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ASTRALIS LTD  
Form 10KSB  
April 01, 2002

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, 2001

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.

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(Name of small business issuer in its charter)

Delaware

84-1508866

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(State or other jurisdiction of  
Incorporation or organization)

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

135 Columbia Turnpike, Suite 301, Florham Park, New Jersey

07932

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(Address of principal executive offices)

(Zip Code)

Issuer's telephone number (973) 377-8008

Securities registered under Section 12(b) of the Exchange Act:

Title of each class

Name of each exchange on which registered

None

Securities registered under Section 12(g) of the Exchange Act:

Common Stock, \$.0001 par value

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(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 if disclosure of delinquent filers in response to Item 405 of Regulation S-B is not contained in this form, and no disclosure will be



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officers and directors resigned from their respective positions and were replaced by the officers and managers of Astralis LLC. See "Executive Officers and Directors".

### Business of Astralis Ltd.

Our sole business is engaging in research and development of treatments for immune system disorders and skin diseases. Our first product candidate is a new drug named Psoraxine, which we are developing as a treatment for the skin disease psoriasis.

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

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leishmaniasis vaccine, experienced complete remission of the plaque psoriasis lesion that had been present on the patient's leg for the past 12 years. Human leishmaniasis infections are caused by at least 20 different species of parasites of the genus *Leishmania*. 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, clinical trials (the "Trials") were undertaken in Caracas, Venezuela during the eight year period from 1992 to 2000. The results of the Trials yielded positive evidence of remission of psoriasis lesions. Almost 3000 patients treated by Dr. O'Daly experienced significant remission of their psoriasis lesions. Astralis LLC lacked the financial resources to commercialize Psoraxine in Venezuela, although it is still being used by Dr. O'Daly for the ongoing clinical treatment of Venezuelan patients. We are now seeking approval for Psoraxine from the United States Food and Drug Administration ("FDA"), which is a necessary and critical step toward the commercialization of Psoraxine.

Representatives of Astralis LLC sent a briefing document to the FDA and held a pre-IND (Investigation of New Drug) conference call with representatives of the FDA on May 16, 2001 to review the clinical results of Dr. O'Daly's work with Psoraxine in Venezuela. Based upon this conference call, we are presently preparing an IND application to be filed with the FDA in the second half of 2002 to conduct Phase I.B. studies of Psoraxine. Phase I.B studies will focus on determining safe dosage ranges for Psoraxine as well as efficacy in several sites in the United States with patients suffering from psoriasis. We anticipate that it will take one year to complete the Phase I.B studies at a cost of approximately \$500,000. Astralis Ltd. and Astralis LLC have spent approximately \$3,231,775 on research and development activities over the past two fiscal years. See "Government Regulation".

### Patient Populations

According to the National Psoriasis Foundation ("NPF"), 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

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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.

About 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.

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According to the NPF, 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.

Psoriasis is a chronic illness that, in many cases, requires continuous treatment. The cost of medications is high and visits to a physician are ongoing. 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 their failure to prevent frequent relapses.

### Psoriasis Treatments in Development

We currently face competition from a number of pharmaceutical companies who have psoriasis treatments under development that have substantially greater financial and other resources. The NPF has identified approximately 41 treatments under development which are in various stages of the FDA approval process, including at least five of which are in Phase III of FDA approval process.

The available developmental psoriasis treatments include topical ointments, systemic treatments, oral treatments and UV light therapy treatments. We understand that several of the largest pharmaceutical companies in the world have more than one psoriasis treatment under development.

### Competition

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 diseases and conditions as

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Psoraxine. 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 them 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.

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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.

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 the 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, may be marketed in the United States generally involves the following:

- preclinical laboratory and animal tests;
- submission of an IND application, which must become effective before clinical trials may begin;
- adequate and well controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use; and
- FDA approval of a new drug application ("NDA"), or biologics license application ("BLA").

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

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three sequential phases, we must submit an IND application to the FDA. The IND 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 IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin.

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Our proposed submission of an IND application during the second half of 2002 may not result in FDA authorization to commence a clinical trial. Further, an independent institutional review board at the medical center proposing to conduct the clinical trial 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 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 NDA or BLA. The FDA may deny a NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data. Even if such data are submitted, the FDA may ultimately decide that the NDA or BLA 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.

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 received 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 any other FDA

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regulatory requirements.

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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 (the "EU"), registration procedures are available to companies wishing to market a product in more than one EU Member State. If the regulatory authority is satisfied that adequate evidence of safety, quality and efficacy has been presented, a marketing authorization will be granted. This foreign regulatory approval process involves all of the risks associated with FDA clearance.

### 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. Preliminary searches have been conducted to ensure that no product similar to Psoraxine has already secured full patent protection. The patent application process may take up to two years to complete. Pursuant to a License Agreement dated as of April 26, 2001 ("License Agreement") 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 ("Assignment of License Agreement"), by and between Astralis LLC and us, Astralis LLC assigned to us all of its rights under the License Agreement.

Our intellectual property consists of 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 our ability to obtain the patent for Psoraxine, 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.

### Employees

As of December 31, 2001, we employed five full-time employees and no part-time employees. None of these employees are covered by a collective bargaining agreement and we believe that our employee relations are good.

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### Risk Factors

We Have No Sales, We Will Not Have Sales In The Foreseeable Future, We Are In An Early Stage of Development And We May Never Sell Products Or Become

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Profitable.

We commenced our current operations in 2001 and such operations are still 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 \$6,195,364 as of December 31, 2001 which has increased to date. We expect that substantial losses will continue for the foreseeable future. If we are ever 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. The amount of time necessary to successfully commercialize any of our product candidates is long and uncertain and successful commercialization may not occur at all. As a result, we may never become profitable.

We May Not Be Successful In The Development And Commercialization Of Products.

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

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

Our initial product candidate, Psoraxine, is in an early stage of development and will require the commitment of substantial resources to move it towards commercialization. Psoraxine will require extensive preclinical and clinical testing before we can submit any applications for regulatory approval. Before obtaining regulatory approvals for the commercial sale of Psoraxine we must demonstrate through preclinical testing and clinical trials that our product candidate is safe and effective in humans. Conducting clinical trials is 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. Our clinical trials, when commenced, may be suspended at any time if we or the U.S. Food and Drug Administration ("FDA") believe the patients participating in our studies are exposed to unacceptable health risks. We may encounter problems in our



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studies which will cause us or the FDA to delay or suspend the studies. Our commencement and rate of completion of clinical trials may be delayed by many factors, including:

- ineffectiveness of the study compound, or perceptions by physicians that the compound is not effective for a particular indication;
- inability to manufacture sufficient quantities of compounds for use in clinical trials;
- failure of the FDA to approve our clinical trial protocols;
- slower than expected rate of patient recruitment;
- unforeseen safety issues; or
- government or regulatory delays.

If any future clinical trials are not successful, our business, financial condition and results of operations will be harmed.

Our Potential Therapeutic Products Are Subject To A Lengthy And Uncertain Regulatory Process. If Our Potential Products Are Not Approved, We Will Not Be Able To Commercialize These Products.

The FDA must approve any therapeutic product before it can be marketed in the United States. Before we can file a new drug application license with the FDA, the product must undergo extensive testing, including animal and human clinical trials, which can take many years and require substantial expenditure. Data obtained from such testing are 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. The regulatory process is expensive and time consuming.

Because our initial product candidate, Psoraxine, involves the application of new technologies and may be used upon new therapeutic approaches, it may be subject to more rigorous review by government regulatory authorities, and government regulatory authorities 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 submitted any applications with 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

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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.

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 a product. Further, once regulatory approval is obtained, a marketed product and its manufacturer are subject 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

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the product from the market. In certain countries, regulatory agencies also set or approve prices.

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

Our initial product candidate, Psoraxine, has not been developed sufficiently or been approved for clinical trials. 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 and sell our products on a commercial scale. For us 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 all development, manufacturing, pre-clinical and clinical development services for Psoraxine for a period lasting until the completion of our Phase II clinical studies; however, we do not currently have a similar agreement covering the period following the completion of our Phase II clinical studies 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.

Any Inability To Adequately Protect Our Proprietary Technologies Could Harm Our Competitive Position. We License Our Technology From A Company Controlled By Dr. O'Daly And We Do Not Own It.

Although a patent application has been filed covering certain technology, 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. We have licensed our technology, including the rights to the patent application from Dr. O'Daly. We do not own the technology and under certain, limited circumstances, such as the event of a breach of the License Agreement by us, Dr. O'Daly has the right to terminate the License Agreement. If Dr. O'Daly terminates the License Agreement, we would likely no longer be able to pursue our proposed business.

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The patent positions of biotechnology companies, including our patent positions, involve complex legal and factual questions and, therefore, validity and enforceability cannot be predicted with certainty. Patents may be challenged, deemed unenforceable, invalidated or circumvented. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies are covered by valid and enforceable patents or are effectively maintained 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.

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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 the use or validity of any of our patents is ever challenged, resulting in litigation or administrative proceedings, we would incur substantial costs and the diversion of management in defending the patent. In addition, we do not control the patent prosecution of technology that we license from others. Accordingly, we are unable to 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 Who Have Greater Resources And Experience Than We Do May Develop Products And Technologies That Make Ours Obsolete.

The biotechnology industry is characterized by rapid technological change and is 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. These organizations may develop technologies that are 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

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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.

We Will Need To Obtain Additional Funds To Support Our Future Operation Expenses.

Based on our current plans, we believe that we currently have sufficient funds to fund our operating expenses and capital requirements through at least the next 12 months. However, the actual amount of funds that we will need during or after the next 12 months will be determined by many factors, including those discussed in this section. We will need additional funds to commence Phase III studies for our product candidate. When additional funds are required and we are unable to obtain them on terms favorable to us, we may be required to delay, scale back or eliminate some or all of our research and development programs or

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to license third parties to develop or market products or technologies that we would otherwise seek to develop or market ourselves. If we raise additional funds by selling additional shares of our capital stock, the ownership interest of our stockholders will be diluted.

If We Lose Our Key Personnel Or Are Unable To Attract And Retain Additional Personnel, We May Be Unable to Discover And Develop Our Products.

We are highly dependent 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 will be successful in attracting and retaining qualified personnel, competition may be intense for experienced scientists. Failure to attract and retain skilled personnel would prevent us from pursuing collaborations and developing our products and core technologies to the extent otherwise possible.

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

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 be sufficient to cover claims that may be made against us. Clinical trial liability insurance is expensive, difficult to obtain and may not be available in the future on acceptable terms, if at all. Any

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claims against us, regardless of their merit, could strain our financial resources in addition to consuming the time and attention of our management. If we are sued for any injuries caused by our products, our liability could exceed our total assets.

Some Of Our Existing Stockholders Can Exert Control Over Us, And May Not Make Decisions That Are In The Best Interests Of All Stockholders.

Our officers, directors and principal stockholders (greater than 5% stockholders) together control approximately 84.58% of our outstanding Common Stock. As a result, these stockholders, if they act together, will be able to 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 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

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transactions or agreements which we would not otherwise consider.

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

The market price of our Common Stock has been and is expected to continue to be highly volatile. 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 shares of Common Stock by stockholders and by us, including any subsequent sale of Common Stock by SkyePharma and the holders of warrants and options, could have an adverse effect on the price of our Common Stock.

There Is A Large Number Of Shares That 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 37,538,179 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, there will be approximately 52,618,416 shares of Common Stock outstanding. Of the outstanding shares, up to 9,931,415 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. If the sale and distribution of our shares were to occur, the market price of our Common Stock could decline as a result of the introduction of these shares into the public market.

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Our Common Stock Is Classified 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 is traded on the Nasdaq 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 is not traded 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 is classified as a "penny stock." SEC Rule 15c-9 under the Securities and Exchange Act of 1934, as amended ("Exchange Act") 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 that investments in penny stocks are suitable 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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### SPECIAL CAUTIONARY NOTE REGARDING 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 and Plan of Operations", 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 Financial Condition and Plan of Operations" section and elsewhere in this annual report could seriously harm our business.

#### Item 2. Description of Property

Our executive offices are located at 135 Columbia Turnpike, Suite 301, Florham Park, New Jersey 07932 which is the same address as Opus International, Ltd. ("Opus International"),

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a company owned by Gina Tedesco, our Chief Financial Officer. We have been occupying the office spaced on a rent-free basis that has been paid for by our current officers and we expect to continue to do so until May 2002. The value of the office space is inconsequential and is not included in the accompanying financial statements. On May 1, 2002 we will move into new office and laboratory space located at 75 Passaic Ave., Fairfield, New Jersey 07004. The yearly rent for such office space will be \$77,500.

#### Item 3. Legal Proceedings

We are not currently party to any material legal proceeding.

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

On November 1, 2001, we held a Special Meeting of Shareholders ("Special Meeting"). At the Special Meeting our shareholders voted on the following proposals:

##### Proposal 1: Ratification of the Contribution Agreement

At the Special Meeting, our shareholders were asked to vote for or against the ratification of the Contribution Agreement, dated as of September 10, 2001 ("Contribution Agreement") between us on the one side 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 (the "Astralis Members") on the other side.

Pursuant to the business combination set forth in the Contribution

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Agreement, the Astralis Members transferred all of their respective membership interests ("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.

Shareholders holding 23,882,000 shares of Common Stock voted in favor of Proposal 1.

No shareholders withheld their votes or voted against Proposal 1.

Shareholders holding 7,459,000 shares of Common Stock were abstentions.

Proposal 2: Ratification of the Amendment to Our Articles of Incorporation Changing Our Name to Astralis Ltd.

At the Special Meeting, our shareholders were asked to vote for or against the amendment to our Articles of Incorporation changing our name from "Hercules Development Group, Inc." to "Astralis Ltd."

Shareholders holding 23,882,000 shares of Common Stock voted in favor of Proposal 2.

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No shareholders withheld their votes or voted against Proposal 2.

Shareholders holding 7,459,000 shares of Common Stock were abstentions.

Proposal 3: Ratification of the Appointment of L J Soldinger Associates Ltd. as Our Independent Certified Public Accountants.

At the Special Meeting, our shareholders were asked to vote for or against the ratification of the appointment of L J Soldinger Associates Ltd. as our independent certified public accountants for the ensuing year.

Shareholders holding 23,882,000 shares of Common Stock voted in favor of Proposal 3.

No shareholders withheld their votes or voted against Proposal 3.

Shareholders holding 7,459,000 shares of Common Stock were abstentions.

Proposal 4: Ratification of Our 2001 Stock Option Plan

At the Special Meeting, our shareholders were asked to vote for or against the ratification of the adoption of our 2001 Stock Option Plan ("2001 Plan"), which contains 5,000,000 shares of Common Stock underlying stock options available for grant thereunder.

Shareholders holding 23,882,000 voted in favor of Proposal 4.

No shareholders withheld their votes or voted against Proposal 4.

Shareholders holding 7,459,000 shares of Common Stock were abstentions.

### PART II

Item 5. Market For Common Equity and Related Stockholder Matters

(a) Market Information, Holders and Dividends

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Our Common Stock is traded on the Nasdaq 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. As of March 25, 2002, there were 37,538,179 shares of Common Stock, par value \$.0001, outstanding which were held by 187 holders of record. Our Common Stock began trading in March 2001.

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	Market Price	
	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	\$1.50
2002		
----		
First Quarter	\$2.75	\$1.50

The closing price for the Common Stock on March 25, 2002 on the OTC Bulletin Board, was \$2.09.

On March 14, 2001, we declared a stock dividend to shareholders 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 shareholders 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 the 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 in the discretion of the Board of Directors and will depend upon our earnings, capital requirements, financial condition and other relevant factors.

### (b) Recent Sales of Unregistered Securities

We entered into a Purchase Agreement dated as of December 10, 2001 ("Purchase Agreement") with SkyePharma PLC, a company incorporated under the laws of England and Wales ("SkyePharma"). Pursuant to the Purchase Agreement, SkyePharma purchased 1,250,000 million shares of the our Series A Convertible Preferred Stock, \$.001 par value per share ("Preferred Stock"), at a purchase price of \$10.00 per share, or an aggregate purchase price of \$12.5 million. Pursuant to the Purchase Agreement, SkyePharma will make a total equity investment in our company of up to \$20 million. The remaining \$7.5 million investment will involve the sale of an additional 750,000 shares of Preferred Stock, to SkyePharma in three equal installments on April 30, 2002, July 31, 2002 and January 31, 2003. Each share of Preferred Stock issued pursuant to the Purchase Agreement is convertible into four shares of Common Stock at the option of SkyePharma. We relied on the exemption from registration with the Securities



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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

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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 (the "Private Placement") pursuant to which we sold an aggregate of 2,026,179 shares of our Common Stock and issued warrants to purchase an aggregate of 405,236 shares of our Common Stock, at an exercise price of \$4.00 per share, for an aggregate purchase price of \$3,241,887. 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 Private Placement was only made available to "Accredited Investors" as defined in Rule 501 of Regulation D, the Private Placement 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 ("Astralis LLC"), the members of Astralis LLC transferred all of their respective membership interests in Astralis LLC to us in exchange (the "Exchange") for 28,000,000 shares of our Common Stock and warrants to purchase 6,300,000 shares of our Common Stock as an exercise price of \$1.60 per share. Pursuant to the Contribution Agreement, we cancelled 23,800,000 of the 23,820,200 shares of Common Stock owned by Mr. Shai Stern who served as our Chief Executive Officer and sole director until his resignation, pursuant to the Contribution Agreement, on November 13, 2001. We relied on the exemption from registration afforded by Section 4(2) of the Securities Act of 1933. We relied on the fact that the Exchange did not constitute a public offering. No underwriter was used in connection with the Exchange.

During October of 2001, we issued a promissory note of \$50,000 to an unrelated third party (the "Note"). The Note had a maturity date of November 13, 2001. We also issued to the lender 12,000 shares of Common Stock. The Note was repaid by us 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 Note did not constitute a public securities offering. No underwriter was used in connection with the issuance of the Note.

On September 1, 2001, Richard Genovese, David Stevenson, Grizzly Consulting Ltd., Wolver Limited and Logarithmic, Inc. 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 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

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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

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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 Act of 1933, the offer to purchase units was made available to under 35 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 underwriters were used in connection with the sale of Units.

During April of 2001, we issued warrants to purchase 75,000 shares of our Common Stock at an exercise price of \$1.75 per share in connection with a loan. The Promissory Notes were repaid by us 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 its 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 7,500,000 shares 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 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 the 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 (23,800,000 shares post stock dividend) of Common Stock representing approximately 76% of our then 3,130,000 (31,300,000 post stock dividend) 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 sales 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 our 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 controlling shareholders at the time of the sales, to make the exemptions available.

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

The Following Discussion Of Our Financial Condition And Results Of Operations 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. ("Hercules"), 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 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.

In connection with the merger, we issued 28,000,000 shares of our Common Stock along with warrants to purchase 6,300,000 shares of our 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 of our shares.

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 acquiror, Astralis LLC. The stockholders' equity of the merged company was recapitalized to reflect the capital structure of the legal entity (Astralis Ltd.) and the retained earnings of Astralis LLC. Pro forma

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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.

We are primarily engaged in identifying a gene for psoriasis, developing the second generation drug, applying for the patent at the United States Patent and Trademark Office, discussing clinical trial design with the FDA and preparing an Investigation of New Drug application ("IND Application") for the FDA which we anticipate filing in the second half of 2002.

### Results of Operations

Our current operations began on March 2001 and therefore we have no prior period with which to compare our results of operations.

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 and agreements:

- o Under a contribution agreement dated September 10, 2001, five investors purchased units ("Units") from Astralis LLC consisting of an aggregate of 2,700,000 membership interests (the "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. 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 aggregate purchase price for such Units was \$1,350,000 and was paid with subscription notes. These subscription notes receivable are 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 ("Preferred Stock") 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:

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- i.) \$5 million payment due to SkyePharma in connection with our purchase of the technology option license from SkyePharma,
- ii.) \$3 million payment due to SkyePharma for services they provided under our services agreement with them which was expensed at the time of payment, and
- iii.) offering costs of approximately \$50,000.

During 2001 we incurred operating expenses amounting to \$4,084,619 which consisted primarily of:

- o Research and development costs amounting to \$3,231,775, including \$3 million that was paid to SkyePharma for services provided under our services 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 amounting to 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 \$2.12 million. This resulted from our December 10, 2001 sale of convertible preferred stock to SkyePharma which had a conversion rate to our Common Stock which was lower than 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.

### Plan of Operation

At December 31, 2001 we had cash balances of \$4,452,000.

On January 31, 2002 we sold 250,000 shares of our preferred stock to SkyePharma at a purchase price of \$10.00 per share, or an aggregate purchase price of \$2,500,000. We received net cash proceeds of approximately \$1,835,000 from this sale after our required monthly payment of \$665,000 to SkyePharma under the services agreement was netted from the proceeds.

SkyePharma has agreed to purchase for \$7,500,000 an additional 750,000 shares of Preferred Stock, in three equal installments on April 30, 2002, July 31, 2002 and January 31, 2003.

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We anticipate collecting our subscription notes receivable. These subscription notes receivable are due in two installments with \$850,000 having been due on February 13, 2002 and the remaining \$500,000 due on May 13, 2002. However, as of March 11, 2002 we have not received payment on the initial notes due.

We anticipate using our cash and expected net proceeds of the Purchase Agreement over the course of the next 12 months as follows:

- o Approximately \$10 million to conduct clinical trials to obtain FDA approval of Psoraxine and transfer the research and development to the United States, which includes leasing appropriate laboratory and corporate office facilities. Included in this amount are payments

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required under our services agreement with SkyePharma which will amount to \$8 million in 2002 and are required to be paid in equal monthly amounts;

- o Approximately \$1.5 million to pay management salaries and those of new employees;
- o Approximately \$1.5 million for public relations and general administrative and working capital requirements

Based on the current operating plan, we anticipate that our existing capital resources and, together with the net proceeds of the Private Placement and the Purchase Agreement, will be adequate to satisfy our capital requirements for approximately the next 12 months. However, our plans may change as we reach milestones and as our circumstances may change.

### Financial Condition

As of December 31, 2001, we had total current assets in the amount of \$4,490,335 total liabilities of \$383,083 and working capital of \$4,107,252. We had a deficit accumulated during the development stage of \$6,195,364 as of December 31, 2001; however, our total shareholders' equity as of December 31, 2001, was \$9,074,368. We expect to continue to operate at a deficit until such time, if ever, our operations generate sufficient revenues to cover our costs. There can be no assurance that our financial condition will improve.

Net cash used in operating activities was \$382,319 for our initial period ended December 31, 2001. During this same period net cash provided by financing activities was \$4,835,813. Cash increase by \$4,451,874, from \$0 at the beginning of the period to \$4,451,874 as of December 31, 2001.

### Inflation

We do not believe that inflation has had a material impact on our business.

### Seasonality

We do not believe that our business is seasonal.

## Item 7. Financial Statements

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.

Our Board of Directors appointed the independent certified accounting firm of L J Soldinger Associates Ltd. to audit our financial statements for the year ended December 31, 2001. Accordingly, our prior accounting firm, Cordovano and Harvey, P.C. was dismissed as our independent auditors effective November 28, 2001, the date when written notification was delivered to that firm. The appointment of L J Soldinger Associates Ltd. as our independent auditors is effective as of November 2, 2001. Our Board of Directors approved the change in independent accountants and our shareholders approved the change in independent accountants at a Special Meeting held on November 1, 2001.

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The audit reports of Cordovano and Harvey, P.C. on our financial statements as of December 31, 2000 and 1999, for the fiscal year ended December 31, 2000 and for the period from June 30, 1999 (the date of our inception) through December 31, 1999, did not contain any adverse opinion or disclaimer of opinion, nor were such audit reports qualified or modified as to uncertainty, audit scope or accounting principles. In addition, there were no disagreements between us and Cordovano and Harvey, P.C. on any matters of accounting principles or practices, financial statement disclosure, or auditing scope and procedures which, if not resolved to the satisfaction of Cordovano and Harvey, P.C., would have caused Cordovano and Harvey, P.C. to make reference to the matter in their reports. A letter from Cordovano and Harvey, P.C. is incorporated by reference as Exhibit 16.1.

### 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	60	Chairman of the Board of Directors; President of Research and Development
Mike Ajnsztajn	37	Chief Executive Officer, Director
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Gaston Liebhaber	67	Director of International Affairs, Director
Gina Tedesco	38	Chief Financial Officer
Michael Aston	55	Director
Steven Fulda	69	Director
Fabien Pictet	43	Director
James Leyden, MD	61	Chairman, Medical Advisory Board
Bruce Epstein	38	Marketing Affairs Director

With the exception of Mike Ajnsztajn and Gina 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 shareholders or until their respective successors have been elected and qualified. Officers serve at the pleasure of the Board of Directors.

On November 13, 2001, pursuant to the Contribution Agreement, Shai Stern, who served as our Chief Executive Officer, President and sole director since February 28, 2001 and Steven Harrington, who served as our Vice President since April 9, 2001, resigned from all of their respective positions with us. At the time of their resignations, Messrs. Stern and Harrington constituted all of our

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executive officers and directors.

Jose Antonio O'Daly, MD, PhD. Dr. O'Daly has served as our Chairman of the Board of Directors and President of Research and Development since November 13, 2001. Dr. O'Daly is the President and sole founder of Center for Research and Treatment for Psoriasis ("CITP") in Caracas, Venezuela. Dr. O'Daly is also the Director and Head of Research of the Microbiology Center of the Venezuelan Institute of Scientific Research. 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.

Michael Ajnsztajn. Mr. Ajnsztajn has served as our Chief Executive Officer and as a director since November 13, 2001. Mr. Ajnsztajn gained 15 years of extensive experience in the pharmaceutical field while working as both an Export Manager for the Far East based in France,

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and as Marketing Director in China. 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 and as a director since November 13, 2001. 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. Currently, Mr. Liebhaber is the Managing Director of Latin America of Sankyo Pharmaceutical, the largest Japanese pharmaceutical company, based in Venezuela. He is also the President 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 Executive Officer since November 13, 2001 and as a director since January 31, 2002. Ms. Tedesco is the President and co-founder of Opus International. Ms. Tedesco has extensive experience in the pharmaceutical industry and in all aspects of finance and business planning. During her 10-year tenure with Rhone Poulenc, Ms. Tedesco held various positions ranging from controller for the European pharmaceutical subsidiaries to Director of Finance and Investor Relations for a Brazilian subsidiary. Ms. Tedesco recently completed a certificate program at Farleigh Dickinson University, earning a second MBA in Entrepreneurial Finance complimenting the MBA she acquired from George Washington University in International Business.

Michael Ashton. Mr. Ashton has served as one of our directors since January 31, 2002. Mr. Ashton is Chief Executive Officer of SkyePharma PLC, a London based drug delivery technology provider. Mr. Ashton has thirty years of experience in the pharmaceutical industry. Prior to joining SkyePharma PLC, Mr. Ashton was Chairman and Chief Executive Officer of Faulding, Australia's largest pharmaceutical company located in the United States. Mr. Ashton has a Bachelor of Pharmacy Degree from Sydney University and a MBA degree from Rutgers University.

Steven Fulda. Mr. Fulda as served as one of our directors and as a member of our audit committee since February 6, 2002. Mr. Fulda is Managing Director of Fulda



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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 opportunities for over 250 emerging businesses. Mr. Fulda is a 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 the audit committee since February 6, 2002. Mr. Pictet is 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,

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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 is a Professor of Dermatology at the Hospital of the University of Pennsylvania in Philadelphia. He 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 from the University of Pennsylvania School of Medicine.

Bruce Epstein. Mr. Epstein has served as our Marketing Affairs Advisor since November 13, 2001. Mr. Epstein is 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. Mr. Epstein worked 10 years for Roche Laboratories, a Swiss pharmaceutical company with a U.S. division based in Nutley, New Jersey, and obtained a MBA from New York University, Stern School of Business, and a Registered Pharmacist Degree from Rutgers, College of Pharmacy.

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

Under the securities laws of the United States, our directors, our executive officers, and any persons holding ten percent or more of our outstanding Common Stock must report on their ownership of our Common Stock and any changes in that ownership to the Securities and Exchange Commission (the "Commission"). Specific due dates for these reports have been established. During the year ended December 31, 2001, we believe that the following reports have been filed late: Shai Stern filed the Form 3 late (filed on October 25, 2001) reporting his February 28, 2001 acquisition of 23,820,000 shares of our Common Stock, which was over 10% of our outstanding Common Stock and filed the Form 4 late (filed on November 26, 2001) reporting our cancellation of

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23,800,000 shares of his 23,820,000 shares of our Common Stock on November 13, 2001.

### 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 to each of our four most highly compensated executive officers, if any such other executive officer received compensation greater than \$100,000 during any of the last three fiscal years.

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#### Summary Compensation Table

##### Annual Compensation (\$)

Name and Principal Position	Year	Salary
Mike Ajnsztajn, CEO	2001	\$81,164
Shai Stern, Sole Director, CEO and President	2001	--

Mr. Shai Stern served as our President, Chief Executive Officer and director from February 28, 2001 through November 13, 2001. Mr. Ajnsztajn has served as our Chief Executive Officer since November 13, 2001. Mr. Ajnsztajn shall receive a salary of \$150,000 for services he performs during the year 2002.

We do not provide our officers or employees with pension, stock appreciation rights, long-term incentive or other plans and we have no present intention of implementing any of these plans, with the exception of our 2001 Stock Option Plan. On December 31, 2001, we granted stock options to two consultants to purchase an aggregate of 300,000 shares of our 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 the options are 4 years, 3 years, 2 years and 1 year for options vesting in 2001, 2002, 2003 and 2004, respectively. The strike price of all these options is \$2.75. In the future, we may offer stock options to employees, non-employee members of the Board of Directors and/or consultants; however, no options have been granted as of the date hereof. It is possible that we may in the future establish various executive incentive programs and other benefits, including reimbursement for expenses incurred in connection with our operations, company automobiles and life and health insurance, but none has yet been granted. The provisions of these plans and benefits will be at the discretion of the Board of Directors.

#### Compensation of Directors

The executive directors will not receive compensation pursuant to any standard arrangement for their services as directors. We will reimburse all outside directors for travel and lodging expenses related to scheduled Board meetings. We will also pay \$3,500 during 2002 and \$1,000 per meeting, for the

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directors serving on 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

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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.

### Indemnification

Our Certificate of Incorporation eliminates the personal liability of directors to the fullest extent permitted by the provisions of paragraph (7) of subsection (b) of Section 102 of the General Corporation Law of Delaware. In addition, our Certificate of Incorporation include provisions to indemnify our officers and directors and other persons against expenses, judgments, fines and amounts paid in settlement in connection with threatened, pending or completed suits or proceeding against those persons by reason of serving or having served as officers, directors or in other capacities to the fullest extent permitted by Section 145 of the General Corporation Law of Delaware.

Our bylaws provide the power to indemnify any director, officer, employee or agent or any person serving at our request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise to the fullest extent permitted by the laws of the State of Delaware.

Under Delaware law, we may indemnify our officers and directors for various expenses and damages resulting from their acting in those capacities. Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended (the "Securities Act") may be permitted to the officers, directors or controlling persons pursuant to those provisions, we have been advised that, in the opinion of the Securities and Exchange Commission, indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

### 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 ("Common Stock") underlying stock options available for grant thereunder. The purpose of the 2001 Plan is to provide additional incentive to our directors, officers, employees and consultants who are primarily responsible for our management and growth. Each option 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, 2001, options to purchase 300,000 shares of Common Stock have been granted under the 2001 Plan.

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

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delegate the authority to perform such functions (in either case, the "Administrator").

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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.

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, 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.

Item 11. Security Ownership of Certain Beneficial Owners and Management

The following table sets forth the names and beneficial ownership of our Common Stock beneficially owned, directly or indirectly, by (i) each person who is a director or executive officer of our company, (ii) all of our directors and executive officers as a group, and, to the best of our knowledge, (iii) all holders of 5% or more of the outstanding shares of our Common Stock. As of March 25, 2002, there were 37,538,179 shares of our Common Stock outstanding. Unless otherwise noted, the address of all the individuals named below is care of Astralis Ltd. at 135 Columbia Turnpike, Suite 301, Florham Park, NJ 07932.

Name and Address	Number of shares of Common Stock Beneficially Owned (1)	Percentage of Common Stock Owned
Dr. Jose Antonio O'Daly	13,640,000	36.34%
Mike Ajnsztajn (2)	8,680,000	23.12%
Gina Tedesco (2)	0	--
Gaston Liebhaber	2,480,000	6.60%
Michael Ashton		
Fabien Pictet (3)	216,000	*
Steven Fulda		
SkyePharma PLC (4) (5)	8,220,000	18%
All Officers and Directors as a Group	25,016,000	66.58%

-----  
\* Less than 1%

(1) Beneficial ownership is determined in accordance with the Rule 13d-3(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") 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.

(2) Gina 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 December 31, 2001 by her husband, Mike Ajnsztajn. Ms. Tedesco disclaims beneficial ownership of such shares.

(3) All of the shares indicated include shares owned by Pictet Private Equity Investors. Also includes warrants to purchase 36,000 shares of Common Stock.

(4) As of December 31, 2001, SkyePharma PLC, a company incorporated under the laws of England and Wales ("SkyePharma") is currently the beneficial owner of 200,000 shares of our Common Stock and 1,000,000 shares of our Series A

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Convertible Preferred Stock ("Preferred Stock"), and may acquire another 1,000,000 shares of Preferred Stock within the next sixty days pursuant to the Purchase Agreement, dated as of December 10, 2001, between us and SkyePharma (the "Purchase Agreement"). Accordingly, SkyePharma has beneficial ownership of 8,220,000 shares of Common Stock, assuming the purchase of the 1,000,000 additional shares of Preferred Stock and the conversion of all shares of Preferred Stock owned or to be purchased by SkyePharma into Common Stock at the current conversion rate of four to one.

(5) In order to facilitate the consummation of the transaction contemplated by the Purchase Agreement, we, certain of our stockholders holding an aggregate of 66.58% of our outstanding Common Stock and SkyePharma executed a Stockholders' Agreement, dated as of December 10, 2001 (the "Stockholders' Agreement"), whereby each stockholder agreed to vote its shares of Common Stock and take all other actions necessary to elect the independent directors nominated by the Board of Directors and to elect the nominee nominated to the Board of Directors by SkyePharma. 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 should not be deemed to have beneficial ownership of all such shares.

### Item 12. Certain Relationships and Related Transactions.

We entered into a Purchase Agreement dated as of December 10, 2001 ("Purchase Agreement") with SkyePharma PLC, a company incorporated under the laws of England and Wales ("SkyePharma"). Pursuant to the Purchase Agreement, SkyePharma purchased 1,250,000 million shares of our Series A Convertible Preferred Stock, \$.001 par value per share ("Preferred Stock"), at a purchase price of \$10.00 per share, or an aggregate purchase price of \$12.5 million. Pursuant to the Purchase Agreement, SkyePharma will make a total equity investment in us of up to \$20 million. The remaining \$7.5 million investment, which will involve the sale of an additional 750,000 shares of Preferred Stock to SkyePharma, will be made in three equal installments on April 30, 2002, July 31, 2002 and January 31, 2003. As a result of the Purchase Agreement, SkyePharma is the beneficial owner of 18% 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, certain of our shareholders holding an aggregate of 66.58% 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

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Stock to elect the independent directors nominated by the Board of Directors to the Board of Directors and, once SkyePharma no longer owns its Preferred Stock, to elect a nominee nominated by SkyePharma to the Board of Directors. We also granted SkyePharma certain registration rights pursuant to a Registration Rights Agreement, dated as of December 10, 2001.

We and SkyePharma entered into two agreements concerning the formulation and development of our initial product candidate, Psoraxine. Under the terms of the Technology Access Agreement, dated December 10, 2001, we paid to SkyePharma a \$5 million license fee for access to DepoFoam and other relevant drug delivery technologies. In addition, pursuant to a Service Agreement, dated December 10, 2001, SkyePharma will provide all development, manufacturing, pre-clinical and clinical development services for second generation Psoraxine, for a period lasting until our completion of Phase II studies of Psoraxine in consideration of an aggregate of \$11 million payable in 2001 and 2002.

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During November of 2001, we completed a private placement offering (the "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, for an exercise price of \$4.00 per share, for an aggregate purchase price of \$3,321,887. We granted certain registration rights to the purchasers of the shares.

On November 13, 2001, pursuant to the Contribution Agreement, dated as of September 10, 2001 ("Contribution Agreement"), by and among us and the members of Astralis LLC (the "Astralis Members"), the Astralis Members transferred all of their respective membership interests in Astralis LLC to us in exchange (the "Exchange") for 28,000,000 shares of our Common Stock and 6,300,000 warrants to purchase our Common Stock as an exercise price of \$1.60 per share. Pursuant to the Contribution Agreement, we cancelled 23,820,000 of the 23,800,200 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 October of 2001, we issued a promissory note of \$50,000 to an unrelated third party (the "Note"). The Note had a maturity date of November 13, 2001. We also issued to the lender 12,000 shares of Common Stock. The Note was repaid out of the proceeds of the Private Placement.

On September 1, 2001, Richard Genovese, David Stevenson, Grizzly Consulting Ltd., Wolver Limited and Logarithmic, Inc. purchased units ("Units") from Astalis 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 for an exercise 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 aforementioned Units were exchanged for an aggregate of 2,700,000 shares of our Common Stock and 6,300,000 warrants to purchase Common Stock for an exercise price of \$1.60 per share.

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During April of 2001, we issued two promissory notes of \$100,000 and \$50,000 to unrelated third parties (the "Promissory Notes"). The Promissory Notes carried a 10% interest rate and had a maturity date of the earlier of September 1, 2001, or the date that we complete an acquisition of a private company. The Promissory Notes may be exchanged for shares of Common Stock at a rate of \$1.75 per share at our option. In addition to the Promissory Notes, we granted the lenders 75,000 warrants to purchase Common Stock at a purchase price of \$1.75 per share. The Promissory Notes were repaid by us out of the proceeds of the Private Placement.

Our executive offices are located at 135 Columbia Turnpike, Suite 301, Florham Park, New Jersey 07932 which is the same address as Opus International, Ltd. ("Opus International"), a company owned by Gina Tedesco, our Chief Financial Officer. We have been occupying the office on a rent-free basis that has been paid for by our current officers and we expect to continue to do so until May 2002. The value of the office space is inconsequential and is not included in the accompanying financial statements.

During the nine months ended September 30, 2001, we advanced \$207,000 to stockholders in exchange for promissory notes. Our former management believed it could earn a higher rate of return with promissory notes issued to stockholders than through investments with financial institutions. As of December 31, 2001 the stockholders have repaid the total amount due thereunder.

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During the period from March 15 through April 26, 2000, we issued and sold an aggregate of 7,500,000 shares 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.

On June 30, 1999, we issued and sold 23,800,000 shares of our Common Stock to J. Peter Garthwaite and Bradley A. Scott in consideration for services performed by each individual for us. The transactions carried a valuation of \$119 in each case (a total of \$238 at the rate of \$.0001 per share. Messrs. Garthwaite and Scott served as the President/Chief Executive Officer/Treasurer and Secretary, respectively, and directors from the date of its inception on June 30, 1999, until their resignation from their respective positions on February 28, 2001. Messrs. Garthwaite and Scott sold their 2,380,000 (23,800,000 post stock dividend) total shares of Common Stock to Mr. Shai Stern on February 28, 2001. Mr. Stern served as our President, Chief Executive Officer and sole director from February 28, 2001 until November 13, 2001.

Item 13. Exhibits, List and Reports on Form 8-K.

(a) (1) Financial Statements

The following consolidated financial statements are filed as part of this annual report on Form 10-KSB as follows:

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Statement of Cash Flows.....	F7
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(a) (2) Financial Statement Schedules

Not applicable.

(a) (3) Exhibits

Exhibit Number	Description
3.1 *	Certificate of Incorporation of Astralis Ltd.
3.2 *	Bylaws of Astarlis 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
16.1 ++	Letter of Cordovano and Harvey, P.C.

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 \* Previously filed with the Securities and Exchange Commission as an Exhibit



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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 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 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 12, 2001.
- + Previously filed with the Securities and Exchange Commission as an Exhibit to the Preliminary Proxy Statement for Hercules Development Group Inc. on October 14, 2001.
- ++ Previously filed with the Securities and Exchange Commission as an Exhibit to the Current Report for Astralis Pharmaceuticals Ltd. on November 29, 2001.

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### (b) Reports on Form 8-K

1. 8-K filed on November 29, 2001 to report the November 2, 2001 change of our certifying accountants from Cordovano and Harvey, P.C. to L.J. Soldingier Associates, Ltd. We filed the letter from Cordovano and Harvey, P.C. regarding the change in certifying accountants as an exhibit thereto. No financial statements were filed as exhibits thereto.

2. 8-K/A filed on December 10, 2001 to report the November 2, 2001 change in our certifying accountants from Cordovano and Harvey, P.C. to L.J. Soldingier Associates, Ltd. We filed the letter from Cordovano and Harvey, P.C. regarding the change in certifying accountants as an exhibit thereto. No financial statements were filed as exhibits thereto.

3. 8-K filed on November 14, 2001 to report the November 13, 2001 consummation of Contribution Agreement pursuant to which we completed the acquisition of Astralis LLC, a New Jersey limited liability company. In addition it reported that Shai Stern, our former CEO and sole director had resigned and that all but 20,000 of Mr. Stern's 23,820,000 shares of Common Stock had been canceled pursuant to the Contribution Agreement. We filed a copy of the Contribution Agreement as an exhibit thereto. No financial statements were filed as exhibits thereto.

4. 8-K filed on December 14, 2001 to report that on December 10, 2001, we sold 1,000,000 shares of our Series A Convertible Preferred Stock, \$.001 par value per share, at a purchase price of \$10.00 per share, or an aggregate purchase price of \$10 million, pursuant to the terms of a Purchase Agreement dated as of December 10, 2001 with Skye Pharma PLC. No financial statements were filed as exhibits thereto.

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SIGNATURES

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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/ Dr. Jose Antonio O'Daly ----- Dr. Jose Antonio O'Daly	Chairman of the Board	March __, 2002
/s/ Mike Ajnsztajn ----- Mike Ajnsztajn	Chief Executive Officer and Director (principal executive officer)	March __, 2002
/s/ Gina Tedesco ----- Gina Tedesco	Chief Financial Officer and Director (principal financial and accounting officer)	March __, 2002
----- Steven Fulda	Director	March __, 2002
/s/ Gaston Liebhaber ----- Gaston Liebhaber	Director	March __, 2002
----- Fabien Pictet	Director	March __, 2002
----- Michael Ashton	Director	March __, 2002

ASTRALIS, LTD.  
(A Development Stage Entity)

December 31, 2001

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INDEPENDENT AUDITORS' REPORT

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

We have audited the accompanying balance sheet of Astralis, Ltd. (a development stage entity) as of December 31, 2001, and the related statements of operations, stockholders' equity, and cash flows, for the period March 12, 2001 (date of inception) through December 31, 2001. 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, 2001, and the results of operations, changes in stockholders' equity and its cash flows for the period then ended in conformity with accounting principles generally accepted in the United States of America.

L J SOLDINGER ASSOCIATES

Arlington Heights, Illinois

February 4, 2002

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ASTRALIS, LTD.  
(A Development Stage Entity)  
Balance Sheet  
December 31, 2001

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### ASSETS

Current Assets	
Cash and cash equivalents	\$4,451,874
Prepaid expenses	38,461
	-----
Total Current Assets	4,490,335
Intangible Assets, Net - Related Party	4,940,476
Other Intangible Assets, Net	25,054
Property and Equipment, Net	1,586
	-----
	\$9,457,451
	=====

### LIABILITIES AND STOCKHOLDERS' EQUITY

Current Liabilities	
Accounts payable - related party	\$ 142,446
Accounts payable and accrued expenses	240,637
	-----
Total Current Liabilities	383,083
Commitments and Contingencies	
Stockholders' Equity	
Convertible preferred stock, Series A, \$ .001 par value; authorized - 2,000,000 shares; issued and outstanding - 1,000,000 shares (liquidation preference - \$10,034,521)	1,000
Common stock; \$.0001 par value; authorized - 75,000,000 shares; issued and outstanding - 37,588,179 shares	3,759
Additional paid-in capital	17,013,223
Deferred compensation	(398,250)
Common stock subscriptions receivable	(1,350,000)
Deficit accumulated in the development stage	(6,195,364)
	-----
Total Stockholders' Equity	9,074,368
	-----
	\$9,457,451
	=====

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

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ASTRALIS, LTD.  
 (A Development Stage Entity)  
 Statements of Operations  
 March 12, 2001 (Date of Inception) to December 31, 2001

Revenues	\$ --
	-----
Operating Expenses	
Research and development - related party	3,203,235
Research and development	28,540
Depreciation and amortization	831
General and administrative	852,013
	-----

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Total Operating Expenses	4,084,619
	-----
Loss From Operations	4,084,619
	-----
Other Income	
Interest income	(9,255)
	-----
Net Loss	(4,075,364)
Preferred Stock Dividends	(2,120,000)
	-----
Net Loss to Common Stockholders	\$ (6,195,364)
	=====
Pro Forma Information (Unaudited)	
Net loss	\$ (6,195,364)
Pro forma tax provision	--
	-----
Pro forma net loss	\$ (6,195,364)
	=====
Basic and diluted loss per common share	\$ (0.23)
	=====
Basic and diluted weighted average common shares outstanding	27,348,030
	=====

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

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ASTRALIS, LTD.

(A Development Stage Entity)

Statement of Stockholders' Equity

March 12, 2001 (Date of Inception) to December 31, 2001

	Preferred Stock		Common Stock		Additional Paid-In Capital	Subscri Receiv
	Shares	Amount	Shares	Amount		
	-----	-----	-----	-----	-----	-----
Balances, March 12, 2001 (Date of Inception)	--	\$ --	--	\$ --	\$ --	\$ --
Members' capital contributions, 3/15/2001	--	--	25,300,000	2,530	30,653	(33,1
Capital contributions received, 3/1 -- 8/13/2001	--	--	--	--	--	33,1
Members' contributed services, 3/15 -- 6/30/2001	--	--	--	--	12,986	
Members' capital contributions, 9/1/2001	--	--	2,700,000	270	1,349,730	(1,350,0
Warrants to purchase common						

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stock issued in private placement; 6,300,000 shares at \$1.60 per share	--	--	--	--	--	--
Common stock issuable for consulting services, 9/1/2001; 500,000 shares	--	--	--	--	135,000	
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	208	3,190,429	
Warrants to purchase common stock issued in private placement, 11/13/2001; 415,237 shares at \$4.00 per share	--	--	--	--	--	--
Balances Brought Forward	--	--	30,076,179	3,008	4,718,798	(1,350,000)

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

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ASTRALIS, LTD.  
(A Development Stage Entity)  
Statement of Stockholders' Equity  
March 12, 2001 (Date of Inception) to December 31, 2001

	Preferred Stock		Common Stock		Additional	Subscri
	Shares	Amount	Shares	Amount	Paid--In Capital	Receiv
	-----	-----	-----	-----	-----	-----
Balances Brought Forward	--	\$ --	30,076,179	\$3,008	\$4,718,798	\$(1,350,000)
Net assets and liabilities acquired in merger with Hercules	--	--	7,512,000	751	(303,071)	
Preferred stock issued, net of issuance costs, 12/10/2001; 1,000,000 shares at \$10.00 per share	1,000,000	1,000	--	--	9,946,496	
Preferred stock dividend, 12/10/2001	--	--	--	--	2,120,000	
Options issued for legal services, 12/31/2001; 200,000 options at \$1.77 per						

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option, based on valuation	--	--	--	--	354,000	
Options issued for consulting services, 12/31/2001; 100,000 options at \$1.77 per option, based on valuation	--	--	--	--	177,000	
Amortization of deferred compensation	--	--	--	--	--	
Net loss	--	--	--	--	--	
Balance, December 31, 2001	1,000,000	\$1,000	37,588,179	\$3,759	\$17,013,223	\$(1,350,000)

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

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ASTRALIS, LTD.  
(A Development Stage Entity)  
Statement of Cash Flows-Audited  
March 12, 2001 (Inception) to December 31, 2001

Cash Flows from Operating Activities

Net loss	\$ (4,075,364)
Adjustments to reconcile net loss to net cash used in operating activities	
Depreciation and amortization	60,355
Members' contributed salaries	12,986
Research and development service fee netted against proceeds received from preferred stock issuance	3,000,000
Operating expenses paid by related parties on behalf of Company	17,587
Amortization of deferred compensation	132,750
Compensatory common stock	135,000
Changes in assets and liabilities	
Prepaid expenses	(38,461)
Intangible assets	(10,255)
Accounts payable-related party	142,446
Accounts payable and accrued expenses	240,637
Net Cash Used in Operating Activities	(382,319)
Cash Flows from Investing Activities	
Purchases of property and equipment	(1,620)
Net Cash Used in Investing Activities	(1,620)
Cash Flows from Financing Activities	
Issuance of common stock, net of offering and transaction cost	2,888,317
Issuance of preferred stock, net of research and development service fee, technology option and costs of offering	1,947,496
Net Cash Provided by Financing Activities	4,835,813

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Net Increase in Cash and Cash Equivalents	4,451,874
Cash and Cash Equivalents, Beginning of Year	--
	-----
Cash and Cash Equivalents, End of Year	\$ 4,451,874
	=====

The accompanying notes are an integral part of the 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 Pharmaceutical, 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 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 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 Pharmaceutical, 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 December 10, 2001, the Company changed its name to Astralis, Ltd. and reincorporated to 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").



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

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

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, its 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 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 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 in the process of raising capital through private placement stock offerings, effecting its business merger, 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 a remaining maturity of 90 days or less at the time of purchase to be cash equivalents.

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

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

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 equipment.

### 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 that the realization of deferred tax assets is less likely than not and, accordingly, has established a valuation allowance.

### Fair Value of Financial Instruments

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

### 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, are as follows:

	Exercise Price	Shares
	-----	-----
Options	\$ 2.79	300,000
Warrants	\$1.60-4.00	6,790,237
Convertible preferred stock	\$ 2.50	4,000,000
	-----	-----

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

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Segment Information

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

Research and Development Costs

The cost of research, development and product improvement expenditures are charged to expense as they are incurred. Research, development and product improvement costs included in operating expenses amounted to \$3,231,775 for the period from March 12, 2001 (date of inception) to December 31, 2001.

Included in this amount were payments to related parties - see Note 8.

Recent Accounting Pronouncements

In June 2001, the Financial Accounting Standards Board, or FASB, approved Statements of Financial Accounting Standards ("SFAS"), No. 141, "Business Combinations" ("SFAS No. 141") and No. 142, "Goodwill and Other Intangible Assets" ("SFAS No. 142"). The statements eliminate the pooling-of-interests method of accounting for business combinations and require that goodwill and intangible assets with indefinite lives not be amortized. Instead, these assets will be reviewed for impairment annually with any related losses recognized when incurred. SFAS 141 is generally effective for business combinations after June 2001.

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

In October 2001, the FASB issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS No. 144"), which is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal years. This Statement develops one accounting model for long-lived assets that are to be disposed of by sale, as well as addressing the principal implementation issues.

The adoption of SFAS 141, 142, 143 and 144 is not expected to have any impact on the Company's financial statements.

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

NOTE 3 - INTANGIBLE ASSETS

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

The Company paid \$5,000,000 for a technology access option from SkyePharma PLC ("SkyePharma"). This option gives the Company the right, until December 13, 2008, to enter into a non-exclusive license agreement to utilize any of three drug delivery systems of SkyePharma in connection with any drugs it develops to treat two specific immunotherapies. Upon exercise of the option, the Company will be required to pay a license fee of 5% of net sales of any product utilizing the drug delivery systems. All other terms of the license agreement will be determined upon exercise of the option.

Management has taken the position that the technology access option fee is a license fee which allows the Company, prior to commercialization of its drugs, to utilize the established delivery system technologies of SkyePharma to test for viability and enhancement of the Company's Psoraxine vaccine. In accordance with Financial Accounting Standard No. 2 - Research and Development Costs ("SFAS No. 2"), the Company has capitalized the technology access option as a research and development intangible asset and is amortizing it over its seven year life. The Company will evaluate this intangible for impairment annually under FAS 121 Accounting For The Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of.

As of December 31, 2001, the Company has amortized \$797 of patent cost and \$59,524 of the cost of the technology option license. The amortization related to the technology option license is recorded as research and development cost as required by SFAS No. 2.

Intangible assets consisted of:

	December 31, 2001
Patent	\$ 25,851
Technology access fee	5,000,000
Less accumulated amortization	(60,321)
	\$4,965,530
	=====

NOTE 4 - PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	December 31, 2001
Computer equipment	\$1,620
Less accumulated depreciation	(34)

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-----  
 \$1,586  
 =====

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

NOTE 4 - PROPERTY AND EQUIPMENT (Continued)

Depreciation expense for the period from March 12, 2001 (date of inception) to December 31, 2001 was \$34.

NOTE 5 - 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, 2001
	-----
Deferred tax assets:	
Accumulated depreciation and amortization	\$ 13,300
Research and development credits carryforward	204,700
Federal and state deferred tax benefit arising from net operating loss carryforwards	1,436,800
	-----
	1,654,800
Less valuation allowance	(1,654,800)
	-----
Total deferred tax assets	\$ --
	=====

Income tax benefit consists of the following:

	December 31, 2001
	-----
Deferred	
Federal	\$ 11,300
State	2,000
Federal and state tax benefit of net operating loss carryforward	1,436,800
Tax benefit from research and development credits carryforward	204,700
	-----
	1,654,800
Less valuation allowance	(1,654,800)
	-----
Total	\$ --
	=====

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

## NOTE 5 - INCOME TAXES (Continued)

As of December 31, 2001, the Company had losses which resulted in net operating loss carryforwards for tax purposes amounting to approximately \$3,500,000 that may be offset against future taxable income. These carryforwards expire in 2021. The Company has also generated research and development credits of \$204,700 that will also 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 earnings in future years. Therefore, the Company has established a valuation allowance for deferred tax assets (net of liabilities) of approximately \$1,654,800 as of December 31, 2001.

In accordance with federal income tax regulations, the net loss incurred by Astralis, LLC from inception to the date of the merger 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 the change in capital structure to a corporation been effective as of March 12, 2001 (Astralis LLC inception) (see Note 2).

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%.

	December 31, 2001
Federal income tax benefit at statutory rate	\$ 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)	207,700
Non-deductible expenses	(118,200)
Research and development credit	204,700
Valuation allowance	(1,654,800)
	-----
Income Tax Benefit	\$ --
	-----
Effective Income Tax Rate	0%
	-----

## NOTE 6 - CAPITAL STOCK ACTIVITY

The Company's Articles of Incorporation authorizes the issuance of 75,000,000 shares of common stock, \$0.0001 par value per share, of which 37,588,179 were outstanding as of December 31, 2001.

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

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### NOTE 6 - CAPITAL STOCK ACTIVITY (Continued)

As discussed in Note 1, the combination of Astralis and Hercules was treated as a recapitalization of Astralis, whereby the Company issued to the members of Astralis, LLC, 28,000,000 shares of common stock and warrants to purchase 6,300,000 shares of Company common stock for \$1.60 per share in a one-for-one exchange for all of the outstanding 28,000,000 Astralis, LLC member units of ownership and 6,300,000 options to purchase member units.

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

Under a contribution agreement dated September 1, 2001, five new members were admitted as members of the LLC through the execution of a subscription agreement. These new members subscribed to units ("Units") from Astralis LLC consisting of an aggregate of 2,700,000 membership interests (the "Membership Interests") in Astralis LLC and 6,300,000 options to purchase additional Membership Interests in Astralis LLC for an exercise price of \$1.60 per Membership Interest. On November 13, 2001 at the closing of the Contribution Agreement, the aforementioned Units were exchanged for an aggregate of 2,700,000 shares of our common stock and 6,300,000 warrants to purchase 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 are due in two installments with \$850,000 being due on February 13, 2002 and the remaining \$500,000 due on May 13, 2002. 3,150,000 of these warrants expire December 13, 2003 and 3,150,000 expire November 13, 2006.

#### Common Stock

In September 2001, Astralis, LLC granted a consultant 500,000 membership units in return for services rendered. Common shares of Company stock were transferred to the consultant subsequent to December 31, 2001. 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 aggregating 103.81 units at \$32,000 per unit. 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 November 13, 2006. The holders of these common shares and warrants received registration rights. The Company has an obligation to file a registration statement by March 13, 2002 to commence registration of these shares and 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 and payable in 24 equal monthly installments of \$6,000.

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

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

NOTE 6 - CAPITAL STOCK ACTIVITY (Continued)

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### Preferred Stock

The Company's Articles of Incorporation authorizes 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 Series A Preferred agreement.

On December 10, 2001, the Company and SkyePharma entered into a purchase agreement whereby SkyePharma agreed to purchase 2,000,000 shares of Series A Preferred at a price of \$10 per share over a 13-month period with five separate closings. On December 10, 2002, the one-year anniversary of the agreement, SkyePharma will receive registration rights on the common stock underlying its Series A Preferred shares. The first closing occurred in December 2001 and the Company sold 1,000,000 shares of Series A Preferred for a purchase price of \$10,000,000. The second closing occurred in January 2002 and the Company sold 250,000 shares of Series A Preferred for a purchase price of \$2,500,000. The remaining 750,000 shares of Series A Preferred totaling \$7,500,000 are contracted to be sold in three equal installments which are scheduled to close on April 30, 2002, July 31, 2002 and January 31, 2003.

The Company's stock price on December 10, 2001 was \$3.03; consequently, pursuant to the requirements of EITF 98-5 "Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios", 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.

### Stock Warrants

At December 31, 2001, the Company had the following outstanding common stock warrants to purchase its securities:

Number of Warrants Issued	Exercise Price Per Share
6,790,237	\$1.60-\$4.00

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

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

NOTE 7 - STOCK OPTION PLAN



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On September 10, 2001 the Company adopted its 2001 Stock Option Plan which provides for the granting of options to officers, directors, employees, and consultants. The number of shares of common stock which can be purchased under this plan is limited to 25,000,000 shares, adjustable for changes in the capital structure of the Company. No options can be granted under this plan after September 10, 2011. Options granted under this plan may be either incentive stock options or non-qualified stock options. Options terms are not to exceed 10 years. The options have limited transferability, and will be subject to various vesting provisions as determined at the date of grant. The Board of Directors or a committee thereof will determine the exercise price of options granted in accordance with the provisions of this plan. The Board has the ability to amend, suspend or terminate this plan at any time, subject to restrictions imposed by applicable law.

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

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.

The components of deferred compensation for the options granted are as follows:

	Consultants
Balance at December 31, 2001	
Deferred compensation recorded	\$ 531,000
Amortization to stock-based compensation	(132,750)
	-----
Balance at December 31, 2001	\$ 398,250
	=====

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

### NOTE 7 - STOCK OPTION PLAN (Continued)

Exercise prices for stock options outstanding as of December 31, 2001 and the weighted average remaining contractual life are as follows:

		Weighted Average Remaining Contractual Life	Number Exercisable
Exercise Prices	Options Outstanding		

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-----  
\$ 2.75

300,000

2.5 years

75,000  
-----

FAS 123 were estimated as of the date of the grant using a Black-Scholes option-pricing model. The fair value of options granted 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.

### NOTE 8 - RELATED PARTY - TRANSACTIONS/COMMITMENTS/INDEMNIFICATIONS

#### Patent

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

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

#### 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. 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.

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

### NOTE 8 - RELATED PARTY-TRANSACTIONS/COMMITMENTS/INDEMNIFICATIONS (Continued)

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 6).

The Company entered into a technology option agreement whereby it agreed to pay SkyePharma \$5,000,000 in return for the right, for 7 years, to enter into a non-exclusive license agreement with SkyePharma to utilize three drug delivery

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

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

The remaining \$8,000,000 is required to be paid in eleven equal monthly installments of \$665,000, and a final payment of \$685,000 for all months in 2002.

SkyePharma has the right of first refusal 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 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.

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### NOTE 8 - RELATED PARTY-TRANSACTIONS/COMMITMENTS/INDEMNIFICATIONS (Continued)

#### Other

A research entity owned by the spouse of the majority shareholder provided research and development services to the Company totaling \$143,711. The full

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amount remained unpaid as of December 31, 2001.

### NOTE 9 - OPERATING LEASES

The Company shares office space for its principal executive offices in Florham Park, New Jersey with a related party at no expense. The value of the shared space is minimal.

### NOTE 10 - CONCENTRATIONS

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

In 2002, the Company's sole source of funding is expected to be generated from sales of its Series A Preferred shares under a purchase agreement with SkyePharma. Should the remaining purchases of shares not occur as specified by the purchase contract, the Company would need to find alternative sources of financing, alter its business plan or curtail its operations.

### NOTE 11 - LIQUIDITY AND CONTINGENCIES NOT DESCRIBED ELSEWHERE

There are many steps to the process that pharmaceutical products must undergo before they can be commercially sold and distributed in the United States. Drugs must undergo testing in compliance with US Food and Drug Administration ("FDA") regulations and ultimately receive FDA approval. The Company's Psoraxine product is expected to enter initial FDA testing in 2002. FDA testing occurs in various phases over a multiple number of years.

The Company anticipates that their current liquid resources, together with the \$7,500,000 in proceeds to contractually be received from the sale of their Series A Preferred (see Note 6) will be sufficient to finance its currently anticipated needs for operating and capital expenditures for the next twelve months and through the completion of Phase II of the FDA testing process in connection with its Psoraxine vaccine. However, the Company will need to raise additional funds from outside sources in order to complete future phases of FDA required testing.

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.

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### NOTE 12 - SUPPLEMENTARY DISCLOSURES OF CASH FLOW INFORMATION

#### Supplemental Disclosures

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

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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.

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

The Company recorded a preferred stock dividend in the amount of \$2,120,000 for the beneficial conversion feature of the preferred stock issued.

### NOTE 13 - SUBSEQUENT EVENTS

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 50,000 shares of common stock. The Company cancelled the respective shares and returned the corresponding amount of funds to the investor amounting to \$80,000.

In February 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 materials basis.

As of March 11, 2002, the Company had not received payment on the initial subscription notes receivable, which were due February 13, 2002 and amounted to \$850,000.

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