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ASTRALIS LTD  
Form 10KSB  
March 31, 2003

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, 2002

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 discharge 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. \$0

The aggregate market value of the voting and non-voting Common Stock held

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by non-affiliates as of March 27, 2003, was approximately \$ 5,146,465.

As of March 27, 2003, there were 37,538,189 shares of 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, incorporated under the laws of the State of Delaware and based in New Jersey, which primarily engages in research and development of treatments for immune system disorders and skin diseases. Our main office is located at 75 Passaic Avenue, Fairfield, New Jersey 07004.

We were originally incorporated under the laws of the State of Colorado on June 30, 1999 under the name "Hercules Development Group, Inc." and engaged in the business of managing real estate. Our real estate operations ceased in the second half of 2001. On November 13, 2001, we entered into a Contribution Agreement, dated as of September 10, 2001 between us on the one side and Astralis, LLC, a New Jersey limited liability company formed on March 12, 2001 and Dr. Jose Antonio O'Daly, Gaston Liebhaber, Mike Ajnsztajn, Richard Genovese, David Stevenson, Grizzly Consulting Ltd., Wolver Limited and Logarithmic Inc., being all of the members of Astralis, LLC, on the other side. At such time, we began our current business which was the prior business of Astralis, LLC.

Pursuant to the business combination set forth in the Contribution Agreement, 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 warrants to purchase 6,300,000 shares of our common stock at an exercise price of \$1.60 per share. Pursuant to the Contribution Agreement, on November 13, 2001, all of our officers and directors resigned from their respective positions with us. The officers and managers of Astralis, LLC replaced them as our officers and directors.

We accounted for this combination as a recapitalization. We were the legal acquirer in the merger. Astralis, LLC was the accounting acquirer since its members acquired a majority interest in our stock. Consequently, all historical financial information prior to November of 2001 represent the operations of Astralis, LLC.

In addition, on November 14, 2001, we filed an amendment to our Articles of Incorporation which changed our name from "Hercules Development Group, Inc." to "Astralis Pharmaceuticals Ltd." On November 19, 2001, we reincorporated in the State of Delaware under our current name.

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##### Business of Astralis Ltd.

We are primarily engaged in research and development of treatments for immune system disorders and skin diseases. Our current activities focus on the

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development of a product candidate named Psoraxine 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;
- o Production of drug supply for use in clinical trials in the United States; and
- o Doctor and site enrollment for clinical trials in the United States.

Dr. William Abramovits of the Texas Dermatology Research Institute has agreed to be our principal investigator for our first clinical trials based in the United States. We are currently engaged in negotiations with other possible clinical sites to conduct additional U.S. based trials. In addition, we are preparing documents in accordance with FDA Guidance Phase I/II for Investigational New Drug Applications. These documents will likely include an investigational plan, clinical protocols, manufacturing controls and an investigator's brochure to obtain approval from the independent ethical review board of the investigational site.

Psoriasis is a genetically based inflammatory and scaly skin disease of currently unknown origins that generally lasts a lifetime and for which there is presently no known cure. While performing a field trial in Caracas, Venezuela in 1992 for a vaccine for leishmaniasis, a disease transmitted by parasites, Dr. O'Daly discovered that a patient, after receiving a third dose of the leishmaniasis vaccine, experienced remission of the plaque psoriasis lesion that had been present on the patient's leg for the past 12 years. After researching and improving the leishmaniasis vaccine, Dr. O'Daly developed Psoraxine specifically for use in clinical trials for the remission of psoriasis.

Psoraxine is a synthesized immuno-therapeutic agent, presented in liquid form and is packed in 0.5 mg ampules for intra-muscular injection. After researching and improving Psoraxine, preliminary clinical trials were undertaken in Caracas, Venezuela during the eight year period from 1992 to 2000. During the preliminary clinical trials, the prevalence of psoriasis was monitored using the Psoriasis Area and Severity Index. The results of the preliminary clinical trials yielded positive evidence of remission of psoriasis lesions. Of the 2,770 patients involved in the preliminary clinical trials, approximately 74% had between 70% and 100% remission of psoriasis lesions as compared with initial PASI values. 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 the financial resources to acquire manufacturing facilities in that country and such facilities are required by regulatory authorities in Venezuela before granting commercial approval for a proposed drug. We do, however, have the approval of regulatory authorities in Venezuela to continue clinical trials of Psoraxine in the country. We are now seeking approval for Psoraxine from the United States Food and Drug Administration,

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which is a necessary and critical step toward the commercialization of Psoraxine. The FDA requires disclosure of previous human clinical trials in any application seeking FDA approval of a new drug. Therefore, we will use data from our clinical trials in Venezuela to support our attempt to obtain FDA approval.

Representatives of Astralis, LLC sent a briefing document to the FDA and held pre-Investigational New Drug conference calls with representatives of the FDA to review the clinical results of Dr. O'Daly's work with Psoraxine in Venezuela. On March 28, 2003, we filed an Investigational New Drug application

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with the FDA to conduct Phase I.B studies of Psoraxine. The purpose of Phase I.B studies is to test the safety of a drug and determine appropriate dosage ranges in patients suffering with the disease or condition that the product is intended to treat. Phase I.B studies would involve the administration of dosages of Psoraxine in a controlled setting to groups of volunteers. We anticipate that it will take at least one year to complete the Phase I.B studies at a cost of not less than \$500,000. During the fiscal year ended December 31, 2002, we spent approximately \$7,761,542 on research and development activities. From March 12, 2001, which was the date of our inception, through December 31, 2001, we spent approximately \$3,231,775 on research and development activities. See "Government Regulation".

### Patient Populations

According to the National Psoriasis Foundation, psoriasis affects about 2.6% of the U.S. population, or more than 7 million people in the United States. Psoriasis also affects 2% to 3% of the world's population. Approximately 150,000 to 260,000 new cases of psoriasis are diagnosed each year. No special blood test or other diagnostic tool exists for psoriasis. The diagnosis is usually determined through examination of the skin by a physician or other health care provider. Less commonly, a skin biopsy is examined under a microscope for biological evidence of psoriasis. The presence of small pits in the fingernails is also an indicator of psoriasis.

Approximately 400 people die from complications caused by psoriasis each year in the United States. Primarily, such complications occur in relation to a severe, extensive form of psoriasis such as generalized Pustular Psoriasis or Erythrodermia 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 compromised to such a great extent, secondary infections are possible. Fluid loss is a complicating factor in these serious forms of psoriasis, and a great strain is also placed on the circulatory system.

According to the National Psoriasis Foundation, 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 it frequently involves the fingers and toes. Other parts of the body can be affected as well, including the wrists, neck, lower back, knees and ankles. In severe cases, psoriatic arthritis can be destructive to joints and disabling. For the most part, people with psoriasis function normally, although some people experience low self-esteem caused by the unsightly effect of the disease on the skin.

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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. It is estimated that 56 million hours of work are lost each year due to psoriasis, and that between \$1.6 billion and \$3.2 billion is spent annually on treating psoriasis.

### 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. Each of these treatments has variable efficacy, with side effects and cosmetic problems in addition to the failure to

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prevent frequent relapses.

### 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 National Psoriasis Foundation has identified not less than 41 treatments under development which are in various stages of the FDA approval process, including several of which are in the final phase of clinical trials in humans required by the FDA approval process. In addition, on January 31, 2003, Biogen announced that the U.S. Food and Drug Administration approved its product, Amevive (R) (alefacept) to treat moderate-to-severe chronic plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. This is the first biologic medicine approved to treat psoriasis. If we succeed in obtaining FDA approval of Psoraxine, Amevive may compete directly with our product. In addition to Biogen, our competitors may include Amgen, Genentech, SmithKline Beecham, Protein Design Labs, Ligand Pharmaceuticals, Schering-Plough, Pfizer 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.

Our major competitors include fully integrated pharmaceutical companies that have extensive drug discovery efforts. We face significant competition from organizations that are pursuing the same or similar technologies as the technologies used by us in our drug discovery 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. We are aware that many other companies or institutions are pursuing development of drugs and technologies directly targeted at applications for the treatment and eventual cure of psoriasis.

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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 promotion of our potential products.

The process required by the FDA before our product candidate, Psoraxine,

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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;
- 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. On March 28, 2003, we filed our Investigational New Drug application 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. Our submission of an Investigational New Drug application may not result in FDA authorization to commence a clinical trial. Further, an independent institutional review board must review and approve the plan for any clinical trial before it commences.

We may not successfully complete any of 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

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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 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.

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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.

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

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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 the manufacture and commercial distribution of Psoraxine in Venezuela.

### Intellectual Property

On March 16, 2001, Dr. O'Daly filed a patent application entitled "Compositions and Methods for the Treatment and Clinical Remission of Psoriasis" with the United States Patent and Trademark Office. The patent application process may take up to two years to complete. Pursuant to a License Agreement dated as of April 26, 2001 between Dr. O'Daly and Astralis, LLC, Dr. O'Daly granted Astralis, LLC the exclusive right and license to use and exploit his patent if and when such patent is issued. Pursuant to an Assignment of License Agreement, dated November 13, 2001, by and between Astralis, LLC and us, Astralis, LLC assigned to us all of its rights under the License Agreement. Dr. O'Daly has not assigned the patent application to us and he will continue to maintain ownership rights thereto.

We filed a petition for special status of the patent application in order to obtain expedited review. On February 8, 2002, the United States Patent and Trademark Office granted special status for the patent application. On March 4, 2002, we also filed an application to obtain patent protection internationally

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under the Patent Cooperation Treaty. Both applications are currently pending.

Our intellectual property consists of our license to Dr. O'Daly's application of a patent for Psoraxine, our rights under the Assignment of License Agreement and trade secrets and know-how. Our ability to compete effectively depends in large part on the ability of Dr. O'Daly to obtain the patent for Psoraxine, and our ability to maintain trade secrets and operate without infringing the rights of others and to prevent others from infringing on our proprietary rights. We will be able to protect our technologies from unauthorized use by third parties only to the extent that they are covered by valid and enforceable patents or copyrights or are effectively maintained as trade secrets. Accordingly, patents or other proprietary rights are an essential element of our business. There can be no assurance that proprietary information will not be disclosed, that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or that we can meaningfully protect our trade secrets.

### Agreements with SkyePharma

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, as of December 31, 2002, SkyePharma purchased 1,750,000 shares of our Series A Convertible Preferred Stock, par value \$.001 per share, at a purchase price of \$10.00 per share,

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or an aggregate purchase price of \$17.5 million. The Purchase Agreement provides that SkyePharma would make a total equity investment of \$20 million. The remaining \$2.5 million investment involved the sale of an additional 250,000 shares of preferred stock to SkyePharma on January 31, 2003. Each share of preferred stock issued pursuant to the Purchase Agreement was initially convertible into four shares of common stock at the option of SkyePharma at a conversion price of \$2.50 per share of common stock. The conversion price is subject to multiple adjustments for three years from the date of the Purchase Agreement depending on our stock price maintaining certain levels. The conversion price is also subject to anti-dilution protection. However, the conversion ratio will not adjust to a level greater than approximately 50 shares of common stock for each share of preferred stock (conversion price of \$0.20). On December 10, 2002, the conversion price was reset to \$1.60 per share of common stock. As a result of the Purchase Agreement, SkyePharma is the beneficial owner of 25.41% of our outstanding common stock. In addition to other rights under the Purchase Agreement, SkyePharma, as the holder of shares of preferred stock, holds the exclusive right to elect one member of our Board of Directors. Pursuant to the Purchase Agreement, we and certain of our stockholders holding an aggregate of 66.07% of our outstanding common stock executed a Stockholders' Agreement, dated as of December 10, 2001, with SkyePharma, whereby each stockholder agreed to vote its shares of common stock to elect the independent directors nominated by our Board of Directors and, once SkyePharma no longer owns its preferred stock, to elect a nominee designated by SkyePharma to our Board of Directors. We also granted SkyePharma certain registration rights effective as of December 10, 2002 pursuant to a Registration Rights Agreement, dated as of December 10, 2001.

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. SkyePharma owns over twenty patents for the drug delivery



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technologies in several countries, including the United States, Japan, Australia, New Zealand and Canada. The majority of these patents will continue in force until 2014. 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 irremediable 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.

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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 payable 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 twenty-four month period following January 1, 2003 with respect to which prior payments will also be credited.

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.

### Other Research and Development Efforts

We are 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 treatments for rheumatoid arthritis, severe dermatitis, papilomas, hiperkeratosis, melanomas, prostate enlargement and Chagas disease.

### Employees

As of December 31, 2002, we employed 8 full-time employees and no

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part-time employees. None of these employees are covered 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 of Financial Condition 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 of

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Financial Condition or Plan of Operation" section and elsewhere in this annual report could seriously harm our business.

### 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 approximately \$18,388,998 as of December 31, 2002 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 at least 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 third quarter of 2003. We will need additional funds to continue our operations following that period. Furthermore, substantial

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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, 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.

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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, our initial product candidate, Psoraxine, may not perform in the manner we anticipate, and may not be accepted for use by the public.

The Development Of Our Initial Product Remains In An Early Stage Of Development And Substantial Additional Funds And Effort Will Be Necessary For Further Development And Commercialization.

Our initial product candidate, Psoraxine, remains in an early stage of development and 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, when commenced, 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;

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- o inability to manufacture sufficient quantities of compounds for use in clinical trials;
- 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.

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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.

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 conducted any clinical trials for Psoraxine in the United States, nor have we received approval from the FDA or any other regulatory authority to test any potential products in humans or to market any product candidate. We may not be able to conduct clinical testing or obtain the necessary approvals from the FDA or other regulatory authorities to market our product. 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 obtained final regulatory approval for the manufacture or commercial distribution of Psoraxine in Venezuela.

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.

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We Are Exposed To International Risks As A Result Of Our Conduct Of Clinical Studies In Venezuela.

We are continuing clinical trials of Psoraxine in Venezuela. During recent months, Venezuela has suffered from political instability and popular unrest. As a result, at times, participants in our clinical trials were unable to reach the facilities where our studies are conducted. This may have impaired the results of our studies. Since the FDA requires that we report all studies conducted on human subjects, in the event our Investigational New Drug application is approved, we must include our Venezuela studies as previous human experience in our annual reporting to the FDA. This data will be used only as supporting information and will not likely increase the chance of faster FDA approval of Psoraxine.

Even If Product Candidates Emerge Successfully From Clinical Trials, We May Not Be Able To Successfully Manufacture, Market And Sell Them.

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We have not completed development of our initial product candidate, Psoraxine, and we have not received approval for its use in clinical trials in the United States. If Psoraxine emerges successfully from clinical trials, we will either commercialize products 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 under which SkyePharma will provide development, manufacturing, 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.

Dr. Jose Antonio O'Daly has filed a patent application for Psoraxine, and under the terms of a license agreement and assignment of license agreement, we have the right to use any patent issued pursuant to that application. We license, and do not own, the intellectual property rights to Psoraxine. In addition, we do not have any protection from issued patents covering any of our technology. 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.

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

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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

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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 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 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, Amgen, Genentech, SmithKline Beecham, Protein Design Labs, Ligand Pharmaceuticals, Schering-Plough, Pfizer 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

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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.

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 our initial product candidate, 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. We currently do not maintain clinical liability insurance coverage. Even if we obtain such an insurance policy, it may not sufficiently cover any claims made against us. Clinical trial liability insurance may be expensive, difficult to obtain 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 75.75% of our outstanding common stock. In addition, as a result of the application of certain preferred stock adjustment rights, SkyePharma's percentage ownership may increase substantially from its current 25.41% and may result in it having control of the company. 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. In addition, this concentration of ownership may delay or prevent a change in control of us and might affect the market price of our common stock, even when a change in control may be in the best interest of all stockholders. 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.

The Market Price Of Our Common Stock May Be Highly Volatile.

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The market price of our common stock has been and will likely continue to be highly volatile. From the date trading of our common stock commenced until March 27, 2003, the range of our stock price has been between \$0.22 and \$7.15. Factors including announcements of technological innovations by us or other companies, regulatory matters, new or existing products or procedures, concerns about our financial position, operating results, government regulation, developments or disputes relating to agreements, patents or proprietary rights may have a significant impact on the market price of our stock. In addition, potential dilutive effects of future sales of

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shares of common stock by stockholders and by us could have an adverse effect on the price of our common stock.

A Large Number Of Shares Of Our Common Stock May Be Sold In The Market, Which May Depress The Market Price Of Our Common Stock.

Sales of substantial amounts of our common stock in the public market, or the perception that these sales might occur, could materially and adversely affect the market price of our common stock or our future ability to raise capital through an offering of our equity securities. We have an aggregate of 37,538,189 shares of our common stock outstanding. If all options and warrants currently outstanding to purchase shares of our common stock are exercised and all of the 2,000,000 shares of preferred stock are converted into common stock at the current conversion price of \$1.60, there will be approximately 57,233,416 shares of common stock outstanding. The conversion price of preferred stock may be further adjusted through 2004, increasing substantially the number of shares of common stock that may be outstanding. Of the outstanding shares, up to 13,163,114 shares are freely tradable without restriction or further registration under the Securities Act, unless the shares are held by one of our "affiliates" as such term is defined in Rule 144 of the Securities Act. The remaining shares may be sold only pursuant to a registration statement under the Securities Act or an exemption from the registration requirements of the Securities Act. The sale and distribution of these shares may cause a decline in the market price of our common stock.

Our Common Stock Qualifies As A "Penny Stock" Under SEC Rules Which May Make It More Difficult For Our Stockholders To Resell Their Shares Of Our Common Stock.

Our common stock trades on the Over-The-Counter Bulletin Board. As a result, the holders of our common stock may find it more difficult to obtain accurate quotations concerning the market value of the stock. Stockholders also may experience greater difficulties in attempting to sell the stock than if it were listed on a stock exchange or quoted on the Nasdaq National Market or the Nasdaq Small-Cap Market. Because our common stock does not trade on a stock exchange or on the Nasdaq National Market or the Nasdaq Small-Cap Market, and the market price of the common stock is less than \$5.00 per share, the common stock qualifies as a "penny stock." SEC Rule 15c-9 under the Securities Exchange Act of 1934 imposes additional sales practice requirements on broker-dealers that recommend the purchase or sale of penny stocks to persons other than those who qualify as an "established customer" or an "accredited investor." This includes the requirement that a broker-dealer must make a determination on the appropriateness of investments in penny stocks for the customer and must make special disclosures to the customer concerning the risks of penny stocks. Application of the penny stock rules to our common stock could adversely affect the market liquidity of the shares, which in turn may affect the ability of holders of our common stock to resell the stock.



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### 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. We previously conducted research at Centro Para La Investigacion y Tratamiento De La Psoriasis, Avenue Las Gencias Calle Codazzi Urb. Los Chaguaramos, Caracas, Venezuela.

### Item 3. Legal Proceedings

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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.

## PART II

### Item 5. Market For Common Equity and Related Stockholder Matters

#### Market Information

Our common stock is traded on the Over-the-Counter Bulletin Board ("OTC Bulletin Board") under the symbol ASTR. The following table sets forth, for the periods indicated, the range of high and low bid quotations for the shares of 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. We began trading our common stock in March 2001.

	High	Low
2001		
First Quarter *	\$3.93	\$0.43
Second Quarter	\$6.85	\$2.50
Third Quarter	\$7.15	\$1.70
Fourth Quarter	\$3.80	\$2.50
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

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\* After stock split

#### Holder of Common Stock

As of March 27, 2003, there were approximately 2,862 holders of record of our common stock.

#### Dividends

On March 14, 2001, we declared a stock dividend to stockholders of record as of 8:00 a.m., eastern standard time, on March 14, 2001, on the basis of ten shares of common stock for

each one share of common stock then issued and outstanding. The payment date and time for the stock dividend were March 15, 2001, at 8:00 a.m., eastern standard time. As a result of the stock dividend, each of our stockholders received nine additional shares of common stock for each one share of common stock owned of record as of the record date and time. 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.

All accrued and unpaid dividends on the outstanding shares of our preferred stock must be paid before we pay any dividends on our common stock.

#### Recent Sales of Unregistered Securities

On January 10, 2002, Messrs. Ajnsztajn, O'Daly and Liebhaber, who each serve on our Board of Directors and who respectively serve as our Chief Executive Officer, Chairman of the Board of Directors and President of Research and Development, and Director of International Affairs, transferred respectively 175,000, 275,000 and 50,000 shares of our common stock owned by them to Manolo 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. They relied upon the fact that the transfer to Mr. Tarabay did not constitute a public offering. No underwriter was used in connection with the transfer.

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, as of December 31, 2002, SkyePharma purchased 1,750,000 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 \$17.5 million. The Purchase Agreement provides that SkyePharma would make a total equity investment of \$20 million. The remaining \$2.5 million investment involved the sale of an additional 250,000 shares of preferred stock to SkyePharma on January 31, 2002. Each share of preferred stock issued pursuant to the Purchase Agreement was initially convertible into four shares of common stock at the option of SkyePharma at a conversion price of \$2.50 per share of common stock (an aggregate of 8 million shares of common stock). The conversion price is subject to multiple adjustments for three years from the date of the Purchase Agreement depending on our stock price maintaining certain levels. The conversion price is also subject to anti-dilution protection. However, the conversion price will not adjust to a level greater than approximately 50 shares of common stock for each share of preferred stock (an equivalent conversion price of \$0.20 per share). On December 10, 2001, the conversion price was reset to \$1.60 per share of common stock (convertible into an aggregate of 12,500,000 shares of common stock). 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. We relied on the fact that the offering was only made available to "Accredited Investors" as defined in Rule 501 of Regulation D, the offering of preferred stock pursuant to the Purchase Agreement was made available to less than 35 purchasers as required by Rule 506(a)(2) of Regulation D and the required number of manually executed originals and true copies of Form D were duly and timely filed with the Securities and Exchange Commission. No underwriter was used in connection with the offering.

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. We relied on the fact that the offering was only made available to "Accredited Investors" as defined in Rule 501 of Regulation D, the offering was made available to less than 35 purchasers as required by Rule 506(a)(2) of Regulation D and the required number of manually executed originals and true copies of Form D were duly and timely filed with the Securities and Exchange Commission. No underwriter was used in connection with the private placement.

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. No underwriters were used in connection with this transaction. We relied on the exemption from registration afforded by Section 4(2) of the Securities Act of 1933. We relied on the fact that this transaction did not constitute a public offering.

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. We relied upon the fact that our issuance of the promissory note did not constitute a public securities offering. No underwriter was used in connection with the issuance of the promissory note.

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. Astralis, LLC relied on the fact that the aggregate offering price for the units did not exceed \$5 million, less the aggregate offering price for all securities sold within the twelve months before the start of and during the offering in reliance on any exemption under Section 3(b) of, or in violation of Section 5(a) of, the Securities

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purchasers and the required number of manually executed originals and true copies of Form D were duly and timely filed with the Securities and Exchange Commission. No underwriter was used in connection with the sale of the units.

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. We relied upon the fact that our issuance of the warrants did not constitute a public securities offering. No underwriter was used in connection with the issuance of the warrants.

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. No underwriter was employed in connection with the offering and sale of the shares. The facts that we relied upon to make the federal exemption available include, among others, that: (i) the aggregate offering price for the offering of the shares of common stock did not exceed \$1,000,000, less the aggregate offering price for all securities sold within the twelve months before the start of and during the offering in reliance on any exemption under Section 3(b) of, or in violation of Section 5(a) of, the Securities Act of 1933; (ii) the required number of manually executed originals and true copies of Form D were duly and timely filed with the Securities and Exchange Commission; (iii) we conducted no general solicitation or advertising in connection with the offering of any of the shares and (iv) at the time of the offering, we were not subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act of 1934.

On June 30, 1999, we issued and sold 23,800,000 shares of common stock to each of Messrs. J. Peter Garthwaite and Bradley A. Scott in consideration for services performed by each individual in connection with our organization valued at \$119 in each case (a total of \$238 at the rate of \$.0001 per share). Messrs. Garthwaite and Scott served as our President/Chief Executive Officer/Treasurer and Secretary, respectively, and directors from the date of our inception on June 30, 1999, until their voluntary resignations on February 28, 2001. Messrs. Garthwaite and Scott sold their 2,380,000 shares of common stock representing approximately 76% of our then 3,130,000 outstanding shares of common stock, to Mr. Shai Stern, who served as our President, Chief Executive Officer and sole director from February 28, 2001 until his resignation pursuant to the Contribution Agreement on November 13, 2001. We relied, in connection with the sale of the shares, upon the exemption from registration afforded by Section 4(2) of the Securities Act of 1933 and Section 11-51-308(1)(p) of the Colorado Uniform Securities Act. We relied upon the fact that the issuance and sale of the shares did not constitute a public securities offering together with the fact that Messrs. Garthwaite and Scott were our executive officers, directors and

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controlling stockholders at the time of the sales, to make the exemptions available. No underwriter was used in connection with this transaction.

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

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### 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 were formerly named Astralis Pharmaceuticals Ltd. and Hercules Development Group, Inc., and were incorporated under the laws of the state of Colorado on June 30, 1999. Subsequently we were reincorporated in the state of Delaware on December 10, 2001 and changed our name to Astralis Ltd. In November 2001, we were a public shell company, defined as an inactive, publicly quoted company with nominal assets and liabilities.

Our operations and financial statements prior to November 2001 are those of Astralis, LLC, a New Jersey limited liability company formed on March 12, 2001. Astralis, LLC was merged into us on November 13, 2001 pursuant to the terms of the Contribution Agreement.

The effect of our combination with Astralis, LLC was a reverse merger. We were the legal acquirer in the merger. Astralis, LLC was the accounting acquirer since its members acquired a majority ownership interest in us. Consequently, the historical financial information included in our financial statements prior to November 2001 are those of the accounting acquirer, Astralis, LLC. In effect the merged company was recapitalized and its stockholders' equity reflects the capital structure of the legal entity (Astralis Ltd.) and the retained earnings of Astralis, LLC. Pro forma financial information is not presented since the combination is a recapitalization and not a business combination.

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:

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- o Ongoing research and development of Psoraxine;
- o Production of drug supply for use in clinical trials in the United States; and
- o Doctor and site enrollment for clinical trials in the United States.

Fiscal year ended December 31, 2002 compared to the period from March 12, 2001 (date of inception) through December 31, 2001

For fiscal year ended December 31, 2002:

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In 2002, we sold to SkyePharma pursuant to a Purchase Agreement dated December 10, 2001, an aggregate of 750,000 shares of our Series A Convertible Preferred Stock, par value \$.001 per share at a purchase price of \$10.00 per share, 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.
- 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.

We recorded an additional preferred stock dividend in December of 2002 in the amount of \$9,078,750. The contingent beneficial conversion feature arose for 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.

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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 expensed during the remaining period of the amended service agreement.

For the period March 12, 2001 (date of inception) through December 31, 2001:

For the period from March 12, 2001, which was the date of our inception, through December 31, 2001, we had no revenue and incurred a net loss of \$6,195,364.

During 2001 we raised funds from the following private placement offerings

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and under the following agreements:

- o Under the Contribution Agreement dated September 10, 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 options to purchase 6,300,000 additional membership interests in Astralis, LLC for an exercise price of \$1.60 per membership interest. The aggregate purchase price for such units was \$1,350,000 and was paid with subscription notes. On November 13, 2001 at the closing of the transaction under the Contribution Agreement, the aforementioned units were exchanged for an aggregate of 2,700,000 shares of our common stock and warrants to purchase 6,300,000 shares of our common stock at an exercise price of \$1.60 per share. The subscription notes were due in two installments with \$850,000 having been due on February 13, 2002 and the remaining \$500,000 due on May 13, 2002.
- o During November of 2001 we engaged in a private placement 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. We received proceeds, net of offering costs and payments of pre-merger shell costs, in the amount of \$2,752,495.
- o In December of 2001, we sold to SkyePharma under the Purchase Agreement, 1,000,000 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 \$10,000,000. We received net proceeds of approximately \$1,950,000 from this placement after the following expenditures were netted out from the proceeds:
  - o \$5,000,000 payment due to SkyePharma in connection with our purchase of the technology option license from SkyePharma,

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- o \$3,000,000 payment due to SkyePharma for services they provided under our Service Agreement with them which was expensed at the time of payment, and
- o offering costs of approximately \$50,000.

During the period March 12, 2001 (inception) through December 31, 2001, we incurred operating expenses of \$4,084,619 which consisted primarily of:

- o Research and development costs of \$3,231,775, including \$3,000,000 that was paid to SkyePharma for services provided under our Service Agreement with them and amortization of approximately \$60,000 of our technology option license which is being amortized over a seven year period.
- o General and administrative costs of approximately \$850,000, including professional fees related to our merger with Astralis, LLC and the related investor relations and marketing expenses and our general corporate expenditures.

We also had a non-cash preferred stock dividend in 2001 in the amount of \$2,120,000. This resulted from our December 10, 2001 sale of preferred stock to SkyePharma which had a conversion rate to our common stock which was lower than

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the market price of our common stock on that date. Therefore, we were required to record a preferred dividend calculated by multiplying the number of preferred shares sold on that date by the difference between the conversion price and the market price.

### The Next Twelve Months

At December 31, 2002 we had cash balances of \$227,193 and marketable securities of \$1,207,179.

In January 2003, pursuant to the Purchase Agreement, 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 net proceeds of \$2,480,000 after we netted out from the proceeds \$20,000 due to SkyePharma in connection with the Service Agreement.

We anticipate collecting our subscription notes receivable. These subscription notes receivable were originally due in two installments during 2002. We did not receive the installment payments. We entered into a payment plan agreement with the note holders of the subscription notes receivable. The note holders agreed to make a \$200,000 initial payment and make payments of \$150,000 per month from July 2002 until January 2003 and a payment of \$100,000 in February 2003. As of December 31, 2002, the note holders failed to make scheduled payments in the aggregate amount of \$635,000 and the aggregate outstanding balance was \$885,000.

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:

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Our primary focus is to further our development efforts of our initial product candidate, Psoraxine. Upon receiving approval of our Investigational New Drug application, we will conduct clinical trials in the process of obtaining FDA approval of Psoraxine. We will maintain ongoing research and development of Psoraxine. We will expend approximately \$ 2,800,000 in connection with these activities.

- o We intend to implement our business plan and facilitate the operations of our company. We will spend approximately \$800,000 to pay management salaries and salaries of employees.
- o We also expect to expend approximately \$1,100,000 million 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 third quarter of 2003. 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



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The financial statements required by this Item 7 are listed in Item 13 and begin at page F-1 of this annual report.

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

As more fully set forth in our annual report on Form 10-KSB filed with the Securities and Exchange Commission on April 1, 2002, we dismissed Cordovano and Harvey, P.C. as our independent auditor, effective November 28, 2001 and engaged L J Soldinger Associates Ltd. as our new independent auditor, effective November 2, 2001.

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### PART III

Item 9. Executive Officers and Directors; Compliance With Section 16(a) of the Exchange Act.

#### Executive Officers and Directors

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

Name	Age	Position
Jose Antonio O'Daly, MD, PhD	61	Chairman of the Board of Directors; President Research and Development
Mike Ajnsztajn	38	Chief Executive Officer; Director
Gaston Liebhaber	68	Director of International Affairs; Director
Gina Tedesco	39	Chief Financial Officer; Director
Michael Aston	57	Director
Steven Fulda	70	Director
Fabien Pictet	44	Director
James Leyden, MD	62	Chairman, Medical Advisory Board
Bruce Epstein	39	Marketing Affairs 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.

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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. Dr. O'Daly has dedicated the last 15 years of his life working on a cure for psoriasis.

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. Fundafarmacia is the largest pharmacy chain in Venezuela. Since 1982, Mr. Liebhaber has served as the Managing Director of Latin America of Sankyo Pharmaceutical, the largest Japanese pharmaceutical company, based in Venezuela. Since 1987, Mr. Liebhaber also has served on the Board of Directors of the Venezuelan Association of Pharmaceutical Companies. Mr. Liebhaber has received several honorary medals and prizes from the Venezuelan government.

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 all aspects of 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.

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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 spanning all facets of business strategy, planning, development and financing. Mr. Fulda has identified and managed growth

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opportunities for over 250 emerging businesses. 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 of International Management Degree from American Graduate School of International Management and a Bachelor's Degree in Economics from the University of San Francisco.

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 been instrumental 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.

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 is a specialist 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.

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

Section 16(a) of the Securities Exchange Act of 1934, as amended, 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, 2002, all the Reporting Persons complied with all applicable filing requirements.

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### 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	
		Salary (\$)	Other Annual Compensation (\$)
Mike Ajnsztajn, Chief Executive Officer (1)	2002	150,000	4,613 (3)
	2001	81,164	--
Jose Antonio O'Daly, Chairman of the Board of Directors and President of Research and Development (2)	2002	150,000	56,671 (4)
	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, 2002, this amount includes \$4,613 in health insurance premiums paid by us for Mr. Ajnsztajn's benefit.

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(4) For the fiscal year ended December 31, 2002, this amount includes \$9,929 in health insurance premiums paid by us for Dr. O'Daly's benefit, an automobile allowance of \$5,729 and \$41,013 for a furnished apartment.

#### 2001 Stock Option Plan

Our 2001 Stock Option Plan ("2001 Plan") was unanimously adopted by the Board of Directors on November 1, 2001 and approved by our stockholders at a special meeting held on November 1, 2001. The 2001 Plan contains 5,000,000 shares of common stock, par value \$.0001 per share 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 shall 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, 2002, options to purchase 315,000 shares of common stock have been granted under the 2001 Plan. On March 24, 2003, our Board of Directors approved a grant to Steven Fulda of options to purchase 50,000 shares of common stock effective April 2, 2003, at

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an exercise price equal to the fair market value of our common stock on such date.

The 2001 Plan shall 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 shall 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 stock of the Company or of any Affiliate (a "10% Shareholder") shall in no event 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 shall be determined in accordance with the applicable provisions of the Code and shall in no event 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 shall in no event 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, shall fix the term of each option, provided that the maximum term of an option shall be ten years. ISOs granted to a 10% Shareholder shall 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.

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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 shall 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 shall 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).

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,

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alteration, suspension or discontinuance shall 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, 2002, we paid \$1,000 to each outside director for each Board meeting attended and paid an additional \$4,500 to each member of the audit committee.

### Employment Agreements

Pursuant to an Employment Agreement dated December 10, 2001 (the "O'Daly Employment Agreement"), 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 O'Daly Employment Agreement has a term of three (3) years and requires Dr. O'Daly to refrain from competing with us for a period of one (1) year following termination of his employment. The O'Daly Employment 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

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The following table sets forth the names and beneficial ownership of our common stock owned as of March 27, 2003, 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 Beneficially Owned (1)	Percentage of Common Owned
Dr. Jose Antonio O'Daly	13,640,000	
Mike Ajnsztajn (2)	8,680,000	
Gina Tedesco (2)	8,680,000	
Gaston Liebhaber	2,480,000	
Michael Ashton (3)	12,720,000	
Fabien Pictet (4)	549,000	
Steven Fulda (5)	4,700	
Bruce Epstein	50,000	

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SkyePharma PLC (6) (7) 105 Piccadilly London W1J 7NJ England	12,720,000
All Officers and Directors as a Group	38,123,700

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\* Less than 1%

(1) Beneficial ownership is determined in accordance with the 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 37,538,189 shares of our common stock outstanding as of March 27, 2003.

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(2) 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 27, 2003 by her husband, Mike Ajnsztajn. Ms. Tedesco disclaims beneficial ownership of such shares.

(3) Includes 12,720,000 shares of common stock beneficially owned by SkyePharma. Mr. Ashton is Chief Executive Officer of SkyePharma.

(4) Includes 180,000 shares of common stock and warrants to purchase 36,000 shares of common stock owned by Pictet Private Equity Investors. Also includes 100,000 shares of common stock and warrants to purchase 233,333 shares of common stock owned by Perly Ltd.

(5) Includes 4,700 shares of common stock owned as of March 27, 2003 by Mr. Fulda's spouse. Mr. Fulda disclaims beneficial ownership of such shares.

(6) SkyePharma is the beneficial owner of 200,000 shares of our common stock, 2,000,000 shares of our preferred stock and warrants to purchase 20,000 shares of common stock. Accordingly, SkyePharma has beneficial ownership of 12,720,000 shares of common stock, assuming the conversion of all shares of preferred stock owned by SkyePharma into common stock at the current conversion rate of 6.25 shares of common stock for each share of preferred stock. The conversion price of the preferred stock owned by SkyePharma is subject to further adjustment through 2004 to a maximum of 50 shares of common stock for each share of preferred stock. Michael Ashton, Chief Executive Officer of SkyePharma and a member of our Board of Directors, exercises voting control over the shares held by SkyePharma.

(7) In order to facilitate the consummation of the transaction contemplated by the Purchase Agreement, we, certain of our stockholders holding an aggregate of 66.07% of our outstanding common stock and SkyePharma executed a Stockholders' Agreement, dated as of December 10, 2001, whereby each stockholder agreed to vote its shares of common stock and take all other actions necessary to elect the independent directors nominated by our Board of Directors and to elect the nominee nominated to our Board of Directors by SkyePharma when all of the shares of preferred stock owned by SkyePharma have been converted into common stock. SkyePharma does not have the right to dispose (or direct the disposition of) any of the 25,016,000 shares of common stock owned by the other parties to the Stockholders' Agreement and accordingly SkyePharma disclaims beneficial

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ownership of all such shares.

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The following table provides information with respect to the equity securities that are authorized for issuance under our compensation plans as of December 31, 2002:

EQUITY COMPENSATION PLAN INFORMATION			
	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for issuance under equity compensation plans (excluding securities reported in column 1)
Equity compensation plans approved by security holders	315,000	\$2.73	4,685,000
Equity compensation plans not approved by security holders	--	--	--
Total	315,000	\$2.73	4,685,000

Item 12. Certain Relationships and Related Transactions.

General

On November 13, 2001, pursuant to the Contribution Agreement, 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 our 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 held 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.

During the nine months ended September 30, 2001, we advanced \$207,000 to two of our stockholders, FAC Enterprises, Inc. and 1025 Investments, Inc., in exchange for promissory notes. The stockholders repaid the total amount prior to November 30, 2001.

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.

Dr. Jose Antonio O'Daly, a founding member of our company, a principal



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stockholder and a member of our Board of Directors 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, in exchange for \$10, we 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.

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### Relationship with SkyePharma

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, as of December 31, 2002, SkyePharma purchased 1,750,000 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 \$17.5 million. The Purchase Agreement provides that SkyePharma would make a total equity investment of \$20 million. The remaining \$2.5 million investment involved the sale of an additional 250,000 shares of preferred stock to SkyePharma on January 31, 2003. Each share of preferred stock issued pursuant to the Purchase Agreement was initially convertible into four shares of common stock at the option of SkyePharma at a conversion price of \$2.50 per share of common stock. The conversion price is subject to multiple adjustments for three years from the date of the Purchase Agreement depending on our stock price maintaining certain levels. The ratio is also subject to anti-dilution protection. However, the conversion ratio will not adjust to a level greater than approximately 50 shares of common stock for each share of preferred stock. On December 10, 2002, the first anniversary date, the conversion price was reset to \$1.60 per share of common stock. If on the second or third anniversary of the original issuance date, the current market price per share of common stock is less than the current conversion price, then the conversion price will be reset to the average closing price of the stock for the ten days prior to the anniversary date. However, the conversion price will not be reset for the second anniversary date lower than the lower of (a) \$1.60 or (b) the price which results from multiplying \$1.60 by a fraction the numerator of which is the then applicable conversion price (taking into account the reset provisions not contingent on stock price and which generally provide anti-dilution protection and ignoring any reset provision related to the first anniversary date) and the denominator of which is \$2.50. The conversion price will not be reset for the third anniversary date lower than the lower of (a) \$0.20 or (b) the price which results from multiplying \$0.20 by a fraction the numerator of which is the conversion price (taking into account the reset provisions not contingent on stock price and which generally provide anti-dilution protection and ignoring any applicable conversion price related to the previous anniversary dates) and the denominator of which is \$2.50. The conversion price will not be reset on the third anniversary date if, prior to that date, the United States Patent and Trademark Office has issued a patent or notice of allowance with claims having substantially the same scope as the patent application filed by Dr. O'Daly and covering a psoriasis vaccine marketed and commercialized by us. Furthermore, the conversion price will not be reset if the average closing price calculated is greater than the conversion price.

As a result of the Purchase Agreement, SkyePharma is the beneficial owner of 25.41% of our outstanding common stock based on our current conversion price. In addition to other rights under the Purchase Agreement, SkyePharma, as the sole holder of shares of our preferred stock, holds the right to elect one member of our Board of Directors. Pursuant to the Purchase Agreement, we and

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certain of our stockholders holding an aggregate of 66.07% of our outstanding common stock executed a Stockholders' Agreement, dated as of December 10, 2001, with SkyePharma, whereby each stockholder agreed to vote its shares of common stock to elect the independent directors nominated by our Board of Directors and, once SkyePharma no longer owns its preferred stock, to elect a nominee designated by SkyePharma to our Board of

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Directors. We also granted SkyePharma certain registration rights effective as of December 10, 2002 pursuant to a Registration Rights Agreement, dated as of December 10, 2001.

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. The option we received under the Technology Access Option Agreement expires on December 10, 2008. In addition, pursuant to a Service Agreement, dated December 10, 2001, SkyePharma agreed to provide us with development, manufacturing, pre-clinical and clinical development services. We paid SkyePharma \$7,980,000 in 2002 for the services provided. 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 twenty-four month period following January 1, 2003.

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 and Astralis LLC
10.8 **	Assignment of License
10.9 **	Form of Warrant
10.10 ++	Agreement for Services dated December 10, 2001 between SkyePharma Inc. and Astralis Ltd.
10.11 ++	Technology Access Option Agreement dated December 10, 2001 by and among SkyePharma Inc., SkyePharma Holding AG and Astralis Ltd.
10.12	Employment Agreement dated December 10, 2001, between Dr. Jose Antonio O'Daly and Astralis Ltd.
10.13	Amendment #1 to Agreement for Services dated March 18, 2003 between SkyePharma Inc. and Astralis Ltd.
99.1	Certification pursuant to Section 906 of the

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Sarbanes-Oxley Act of 2002

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\* 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 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 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.

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(b) Reports on Form 8-K

On December 12, 2002, we filed a current report on Form 8-K reporting that we mailed a marketing brochure to our shareholders. The current report provides the text of the brochure.

Item 14. Controls and Procedures

(a) Evaluation of disclosure controls and procedures.

Based on their evaluation as of a date within 90 days of the filing date of 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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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 -----	Title -----	Date ----
/s/ Jose Antonio O'Daly ----- Dr. Jose Antonio O'Daly	Chairman of the Board	March 28, 2003
/s/ Mike Ajnsztajn ----- Mike Ajnsztajn	Chief Executive Officer and Director (principal executive officer)	March 28, 2003
/s/ Gina Tedesco ----- Gina Tedesco	Chief Financial Officer and Director (principal financial and accounting officer)	March 28, 2003
----- Steven Fulda	Director	March 28, 2003
----- Gaston Liebhaber	Director	March 28, 2003
----- Fabien Pictet	Director	March 28, 2003
/s/ Michael Ashton ----- Michael Ashton	Director	March 28, 2003

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### INDEPENDENT AUDITORS' REPORT

Board of Directors and Shareholders  
Astralis Ltd.  
Florham Park, New Jersey

We have audited the accompanying balance sheets of Astralis Ltd. (a development stage entity) as of December 31, 2002 and 2001, and the related statements of operations, stockholders' equity, and cash flows for the period March 12, 2001 (date of inception) through December 31, 2002. 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, 2002 and 2001, and the results of operations, changes in stockholders' equity and its cash flows for the period March 12, 2001 (date of inception) through December 31, 2002 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 incurred a net loss of \$24,584,362 (including a non-cash preferred dividend of \$11,468,750) during the period from March 12, 2001 (date of inception) to December 31, 2002. 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.

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L J SOLDINGER ASSOCIATES

Arlington Heights, Illinois

March 6, 2003

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ASTRALIS LTD.  
(A Development Stage Entity)  
Balance Sheets

ASSETS

	December 31	December 31
	2002	2001
Current Assets		
Cash and cash equivalents	\$ 227,193	\$ 1,207,179
Marketable securities - current	1,207,179	5,891
Interest receivable (net of allowance for doubtful accounts of \$16,088)	5,891	1,995,000
Prepaid expense - related party	1,995,000	73,249
Prepaid expenses	73,249	30,239
Supplies	30,239	-----
Total Current Assets	3,538,751	-----
Intangible Assets, Net - Related Party	4,226,188	-----
Other Intangible Assets, Net	43,833	-----
Property and Equipment, Net	362,713	-----
Deposits	29,953	-----
	\$ 8,201,438	\$ 2,608,212
	=====	=====

LIABILITIES

Current Liabilities		
Accounts payable and accrued expenses - related party	\$ --	\$ 263,245
Accounts payable and accrued expenses	263,245	-----
Total Current Liabilities	263,245	-----

Commitments and Contingencies

Stockholders' Equity

Convertible preferred stock, Series A, \$.001 par value; 2,000,000 shares authorized at 2002 and 2001; 1,750,000 and 1,000,000 issued and outstanding at 2002 and 2001, respectively (liquidation preference - \$18,435,343 at 2002)	1,750
---	-------

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Common stock; \$.0001 par value; 75,000,000 shares authorized at 2001; 37,538,189 and 37,588,179 issued and outstanding at 2002 and 2001, respectively	3,754	
Additional paid-in capital	33,429,396	
Deferred compensation	(12,164)	
Common stock subscriptions receivable	(885,000)	
Accumulated other comprehensive loss	(15,181)	
Deficit accumulated in the development stage	(24,584,362)	
	-----	-----
Total Stockholders' Equity	7,938,193	-----
	\$ 8,201,438	\$ -----
	=====	=====

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

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### ASTRALIS LTD. (A Development Stage Entity) Statements of Operations

	Year Ended December 31, 2002	March 12, 2001 (Inception) to December 31, 2001	March 12, 2001 (Inception) to December 31, 2002
	-----	-----	-----
Revenues	\$ --	\$ --	\$ --
	-----	-----	-----
Operating Expenses			
Research and development - related party	6,834,399	3,203,235	10,037,634
Research and development	927,143	28,540	955,683
Depreciation and amortization	15,728	831	16,559
General and administrative	1,374,251	852,013	2,226,264
	-----	-----	-----
Total Operating Expenses	9,151,521	4,084,619	13,236,140
	-----	-----	-----
Loss From Operations	(9,151,521)	(4,084,619)	(13,236,140)
Investment Income	111,273	9,255	120,528
	-----	-----	-----
Net Loss	(9,040,248)	(4,075,364)	(13,115,612)
Preferred Stock Dividends	(9,348,750)	(2,120,000)	(11,468,750)
	-----	-----	-----
Net Loss to Common Stockholders	\$ (18,388,998)	\$ (6,195,364)	\$ (24,584,362)
	=====	=====	=====

Pro Forma Information

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Net loss		\$ (6,195,364)
Pro forma tax provision		--
		-----
Pro forma net loss		\$ (6,195,364)
		=====
Basic and Diluted Loss per Common Share	\$ (0.49)	\$ (0.23)
	=====	=====
Basic and Diluted Weighted Average Common Shares Outstanding	37,541,339	27,348,030
	=====	=====

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 Stock	
	Shares	Amount	Shares	Amount
	-----	-----	-----	-----
Balances, March 12, 2001 (Date of Inception)	--	\$ --	--	\$ --
Members' capital contributions, 3/15/2001	--	--	25,300,000	2
Capital contributions received, 3/1 - 8/13/2001	--	--	--	--
Members' contributed services, 3/15 - 6/30/2001	--	--	--	--
Members' capital contributions, 9/1/2001	--	--	2,700,000	
Warrants to purchase 6,300,000 shares of common stock at \$1.60 per share issued in private placement	--	--	--	
Common stock issuable for consulting services, 9/1/2001; 500,000 shares	--	--	--	
Common stock issued in private placement net of issuance costs, 11/13/2001; 2,076,179 shares at \$1.60 per share	--	--	2,076,179	
Warrants to purchase 415,237 shares of common stock at \$4.00 per share issued				



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in private placement, 11/13/2001	--	--	--	
Net assets and liabilities acquired in merger with Hercules	--	--	7,512,000	
Preferred stock issued, net of issuance costs, 12/10/2001; 1,000,000 shares at \$10.00 per share	1,000,000	1,000	--	
Preferred stock dividend, 12/10/2001	--	--	--	
Options to purchase 200,000 shares of common stock at \$1.77 (based on valuation) issued for legal services, 12/31/2001	--	--	--	
Options to purchase 100,000 shares of common stock at \$1.77 (based on valuation) issued for consulting services, 12/31/2001	--	--	--	
Amortization of deferred compensation	--	--	--	
Net loss	--	--	--	
Balance, December 31, 2001	1,000,000	\$ 1,000	37,588,179	\$ 3

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 Receivable	Deferred Compensation	Accumulated Other Comprehensive Loss	Deficit Accumulated During Development Stage
	-----	-----	-----	-----
Balances, March 12, 2001 (Date of Inception)	\$ --	\$ --	\$ --	\$ --
Members' capital contributions, 3/15/2001	(33,183)	--	--	--
Capital contributions received, 3/1 - 8/13/2001	33,183	--	--	--

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Members' contributed services, 3/15 - 6/30/2001	--	--	--	
Members' capital contributions, 9/1/2001	(1,350,000)	--	--	
Warrants to purchase 6,300,000 shares of common stock at \$1.60 per share issued in private placement	--	--	--	
Common stock issuable for consulting services, 9/1/2001; 500,000 shares	--	--	--	
Common stock issued in private placement net of issuance costs, 11/13/2001; 2,076,179 shares at \$1.60 per share	--	--	--	
Warrants to purchase 415,237 shares of common stock at \$4.00 per share issued in private placement, 11/13/2001	--	--	--	
Net assets and liabilities acquired in merger with Hercules	--	--	--	
Preferred stock issued, net of issuance costs, 12/10/2001; 1,000,000 shares at \$10.00 per share	--	--	--	
Preferred stock dividend, 12/10/2001	--	--	--	(2,120,
Options to purchase 200,000 shares of common stock at \$1.77 (based on valuation) issued for legal services, 12/31/2001	--	(354,000)	--	
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,
	-----	-----	-----	-----
Balance, December 31, 2001	\$ (1,350,000)	\$ (398,250)	\$ --	\$ (6,195,
	-----	-----	-----	-----

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 St
	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, July 2002	--	--	--
Collection of subscription receivable, August 2002	--	--	--
Collection of subscription receivable, September 2002	--	--	--
Options issued for consulting services, 9/10/2002; 15,000 options at \$0.38 per option, based on valuation	--	--	--
Collection of subscription receivable, November 2002	--	--	--
Preferred stock dividend, 12/10/2002	--	--	--
Amortization of deferred compensation	--	--	--
Fair value adjustment on deferred Compensation	--	--	--
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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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 Receivable	Deferred Compensation	Accumulated Other Comprehensive Loss	Def Accum Duri Devel St
	-----	-----	-----	-----
Balances Brought Forward	\$ (1,350,000)	\$ (398,250)	\$ --	\$ (6,1
Oversubscription of common stock issued in private placement, 11/13/2001; 49,990 shares cancelled at \$1.60 per share, 1/24/2002	--	--	--	
Preferred stock issue, net of issuance costs, 1/31/2002; 250,000 shares at \$10.00 per share	--	--	--	
Preferred stock issue, net of issuance costs, 4/30/2002; 250,000 shares at \$10.00 per share	--	--	--	
Preferred stock dividend, April 30, 2002	--	--	--	(2
Preferred stock issue, net of issuance costs, 7/31/2002; 250,000 shares at \$10.00 per share	--	--	--	
Collection of subscription receivable, July 2002	280,000	--	--	
Collection of subscription receivable, August 2002	65,000	--	--	
Collection of subscription receivable, September 2002	48,000	--	--	
Options issued for consulting services, 9/10/2002; 15,000 options at \$0.38 per option, based on valuation	--	(5,700)	--	
Collection of subscription receivable, November 2002	72,000	--	--	
Preferred stock dividend, 12/10/2002	--	--	--	(9,0
Amortization of deferred compensation	--	34,254	--	
Fair value adjustment on deferred				

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compensation	--	357,532	--	
COMPREHENSIVE LOSS				
Net loss	--	--	--	(9,0
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)	\$ (24,5
	=====	=====	=====	=====

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

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ASTRALIS LTD.  
(A Development Stage Entity)  
Statements of Cash Flows

	Year Ended December 31, 2002	March 1 (Incept December
	-----	-----
Cash Flows from Operating Activities		
Net loss	\$ (9,040,248)	\$ (4,
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	786,740	
Amortization of net premium paid on investments	48,814	
Dividend income reinvested	(9,796)	
Members' contributed salaries	--	
Research and development service fee netted against proceeds received from preferred stock issuance	1,995,000	3,
Operating expenses paid by related parties on behalf of Company	--	
Amortization of deferred compensation	34,254	
Compensatory common stock	--	
Loss on sale of available-for-sale securities	7,145	
Changes in assets and liabilities		
Prepaid expenses	(2,029,788)	
Interest receivable	(5,891)	
Supplies	(30,239)	
Deposits	(29,953)	
Accounts payable - related party	(142,446)	
Accounts payable and accrued expenses	22,608	
	-----	-----

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Net Cash Used in Operating Activities	(8,393,800)	(
-----		
Cash Flows from Investing Activities		
Purchases of available-for-sale securities	(7,638,437)	
Proceeds from sale of available-for-sale securities	6,369,914	
Expenditures related to patent	(20,914)	
Purchases of property and equipment	(431,444)	
-----		
Net Cash Used in Investing Activities	(1,720,881)	
-----		
Cash Flows from Financing Activities		
Repurchase of common stock	(80,000)	
Collection of subscription receivable	465,000	
Issuance of common stock, net of offering and transaction costs	--	2,
Issuance of preferred stock, net of research and development service fee, technology option and costs of offering	5,505,000	1,
-----		
Net Cash Provided by Financing Activities	5,890,000	4,
-----		
Net Increase (Decrease) in Cash and Cash Equivalents	(4,224,681)	4,
Cash and Cash Equivalents, Beginning of Period	4,451,874	
-----		
Cash and Cash Equivalents, End of Period	\$ 227,193	\$ 4,
=====		

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 biotechnology company based in New Jersey and engaged primarily in the research and development of novel treatments for immune system disorders and skin diseases. The Company is currently developing two products. Its primary product, Psoraxine, is an innovative vaccine under development for the treatment of psoriasis. The Company's second product is for the treatment of leishmaniasis.

History

The Company, formerly Astralis Pharmaceuticals, Ltd. and Hercules Development Group, Inc. ("Hercules"), was incorporated under the laws of the state of Colorado on June 30, 1999 and reincorporated in the state of Delaware on

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December 10, 2001. In November 2001, the Company was a public shell company, defined as an inactive, publicly quoted company with nominal assets and liabilities.

The operations and financial statements of the Company, prior to November 13, 2001, are those of Astralis, LLC, ("Astralis, LLC") a New Jersey limited liability company formed on March 12, 2001. Astralis, LLC was merged into the Company on November 13, 2001 at which time the Company changed its name to Astralis Pharmaceuticals, Ltd. The Company is the surviving legal entity.

In connection with the merger, the Company issued 28,000,000 shares of its common stock along with warrants to purchase 6,300,000 shares of the Company's common stock at \$1.60 per share to the members of Astralis, LLC in a one-for-one exchange for all of the 28,000,000 outstanding Astralis, LLC member units of ownership and all of the 6,300,000 outstanding options to purchase member units. As a result of the transaction, the former members of Astralis, LLC acquired a majority interest in the Company.

On November 19, 2001, the Company changed its name to Astralis Ltd. and reincorporated in the state of Delaware.

### 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").

The combination of the Company and Astralis, LLC has been treated as a recapitalization of the Company. The Company was the legal acquirer in the merger. Astralis, LLC was the accounting acquirer since its members acquired a majority ownership interest in the Company. Consequently, the historical financial information included in the financial statements of the Company prior to November 2001 is that of Astralis, LLC. Pro forma financial information is not presented since the combination is a recapitalization and not a business combination.

#### Pro Forma Financial Information

As discussed in Note 1, Astralis, LLC was originally organized in the form of a Limited Liability Company. Upon the merger of Astralis, LLC into the Company, the capital structure changed to that of a corporation. The change resulted in the Company retaining the tax benefit for the portion of the losses generated subsequent to November 13, 2001, whereas the previous losses were passed through to the Astralis, LLC members. Pursuant to Staff Accounting Bulletin Number 1B.2 "Pro Forma Financial Statements and Earnings per Share" ("SAB 1B.2"), a pro forma income statement has been presented which reflects the impact of the Company's change in capital structure as if it had occurred March 12, 2001 (Astralis, LLC's inception). This presentation reflects the Company generating a tax

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ASTRALIS LTD.  
(A Development Stage Entity)  
Notes to Financial Statements

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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benefit, which has been offset with a valuation allowance, which includes the net operating losses incurred by Astralis, LLC during the period from March 12, 2001 to November 13, 2001, the operating period prior to Astralis, LLC's termination.

### Development Stage Enterprise

The Company is a Development Stage Enterprise, as defined in Statement of Financial Accounting Standards ("SFAS") 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.

Since the inception of the Company, management has been engaged in raising capital through private placement stock offerings and performing research and development activities.

### 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.

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.

### 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 been offset by a valuation reserve because management has determined it is more likely than not that the realization of deferred tax assets will not be realized and, accordingly, has established a valuation allowance.

### Fair Value of Financial Instruments



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

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ASTRALIS LTD.  
(A Development Stage Entity)  
Notes to Financial Statements

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

#### 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:

	2002	2001
	-----	-----
Options	315,000	300,000
Warrants	6,780,237	6,790,237
Convertible preferred stock	10,937,500	4,000,000
	-----	-----
	18,032,737	11,090,237
	=====	=====

#### 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."

#### 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 \$3,231,775 and \$7,761,542 for the periods from March 12, 2001 (date of inception) to December 31, 2001 and the year ending December 31, 2002, respectively.

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

#### Recent Accounting Pronouncements

In June 2001, the FASB issued SFAS No. 143, "Accounting for Asset Retirement Obligations" ("SFAS No. 143"), which is effective for fiscal years beginning

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after June 15, 2002. This Statement addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. SFAS No. 143 requires, among other things, that the retirement obligations be recognized when they are incurred and displayed as liabilities on the balance sheet. In addition, the asset's retirement costs are to be capitalized as part of the asset's carrying amount and subsequently allocated to expense over the asset's useful life. SFAS No. 143 is not expected to affect the Company.

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ASTRALIS LTD.  
(A Development Stage Entity)  
Notes to Financial Statements

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

#### Recent Accounting Pronouncements (continued)

In April 2002, the FASB issued SFAS No. 145, "Rescission of FASB Statements No. 4, 44, and 62, Amendment of FASB Statement No. 13, and Technical Corrections." For most companies, SFAS No. 145 will require gains and losses on extinguishments of debt to be classified as income or loss from continuing operations rather than as extraordinary items as previously required under SFAS No. 4. Extraordinary treatment will be required for certain extinguishments as provided in Accounting Principles Board Opinion No. 30. SFAS No. 145 also amends SFAS No. 13 to require certain modifications to capital leases be treated as a sale-leaseback and modifies the accounting for sub-leases when the original lessee remains a secondary obligor (or guarantor). SFAS No. 145 is effective for financial statements issued on or after May 15, 2002, and is not expected to have a material impact on the results of operations or financial position of the Company.

FASB Statement 146, "Accounting for Costs Associated with Exit or Disposal Activities," addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies EITF Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)." The principal difference between Statement 146 and Issue 94-3 relates to Statement 146's requirements for recognition of a liability for a cost associated with an exit or disposal activity. Statement 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. Under Issue 94-3, a liability for an exit cost as generally defined in Issue 94-3 was recognized at the date of an entity's commitment to an exit plan. A fundamental conclusion reached by the FASB in this Statement is that an entity's commitment to a plan, by itself, does not create an obligation that meets the definition of a liability. Therefore, this Statement eliminates the definition and requirements for recognition of exit costs in Issue 94-3. This Statement also establishes that fair value is the objective for initial measurement of the liability. The provisions of this statement are effective for exit or disposal activities that are initiated after December 31, 2002, and is not expected to have a material impact on the results of operations or financial position of the Company.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock Based Compensation - Transition and Disclosure - an amendment of FASB Statement No. 123." SFAS No. 148 amends SFAS No. 123 to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require more prominent disclosure in

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both annual and interim financial statements. The transition guidance and annual disclosure provisions of SFAS No. 148 are effective for fiscal years ending after December 15, 2002. The interim disclosure provisions are effective for financial reports containing financial statements for interim periods beginning after December 15, 2002. The Company did not adopt the fair value method of valuing stock options and will continue to apply Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations in accounting for stock options. The adoption of the disclosure provisions of SFAS No. 148 did not have an impact on the Company's financial condition or results of operations for the year ended December 31, 2002.

### NOTE 3 - GOING CONCERN

The Company incurred net losses of \$18,388,998 and \$6,195,364 during the year ended December 31, 2002 and the period from March 12, 2001 (date of inception) to December 31, 2001, respectively. Included in these net losses were non-cash preferred stock dividends generated from beneficial conversion features of preferred stock sales in the amounts of \$9,348,750 and \$2,120,000 for 2002 and 2001, respectively (see Note 8).

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ASTRALIS LTD.  
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### NOTE 3 - GOING CONCERN (Continued)

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 commence clinical testing of Psoraxine in 2003. 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 2003. These funds, in addition to its cash and marketable securities held at December 31, 2002 and the \$2,500,000 in proceeds received in January 2003 from the final installment sale of its Series A Preferred stock (see Note 8), will be needed in order to finance the Company's currently anticipated needs for operating and capital expenditures for 2003, including the cost to complete Phase II of the FDA testing process for Psoraxine. The Company will also need to raise significant 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.

### NOTE 4 - MARKETABLE SECURITIES

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The Company's marketable equity securities consisted of certificates of deposit and mutual funds that have a readily determinable fair market value. Management determines the appropriate classifications of its investments using 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 Stockholders' 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.

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ASTRALIS LTD.  
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Notes to Financial Statements

NOTE 4 - MARKETABLE SECURITIES (Continued)

There were no marketable securities at December 31, 2001. As of December 31, 2002, available-for-sale securities consist of the following:

	Due	Amortized Cost	Gross Unrealized Loss	Gross Unrealized Gains	Fair Value
	-----	-----	-----	-----	-----
* Certificates of Deposit	1/2003 to 11/2014	\$ 512,584	\$ (8,294)	\$ 24	\$
Fixed Income Funds	current	709,776	(6,911)	--	---
		----- \$ 1,222,360 =====	----- \$ (15,205) =====	----- \$ 24 =====	----- \$ 1 =====

\* It will be necessary for the Company to utilize the proceeds from these certificates of deposits to fund its operations in 2003 and therefore they have been classified as short-term investments.

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 of application for the patent or 17 years from the date of grant, whichever is longer. The Company's policy is to amortize these capitalized costs on a straight-line basis over the remaining portion of the 20-year period, which commenced on March 16, 2001, the date the patent application was filed.

The Company paid \$5,000,000 for a technology access option from SkyePharma, PLC ("SkyePharma"), a related party. This option gives the Company the right, until

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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 immunotherapeutic drugs it develops to treat psoriasis or leishmaniasis. 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.

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 the viability and efficacy of Psoraxine. In accordance with SFAS 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 for impairment annually under SFAS 144, "Accounting for the Impairment or Disposal of Long-Lived Assets".

The Company has amortized \$2,135 and \$797 of patent costs and \$714,288 and \$59,524 of the cost of the technology option license in 2002 and 2001, respectively. The amortization related to the technology option license is recorded as research and development cost as required by SFAS No. 2.

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NOTE 5 - INTANGIBLE ASSETS (Continued)

Intangible assets consisted of the following at December 31,

	2002	2001
	-----	-----
Patent	\$ 46,765	\$ 25,851
Technology access fee	5,000,000	5,000,000
Less accumulated amortization	(776,744)	(60,321)
	-----	-----
	\$ 4,270,021	\$ 4,965,530
	=====	=====

NOTE 6 - PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at December 31,

	2002	2001
	-----	-----
Furniture and Fixtures	\$ 27,813	\$ --
Computer Equipment	17,120	1,620
Leasehold Improvements	181,604	--
Lab Equipment	195,962	--
Automobiles	8,945	--
	-----	-----
	\$ 431,444	\$ 1,620

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Accumulated depreciation and amortization	(68,731)	(34)
	-----	-----
	\$ 362,713	\$ 1,586
	=====	=====

Depreciation expense amounted to \$34 and \$68,697 for the period from March 12, 2001 (date of inception) to December 31, 2001 and the year ending December 31, 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,	
	2002	2001
	-----	-----
Deferred tax assets:		
Prepaid research and development	\$ 1,062,100	\$ --
Accumulated depreciation and amortization	173,100	13,300
Research and development credits carryforward	437,200	204,700
Net operating loss carryforwards	3,838,000	1,436,800
	-----	-----
	5,510,400	1,654,800
Less valuation allowance	(5,510,400)	(1,654,800)
	-----	-----
Total deferred tax assets	\$ --	\$ --
	=====	=====

As of December 31, 2002, the Company had losses, which resulted in net operating loss carryforwards for tax purposes amounting to approximately \$8,000,000 that may be offset against future taxable income. These carryforwards start to expire in 2021. The Company has also generated research and development credits of \$360,000 that will expire in 2021. 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 will generate any earnings or any specific level of

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earnings in future years. Therefore, the Company has established a valuation allowance for deferred tax assets (net of liabilities) of approximately \$3,855,600 and \$1,654,800 as of December 31, 2002 and 2001, respectively.

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 pro forma presentation on the statement of operations reflects the effect on the Company had its capital structure changed to that of a corporation as of March 12, 2001 (Astralis, LLC's inception) (see Note 2).

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ASTRALIS LTD.  
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NOTE 7 - INCOME TAXES (Continued)

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 35%.

	Year Ended December 31, 2002	March 12, 2001 (Inception) to December 31, 2001
	-----	-----
Federal income tax benefit at statutory rate	\$ 3,165,000	\$ 1,426,400
Federal income tax benefit passed through to the members of Astralis, LLC	--	(65,800)
State income tax benefit (net of effect of federal benefit)	600,800	207,700
Non-deductible expenses	(142,700)	(118,200)
Research and development credit	232,500	204,700
Change in valuation allowance	(3,855,600)	(1,654,800)
	-----	-----
Income Tax Benefit	\$ --	\$ --
	=====	=====
Effective Income Tax Rate	0%	0%
	=====	=====

NOTE 8 - CAPITAL STOCK ACTIVITY

The Company's Certificate of Incorporation authorizes the issuance of 75,000,000 shares of common stock, \$0.0001 par value per share, of which 37,538,189 were outstanding as of December 31, 2002.

As discussed in Note 1, the combination of Astralis, LLC and Hercules was treated as a recapitalization of Astralis, LLC 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

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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 the year, the members paid \$33,183 on behalf of the Company to satisfy their subscription receivable.

On September 1, 2001, five new members purchased 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. Pursuant to a contribution agreement, the aforementioned Units were exchanged for an aggregate of 2,700,000 shares of 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. These subscription notes receivable were due in two installments, with \$850,000 being due on February 13, 2002 and the remaining \$500,000 due on May 13, 2002. Warrants to purchase 3,150,000 shares of common stock expire on December 13, 2003 and warrants to purchase 3,150,000 shares of common stock expire on November 13, 2006.

The \$1,350,000 due to the Company, under stock subscription agreements, on February 13, and May 13, 2002 was not paid causing the notes to be in default. The Company entered into a payment plan agreement with the stockholders, whereby the stockholders were to pay the amounts due, in approximately equal amounts, over a nine-

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ASTRALIS LTD.  
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NOTE 8 - CAPITAL STOCK ACTIVITY (Continued)

month period commencing in June 2002. The stockholders are subject to forfeiture of a percentage of their shares for not making the required payments. The Company has also agreed to extend the expiration date of warrants to purchase 3,150,000 shares of its common stock from December 13, 2003 to December 13, 2004.

As of December 31, 2002, the stockholders were late on the scheduled payments in the aggregate amount of \$635,000 and the aggregate outstanding balance was \$885,000.

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



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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 subscription amount of \$80,000 to the investor.

### Preferred Stock

The Company's Certificate of Incorporation authorize the issuance of 3,000,000 shares of preferred stock, with a \$0.001 par value per share. On December 13, 2001, the Company authorized 2,000,000 shares to be designated as "Series A Convertible Preferred Stock" ("Series A Preferred"). If the Company declares a dividend, holders of each share of Series A Preferred are entitled to non-cumulative cash dividends which shall 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 or declared on the Series A Preferred. Holders of each share of Series A Preferred are also entitled to vote on all matters at stockholder meetings. Holders of each share of the Series A Preferred may convert their shares to common stock at an initial conversion price of \$2.50. This conversion price may 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, SkyePharma received both piggyback and demand registration rights on the common stock underlying its Series A Preferred shares. On the first closing date in December 2001, the Company sold 1,000,000 shares of Series A Preferred for a purchase price of \$10,000,000.

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

The second, third and fourth closings 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. On the final closing date, January 31, 2003, the Company sold 250,000 shares of Series A Preferred for a purchase price of \$2,500,000.

Preferred Stock (Continued)

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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" ("EITF 98-5"), as amended by EITF 00-27, the issuance of the Series A Preferred, which are 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.

The Company's stock price on April 30, 2002 was \$2.77; consequently, pursuant to the requirements of EITF 98-5, as amended by EITF 00-27, the issuance of the Series A Preferred, which are 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.

There are two additional reset provisions on the second and the third anniversary of the purchase agreement for the Series A Preferred. The second reset provision called for a conversion price of \$1.60 (same as the first reset). Since the first reset provision was triggered, the second reset does not apply since it is for the same amount. The third reset provision will be triggered if on the third anniversary of the agreement, the average closing price is less than \$1.60 with a floor of \$0.20. This reset provision will become void if, prior to the third reset date, the patent entitled "Composition and Methods For The Treatment And Clinical Remission Of Psoriasis" filed with the United States Patent and Trademark Office is approved. The contingent beneficial conversion feature, related to the third reset provision, would result in an additional preferred stock dividend of \$6,031,250.

### Stock Warrants

At December 31, 2002, the Company had the following outstanding warrants to purchase its common stock:

Number of Warrants Issued -----	Exercise Price 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

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NOTE 9 - STOCK OPTION PLAN (Continued)

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 of 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.

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.

NOTE 10 - DEFERRED COMPENSATION

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

	2002	2001
	-----	-----
Beginning balance	\$ 398,250	\$ --
Deferred compensation recorded	5,700	531,000
Fair value adjustments	(357,532)	--
Amortization to stock-based compensation	(34,254)	(132,750)
	-----	-----
Balance at December 31, 2002 (audited)	\$ 12,164	\$ 398,250
	=====	=====

Exercise prices for stock options outstanding as of December 31, 2002 and the weighted average remaining contractual life are as follows:

Exercise Prices	Options Outstanding	Weighted Average Remaining Contractual Life	Number Exercisable
-----	-----	-----	-----

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\$ 2.50 - 2.75

315,000

2.5 years

150,000

In accordance with SFAS 123, the fair value of the options granted was calculated as of the date of the grant using the Black-Scholes option-pricing model. The fair value of options granted on December 31, 2001 were determined under the Black-Scholes option-pricing model using a volatility of 110%, a risk-free interest rate of approximately 4.1%, an expected life of 1 - 4 years and a dividend yield of zero. The fair value of options granted December 31, 2001 and September 10, 2002, which had not vested, were revalued at December 31, 2002, using a volatility of 130%, a risk-free interest rate of 2.4% and a dividend yield of zero.

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### NOTE 11 - RELATED PARTY - TRANSACTIONS/COMMITMENTS/INDEMNIFICATIONS

#### Patent

Jose O'Daly, a founding member of the Company, a principal stockholder and a member of our Board of Directors 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.

#### Contributed Services

Certain members of the Company have provided services to the Company without compensation. In accordance with the accounting treatment proscribed in the SEC Staff Accounting Bulletin Topic 5-T, the Company has recorded as expense an amount representing the value of these services totaling \$12,986 during the 2001 year. An offsetting entry was recorded to members' capital.

#### 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

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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 pursuant to this license agreement is 5% of the net sales of any product the Company sells that uses any of the three drug delivery systems. 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 immunotherapeutic drugs that treat 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 agreed to pay \$11,000,000 to SkyePharma in return for SkyePharma providing certain development, manufacturing, pre-clinical and clinical development services. The contract recognized that SkyePharma performed \$3,000,000 of these services in the fourth quarter of 2001 and that SkyePharma would perform and be paid for the remaining \$8,000,000 of services in 2002 and 2003. The payment terms for the services agreement were fixed. \$3,000,000 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. This \$3,000,000 was expensed in 2001.

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ASTRALIS LTD.  
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Notes to Financial Statements

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

The service agreement terminated on December 31, 2002. In March 2003, the Company and SkyePharma amended the original service agreement, effective as of 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 addition, the amendment sets forth milestones expected to be reached during the twenty-four month period following January 1, 2003. Consequently, as of December 31, 2002, the Company recorded \$1,995,000, that it paid to SkyePharma 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 2002, the Company expensed \$5,985,000 in connection with the services agreement.

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.

### 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

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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 \$143,711 and \$135,111 for the periods from March 12, 2001 (date of inception) to December 31, 2001 and the year ending December 31, 2002, respectively.

### NOTE 12 - OPERATING LEASES

The Company shared office space in Florham Park, New Jersey with a related party for part of 2001 and 2002. The value of the shared space was minimal.

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 will be \$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.

On March 15, 2002, the Company leased an apartment for one key employee and officer. The lease commenced on April 15, 2002 and expires on April 14, 2003. Monthly rent of \$2,865 is being paid by the Company.

On June 22, 2002, the Company leased an automobile for an officer of the Company for 39 months. The lease commenced on June 22, 2002 and expires on September 22, 2005. Monthly payments are \$477, which are being paid by the Company.

On June 26, 2002, the Company leased an apartment for a key employee for one year. The lease commenced on July 1, 2002 and expires on June 30, 2003. Monthly rent of \$1,175 is being paid by the Company.

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ASTRALIS LTD.  
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### NOTE 12 - OPERATING LEASES (Continued)

The Company incurred \$80,071 of rent in 2002.

The following is a schedule by year of future minimum rental payments required under operating leases that have initial or remaining noncancellable lease terms of one year or greater, as of December 31, 2002:

Year ending December 31:

2003	\$ 83,224
2004	83,224
2005	49,501
	-----
	\$ 215,949
	=====

### NOTE 13 - COMPREHENSIVE LOSS

Excluding net loss, the Company's source of comprehensive loss is from the net

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unrealized loss on its marketable debt securities, which are classified as available-for-sale.

### 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 products to be offered by the Company. These changes could materially affect the price of the Company's products or render them obsolete.

In 2003, the Company's sole source of funding is expected to be generated from the final installment of \$2,500,000, of its Series A Preferred shares purchase agreement with SkyePharma, which was received January 31, 2003, and collection of outstanding subscription receivables.

### NOTE 15 - SUPPLEMENTARY DISCLOSURES OF CASH FLOW INFORMATION

	2002	2001
	-----	-----
Supplemental Disclosures		
Cash Paid for Interest and Taxes	\$     --	\$   236
	=====	=====
Non-Cash Transactions		
Intangible expenses paid by Members on behalf of the Company	\$     --	\$15,596
	=====	=====

The technology access option in the amount of \$5,000,000 and services fees of \$3,000,000 were deducted from proceeds of preferred stock in December 2001.

The Company received stock subscriptions during 2001 in the amount of \$1,350,000, which remained outstanding as of December 31, 2001.

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ASTRALIS LTD.  
(A Development Stage Entity)  
Notes to Financial Statements

### NOTE 15 - SUPPLEMENTARY DISCLOSURES OF CASH FLOW INFORMATION (Continued)

The Company recorded preferred stock dividends in the amount of \$2,120,000 and \$9,348,750 in 2001 and 2002, respectively, for the beneficial conversion feature of the preferred stock issued in 2001 and 2002.

Payment of the January, April and July 2002 service fees totaling \$1,995,000 were netted against the SkyePharma January 31, 2002 and April 30, 2002, and July 31, 2002 installment purchases of the Company's Series A Preferred stock.

The Company recorded an unrealized loss on its securities available-for-sale of \$15,181 for the year ending December 31, 2002.

In December 2002 the Company financed \$39,000 of business insurance.

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### NOTE 16 - COMMITMENT AND CONTINGENCIES

In December of 2002 Astralis, Ltd. entered into an agreement with MPI Research ("MPI"), in which the Company will pay MPI for services relating to Toxicology I and Toxicology II studies, which are required by the FDA. The total expected cost of the two studies is expected to be \$426,000 and to be completed by September of 2003. \$107,400 is included as an accrued expense as of December 31, 2002.

### NOTE 17 - SUBSEQUENT EVENTS

The Company received a total of \$48,000 and \$91,315 for payment of stock subscription receivables during January 2003 and February 2003, respectively.

On January 31, 2003, the Company sold 250,000 shares of its Series A Preferred stock for \$2,500,000 in the final installment of the purchase agreement with SkyePharma.

On March 24, 2003, the Company's Board of Directors approved a grant, to a director of the Company, of options to purchase 50,000 shares of common stock.

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### Certification of Annual Report

I, Mike Ajnsztajn, certify that:

1. I have reviewed this annual report on Form 10-KSB of Astralis Ltd.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of



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registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 28, 2003

/s/ Mike Ajnsztajn

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Name: Mike Ajnsztajn

Title: Chief Executive Officer

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### Certification of Annual Report

I, Gina Tedesco, certify that:

1. I have reviewed this annual report on Form 10-KSB of Astralis Ltd.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

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5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

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6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 28, 2003

/s/ Gina Tedesco

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Name: Gina Tedesco

Title: Chief Financial Officer

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