operating expenses amounted to \$4,045,673 and \$7,761,542 for the years ending December 31, 2003 and 2002, respectively; and \$15,038,990 for the period from March 12, 2001 (date of inception) to December 31, 2003.

Included in this amount were payments to related parties (see Note 11).

### Recent Accounting Pronouncements

In January 2003, the Financial Accounting Standards Board ("FASB") issued Financial Interpretation No. 46, "Consolidation of Variable Interest Entities - An Interpretation of ARB No. 51" (FIN 46 or Interpretation). FIN 46 is an interpretation of Accounting Research Bulletin 51, "Consolidated Financial Statements," and addresses consolidation by business enterprises of variable interest entities (VIEs). The primary objective of the Interpretation is to provide guidance on the identification of, and financial reporting for, entities over which control is achieved through means other than voting rights; such entities are known as VIEs. The Interpretation requires an enterprise to consolidate a VIE if that enterprise has a variable interest that will absorb a majority of the entity's expected losses if they occur, receive a majority of the entity's expected residual returns if they occur or both. An enterprise is required to consider the rights and obligations conveyed by its variable interests in making this determination. On October 9, 2003, the FASB issued Staff Position No. 46-6 which deferred the effective date for applying the provisions of FIN 46 for interests held by public entities in variable interest entities or potential variable interest entities created before February 1, 2003. On December 24, 2003, the FASB issued a revision to FIN 46. Under the revised interpretation, the effective date was delayed to periods ending after March 15, 2004 for all variable interest entities, other than SPEs. The adoption of FIN 46 is not expected to have an impact on the Company's financial condition, results of operations or cash flows.

In April 2003, the FASB issued SFAS No. 149, Amendment of Statement No. 133 on Derivative Instruments and Hedging Activities. This statement amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities under SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities. SFAS No. 149 requires that contracts with comparable characteristics be accounted for similarly. The statement is effective for contracts entered into or modified after June 30, 2003 and for hedging relationships designated after June 30, 2003. The provisions of SFAS No. 149 generally are to be applied prospectively only. The adoption of SFAS No. 149 did not have a material impact on the Company's results of operations or financial position.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity. SFAS No. 150 establishes standards for classification and measurement by an issuer of certain financial instruments with characteristics of both liabilities and equity. The statement requires that an issuer classify a financial instrument that is within its scope as a liability (or asset in some circumstances). Many of those instruments were previously classified as equity. This Statement also addresses questions about the classification of certain financial instruments that embody obligations to issue equity shares. This statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15,

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2003, except as it relates to consolidated limited-life subsidiaries. The FASB

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### NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

indefinitely deferred the effective date of this statement as it relates to certain mandatorily redeemable non-controlling interests in consolidated limited-life subsidiaries. The adoption of the effective provisions of SFAS No. 150 did not have a material impact on the Company's results of operations or financial position.

On December 17, 2003, the Staff of the Securities and Exchange Commission (or SEC) issued Staff Accounting Bulletin No. 104 ("SAB 104"), Revenue Recognition, which supersedes Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements ("SAB 101"). SAB 104's primary purpose is to rescind the accounting guidance contained in SAB 101 related to multiple-element revenue arrangements that was superseded as a result of the issuance of EITF 00-21, Accounting for Revenue Arrangements with Multiple Deliverables. Additionally, SAB 104 rescinds the SEC's related Revenue Recognition in Financial Statements Frequently Asked Questions and Answers issued with SAB 101 that had been codified in SEC Topic 13, Revenue Recognition. While the wording of SAB 104 has changed to reflect the issuance of EITF 00-21, the revenue recognition principles of SAB 101 remain largely unchanged by the issuance of SAB 104, which was effective upon issuance. The adoption of SAB 104 did not have a material effect on the Company's financial position or results of operations.

### NOTE 3 - GOING CONCERN

The Company incurred net losses to common stockholders of \$5,080,427 and \$29,664,789 for the year ended December 31, 2003 and for the period March 12, 2001 (date of inception) to December 31, 2003, respectively. Included in these net losses were non-cash preferred stock dividends generated from beneficial conversion features of preferred stock in the amounts of \$0 for the year ended December 31, 2003 and \$11,468,750 in the cumulative net loss (see Note 8).

Pharmaceutical products must undergo an extensive process, including testing in compliance with U.S. Food and Drug Administration ("FDA") regulations, before they can be commercially sold and distributed in the United States. FDA testing occurs in various phases over a multiple number of years. The Company expects to continue clinical testing of Psoraxine in 2004. The Company will need significant additional funds to complete all of the testing required by the FDA. Currently, the Company has no products approved for commercial sale and therefore no means to generate revenue.

Consequently, the aforementioned items raise substantial doubt about the Company's ability to continue as a going concern.

Management plans to raise additional capital through private placement equity offerings in 2004 (see Note 16). These funds, in addition to its cash and marketable securities held at December 31, 2003, will be needed in order to finance the Company's currently anticipated needs for operating and capital expenditures for 2004, including the cost to complete Phase II of the FDA testing process for Psoraxine. The Company will also need to raise significant

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additional funds from outside sources in future years in order to complete future phases of FDA required testing.

The Company's ability to continue as a going concern is dependent upon raising capital through debt and equity financing. There can be no assurance that the Company will successfully raise the required future financing on terms desirable to the Company or that the FDA will approve Psoraxine for use in the United States. If the Company does not obtain the needed funds, it will likely be required to delay development of its products, alter its business plan, or in the extreme situation, cease operations. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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#### NOTE 4 - MARKETABLE SECURITIES

The Company's marketable equity securities consisted of certificates of deposit, fixed income funds that have a readily determinable fair market value. Management determines the appropriate classifications of its investments using Statement of Financial Accounting Standards ("SFAS") No. 115 "Accounting for Certain Investments in Debt and Equity Securities" at the time of purchase, and re-evaluates such determinations at each balance sheet date.

The securities reflected in these financial statements are deemed by management to be "available-for-sale" and, accordingly, are reported at fair value, with unrealized gains and losses reported in other comprehensive income and reflected as a separate component within the Stockholder's Equity section of the balance sheets. Realized gains and losses on securities available-for-sale are included in other income/expense and, when applicable, are reported as a reclassification adjustment, net of tax, in other comprehensive income. Gains and losses on the sale of available-for-sale securities are determined using the specification method.

As of December 31, 2002, available-for-sale securities consist of the following:

|                         | Due               | Amortized<br>Cost | Gross<br>Unrealized<br>Loss |       |
|-------------------------|-------------------|-------------------|-----------------------------|-------|
|                         | -----             | -----             | -----                       | ----- |
| Certificates of Deposit | 1/2003 to 11/2014 | \$ 512,584        | \$ (8,294)                  | \$    |
| Fixed Income Fund       | current           | 709,776           | (6,911)                     | ---   |
|                         |                   | -----             | -----                       | ----- |
|                         |                   | \$ 1,222,360      | \$ (15,205)                 | \$    |
|                         |                   | =====             | =====                       | ===== |

As of December 31, 2003, available-for-sale securities consist of the following:

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|                   | Due     | Amortized<br>Cost | Gross<br>Unrealized<br>Loss | Gross<br>Unrealized<br>Gains |
|-------------------|---------|-------------------|-----------------------------|------------------------------|
|                   | -----   | -----             | -----                       | -----                        |
| Fixed Income Fund | Current | \$ 1,401,873      | \$ (27,740)                 | \$ 42                        |
|                   |         | -----             | -----                       | -----                        |
|                   |         | \$ 1,401,872      | \$ (27,740)                 | \$ 42                        |
|                   |         | =====             | =====                       | =====                        |

NOTE 5 - INTANGIBLE ASSETS

The Company's policy is to capitalize the costs of purchased and internally developed patents and those expenses in connection with patent rights licensed to the Company. The life of the patent is 20 years from the date the patent is applied for or 17 years from when it is granted, whichever is longer. The Company's policy is to capitalize direct costs related to the rights it has licensed, and amortize them on a straight-line basis over the remaining portion of the 20-year period, which commenced on March 16, 2001, the date the application was filed for the patent the Company has licensed.

The Company paid \$5,000,000 for a technology access option from SkyePharma PLC ("SkyePharma"). This option gives the Company the right, until December 10, 2008, to enter into a non-exclusive license agreement to utilize any of three drug delivery systems of SkyePharma in connection with any drugs it develops to treat two specific immunotherapies. Upon exercise of the option, the Company will be required to pay a license fee of 5% of net sales of any product utilizing the drug delivery systems. All other terms of the license agreement will be determined upon exercise of the option.

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ASTRALIS LTD.  
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NOTE 5 - INTANGIBLE ASSETS (Continued)

Management has taken the position that the technology access option fee is a license fee which allows the Company, prior to commercialization of its drugs, to utilize the established delivery system technologies of SkyePharma to test for viability and enhancement of the Company's product, Psoraxine. In accordance with Financial Accounting Standard No. 2 - Research and Development Costs ("SFAS No. 2"), the Company has capitalized the technology access option as a research and development intangible asset and is amortizing it over its seven-year life. The Company will evaluate this intangible annually for impairment under FAS 144 "Accounting For The Impairment or disposal of Long-Lived Assets."

The Company has amortized \$2,892 and \$2,135 of patent costs and \$714,288 of the cost of the technology option license in 2003 and 2002, respectively. The amortization related to the technology option license is recorded as research and development cost as required by SFAS No. 2.

Intangible assets consisted of the following at December 31,

2003

2002

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|                               |              |              |
|-------------------------------|--------------|--------------|
|                               | -----        | -----        |
| Patent                        | \$ 100,464   | \$ 46,765    |
| Technology access fee         | 5,000,000    | 5,000,000    |
| Less accumulated amortization | (1,493,924)  | (776,744)    |
|                               | -----        | -----        |
|                               | \$ 3,606,540 | \$ 4,270,021 |
|                               | =====        | =====        |

NOTE 6 - PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at December 31,

|  |            |            |
|--|------------|------------|
|  | 2003       | 2002       |
|  | -----      | -----      |
| Furniture and Fixtures                       | \$ 28,281  | \$ 27,813  |
| Computer Equipment                           | 21,803     | 17,120     |
| Leasehold Improvements                       | 196,544    | 181,604    |
| Lab Equipment                                | 236,781    | 195,962    |
| Automobiles                                  | 8,945      | 8,945      |
|  | -----      | -----      |
|  | \$ 492,354 | \$ 431,444 |
|  |            |            |
| Accumulated depreciation and<br>amortization | (199,305)  | (68,731)   |
|  | -----      | -----      |
|  | \$ 293,049 | \$ 362,713 |
|  | =====      | =====      |

Depreciation expense amounted to \$130,574 and \$68,697 for the years ended December 31, 2003 and 2002, respectively. The depreciation related to the Company's laboratory and related equipment is recorded as research and development as required by SFAS No. 2.

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NOTE 7 - INCOME TAXES

Deferred income taxes reflect the net tax effects of temporary timing differences between the carrying amounts of assets and liabilities reflected on the financial statements and the amounts used for income tax purposes. The tax effects of temporary differences and net operating loss carryforwards and tax credits that give rise to significant portions of the deferred tax assets recognized are presented below:

December 31,  
2003 ----- 2

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Deferred tax assets :

|   |             |       |
|---|-------------|-------|
| Prepaid research and development  | \$ 798,800  | \$ 1, |
| Deferred compensation   | 77,000      |       |
| Accumulated depreciation and amortization   | 332,000     |       |
| Research and development credits carryforward   | 1,125,400   |       |
| Federal and state deferred tax benefit arising from<br>net operating loss carryforwards | 5,612,500   | 3,    |
|   | 7,945,700   | 5,    |
| Less valuation allowance  | (7,945,700) | (5,   |
|   | \$ --       | \$    |
| Total deferred tax assets   | =====       | ===== |

As of December 31, 2003, the Company had losses, which resulted in net operating loss carryforwards for tax purposes amounting to approximately \$14,500,000 that may be offset against future taxable income. These carryforwards start to expire in 2021. The Company generated federal research and development credits of \$784,400 that will expire in 2021 and state credits of \$341,000 that will expire in 2008. However, these carryforwards and credits may be significantly limited due to changes in the ownership of the Company as a result of future equity offerings.

Recognition of the benefits of the deferred tax assets and liabilities will require that the Company generate future taxable income. There can be no assurance that the Company generates any earnings or any specific level of earnings in future years. Therefore, the Company has established a valuation allowance for deferred tax assets (net of liabilities) of approximately \$7,945,700 and \$5,510,400 as of December 31, 2003 and 2002.

In 2003, the Company sold \$2,863,511 of its gross New Jersey net operating loss carryforwards under the State of New Jersey's Technology Business Tax Certificate Transfer Program (the "Program"). The Program allows qualified technology and biotechnology businesses in New Jersey to sell unused amounts of net operating loss carryforwards and defined research and development tax credits for cash. The proceeds from the sale of the Company's carryforwards was \$221,600 (net of fees) and the amount was recorded as a tax benefit in the statements of operations. The State of New Jersey renews the Program annually and limits the aggregate proceeds of the program to \$10,000,000. Due to the uncertainty at any time as to the Company's ability to effectuate the sale of available New Jersey net operating losses, and since the Company has no control or influence over the Program, the benefits are recorded once the agreement with the counterpart is signed and the sale is approved by the State.

In accordance with federal income tax regulations, the net loss incurred by Astralis, LLC from inception to the date of its merger with the Company has been excluded from the benefits of the net operating loss carryforwards reflected in this footnote.

The following table presents the principal reasons for the difference between the Company's effective tax rates and the United States federal statutory income tax rate of 34%.

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Notes to Financial Statements

NOTE 7 - INCOME TAXES (Continued)

|   | December 31<br>2003<br>----- |
|---|------------------------------|
| Federal income tax benefit at statutory rate                | \$ 1,727,300                 |
| State income tax benefit (net of effect of federal benefit) | 296,300                      |
| Non-deductible expenses                                     | (54,900)                     |
| Research and development credit                             | 688,200                      |
| Valuation allowance   | (2,435,300)<br>-----         |
| Income Tax Benefit  | \$ 221,600<br>=====          |
| Effective Income Tax Rate                                   | (13%)<br>=====               |

NOTE 8 - CAPITAL STOCK ACTIVITY

On December 15, 2003, the Company amended it's Articles of Incorporation to authorize the issuance of 150,000,000 shares of common stock, \$0.0001 par value per share, and 3,000,000 shares of Series A preferred stock, \$0.001 par value per share, of which 37,538,189 shares of common and 2,000,000 shares of Series A preferred were outstanding as of December 31, 2003.

In 2001 Astralis LLC and the Company merged and this transaction was treated as a recapitalization of the Company, whereby the Company issued to the members of Astralis, LLC, 28,000,000 shares of common stock and warrants to purchase 6,300,000 shares of Company common stock for \$1.60 per share in a one-for-one exchange for all of the outstanding 28,000,000 Astralis, LLC member units of ownership and 6,300,000 options to purchase member units.

Astralis LLC issued 25,300,000 units on April 25, 2001 to various members for an aggregate subscription receivable amount of \$33,183. During 2001, the members paid \$33,183 on behalf of the Company to satisfy their subscription receivable.

On September 1, 2001, five new members were admitted as members of the LLC through the execution of a subscription agreement. These new members subscribed to units ("Units") from Astralis LLC consisting of an aggregate of 2,700,000 membership interests (the "Membership Interests") in Astralis LLC and 6,300,000 options to purchase additional Membership Interests in Astralis LLC for an exercise price of \$1.60 per Membership Interest. On November 13, 2001, the aforementioned Units were exchanged for an aggregate of 2,700,000 shares of the Company's common stock and warrants to purchase 6,300,000 shares of common stock at an exercise price of \$1.60 per share. The aggregate purchase price for such Units was \$1,350,000 and was paid with subscription notes. Warrants to purchase 3,150,000 shares of common stock, as amended, expire on December 13, 2004 and 3,150,000 expire November 13, 2006.

In 2002 and 2003, the Company collected \$465,000 and \$825,000 in cash of the

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subscription receivables, respectively. In April 2003, the Company entered into the Amended Investor Relation Agreement with one of the stockholders who has outstanding subscription receivable with the Company. The Company reduced the stockholder's subscription receivable for services received, valued at \$36,000, that the stockholder provided to the Company. The Company will receive services valued at \$24,000 in 2004 in lieu of payment of the outstanding subscription receivable balance.

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ASTRALIS LTD.  
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Notes to Financial Statements

### NOTE 8 - CAPITAL STOCK ACTIVITY (Continued)

#### Common Stock

In September 2001, Astralis, LLC granted 500,000 membership units to a consultant in return for services rendered. The membership units were subsequently exchanged for shares of common stock of the Company. The cost of the services, based on an independent valuation of the units granted, which amounted to \$135,000, were recorded at the time the services were rendered in 2001.

In November 2001, the Company completed a \$3,321,887 private placement offering pursuant to which it sold 103.81 units at \$32,000 per unit for an aggregate amount of \$3,321,887. Each unit consisted of 20,000 shares of common stock and warrants to purchase 4,000 shares of the Company's common stock at \$4.00 per share. The warrants expire on November 13, 2006. The holders of these shares of common stock and warrants received registration rights. The Company was required to file a registration statement by March 13, 2002 to register the sale of these shares and the shares underlying the warrants. Upon consummation of the private placement, the Company paid a \$100,000 investment banking fee and entered into an agreement for future investment banking services amounting to \$144,000, payable in 24 equal monthly installments of \$6,000.

In April 2001, the Company issued warrants to purchase 75,000 shares of common stock at an exercise price of \$1.75 per share. These warrants expire in April 2004.

In January 2002, the Company agreed to amend a subscription agreement with one of the investors who participated in the November 2001 private placement offering. The Company consented to reduce the number of shares in the subscription agreement by 49,990 shares of common stock. The Company cancelled the respective shares and returned the corresponding amount of funds to the investor amounting to \$80,000.

#### Preferred Stock

On December 13, 2001, the Company authorized 2,000,000 shares of preferred stock to be designated as "Series A Convertible Preferred Stock" ("Series A Preferred") with a \$0.001 par value per share. If the Company declares a dividend, holders of each share of Series A Preferred are entitled to non-cumulative cash dividends which will be the greater of i) 6% of the preferred share purchase price; or ii) the amount such holders would have received had the holders converted to common stock immediately prior to record date for payment of a dividend to holders of common stock. No dividend can be declared or paid on common stock without an equal or greater dividend being paid

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or declared on the Series A Preferred. Holders of each share of Series A Preferred were entitled to vote on all matters at stockholder meetings. Holders of each share of the Series A Preferred could convert their shares to common stock at an initial conversion price of \$2.50. The conversion price could be adjusted and reset as set forth in the purchase agreement for the Series A Preferred.

On December 10, 2001, the Company and SkyePharma entered into a purchase agreement whereby SkyePharma agreed to purchase 2,000,000 shares of Series A Preferred at a price of \$10 per share over a 13-month period with five separate closings. On December 10, 2002, the one-year anniversary of the agreement, SkyePharma received registration rights on the common stock underlying its Series A Preferred shares. The first closing occurred in December 2001 and the Company sold 1,000,000 shares of Series A Preferred for a purchase price of \$10,000,000.

The second, third and fourth closing occurred in January 2002, April 2002, and July 2002. On each closing, the Company sold 250,000 shares of Series A Preferred for a purchase price of \$2,500,000. The final 250,000 shares of Series A Preferred totaling \$2,500,000 closed on January 31, 2003.

The Company's stock price on December 10, 2001 was \$3.03; consequently, pursuant to the requirements of EITF 98-5 "Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios", as amended by EITF 00-27, the issuance of the Series A Preferred, which was convertible initially at \$2.50 per share at any time, resulted in a beneficial conversion feature recorded as a preferred stock dividend in the amount of \$2,120,000.

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### NOTE 8 - CAPITAL STOCK ACTIVITY (Continued)

The Company's stock price on April 30, 2002 was \$2.77; consequently, the issuance of the Series A Preferred, which was convertible initially at \$2.50 per share at any time, resulted in a beneficial conversion feature recorded as a preferred stock dividend in the amount of \$270,000.

Since the conversion price of the Series A Preferred was subject to reset provisions as described above, there was a beneficial conversion feature applicable to the Series A Preferred. Using the potential conversion price of \$1.60 for the first anniversary date as specified in the purchase agreement, the beneficial conversion feature resulted in an additional preferred stock dividend of \$9,078,750 in December 2002.

On January 20, 2004, SkyePharma converted 2,000,000 shares of Series A Preferred into 25,000,000 shares of common stock at a reduced conversion price of \$0.80 per share (see Note 16).

### Stock Warrants

At December 31, 2003, the Company had the following outstanding common stock warrants to purchase its securities:

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| Number of Warrants<br>Issued | Exercise Price<br>Per Share |
|------------------------------|-----------------------------|
| 6,780,237                    | \$1.60 - \$4.00             |

These warrants were primarily issued in connection with the exchange with Astralis, LLC and the private placement offering.

NOTE 9 - STOCK OPTION PLAN

On September 10, 2001, the Company adopted its 2001 Stock Option Plan that provides for the granting of options to officers, directors, employees, and consultants. The number of shares of common stock that can be purchased under this plan is limited to 5,000,000 shares, adjustable for changes in the capital structure of the Company. No options can be granted under this plan after September 10, 2011. Options granted under this plan may be either incentive stock options or non-qualified stock options. Options terms are not to exceed 10 years. The options have limited transferability, and will be subject to various vesting provisions as determined at the date of grant. The Board of Directors or a committee thereof will determine the exercise price of options granted in accordance with the provisions of this plan. The Board has the ability to amend, suspend or terminate this plan at any time, subject to restrictions imposed by applicable law.

On December 31, 2001, the Company granted two consultants options to purchase an aggregate 300,000 shares of the Company's common stock in exchange for their services. These options vest ratably, at 75,000 per year, over a four-year period commencing in 2001. The expiration terms of these options are 4 years, 3 years, 2 years and 1 year, for options vesting in 2001, 2002, 2003 and 2004, respectively. The strike price for all of these options is \$2.75.

During July 2002, the Company granted 15,000 stock options with a strike price of \$2.50, as compensation to a consultant.

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ASTRALIS LTD.  
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NOTE 9 - STOCK OPTION PLAN (Continued)

The Company records deferred compensation when it makes compensatory stock option grants to employees, members of the Board of Directors, consultants or advisory board members. For the options granted to consultants, the amount of deferred compensation recorded is the fair value of the stock options on the grant date as determined using a Black-Scholes option-pricing model. The Company records deferred compensation as a reduction to shareholders' equity with an offsetting increase to additional paid-in capital. The Company then amortizes deferred compensation into stock-based compensation expense over the performance period, which typically coincides with the vesting period of the stock-based award.

During April 2003, the Company granted options to purchase 50,000 shares of

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common stock at an exercise price of \$0.45 per share to one of its directors. Options to purchase 12,500 shares of common stock vested on April 4, 2003, and options to purchase an additional 12,500 shares will vest each year thereafter for the following three years.

### NOTE 10 - DEFERRED COMPENSATION

The components of deferred compensation for the options granted are as follows at December 31,

|  | 2003      | 2002       |
|--|-----------|------------|
| Balance at January 1                     | \$ 12,164 | \$ 398,250 |
| Deferred compensation recorded           | --        | 5,700      |
| Fair value adjustments                   | 18,321    | (357,532)  |
| Amortization to stock-based compensation | (25,663)  | (34,254)   |
|  | -----     | -----      |
| Balance at December 31                   | \$ 4,822  | \$ 12,164  |
|  | =====     | =====      |

Exercise prices for stock options outstanding as of December 31, 2003 and the weighted average remaining contractual life are as follows:

| Exercise Prices | Options Outstanding | Weighted Average Remaining Contractual Life | Number Exercisable | Weighted Average Exercise Price |
|-----------------|---------------------|---|--------------------|---------------------------------|
| -----           | -----               | -----                                       | -----              | -----                           |
| \$ 0.45         | 50,000              | 2.25 years                                  | 12,500             | \$                              |
| \$ 2.50 - 2.75  | 315,000             | 1.0 years                                   | 232,500            | \$                              |

In accordance with FAS 123 the fair value of the options were estimated as of the date of the grant or subsequent vesting date, or December 31, 2003 if not vested, using a Black-Scholes option-pricing model. The assumptions used in estimating the fair value of the options ranged as follows:

|                         |             |
|-------------------------|-------------|
| Volatility              | 100% - 130% |
| Risk-free interest rate | 2.0% - 4.1% |
| Expected life           | 1 - 5 years |
| Dividend yield          | -           |

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NOTE 11 - RELATED PARTY - TRANSACTIONS/COMMITMENTS/INDEMNIFICATIONS

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### Patent

A founding member of the Company is the owner of a patent application, filed March 16, 2001 with the United States Patent and Trademark Office, entitled "Compositions and Methods for the Treatment and Clinical Remission of Psoriasis" (the "Invention"). On April 26, 2001, the Company, in exchange for \$10, entered into an exclusive license agreement to use and exploit the Invention, the technology related thereto, and the related patent rights, including the ability to license foreign patent rights. The term of the license agreement expires on the last date of expiration of the patent or earlier date as specified in the license agreement.

During the term of the license agreement, the Company is required to pay all fees and costs relating to the filing, prosecution, and maintenance of the patent and associated rights. In addition, the Company is required to pay all reasonable attorneys' fees of the Company, or patent owner, in the pursuit of any patent infringement litigation.

### SkyePharma PLC Agreements

On December 10, 2001, the Company executed three agreements with SkyePharma, a pharmaceutical company located in England.

The Company entered into a stock purchase agreement whereby SkyePharma agreed to purchase 2,000,000 shares of Series A Preferred at a price of \$10 per share in five separate closings over a 13-month period commencing in December 2001 (see Note 8).

The Company entered into a technology option agreement whereby it agreed to pay SkyePharma \$5,000,000 in return for the right, for 7 years, to enter into a non-exclusive license agreement with SkyePharma to utilize three drug delivery systems (\$2,000,000, \$2,000,000, and \$1,000,000, respectively per delivery system). The royalty fee in this license agreement is specified to be 5% of the net sales of any product the Company sells utilizing a SkyePharma drug delivery system. All other terms of this license agreement would need to be determined upon exercise of the option. The Company can transfer this option to another party, subject to approval by SkyePharma. This license would only allow the Company to use these delivery systems for drugs that treat two particular immunotherapies - psoriasis and leishmaniasis. The \$5,000,000 fee was required to be paid on December 10, 2001 and was netted (for convenience purposes) out of the first \$10,000,000 installment purchase of preferred stock by SkyePharma.

The Company entered into a services agreement whereby it paid \$11,000,000 to SkyePharma in return for SkyePharma providing all development, manufacturing, pre-clinical and clinical development services for the Company's primary - second generation Psoraxine, up to the completion of Phase II clinical studies. The contract recognized that SkyePharma performed \$3,000,000 of these services in the fourth quarter of 2001 and that SkyePharma will perform and be paid for the remaining \$8,000,000 of services in 2002 and 2003. The payment terms for the services agreement are fixed. The Company paid \$3,000,000 in 2001, \$7,980,000 in 2002 and \$20,000 in 2003.

The service agreement terminated on December 31, 2002. In March 2003, the Company and SkyePharma amended the original service agreement, effective January 1, 2003, to extend the term of the agreement and modify the services to be provided by SkyePharma. SkyePharma will continue to provide certain services to the Company through December 31, 2004 in consideration for payments it received from the Company during 2002 in connection with this agreement, as a prepaid expense. This prepaid amount will be expensed during the remaining period of the amended service agreement. In 2003 and 2002, the Company expensed \$1,007,500 and \$5,985,000, respectively, in connection with the services agreement.

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SkyePharma has the right of first negotiation to acquire the worldwide licensing and distribution rights to Psoraxine up to the completion of the Phase II studies. On completion of Phase II studies, Astralis will offer SkyePharma the option to acquire the worldwide licensing and distribution rights to Psoraxine. If SkyePharma does not take the option, Astralis will seek a marketing partner to fund Phase III clinical studies and to provide a sales and marketing infrastructure.

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### NOTE 11 - RELATED PARTY - TRANSACTIONS/COMMITMENTS/INDEMNIFICATIONS (Continued)

#### Indemnification

The Company has agreed, subject to specific provisions in the Technology Access Agreement, to indemnify SkyePharma, its directors and employees against any and all losses, claims, demands, proceedings, actions, etc. which may be brought or established against them as a result of, among other items, i) negligence of Company personnel or contractors or ii) death, personal injury or property damage or loss caused by the Company selling a product containing a SkyePharma delivery system which is defective or not merchantable. However, this indemnification does not apply to any death or personal injury arising from defects inherent in the delivery systems or technical know-how of SkyePharma licenses with the delivery system technology.

#### Other

A research entity owned by the spouse of the majority shareholder provided research and development services to the Company totaling \$0 and \$135,111 for the years ended December 31, 2003 and 2002, respectively.

### NOTE 12 - OPERATING LEASES

On March 13, 2002, the Company entered into a lease agreement for laboratory and office space. The lease period is for three years and rent is \$77,500 annually. The Company also entered into a concurrent service agreement with the lessor of the laboratory space on a time and material basis.

During 2002 and 2003, the Company leased two apartments and an automobile for two different key employees, one of whom is an officer.

The Company incurred rent expense in the amount of \$137,070 and \$80,071 for 2003 and 2002, respectively.

The following is a schedule by year of future minimum rental payments required under operating leases that have initial or remaining lease terms of one year or greater, as of December 31, 2003:

Year Ending December 31:

|      |    |        |
|------|----|--------|
| 2004 | \$ | 83,224 |
| 2005 |    | 19,454 |
|      |    | -----  |

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\$ 102,678  
 =====

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NOTE 13 - COMPREHENSIVE LOSS

Excluding net loss, the Company's source of comprehensive loss is from the net unrealized loss on its marketable debt securities, which are classified as available-for-sale. The following summarizes the components of comprehensive loss:

|  | Year Ended December 31, |              |
|--|-------------------------|--------------|
|  | 2003                    | 2002         |
|  | -----                   | -----        |
| Net loss   | \$ (5,080,427)          | \$ (9,040,24 |
|  | -----                   | -----        |
| Unrealized gain (loss) on securities:                        |                         |              |
| Unrealized gain arising during period                        | (26,245)                | (15,18       |
| Reclassification adjustment for loss realized<br>in net loss | 13,728                  | -            |
|  | -----                   | -----        |
| Unrealized gain (loss), net                                  | (12,517)                | (15,18       |
|  | -----                   | -----        |
| Comprehensive loss   | \$ (5,092,944)          | \$ (9,055,42 |
|  | =====                   | =====        |

NOTE 14 - CONCENTRATIONS

The Company currently has two products that are under development. Lack of product development or customer interest could have a materially adverse effect on the Company. Further, significant changes in technology could lead to new products or services that compete with the product to be offered by the Company. These changes could materially affect the price of the Company's products or render them obsolete.

NOTE 15 - SUPPLEMENTARY DISCLOSURES OF CASH FLOW INFORMATION

The Company did not pay any interest or taxes in 2003 or 2002.

Payment of the 2002 service fees totaling \$1,330,000 were netted against the SkyePharma 2002 installment purchases of the Company's Series A Preferred stock.

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The Company recorded an unrealized loss on its securities available-for-sale in the amount of \$27,698 and \$15,181 for the years ended December 31, 2003 and 2002, respectively.

### NOTE 16 - SUBSEQUENT EVENTS

On January 20, 2004, the Company closed a private placement from which it received gross proceeds of approximately \$4,080,000. The transaction consisted of the sale to accredited investors of units consisting of 8,159,964 shares of common stock and warrants to purchase 8,159,964 shares of common stock. The warrants have an exercise price of \$.73 and expire in four years.

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### NOTE 16 - SUBSEQUENT EVENTS (Continued)

Concurrently with the closing of the private placement, Skyepharma converted all of its outstanding shares of Series A Preferred Stock of the Company into 25,000,000 shares of common stock at a reduced conversion price of \$0.80 per share. Skyepharma agreed that up to 12,500,000 shares of its common stock issued upon conversion of the Series A Preferred Stock will be subject to a call option at the discretion of the Company upon completion of an agreed upon milestone at a premium in excess of the conversion price. The call option can be exercised on or after July 21, 2004. In connection with this transaction and in accordance with SFAS 84, "Induced Conversions of Convertible Debt, an Amendment of APB Opinion No. 26" the Company will record a non-cash preferred stock dividend in January 2004 amounting to \$10,750,000.

On the closing date of conversion, January 20, 2004, the Company and other original stockholders amended the stockholders agreement dated as of December 10, 2001. After the date of that Amendment, the Board of Directors is required to be comprised of at least seven directors and include at least two independent directors. Per the Amendment, SkyePharma shall have the right to nominate one director, who shall initially be Michael Ashton. From the date of the Amendment until the third anniversary, Jose Antonio O'Daly, Mike Ajnsztajn, Gaston Liebhaber and Gina Tedesco (the "Founders"), each has the right to nominate one director. The Founders will initially be directors. The Agreement will terminate upon the later of (i) the SkyePharma Termination Date or (ii) the third anniversary of this Amendment, which is January 20, 2007. Further, this agreement may be terminated by the mutual written consent. "The SkyePharma Termination Date" is the date on which SkyePharma no longer beneficially owns, in the aggregate, at least 20% of the outstanding common stock of the Company.

On February 19, 2004, the Company closed the second round of its private placement from which it received \$1,150,000. The transaction consisted of the sale to accredited investors of units consisting of 2,299,902 shares of common stock and warrants to purchase 2,299,902 shares of common stock.

The Company paid a 5% commission in the amount of \$261,496 to a related party in February 2004 for the consulting services related to two private placements completed in 2004. In addition, the related party and his assignees received warrants to purchase an aggregate of 418,394 shares of the Company's common stock at \$0.50 per share and warrants to purchase an aggregate of 418,394 shares of

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the Company's common stock at \$0.73 per share. An additional cash commission will be paid upon exercise of the warrants.

On February 19, 2004, after including the effects of the above transactions, the Company had approximately 73 million shares of common stock and no shares of preferred stock outstanding.

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