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ASTRALIS LTD  
Form SB-2/A  
October 12, 2005

As filed with the Securities and Exchange Commission on October 12, 2005  
Registration No. 333-115974

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SECURITIES AND EXCHANGE COMMISSION  
Washington D.C. 20549

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POST-EFFECTIVE AMENDMENT NO. 1  
To  
FORM SB-2  
REGISTRATION STATEMENT  
Under  
THE SECURITIES ACT OF 1933

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ASTRALIS LTD.  
(Name of small business issuer in its charter)

|   |  |   |
|---|--|---|
| Delaware  | 6531   | 4-1508866                                     |
| -----   | -----  | -----   |
| (State or other jurisdiction<br>of incorporation or organization) | (Primary Standard<br>Industrial Classification<br>Code Number) | (I.R.S. Employer<br>Identification<br>Number) |

75 Passaic Avenue  
Fairfield, New Jersey 07004  
(973) 227-7168  
(Address and telephone number of principal executive offices and  
principal place of business)

James Sharpe  
Chief Executive Officer  
Astralix Ltd.  
75 Passaic Avenue  
Fairfield, New Jersey 07004  
(973) 227-7168  
(Name, address and telephone number of agent for service)

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Copies of Communications to:  
Jeffrey A. Baumel, Esq.  
McCarter & English, LLP  
Four Gateway Center  
100 Mulberry Street  
Newark, New Jersey 07102  
(973) 622-4444

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Approximate date of commencement of proposed sale of the  
securities to the public:

As soon as practicable after the effective date of this Registration Statement.

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If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. |\_ |

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. |\_ |

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. |\_ |

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. |\_ |

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The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

Subject to Completion, dated October 12, 2005

PRELIMINARY PROSPECTUS

ASTRALIS LTD.

47,056,520 Shares of Common Stock

The stockholders named in this prospectus are selling up to 47,056,520 shares of our common stock. 11,446,654 of the shares we are registering are issuable upon the exercise of outstanding warrants. The selling stockholders may offer and sell their shares on a continuous or delayed basis in the future. These sales may be conducted in the open market or in privately negotiated transactions and at market prices, fixed prices or negotiated prices. We will not receive any of the proceeds from the sale of shares by the selling stockholders, but we will receive funds from the exercise of their warrants.

Our common stock is currently listed on the OTC Bulletin Board under the symbol "ASTR." On October 6, 2005, the last reported sale price of our common stock on the OTC Bulletin Board was \$0.14 per share.

Investing in our common stock involves risks. Please read the "Risk Factors" section beginning on page 4 to read about certain risks that you should consider before purchasing shares of our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this Prospectus is October 12, 2005

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No dealer, salesperson or other person has been authorized to give any information or to make any representations other than those contained in this prospectus, and if given or made, such information or representations must not be relied upon as having been authorized by us, the selling stockholders or any underwriter. You should rely only on the information contained in this prospectus. This prospectus does not constitute an offer to sell or the solicitation of an offer to buy any security other than the common stock offered by this prospectus, or an offer to sell or a solicitation of an offer to buy any security by any person in any jurisdiction in which such offer or solicitation would be unlawful. Neither the delivery of this prospectus nor any sale made hereunder shall, under any circumstances, imply that the information in this prospectus is correct as of any time subsequent to the date of this prospectus.  
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## SUMMARY

You should read this summary together with the more detailed information, including our financial statements and related notes, appearing elsewhere in this prospectus.

### Our Company

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

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

- o Ongoing research and development of Psoraxine(R);
- o Recommencing clinical trials to obtain the approval of the United States Food and Drug Administration for the marketing of Psoraxine(R); and
- o Developing technology underlying Psoraxine(R) for the treatment of indications other than psoriasis, such as arthritis, eczema, seborrheic dermatitis and leishmaniasis.

In March 2005, we announced that the Phase II study of Psoraxine(R) for the treatment of Psoriasis did not meet the primary study endpoint upon completion of the treatment phase of the study. In the study, Psoraxine(R) was found to be safe and well-tolerated. We expect to redesign and recommence clinical trials in 2006.

We are incorporated under the laws of the State of Delaware. Our principal executive offices are located at 75 Passaic Avenue, Fairfield, New Jersey 07004 and our telephone number is (973) 227-7168. Our Internet address is [www.astralisltd.com](http://www.astralisltd.com). The information on our web site is not incorporated by reference into, and does not constitute part of, this prospectus.

### The Offering

|                                |  |
|--------------------------------|--|
| Shares of common stock offered | 47,056,520   |
| Use of Proceeds                | We will not receive any proceeds from the sale of the common stock offered by the selling stockholders. However, we may receive an aggregate of approximately \$8,259,827 upon the exercise of all the warrants held by selling stockholders, if such warrants are exercised for cash. We will use such funds, if any, to fund clinical trials and for working capital and general corporate purposes. |
| OTC Bulletin Board Symbol      | ASTR   |

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The summary financial data is derived from the historical financial statements of Astralis Ltd. (the "Company"). This summary financial data should be read in conjunction with "Management's Discussion and Analysis or Plan of Operations" as well as our historical financial statements and the related notes thereto, included elsewhere in this prospectus.

Statement of operations data:

|   | Three Months Ended June 30, |             | Year Ended De |
|---|-----------------------------|-------------|---------------|
|   | 2005                        | 2004        | 2004          |
| Revenues  | \$ --                       | \$ --       | \$ --         |
| Operating Expenses  |                             |             |               |
| Research and development - related party                        | --                          | 430,447     | 4,519,400     |
| Research and development  | 507,708                     | 689,800     | 3,169,660     |
| Depreciation and amortization                                   | 6,724                       | 7,530       | 30,403        |
| General and administrative                                      | 365,288                     | 762,317     | 1,860,844     |
| Total Operating Expenses  | (879,720)                   | 1,890,094   | 9,580,307     |
| Loss From Operations  | (879,720)                   | (1,890,094) | (9,580,307)   |
| Investment Income   | 4,972                       | 15,349      | (722)         |
| Loss before income tax benefit                                  | (874,748)                   | (1,874,745) | (9,581,029)   |
| Income tax benefit  | --                          | --          | 293,461       |
| Net Loss  | (874,748)                   | (1,874,745) | (9,287,568)   |
| Preferred Stock Dividends                                       | --                          | --          | (10,750,000)  |
| Net Loss to Common Stockholders                                 | (874,748)                   | (1,874,745) | (20,037,568)  |
| Basic and Diluted Loss per Common Share                         | \$ (0.01)                   | \$ (0.03)   | \$ (0.28)     |
| Basic and Diluted Weighted Average<br>Common Shares Outstanding | 73,273,055                  | 73,042,560  | 71,073,507    |

Balance sheet data:

|  | Three Months Ended            | Year Ended        |
|--|-------------------------------|-------------------|
|  | June 30, 2005<br>December 31, | December 31, 2004 |
|  |                               |                   |
| Total current assets                         | 601,026                       | 2,439,147         |
| Total assets                                 | 893,413                       | 2,797,973         |
| Total current liabilities                    | 983,147                       | 397,762           |
| Deficit accumulated in the development stage | (52,257,302)                  | (49,702,357)      |

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Total stockholders' equity

893,413

2,797,973

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### RISK FACTORS

Prospective investors should carefully consider the following factors, in addition to the other information contained in this prospectus, in connection with an investment in our common stock. This prospectus contains certain forward-looking statements, which involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of certain factors, including those set forth below and elsewhere in this prospectus. An investment in our common stock involves a high degree of risk and is suitable only for investors who can afford to lose their entire investment.

We will need to obtain additional funds to support our future operation expenses. Our auditors have expressed uncertainty regarding our ability to continue as a going concern.

Based on our current plans, we believe that we have sufficient funds to meet our operating expenses and capital requirements through approximately January 2006. We will need to raise additional funds to continue our operations following that period. Furthermore, substantial additional funds will be needed in order to fund our continued efforts to obtain FDA approval of Psoraxine(R), especially given the failure of our Phase II study to meet its primary endpoint. No assurance can be given that we will be able to obtain financing, or successfully sell assets or stock, or, even if such transactions are possible, that they will be on terms reasonable to us or that they will enable us to satisfy our cash requirements. In addition, raising additional funds by selling additional shares of our capital stock will dilute the ownership interest of our stockholders. If we do not obtain additional funds, we will likely be required to eliminate programs, delay development of our products, alter our business plans, or in the extreme situation, cease operations.

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

We have no sales; we will not have sales in the foreseeable future; we are in an early stage of development and we may never sell products or become profitable.

We commenced our current operations in 2001 and such operations remain in an early stage of development. We have no products approved for sale and therefore, no means to generate revenue. We have not commercialized any products, had no revenues and had incurred a cumulative net loss of \$52,257,302 as of June 30, 2005 which has increased to date. The cumulative net loss through June 30, 2005 includes non-cash preferred stock dividends of \$22,218,750. We expect that substantial losses will continue for the foreseeable future. In order to obtain revenue from the sales of our product candidate, Psoraxine(R), we must successfully develop, test, obtain regulatory approval for, manufacture, market and eventually sell such product candidate. Our expenses have consisted principally of costs incurred in research and development and from general and administrative costs associated with our operations. We expect our expenses to increase and to continue to incur operating losses for the next several years as

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we continue our research and development efforts for Psoraxine(R) and any subsequent product candidates. Commercialization of any of our products will take a significant amount of time and successful commercialization may not occur at all. As a result, we may never become profitable.

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Psoraxine(R) may never be approved by the FDA because the results of our Phase II study failed to meet its primary study endpoint.

We have focused our development efforts to date on conducting clinical trials for an immuno-stimulatory drug, Psoraxine(R), for the treatment of psoriasis. We recently conducted a randomized, double-blinded, placebo-controlled clinical study involving 120 patients with moderate to severe psoriasis who received six (6) intramuscular injections of Psoraxine(R). The primary endpoint of the study was a specified level of improvement of symptoms measured in accordance with the Psoriasis Area and Severity Index, or PASI, which is a measurement scale that ranks the severity of symptoms of patients suffering from psoriasis. Our initial analysis of the preliminary data showed no statistically significant improvement of those Phase II study patients who received six injections of Psoraxine(R) for a twelve weeks treatment period compared to patients taking a placebo.

The failure of our Phase II study to meet its primary endpoint makes FDA approval of Psoraxine(R) substantially more uncertain. To continue Psoraxine(R)'s development and to obtain FDA approval to market Psoraxine(R), we must analyze the data from the Phase II study to identify why the Phase II study failed to meet its primary endpoint. We must then undertake additional Phase I or Phase II clinical trials that are adjusted to account for the cause or causes of the initial Phase II study's failure. Although we have already identified a number of possible reasons for the failure to demonstrate efficacy in the recent Phase II trial, and we have also developed a preliminary plan for new clinical studies, there can be no guarantee that we will be able to identify with certainty why our Phase II study failed to meet its primary endpoint and that we will be able to make the needed adjustments for further Phase II studies to be successful. There is also no guarantee that the FDA would approve Psoraxine(R) even if we deem additional clinical trials to be successful.

We have devoted most of our resources to the development of Psoraxine(R) and our business is dependent on its success. In the United States, the marketing of Psoraxine(R) depends on FDA approval of the product. Analyzing the Phase II study data and conducting additional Phase II clinical trials will delay FDA approval. We may also decide to discontinue further clinical trials of Psoraxine(R), which would prevent us from obtaining FDA approval. If we are not able to obtain FDA approval for Psoraxine(R), we would be unable to sell the product.

We may not be successful in the development and commercialization of products.

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

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successfully complete our research and development efforts, Psoraxine(R) may not perform in the manner we anticipate, and may not be accepted for use by the public.

Substantial additional funds and effort will be necessary for further development and commercialization of Psoraxine(R).

Our initial product candidate, Psoraxine(R), will require the commitment of substantial resources to move it towards commercialization. Before obtaining regulatory approvals for the commercial sale of Psoraxine(R), we must demonstrate the safety and efficacy of our product candidate through preclinical testing and clinical trials. Conducting clinical trials involves a lengthy, expensive and uncertain process. Completion of clinical trials may take several years or more. The length of time generally varies substantially according to

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the type, complexity, novelty and intended use of the product. If we or the U.S. Food and Drug Administration believe that our clinical trials expose participating patients to unacceptable health risks, we may suspend such trials. We may encounter problems in our studies which will cause us or the FDA to delay or suspend the studies. Some of the factors that may delay our commencement and rate of completion of clinical trials include:

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

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

Our potential therapeutic products face a lengthy and uncertain regulatory process. If we do not obtain regulatory approval of our potential products, we will not be able to commercialize these products.

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

Because our initial product candidate, Psoraxine(R), involves the



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

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

Even if product candidates emerge successfully from clinical trials, we may not be able to successfully manufacture, market and sell them.

We have not successfully completed clinical trials of Psoraxine(R). If Psoraxine(R) emerges successfully from clinical trials and obtains regulatory approval, we will either commercialize products resulting from our proprietary programs directly or through licensing arrangements with other companies. We have no experience in manufacturing and marketing, and we currently do not have the resources or capability to manufacture, market or sell our products on a commercial scale. In order to commercialize Psoraxine(R) directly, we would need to develop or obtain through outsourcing arrangements the capability to manufacture, market and sell products. In addition, we currently do not have any agreements for the marketing or sale of any of our products and we may not be able to enter into such agreements on commercially reasonable terms, or at all.

We license and do not own our intellectual property. Any inability to protect our proprietary technologies adequately could harm our competitive position.

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

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

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

Many potential competitors which have greater resources and experience than we do may develop products and technologies that could make ours obsolete.

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

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

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

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products more easily, which would render our technologies and products obsolete and noncompetitive.

If we lose our key personnel or fail to attract and retain additional personnel, we may be unable to discover and develop our products.

We depend on the services of Dr. Jose Antonio O'Daly, the Chairman of our Board of Directors and our Chief Scientific Officer, the loss of whose services would adversely impact the achievement of our objectives. We recently hired a Chief Executive Officer and Chief Financial Officer. To execute our business plan fully it is essential that we retain these executives. In addition, recruiting and retaining qualified scientific personnel to perform future research and development work will be critical to our success. Although we believe we can successfully attract and retain qualified personnel, we face intense competition for experienced scientists. Failure to attract and retain skilled personnel would prevent us from pursuing collaborations and developing our products and core technologies to the extent otherwise possible.

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

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If we face claims in clinical trials of a drug candidate, these claims will divert our management's time and we will incur litigation costs.

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

Some of our existing stockholders can exert control over us and many not make decisions that further the best interests of all stockholders.

Our officers, directors and principal stockholders (greater than 5% stockholders) together control approximately 84% of our outstanding common stock. As a result, these stockholders, if they act individually or together, may exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. Furthermore, the interests of this concentration of ownership may not always coincide with our interests or the interests of other stockholders and accordingly, they could cause us to enter into transactions or agreements which we would not otherwise consider. In addition, this concentration of ownership may delay or prevent a merger or acquisition resulting in a change in control of us and might affect the market price of our common stock, even when such a change in control may be in the best interest of all stockholders.

The market price of our common stock may be highly volatile.

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The market price of our common stock has been and will likely continue to be highly volatile. From the date trading of our common stock commenced until October 1, 2005, the range of our stock price has been between \$0.16 and \$7.15. On August 19, 2005 we completed a private placement of common stock at a price \$0.11 per share. 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, or 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 us, our stockholders, or the holders of warrants and options, could have an adverse effect on the price of our common stock.

A large number of shares of our common stock may be sold in the market, which may depress the market price of our common stock.

Sales of substantial amounts of our common stock in the public market, or the perception that these sales might occur, could materially and adversely affect the market price of our common stock or our future ability to raise capital through an offering of our equity securities. We have an aggregate of 91,354,873 shares of our common stock outstanding. If all options and warrants currently outstanding to purchase shares of our common stock are exercised, there will be approximately 140,120,340 shares of common stock outstanding. Of the outstanding shares, up to 11,605,224 shares are freely tradable without restriction or further registration under the Securities Act, unless the shares are held by one of our "affiliates" as such term is defined in Rule 144 of the Securities Act. The remaining shares may be sold only pursuant to a registration statement under the Securities Act or an exemption from the registration requirements of the Securities Act. The sale and distribution of these shares may cause a decline in the market price of our common stock. In addition we will

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be obligated to file a registration statement within approximately 30 days of the final closing of our most recent private placement covering the resale of all shares included therein, as well as the shares underlying the warrants. Certain existing stockholders have the right to include their securities in such registration statement.

Our common stock qualifies as a "penny stock" under SEC rules which may make it more difficult for our stockholders to resell their shares of our common stock.

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

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holders of our common stock to resell the stock.

### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus 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 in the importance of communicating our future expectations to our investors. However, we may be unable to accurately predict or control events in the future. The factors listed in the sections captioned "Risk Factors" and "Management's Discussion and Analysis or Plan of Operations," as well as any other cautionary language in this prospectus, 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.

### USE OF PROCEEDS

We will not receive any proceeds from the sale of common stock by the selling stockholders. We will receive proceeds upon the exercise of any warrants. If all of the selling stockholders exercise all of their warrants for cash, we will receive an aggregate of approximately \$8,259,827. We will use such funds, if any, to fund clinical trials and for working capital and general corporate purposes.

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### MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock is traded on the OTC Bulletin Board under the symbol ASTR. The closing price for our common stock on October 6, 2005 was \$0.14.

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

|                | High   | Low    |
|----------------|--------|--------|
| 2003           |        |        |
| First Quarter  | \$0.72 | \$0.34 |
| Second Quarter | \$1.01 | \$0.40 |
| Third Quarter  | \$1.41 | \$0.36 |
| Fourth Quarter | \$0.87 | \$0.42 |
| 2004           |        |        |
| First Quarter  | \$1.66 | \$0.80 |
| Second Quarter | \$1.46 | \$1.04 |
| Third Quarter  | \$1.05 | \$0.51 |
| Fourth Quarter | \$0.85 | \$0.42 |
| 2005           |        |        |

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|                |        |        |
|----------------|--------|--------|
| First Quarter  | \$0.84 | \$0.16 |
| Second Quarter | \$0.40 | \$0.20 |

### Holder of common stock

As of October 1, 2005, there were approximately 2,833 holders of record of our common stock.

### Dividends

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

### MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATIONS

The following discussion of our financial condition and plan of operation should be read in conjunction with our financial statements and the related notes included elsewhere in this prospectus. This prospectus 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

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specifically consider the various factors identified in this prospectus, including the matters set forth under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We disclaim any obligation to update information contained in any forward-looking statement.

### Overview

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

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

- o Ongoing research and development of Psoraxine(R);
- o Recommencing clinical trials to obtain the approval of the United States Food and Drug Administration for the marketing of Psoraxine(R); and
- o Developing technology underlying Psoraxine(R) for the treatment of indications other than psoriasis, such as arthritis, eczema, seborrheic dermatitis and leishmaniasis.

### Recent Developments

On August 19, 2005, we completed a private placement of securities from which we received gross proceeds of approximately \$2,000,000. The transaction consisted of the sale to one accredited investor, Blue Cedar Limited ("Blue

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Cedar"), of units consisting of: (i) 18,181,818 shares of common stock, (ii) warrants to purchase over a 5-year period 18,181,818 shares of common stock with an exercise price of \$0.165, and (iii) warrants to purchase over a 12-month period 12,121,212 shares of common stock with an exercise price of \$0.165. We relied upon the exemption from registration provided under Section 4(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder. The private placement was only made available to one "accredited investor" as defined in Rule 501 of Regulation D. Lipworth Capital Limited acted as our placement agent in connection with the private placement. We paid an 8% fee to our placement agent and issued warrants to purchase 1,454,545 shares of common stock with an exercise price of \$0.165, in connection with the financing in addition to other costs. Additionally, we granted Blue Cedar certain registration rights pursuant to a registration rights agreement, dated as of August 17, 2005, in connection with this transaction. The registration rights agreement requires us to file a registration statement within approximately 30 days of the final closing of our private placement covering the resale of all shares included therein, as well as the shares underlying the warrants. If the registration statement is not filed or effective by the dates specified in the agreement, we are subject to a penalty of 0.5% per month of the aggregate purchase price .

Concurrently with the closing of the private placement, we entered into a stockholder's agreement with Blue Cedar, dated as of August 17, 2005 (the "Blue Cedar Stockholder's Agreement"). Pursuant to the Blue Cedar Stockholder's Agreement, Blue Cedar may designate one director to our Board of Directors. Further, we agreed not to enter into any service agreement, distribution arrangement or transfer of personnel with any of our stockholders owning more than 10% of the outstanding shares of common stock until we complete Phase II clinical trials of Psoraxine(R), without the prior written consent of Blue Cedar, which shall not be unreasonably withheld. Additionally, for a period of two years following the closing date of the private placement, we granted Blue Cedar certain pre-emptive rights, allowing Blue Cedar to participate in substantially all sales of securities. The Blue Cedar Stockholder's Agreement will terminate upon the later of the Blue Cedar Termination Date or August 15, 2008. The "Blue Cedar Termination Date" is the date on which Blue Cedar no longer beneficially owns, in the aggregate, at least 20% of our common stock.

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Based on our current plans we believe that we have sufficient funds to meet our operating needs through approximately February 2006. Our ability to continue operations beyond January 2006 is contingent upon the success of efforts to raise additional capital.

The Board of Directors has approved an amendment to our Certificate of Incorporation, pursuant to which we will be authorized to issue an additional 200,000,000 shares of Common Stock. The Amendment will be subject to the approval of our stockholders to be sought at a Special Meeting to be held in the fall of 2005.

### Plan of Operation

Three months ended June 30, 2005 compared to three months ended June 30, 2004

For three months ended June 30, 2005:

For the three months ended June 30, 2005, we had no revenue from operations and incurred operating expenses of \$879,720 which consisted primarily of:

- o Research and development costs of \$507,708, including evaluation of

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clinical trial results, reformulation of Psoraxine(R) and activity testing in animals. Research and development costs did not include any allocation of costs related to the formulation and development of Psoraxine(R) under our Services Agreement with SkyePharma PLC ("SkyePharma"), dated December 10, 2001 (the "Services Agreement"), due to the expiration of the Services Agreement in December 2004.

- o General and administrative costs of approximately \$365,288, including professional fees, rent, salaries for management and our general corporate expenditures.

As a result, during the three months ended June 30, 2005, we incurred a net loss of \$874,748.

For the three months ended June 30, 2004:

For the three months ended June 30, 2004, we had no revenue from operations and incurred operating expenses of \$1,890,094 which consisted primarily of:

- o Research and development costs of \$1,120,247, including \$430,447 that we incurred in connection with services provided by SkyePharma under our Service Agreement with them and amortization of approximately \$178,572 in technology access option fees pursuant to our Technology Access Option Agreement with SkyePharma, dated December 10, 2001 ("Technology Access Option Agreement").
- o General and administrative costs of approximately \$762,317, including professional fees and our general corporate expenditures. In addition, in connection with the conversion by SkyePharma of its shares of our Series A Convertible Preferred Stock, par value \$.001 per share ("Series A Preferred Stock"), we assigned to FPP Capital Advisors, as compensation, 10% of the call option granted to us under our Call Option Agreement with SkyePharma, dated January 20, 2004 ("Call Option Agreement"). Accordingly, a non-cash charge of \$376,508 was recorded as a general and administrative expense in June 2004.

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As a result, during the three months ended June 30, 2004, we incurred a net loss of \$1,874,745.

Comparison:

Our research and development expenses declined from \$1,120,247 during the three months ended June 30, 2004 to \$507,708 during the three months ended June 30, 2005, primarily due to the completion of the clinical trial of Psoraxine(R) during the first quarter of 2005, the expiration of our Services Agreement with SkyePharma and the impairment of the technology access option granted to us by SkyePharma under the Technology Access Option Agreement.

By comparison to the three months ended June 30, 2004, our general and administrative costs for the three months ended June 30, 2005 decreased by \$397,029 primarily due to a one-time non-cash charge of \$376,508 in June 2004 that resulted from our assignment to FPP Capital Advisors of 10% of the call option granted to us by SkyePharma under the Call Option Agreement and management's actions to control costs.

Losses of \$874,748 for the three months ended June 30, 2005 were \$999,997



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less than losses for the three months ended June 30, 2004, reflecting the completion of the Psoraxine(R) clinical trial, the expiration of our Services Agreement with SkyePharma and management's cost control initiatives.

Six months ended June 30, 2005 compared to six months ended June 30, 2004

For six months ended June 30, 2005:

For the six months ended June 30, 2005, we had no revenue from operations and incurred operating expenses of \$2,570,815 which consisted primarily of:

- o Research and development costs of \$1,594,372, including evaluation of clinical trial results, reformulation of Psoraxine(R) and activity testing in animals. Research and development costs did not include any allocation of costs related to the formulation and development of Psoraxine(R) under our Services Agreement with SkyePharma PLC, dated December 10, 2001, due to the expiration of the Services Agreement in December 2004.
- o General and administrative costs of approximately \$961,797, including professional fees, rent, salaries for management and our general corporate expenditures.

As a result, during the six months ended June 30, 2005, we incurred a net loss of \$2,554,945.

For the six months ended June 30, 2004:

For the six months ended June 30, 2004, we had no revenue from operations and incurred operating expenses of \$3,650,643 which consisted primarily of:

- o Research and development costs of \$2,451,388, including \$503,750 that we incurred in connection with services provided by SkyePharma under our Service Agreement with them and amortization of approximately \$357,144 in technology access option fees pursuant to our Technology Access Option Agreement with SkyePharma, dated December 10, 2001.
- o General and administrative costs of approximately \$1,184,215, including professional fees and our general corporate expenditures. In addition, in connection with the conversion by SkyePharma of its shares of our Series A Preferred Stock, we assigned to FPP Capital Advisors, as compensation, 10% of the call option granted to us under our Call Option Agreement with SkyePharma, dated January 20, 2004. Accordingly, a non-cash charge of \$376,508 was recorded as a general and administrative expense in June 2004.

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As a result, during the six months ended June 30, 2004, we incurred a net loss of \$3,622,718.

Comparison:

Our research and development expenses declined from \$2,451,388 during the six months ended June 30, 2004 to \$1,594,372 during the six months ended June 30, 2005, primarily due to the completion of the clinical trial of Psoraxine(R) during the first quarter of 2005, the expiration of our Services Agreement with SkyePharma and the impairment of the technology access option granted to us by SkyePharma under the Technology Access Option Agreement.

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By comparison to the six months ended June 30, 2004, our general and administrative costs for the six months ended June 30, 2005 decreased by \$222,418 primarily due to a one-time non-cash charge of \$376,508 in June 2004 that resulted from our assignment to FPP Capital Advisors of 10% of the call option granted to us by SkyePharma under the Call Option Agreement and management's actions to control costs.

Losses of \$2,554,945 for the six months ended June 30, 2005 were \$1,067,773 less than losses for the six months ended June 30, 2004, reflecting the completion of the Psoraxine(R) clinical trial, the expiration of our Services Agreement with SkyePharma and management's cost control initiatives.

Fiscal year ended December 31, 2004 compared to fiscal year ended December 31, 2003

For fiscal year ended December 31, 2004:

On January 20, 2004, we closed a private placement from which we received gross proceeds of approximately \$4.08 million. The transaction consisted of the sale to accredited investors of units consisting of 8,159,964 shares of common stock and warrants to purchase 8,159,964 shares of common stock. Concurrently with this transaction, SkyePharma converted all of its outstanding shares of Series A Preferred Stock into 25,000,000 shares of common stock at a reduced conversion price of \$0.80 per share. In accordance with Statement of Financial Auditing Standard 84, "Induced Conversions of Convertible Debt, an Amendment of APB Opinion No. 26," we recorded this conversion transaction as a non-cash preferred stock dividend in January 2004 in the amount of \$10,750,000.

On February 19, 2004, we held a second closing for our private placement from which we received gross proceeds of approximately \$1.15 million. The transaction consisted of the sale to accredited investors of units consisting of 2,299,902 shares of common stock and warrants to purchase 2,299,902 shares of common stock. In connection with our private placements and the conversion of SkyePharma's Series A Preferred Stock, SkyePharma agreed that 12,500,000 shares of the common stock issued upon conversion will be subject to a right of repurchase by us under certain circumstances at a premium to the conversion price. We assigned the right to purchase 1,250,000 of these shares to FPP Capital Advisors as consideration for services it provided to us in negotiating the Series A Preferred Stock conversion by SkyePharma. Accordingly, we recorded a non-cash charge of \$376,508 in June 2004 in connection with this assignment.

In February 2004, in connection with the private placement, FPP Capital Advisors received a consulting fee of \$261,496, warrants to purchase 418,394 shares of our common stock at \$0.50 per share and warrants to purchase 418,394 shares of our common stock. In June 2004, we issued units consisting of 150,000 shares of common stock and warrants to purchase 150,000 shares of common stock to FPP Capital Advisors in consideration for services rendered to us in negotiating our right to repurchase 12,500,000 shares of common stock from SkyePharma.

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For the fiscal year ended December 31, 2004, we had no revenue from operations and incurred operating expenses of \$9,580,307 which consisted primarily of:

- o Research and development costs of \$7,689,060, including \$2,360,000 that we incurred to conduct our Phase I and Phase II clinical studies, \$1,007,500 for services provided by SkyePharma under our

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Service Agreement with them, amortization of approximately \$714,288 of the technology option license under our Technology Access Option Agreement with SkyePharma as an intangible asset over its seven-year life, and a charge of \$2,797,612 to record an impairment of the technology option license.

- o General and administrative costs of approximately \$1,860,844, including professional fees and our general corporate expenditures.

As a result, during the fiscal year ended December 31, 2004, we incurred a net loss of \$20,037,568, which also included a non-cash preferred stock dividend of \$10,750,000.

In December 2004, we received \$293,461 in cash from the sale of a portion of our tax related net operating losses ("NOLS") under the State of New Jersey's Technology Business Tax Certificate Transfer Program. The program is an initiative adopted by the New Jersey State legislature that allows qualified technology and biotechnology businesses in New Jersey to sell unused amounts of NOLS and defined research and development tax credits for cash.

For fiscal year ended December 31, 2003:

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

During the fiscal year ended December 31, 2003, we received \$825,000 outstanding under subscription notes. In April 2003, we entered into an Amended Investor Relation Agreement with a stockholder who had outstanding subscription notes. In exchange for services rendered, we reduced the outstanding amount by \$36,000. In 2004, the stockholder will provide services valued at \$24,000 in lieu of payment of the outstanding subscription receivable balance.

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

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

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

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

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### The Next Twelve Months

At June 30, 2005, we had cash balances of \$483,809, which we estimate will last us through approximately August 2005, and no marketable securities. On August 19, 2005, we received gross proceeds in cash of \$2,000,000 from a private placement of our securities, which we believe will last us through approximately January 2006. Lipworth Capital Limited acted as our placement agent in connection with the private placement. We paid an 8% fee to our placement agent and issued warrants to purchase 1,454,545 shares of common stock with an exercise price of \$0.165, in connection with the financing in addition to other costs.

Based on our current operating plan and subject to raising more capital as discussed below, we anticipate conducting the following activities and using our cash over the course of the next twelve months as follows:

- o Our primary focus is to further development efforts of our initial product candidate, Psoraxine(R). In March 2005, we announced that the Phase II study of our novel immuno-stimulatory product for the treatment of Psoriasis did not meet the primary study endpoint upon completion of the treatment phase of the study. In the study, Psoraxine(R) was found to be safe and well-tolerated. In this regard, we have implemented cost containment measures and realigned development activities to focus on product formulation, manufacturing, analytical protocols and potency. We remain committed to Psoraxine(R) and its future development, and expect to redesign and recommence clinical trials in 2006. We also remain committed to exploring applications of our technology platform in other dermatological diseases, as well as in other therapeutic areas including arthritis. We expect that we would be required to incur expenses of no less than \$1,930,000 to third parties in connection with continuing development of Psoraxine(R) and exploration of other applications of the technology.
- o We intend to implement our business plan and facilitate the continuing operations of our company. We will spend approximately \$1,690,000 to pay management salaries and salaries of employees, a portion of which is treated as research and development expense.

We will need to raise additional funds to continue our operations for the period following January 2006 and to fund the activities described above. If we are able to identify additional capital to fund operating and capital expenditures for 2006, such funds will be used to cover the costs associated with our evaluation of the results from our Phase II clinical studies for Psoraxine(R), to continue clinical trials for Psoraxine(R) and to develop products for the treatment of arthritis and leishmaniasis. Substantial additional funds will be needed in future years in order to fund our efforts to obtain FDA approval to market these products. No assurance can be given that we will be able to obtain financing on terms that we find acceptable, or that they will enable us to satisfy our cash requirements. In addition, raising additional funds by selling additional shares of our capital stock will dilute the ownership interest of our stockholders. If we do not obtain additional funds, we will likely be required to eliminate programs, delay development of our products, or in the extreme situation, cease operations.

### BUSINESS

You should read the following description of our business in conjunction

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with the information included elsewhere in this prospectus. This description contains certain forward-looking statements that involve risk and uncertainties. Our actual results could differ significantly from the results discussed in the forward-looking statements as a result of certain of the factors set forth in the "Risk Factors" section and elsewhere in this prospectus.

### General

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

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

- o Ongoing research and development of Psoraxine(R);
- o Recommencing clinical trials to obtain the approval of the United States Food and Drug Administration for the marketing of Psoraxine(R); and
- o Developing technology underlying Psoraxine(R) for the treatment of indications other than psoriasis, such as arthritis, eczema, seborrheic dermatitis and leishmaniasis.

We were originally incorporated under the laws of the State of Colorado in 1999 under the name Hercules Development Group, Inc. We subsequently changed our name to Astralis Pharmaceuticals Ltd. and, in November 2001, reincorporated under the laws of the State of Delaware under our present name.

### Psoriasis

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

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

### Market Opportunity

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

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

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

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

#### Psoraxine (R)

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

Dr. O'Daly licensed Psoraxine(R) to us in 2001 and moved to the United States in 2002. We made capital investments to our research and development facility of approximately \$500,000 in 2002 and we filed an Investigational New Drug application with the FDA for Psoraxine(R) in March 2003. On August 4, 2003 the FDA allowed us to commence our Phase I clinical trials for Psoraxine(R).

The purpose of Phase I studies is to test the safety of a drug. We have completed our Phase I studies, which involved the administration by intramuscular injection of a single dose of 50, 150 or 300 micrograms of Psoraxine(R) or a placebo in a controlled setting to groups of psoriatic patients. Our Phase I results indicate that Psoraxine(R) is safe and well-tolerated. We spent approximately \$130,000 on our Phase I studies in 2003 and approximately \$210,000 on our Phase I studies in 2004.

We commenced Phase II studies in April 2004. The purpose of Phase II studies is to test the safety and efficacy of a drug. The Phase II studies have been completed. We spent approximately \$2,150,000 on our Phase II studies in 2004. The initial analysis of the preliminary data from the Phase II studies

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indicates that treatment with Psoraxine(R) did not provide any statistically significant clinical improvement of psoriasis in participants of the studies. We are currently analyzing the data from the Phase II studies to understand why

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statistical significance at its primary endpoint was not achieved and to evaluate our clinical development options for Psoraxine(R). We expect that we will be required to spend a total of approximately \$4,500,000 during fiscal year 2005 to complete Phase II studies, analyze results, and redesign and implement our clinical development strategy. For the year ended December 31, 2004, we reflected \$7,689,060 in research and development expenses, including \$4,519,400 related to SkyePharma. For the year ended December 31, 2003, we reflected \$4,045,673 in research and development expenses, including \$1,721,788 related to SkyePharma.

### Current Psoriasis Therapies

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

### Competition and Psoriasis Treatments in Development

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

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

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

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### Government Regulation

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

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

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

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

Prior to commencing clinical trials, which are typically conducted in three sequential phases, a company must submit an Investigational New Drug application to the FDA. In March 2003, we filed our Investigational New Drug application for Psoraxine(R) with the FDA. The Investigational New Drug application automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the trial. In such a case, the Investigational New Drug sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. In August 2003, the FDA informed us that we could commence our clinical trials of Psoraxine(R). We have completed Phase I clinical trials in which Psoraxine(R) was found to be generally safe and well-tolerated in Phase I test patients. We have also recently completed a Phase II clinical trial, which did not achieve its primary endpoint for PASI (Psoriasis Area and Severity Index) reduction. We are currently analyzing the data collected during the Phase II study, including biopsy data indicating cellular level changes that has not been previously available, to gain a better understanding of the results, and to direct our future efforts.

Although we remain committed to the future clinical development of Psoraxine(R), we may not successfully complete the three phases of clinical trials of Psoraxine(R) within any specific time period, if at all. Furthermore, the FDA or an institutional review board or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The results of product development, pre-clinical studies and clinical studies are submitted to the FDA as part of a new drug application or biologics



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

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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 receives regulatory approval, the approval may be significantly limited to specific indications and dosages. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delays in obtaining, or failures to obtain, additional regulatory approvals for any of our product candidates would have a material adverse effect on our business.

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

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

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### Intellectual Property

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

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In March 2002, Akiva LLC, an entity controlled by Dr. O'Daly, also filed an application to obtain patent protection internationally under the Patent Cooperation Treaty. In addition, in August 2003, Akiva LLC filed patent applications in the European Union, Australia, Brazil, Canada, Mexico and Japan. We have rights to these applications, which are currently pending, pursuant to the license and assignment of license agreements described above.

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

### Agreements with SkyePharma

We entered into a Purchase Agreement, dated as of December 10, 2001 with SkyePharma pursuant to which SkyePharma purchased an aggregate of 2,000,000 shares of our Series A Preferred Stock, for an aggregate purchase price of \$20.0 million. On January 20, 2004, pursuant to our Omnibus Conversion Agreement with SkyePharma, dated January 12, 2004, SkyePharma converted all of its 2,000,000 shares of our Series A Preferred Stock into 25,000,000 shares of our common stock at a conversion price of \$0.80 per share. Further, pursuant to a Stock Purchase Agreement, dated December 29, 2004, between SkyePharma, Mike Ajnsztajn, our former Chief Executive Officer and former member of our Board of Directors, and Gaston Liebhaber, a former member of our Board of Directors, effective March 3, 2005, SkyePharma purchased 11,160,000 shares, collectively, of our common stock from Mr. Ajnsztajn and Mr. Liebhaber. As a result of this purchase, SkyePharma, as of April 29, 2005, owned 36,360,000 shares, or 49.8%, of our issued and outstanding common stock. See Risk Factor entitled "One of our existing stockholders can exert control over us and may not make decisions that further the best interests of all stockholders" for a discussion of the possible consequences of SkyePharma's ownership of our common stock.

On January 20, 2004, in connection with SkyePharma's conversion of the Series A Preferred Stock, we entered into the Call Option Agreement with SkyePharma, pursuant to which we received the right to repurchase some or all of 12,500,000 shares of our common stock from SkyePharma at a premium to the \$0.80 conversion price. In the event we exercise the call option, the exercise price will be between \$1.28 and \$1.52 per share, depending on the date of exercise.

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The call option will be exercisable by us for a period commencing upon our achievement of a certain milestone event and ending on January 20, 2007. In June 2004, we assigned the right to purchase 1,250,000 shares under the Call Option Agreement to FPP Capital Advisors as consideration for services it provided in negotiating the Omnibus Conversion Agreement. FPP Capital Advisors is controlled by Fabien Pictet, a member of our Board of Directors.

On January 20, 2004, the closing date of the conversion of SkyePharma's 2,000,000 shares of our Series A Preferred Stock, we, SkyePharma and our other original stockholders amended the stockholders agreement, dated as of December 10, 2001 (the "Amended Stockholders' Agreement"). Pursuant to the Amended Stockholders' Agreement, our board of directors must include at least two independent directors and SkyePharma has the right to nominate one director. Michael Ashton is SkyePharma's initial and current nominated director. Until January 20, 2007, Jose Antonio O'Daly has the right to nominate one director. The Amended Stockholders' Agreement will terminate upon the later of (i) the date on which SkyePharma no longer beneficially owns, in the aggregate, at least 20% of our outstanding common stock or (ii) January 20, 2007. Further, the Amended Stockholders' Agreement may be terminated by the mutual written consent

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of the parties. Pursuant to the Amended Stockholders' Agreement, SkyePharma is required to vote its shares of our common stock in favor of certain enumerated transactions that have been approved by our Board of Directors and all of our independent directors. These transactions include (i) the amendment of our certificate of incorporation solely to increase our authorized capital stock, (ii) the adoption or amendment of an employee benefit plan applicable to all employees, (iii) the issuance of additional securities for cash and (iv) the sale of all of our outstanding capital stock or all or substantially all of our assets, or our merger with another entity, provided that SkyePharma will receive the same consideration for its shares as other holders of common stock and will be able to participate in the sale or merger on the same terms as the most favorable terms available to any of our other stockholders and the total consideration for the transaction is greater than \$135 million.

We also entered into two agreements concerning the formulation and development of our initial injectable product candidate, Psoraxine(R), with SkyePharma. Under the terms of the Technology Access Option Agreement, dated December 10, 2001, we paid to SkyePharma a \$5.0 million technology access fee for the option to acquire a license for DepoFoam and other relevant drug delivery technologies owned by SkyePharma. Under the terms of the Technology Access Option Agreement, if we exercise our option, we must pay a royalty of 5% of net sales of all products manufactured or sold that use or exploit the drug delivery technologies that we license from SkyePharma. In addition, if we exercise our option, SkyePharma retains the right during the term of the Technology Access Option Agreement to undertake the manufacture of all of our products that incorporate or utilize the drug delivery technologies. The option we received under the Technology Access Option Agreement expires on December 10, 2008. The Technology Access Option Agreement may be terminated by either party if (i) the other party commits any irremediable breach of the agreement, (ii) the other party commits any remediable breach and fails to remedy such breach within sixty days of service of notice of the breach, (iii) a court makes an administration order with respect to the other party or any composition in satisfaction of the debts of, or scheme of arrangement of the affairs of, the other party, or (iv) the other party becomes insolvent, has a receiver appointed over any of its assets, enters into any composition with creditors generally or has an order made or resolution passed for it to be wound up. SkyePharma has the right of first negotiation to acquire the worldwide marketing rights to Psoraxine(R). We have evaluated the technology access option fee we paid under

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the Technology Access Option Agreement, which we have been capitalizing as a research and development intangible asset and amortizing over a seven-year period, and have determined that as of December 31, 2004, the technology access option fee exceeded its fair market value. Consequently, we recorded as additional research and development costs in 2004 a charge of \$2,797,612 to reflect an impairment of this intangible asset.

In addition, we entered into the Service Agreement, dated December 10, 2001, pursuant to which SkyePharma was to provide us with development, manufacturing, pre-clinical and clinical development services in consideration of \$11 million, of which \$3 million was paid in 2001, with the remaining \$8 million paid primarily during 2002 for second generation Psoraxine(R). The Service Agreement terminated on December 31, 2002. We entered into an Amendment to the Service Agreement with SkyePharma, effective as of January 1, 2003, to extend the term of the Service Agreement and modify the services to be provided by SkyePharma such that SkyePharma continued to provide certain services to us through December 31, 2004, in consideration for payments made during 2002. The agreement expired on December 31, 2004.

### Blue Cedar Private Placement

On August 19, 2005, we completed a private placement of securities from which we received gross proceeds of approximately \$2,000,000. The transaction consisted of the sale to one accredited investor, Blue Cedar, of units consisting of: (i) 18,181,818 shares of common stock, (ii) warrants to purchase over a 5-year period 18,181,818 shares of common stock with an exercise price of

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\$0.165 and (iii) warrants to purchase over a 12-month period 12,121,212 shares of common stock with an exercise price of \$0.165. We relied upon the exemption from registration provided under Section 4(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder. The private placement was only made available to one "accredited investor" as defined in Rule 501 of Regulation D. Lipworth Capital Limited acted as our placement agent in connection with the private placement. We paid an 8% fee to our placement agent and issued warrants to purchase 1,454,545 shares of common stock with an exercise price of \$0.165, in connection with the financing in addition to other costs. Additionally, we granted Blue Cedar certain registration rights pursuant to a registration rights agreement, dated as of August 17, 2005, in connection with this transaction. The registration rights agreement requires us to file a registration statement within approximately 30 days of the final closing of our private placement covering the resale of all shares included therein, as well as the shares underlying the warrants. If the registration statement is not filed or effective by the dates specified in the agreement, we are subject to a penalty of 0.5% per month of the aggregate purchase price.

Concurrently with the closing of the private placement, we and Blue Cedar entered into the Blue Cedar Stockholder's Agreement. Pursuant to the Blue Cedar Stockholder's Agreement, our Board of Directors is now required to be comprised of at least eight directors and Blue Cedar may designate one director our Board of Directors. Manuel Tarabay is Blue Cedar's initial and current designated director. Further, pursuant to the Blue Cedar Stockholder's Agreement, we agreed not to enter into any service agreement, distribution arrangement or transfer of personnel with any of our stockholders owning more than 10% of the outstanding shares of common stock until we complete Phase II clinical trials of Psoraxine(R), without the prior written consent of Blue Cedar, which shall not be unreasonably withheld. Additionally, for a period of two years following the closing date of the private placement, we granted Blue Cedar certain pre-emptive rights, allowing Blue Cedar to participate in substantially all sales of

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securities. The Blue Cedar Stockholder's Agreement will terminate upon the later of the Blue Cedar Termination Date or August 15, 2008. The "Blue Cedar Termination Date" is the date on which Blue Cedar no longer beneficially owns, in the aggregate, at least 20% of our outstanding common stock.

### Other Research and Development Efforts

In addition to our development of Psoraxine(R) for the treatment of psoriasis, we are researching its possible application for the treatment of other conditions, such as eczema, seborrheic dermatitis and leishmaniasis. We are also developing a second product for the treatment of arthritis. We intend to market this product primarily in the United States, although we have not named this product yet and we do not have any approvals from, nor has any application been filed with, the FDA or any foreign governmental regulatory authority for this product. Currently, we do not have any collaborators for this product. We are also engaged in preliminary research of a treatment for transplant rejection.

### Employees and Consultants

As of October 1, 2005, we employed seven full-time employees, including four scientists and one laboratory technician. We also have 14 consultants. We have no part-time employees. None of our employees are covered by a collective bargaining agreement and we believe that our employee relations are good.

### Legal Proceedings

We are not currently a party to any material legal proceedings.

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### Property

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

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## MANAGEMENT

### 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, M.D., Ph.D. | 63  | Chairman of the Board of Directors and Chief Scientific Officer |
| James Sharpe                     | 53  | President, Chief Executive Officer and Director                 |
| Michael Garone                   | 46  | Chief Financial Officer   |
| Michael Ashton                   | 59  | Director  |

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|                        |    |          |
|------------------------|----|----------|
| Samuel Barnett, Ed.D.  | 57 | Director |
| Steven Fulda           | 72 | Director |
| Fabien Pictet          | 46 | Director |
| Gordon Schooley, Ph.D. | 59 | Director |
| Manuel Tarabay         | 53 | Director |

There are no familial relationships among our directors and/or officers. Directors hold office until the next annual meeting of our stockholders or until their respective successors have been elected and qualified. Officers serve at the pleasure of the Board of Directors.

Jose Antonio O'Daly, M.D., Ph.D. Dr. O'Daly has served as our Chairman of the Board of Directors since November 2001, and was appointed our Chief Scientific Officer on December 22, 2004. From November 2001 to December 22, 2004, Dr. O'Daly served as our President of Research and Development. Dr. O'Daly is the sole founder of the Center for Research and Treatment for Psoriasis in Caracas, Venezuela and has served as its President since 1998. From 1972 to 1998, Dr. O'Daly served as Director and Head of Research of the Microbiology Center of the Venezuelan Institute of Scientific Investigations. Dr. O'Daly attended the Central University of Venezuela, Caracas, receiving his Doctorate of Medical Sciences in 1968. In 1971, Dr. O'Daly earned a Doctorate of Philosophy from the Johns Hopkins University in Baltimore, Maryland. Dr. O'Daly is an honorary member of the Venezuelan Medical Academy.

James Sharpe. Mr Sharpe has served as our President and Chief Executive Officer and as one of our directors since January 27, 2005. From 1999 to 2005, Mr. Sharpe served as President and founder of Ankyr Consulting, L.L.C, an independent consulting company for healthcare and biotechnology companies. In early 1999, he served as President of Small Molecule Therapeutics, a privately-owned drug discovery company. From 1997 to 1998, Mr. Sharpe served as Chief Operating Officer of FEI Technologies, Inc., a privately-owned drug delivery company. From 1991 to 1996, Mr. Sharpe served as President and co-founder of GX BioSystems A/S, a privately-owned biotechnology company focused

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on vaccines and biopesticides. Mr. Sharpe recently founded Metacine, Inc., a cancer vaccine company, and co-founded Optigenix, Inc., a directed evolution company. He was a founding member of the Pennsylvania Biotechnology Association, where he served as President from 1990 to 1992 and was a member of the Board of Directors from 1989 to 1997. From 1993 to 1996 he served as a member of the Board of Governors of the Emerging Company Section of the Biotechnology Industry Association. Mr. Sharpe holds a B.S. in Chemistry from Union College and an M.B.A. in Marketing and Finance from the University of Rochester.

Michael Garone. Mr. Garone has served as our Chief Financial Officer since February 21, 2005. From October 13, 2004 to February 21, 2005, Mr. Garone served as our Interim Chief Financial Officer. During 2004, Mr. Garone founded Gar-1 Business Advisory Services, L.L.C., an independent consulting company for information movement and management companies. From 1983 to 2003, Mr. Garone was employed by AT&T, Inc. where he held various positions of increasing responsibilities, including Chief Financial Officer of AT&T Alascom and Financial Planning Vice President, Broadband and Internet Services. Mr. Garone began his career in finance as an Over-the-Counter stock trader specializing in high technology start-up companies. Mr. Garone holds a B.A. in Mathematics from

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Colgate University and an M.B.A. from Columbia University.

Michael Ashton. Mr. Ashton has served as one of our directors since January 2002. Mr. Ashton has 30 years of experience in the pharmaceutical industry, and since 1997 he has held the position of Chief Executive Officer of SkyePharma PLC, a London-based drug delivery technology provider. Prior to joining SkyePharma, Mr. Ashton served as Chairman and Chief Executive Officer of the U.S. subsidiary of Faulding, Australia's largest pharmaceutical companies. Mr. Ashton is a member of the Board of Directors of Transition Inc. Mr. Ashton holds a Bachelor of Pharmacy Degree from Sydney University and an M.B.A. from Rutgers University.

Samuel Barnett, Ed.D. Mr. Barnett has served as one of our directors and a member of our audit committee since June 2004. In 1979, Mr. Barnett founded Barnett International, a consulting firm, and served as Chief Consultant from 1979 to 1999. From 1999 to 2000, Mr. Barnett served as Lead Partner of the Americas Pharmaceutical Practice of PricewaterhouseCoopers Consulting. From 2000 to 2005, he served as Lead Partner of the Americas Life Sciences Consulting Practice for IBM Business Consulting Services. Mr. Barnett holds a Bachelor's Degree from Wesleyan University and received both his Master's and Doctorate Degrees from Temple University.

Steven Fulda. Mr. Fulda has served as one of our directors and a member of our audit committee since February 2002. Since 1989, Mr. Fulda has served as Managing Director of Fulda Business Planners. Mr. Fulda has 40 years of management and consulting experience including business strategy, planning, development and financing. Since 1992, Mr. Fulda has been an Adjunct Professor of Entrepreneurship and Director of the Small Business Institute at Fairleigh Dickinson University. Mr. Fulda holds a Master's Degree in Quantitative Business Analysis from New York University and a Master's Degree in Systems Engineering from Bell Laboratories' New York University Graduate Program.

Fabien Pictet. Mr. Pictet has served as one of our directors since February 2002. Since 1998, Mr. Pictet has served as Chairman of Fabien Pictet and Partners, a London-based investment firm. Mr. Pictet has 20 years of experience in investing in emerging markets. During his 11 year tenure with Pictet and Cie, from 1986 to 1997, Mr. Pictet held various positions ranging from Manager responsible for U.S. equity investments to Partner responsible for all of the firm's institutional activities in Geneva, Zurich and London. Mr. Pictet holds a Bachelor's Degree in Economics from the University of San Francisco and a Master's Degree in International Management from American Graduate School of International Management.

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Gordon Schooley, Ph.D. Dr. Schooley has served as one of our directors and a member of our Medical Advisory Board since April 11, 2005. Dr. Schooley has over 33 years of experience in the pharmaceutical field, including extensive experience in clinical and product development. Since 1999, Dr. Schooley has served as Chief Scientific Officer of SkyePharma PLC. From 1989 to 1998, Dr. Schooley served as Vice President of Clinical and Regulatory Affairs for Alliance Pharmaceutical Corp. From 1987 to 1989, Dr. Schooley served as Vice President of Clinical and Regulatory Affairs for Newport Pharmaceuticals International, Inc. From 1979 to 1987, Dr. Schooley served as Director of Clinical Research, Biostatistics and Computing Services for Allergan Pharmaceuticals. Dr. Schooley currently serves as a member of the Scientific Advisory Boards of Topigen Pharmaceuticals, Inc., Progen Ltd., and Seacology Foundation. Dr. Schooley holds a B.S. and an M.S. in Business and Statistics from Brigham Young University and received his Doctorate of Philosophy in Biostatistics from the University of Michigan School of Public Health.

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Manuel Tarabay. Mr. Tarabay has served as a director of Astralis since August 2005. Mr. Tarabay has worked with Merrill Lynch in Beirut, New York, and Kuwait. In his career, Mr. Tarabay has been employed in the Treasury departments of Paris and Geneva as a private banker and portfolio manager. He has worked with JP Morgan as Head of Investment Management and on the International Asset Allocation Committee. He has spent time at Bankers Trust serving on the Global Advisory Team, as well as at Credit Suisse First Boston, where he worked in international business. Mr. Tarabay now works as a private banker and financial advisor based in Beirut. Mr. Tarabay has his Bachelors in Mathematics & Computer Science from Dartmouth College as well as his M.B.A. from the European Institute of Business Administration.

### Advisors

#### Medical Advisory Board

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

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

Our Medical Advisory Board does not hold any formal meetings. However, management consults with the Medical Advisory Board from time to time. On April 11, 2005, we also appointed Dr. Schooley to serve on our Medical Advisory Board.

### Board Composition

We currently have eight directors, each serving a term until the next annual meeting of stockholders. Pursuant to the Blue Cedar Stockholder's Agreement, Blue Cedar may designate one director to our Board of Directors. Manuel Tarabay is Blue Cedar's initial and current designated director. The Blue Cedar Stockholder's Amendment will terminate upon the later of the Blue Cedar Termination Date or August 15, 2008. The "Blue Cedar Termination Date" is the date on which Blue Cedar no longer beneficially owns, in the aggregate, at least 20% of the outstanding common stock of the Company. Further, pursuant to the Amended Stockholders' Agreement, our Board of Directors must include at least two independent directors and SkyePharma has the right to nominate one director. Michael Ashton is SkyePharma's initial and current nominated director. Until



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January 20, 2007, Dr. O'Daly has the right to nominate one director. The Amended Stockholders' Agreement will terminate upon the later of (i) the date on which SkyePharma no longer beneficially owns, in the aggregate, at least 20% of our outstanding common stock or (ii) January 20, 2007. Further, the Amended Stockholders' Agreement may be terminated by the mutual written consent of the parties.

### Compensation of Directors

We reimburse all outside directors for travel and lodging expenses related to scheduled board meetings. Our Board of Directors authorized the following payments for non-executive directors during the fiscal year-ended December 31, 2004: \$1,000 for each board meeting attended in person and \$400 for each meeting attended by teleconference; an annual retainer of \$4,000 paid to the Chairman of the Audit Committee; \$1,000 paid to each Audit Committee member per financial filing; an annual retainer of \$2,500 paid to the Chairman of the Compensation Committee; an annual retainer of \$1,500 paid to each Compensation Committee member, other than the Chairman; an annual retainer of \$3,000 paid to the Chairman of the Strategic Planning Committee; an annual retainer of \$1,000 paid to each Strategic Planning Committee member, other than the Chairman; and \$1,000 paid to each Strategic Planning Committee member for each half-day strategic planning meeting attended in person. In addition, each non-executive Director will receive a one-time grant upon election to the Board of stock options to purchase 50,000 shares of our common stock, vesting over a four-year period with the first 25% vesting on the date of grant, and an annual grant upon the anniversary of election to the Board of stock options to purchase 20,000 shares of our common stock, vesting over a four-year period with the first 25% vesting on the date of grant. Other than the foregoing, our directors do not receive compensation pursuant to any standard arrangement for their services as directors.

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### Indemnification Matters

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 includes 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 proceedings 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 our officers, directors, employees and agents 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 Delaware law.

### EXECUTIVE COMPENSATION

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

#### Summary Compensation Table

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| Name and Principal Position<br>-----   | Year<br>---- | Annual Compensation<br>----- |  |
|--|--------------|------------------------------|--|
|  |              | Salary (\$)<br>-----         | Other Annual<br>Compensation (\$)<br>----- |
| James Sharpe,<br>President and Chief Executive<br>Officer (1)                                  | 2004         | --                           | --   |
|  | 2003         | --                           | --   |
|  | 2002         | --                           | --   |
| Mike Ajnsztajn<br>Prior Chief Executive Officer (2)  | 2004         | 109,875                      | 2,437 (4)                                  |
|  | 2003         | 154,375                      | 4,613                                      |
|  | 2002         | 150,000                      | 4,613                                      |
| Jose Antonio O'Daly,<br>Chairman of the Board of Directors and<br>Chief Scientific Officer (3) | 2004         | 188,487                      | 41,004 (5)                                 |
|  | 2003         | 158,750                      | 73,740                                     |
|  | 2002         | 150,000                      | 56,671                                     |

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 (1) Mr. Sharpe became our President and Chief Executive Officer on January 27, 2005.

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- (2) On July 28, 2004, we accepted the resignation of Mr. Ajnsztajn, effective immediately with respect to his position as a member of our Board of Directors and effective August 26, 2004 with respect to his position as our Chief Executive Officer.
- (3) Dr. O'Daly became one of our employees on July 1, 2002. Prior to July 1, 2002, Dr. O'Daly provided services as a consultant to the company.
- (4) For the fiscal year ended December 31, 2004, this amount includes \$2,437 in health insurance premiums paid by us for Mr. Ajnsztajn's benefit.
- (5) For the fiscal year ended December 31, 2004, this amount includes \$8,707 in health insurance premiums paid by us for Dr. O'Daly's benefit, an automobile allowance of \$5,729 and \$26,568 for a furnished apartment.

Employment Agreements

On December 22, 2004, we entered into an employment agreement with Jose Antonio O'Daly, the Chairman of our Board of Directors and our Chief Scientific Officer. Under the terms of his employment agreement, Dr. O'Daly is entitled to an annual base salary of \$231,000 payable in arrears in bi-monthly installments, less statutory deductions and an annual bonus of up to 25% of his base salary and based upon achievement of such goals and subject to such additional terms as may be determined by the Board of Directors. As a member of our senior management team, Dr. O'Daly has been granted the option to purchase 728,000 shares of our common stock with an initial exercise price of \$0.70 per share. The options are fully vested and have a term of ten years. In the event of a voluntary termination for "good reason" or if Dr. O'Daly is terminated following a change in control or without "cause," he generally will receive, among other things, the following severance benefits: (a) an amount equal to two times his annual base salary established for the fiscal year in which the date of termination occurs and (b) an amount equal to two times his annual bonus award established for the fiscal year in which his date of termination occurs. In the

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event of a voluntary termination by Dr. O'Daly without good reason, or if Dr. O'Daly is terminated by us for cause, he will receive the following severance benefits: (a) an amount equal to his base salary for one year and (b) an amount equal to one times his annual bonus award established for the fiscal year in which his date of termination occurs. The employment agreement includes certain non-competition and confidentiality provisions.

On January 27, 2005, we entered into an employment agreement which expires January 15, 2007 with James Sharpe, our President and Chief Executive Officer and a member of Board of Directors. Under the terms of his employment agreement, Mr. Sharpe is entitled to an annual base salary of \$231,000 payable in arrears in bi-monthly installments, less statutory deductions and an annual bonus of up to 25% of his base salary based upon the achievement of certain goals and subject to such additional terms as may be determined by the Board of Directors. As a member of our senior management team, Mr. Sharpe has been granted the option to purchase 728,000 shares of our common stock, which will vest immediately to the extent of 182,000 shares and then an additional 182,000 shares per year on a cumulative basis until all options have vested. The options have an initial exercise price of \$0.70 per share and have a term of ten years. In addition, on the first date of his employment, Mr. Sharpe was issued 100,000 shares of common stock and on the date that is one year following the first date of employment, an additional 100,000 shares, which will be fully vested and fully paid as of the date of issuance. Also, pursuant to the agreement, we will make the following payments to Mr. Sharpe: (a) \$35,000, no later than January 15, 2006 and (b) an additional amount of not less than \$35,000 and not more than \$65,000 no later than January 15, 2007, provided however, that if prior to January 15, 2007, our cash balance falls below \$350,000, we will immediately pay the minimum remaining amount to Mr. Sharpe. In the event that Mr. Sharpe is terminated after a change of control, he generally will receive, among other things, the following severance benefits: (a) an amount equal to two times his

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annual base salary established for the fiscal year in which his date of termination occurs and (b) an amount equal to two times his annual bonus award established for the fiscal year in which his date of termination occurs. In the event Mr. Sharpe is terminated for good reason, without cause, or non-renewal, he will generally receive the following severance benefits: (a) an amount equal to one times his annual base salary established for the fiscal year in which the date of termination occurs and (b) an amount equal to one times his annual bonus award established for the fiscal year in which the date of termination occurs. The employment agreement includes certain non-competition and confidentiality provisions.

On February 21, 2005, we entered into a consultant agreement with Michael Garone, whereby Mr. Garone was retained on a full-time, exclusive basis to serve as our Chief Financial Officer. As Chief Financial Officer, Mr. Garone reports to our Chief Executive Officer and is responsible for, among other things, our financial planning and funding and assists our Chief Executive Officer lead and implement our long-term strategy and vision to provide successful growth in value for our investors and stockholders. Under the terms of the consultant agreement, Mr. Garone is entitled to a monthly fee of at least \$15,600. We have agreed to indemnify Mr. Garone against any claims that may arise as a result of the performance of his duties as our Chief Financial Officer under the consultant agreement and to include him, at our cost, as an insured party under our current directors' and officer' liability insurance policy. The term of the consultant agreement will continue until terminated by either party without cause upon 30 days written notice or with cause upon 10 days written notice.

None of our other executive officers receive compensation pursuant to any

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standard arrangement for their services as executive officers.

### 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 provides for the issuance of 5,000,000 shares of common stock underlying stock options available for grant thereunder. The purpose of the 2001 Plan is to provide additional incentive to our directors, officers, employees and consultants who are primarily responsible for our management and growth. Each option will be designated at the time of grant as either an incentive stock option (an "ISO") or as a non-qualified stock option (a "NQSO"). As of December 31, 2004, options to purchase 1,143,000 shares of common stock have been granted under the 2001 Plan.

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

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

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

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

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

If for any reason other than death or permanent and total disability, an optionee ceases to be employed by us or any of our affiliates (such event being called a "Termination"), options held at the date of Termination (to the extent then exercisable) may be exercised in whole or in part at any time within three months of the date of such Termination, or such other period of not less than thirty days after the date of such Termination as is specified in the Option

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Agreement or by amendment thereof (but in no event after the expiration date of the option (the "Expiration Date")); provided, however, that if such exercise of the option would result in liability for the optionee under Section 16(b) of the Exchange Act, then such three-month period automatically will be extended until the tenth day following the last date upon which the 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 will require stockholder approval unless (i) stockholder approval is required to preserve incentive stock option treatment for federal income tax purposes or (ii) the board of directors otherwise concludes that stockholder approval is advisable.

### CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

#### General

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

#### Relationship with Blue Cedar and Lipworth Capital

On August 19, 2005, we completed a private placement of securities from which we received gross proceeds of approximately \$2,000,000. The transaction consisted of the sale to one accredited investor, Blue Cedar, of units consisting of: (i) 18,181,818 shares of common stock, (ii) warrants to purchase over a 5-year period 18,181,818 shares of common stock with an exercise price of \$0.165 and (iii) warrants to purchase over a 12-month period 12,121,212 shares of common stock with an exercise price of \$0.165. We relied upon the exemption from registration provided under Section 4(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder. The private placement was only made available to one "accredited investor" as defined in Rule 501 of Regulation D. Lipworth Capital Limited acted as our placement agent in connection with the private placement. We paid an 8% fee to our placement agent and issued warrants to purchase 1,454,545 shares of common stock with an exercise price of \$0.165, in connection with the financing in addition to other costs. Additionally, we

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granted Blue Cedar certain registration rights pursuant to a registration rights agreement, dated as of August 17, 2005, in connection with this transaction. The registration rights agreement requires us to file a registration statement within approximately 30 days of the final closing of our private placement covering the resale of all shares included therein, as well as the shares underlying the warrants. If the registration statement is not filed or effective by the dates specified in the agreement, we are subject to a penalty of 0.5% per month of the aggregate purchase price .

Concurrently with the closing of the private placement, we and Blue Cedar entered into the Blue Cedar Stockholder's Agreement. Pursuant to the Blue Cedar Stockholder's Agreement, our Board of Directors is now required to be comprised of at least eight directors and Blue Cedar may designate one director to the Board of Directors of the Company. Manuel Tarabay is Blue Cedar's initial and

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current designated director. Further, pursuant to the Blue Cedar Stockholder's Agreement, we agreed not to enter into any service agreement, distribution arrangement or transfer of personnel with any of our stockholders owning more than 10% of the outstanding shares of common stock until we complete Phase II clinical trials of Psoraxine(R), without the prior written consent of Blue Cedar, which shall not be unreasonably withheld. Additionally, for a period of two years following the closing date of the private placement, we granted Blue Cedar certain pre-emptive rights, allowing Blue Cedar to participate in substantially all sales of securities. The Blue Cedar Stockholder's Agreement will terminate upon the later of the Blue Cedar Termination Date or August 15, 2008. The "Blue Cedar Termination Date" is the date on which Blue Cedar no longer beneficially owns, in the aggregate, at least 20% of our outstanding common stock.

### Relationship with SkyePharma

We entered into a Purchase Agreement, dated as of December 10, 2001 with SkyePharma pursuant to which SkyePharma purchased an aggregate of 2,000,000 shares of our Series A Preferred Stock, for an aggregate purchase price of \$20.0 million. On January 20, 2004, pursuant to the Omnibus Conversion Agreement dated January 12, 2004 between us and SkyePharma ("Omnibus Conversion Agreement"), SkyePharma converted all of its 2,000,000 shares of Series A Preferred Stock into 25,000,000 shares of our common stock at a conversion price of \$0.80 per share. On March 3, 2005, SkyePharma acquired 11,160,000 additional shares of our common stock in a privately negotiated transaction. As a result, as of April 29, 2005 SkyePharma beneficially owns 49.8% of our common stock on a fully diluted basis.

On January 20, 2004, in connection with SkyePharma's conversion of our Series A Preferred Stock, we entered into the Call Option Agreement with SkyePharma, pursuant to which we received the right to repurchase some or all of 12,500,000 shares of our common stock from SkyePharma at a premium to the \$0.80 conversion price. In the event we exercise the call option, the exercise price will be between \$1.28 and \$1.52 per share, depending on the date of exercise. The call option will be exercisable by us upon our achievement of a certain milestone event and ending on January 20, 2007.

Pursuant to the Amended Stockholders' Agreement, our Board of Directors must include at least two independent directors and SkyePharma has the right to nominate one director to the Board. Michael Ashton is SkyePharma's initial and current nominated director. Until January 20, 2007, Dr. O'Daly has the right to nominate one director. The Amended Stockholders' Agreement will terminate upon the later of (i) the date on which SkyePharma no longer beneficially owns, in the aggregate, at least 20% of our outstanding common stock or (ii) January 20, 2007. Further, the Amended Stockholders' Agreement may be terminated by the mutual written consent of the parties. Pursuant to the Amended Stockholders' Agreement, SkyePharma is required to vote its shares of our common stock in favor of certain enumerated transactions, where those transactions have been approved by our Board of Directors and all of the independent directors. These

transactions include (i) the amendment of our certificate of incorporation solely to increase our authorized capital stock, (ii) the adoption or amendment of an employee benefit plan applicable to all employees, (iii) the issuance of additional securities for cash and (iv) the sale of all of our outstanding capital stock or all or substantially all of our assets, or our merger with another entity, provided that SkyePharma will receive the same consideration for its shares as other holders of common stock and will be able to participate in the sale or merger on the same terms as the most favorable terms available to

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any of our other stockholders and the total consideration for the transaction is greater than \$135 million.

We also entered into two agreements concerning the formulation and development of Psoraxine(R) with SkyePharma. Under the terms of the Technology Access Option Agreement, we paid to SkyePharma a \$5.0 million technology access fee for the option to acquire a license for certain drug delivery technologies owned by SkyePharma. Under the terms of the Technology Access Option Agreement, if we exercise our option, we must pay a royalty of 5% of net sales of all products manufactured or sold that use or exploit the drug delivery technologies that we license from SkyePharma. In addition, if we exercise our option, SkyePharma retains the right during the term of the Technology Access Option Agreement to undertake the manufacture of all of our products that incorporate or utilize the drug delivery technologies. The option we received under the Technology Access Option Agreement expires on December 10, 2008, unless terminated sooner pursuant to the terms of the Technology Access Option Agreement. Pursuant to the Technology Access Option Agreement, SkyePharma also has the right of first negotiation to acquire the worldwide marketing rights to Psoraxine(R). Based on an evaluation of the technology access option fee we paid under the Technology Access Option Agreement, which we have been capitalizing as a research and development intangible asset over a seven-year period, we have determined that as of December 31, 2004, the technology access option fee exceeded its fair market value. Consequently, we recorded as additional research and development costs in 2004 a charge of \$2,797,612 to reflect an impairment of this intangible asset.

On December 10, 2001, we entered into the Service Agreement with SkyePharma pursuant to which SkyePharma was to provide us with development, manufacturing, pre-clinical and clinical development services in consideration of \$11 million. The Service Agreement terminated on December 31, 2002. We entered into an Amendment to the Service Agreement with SkyePharma, effective as of January 1, 2003, to extend the term of the Service Agreement and modify the services to be provided by SkyePharma such that SkyePharma continued to provide certain services to us through December 31, 2004, in consideration for payments made during 2002. The agreement expired on December 31, 2004.

### Relationship with FPP Capital Advisors

In connection with private placements of units consisting of common stock and warrants that occurred in 2004, FPP Capital Advisors, an entity controlled by our board member, Fabien Pictet, received a consulting fee of \$261,496. In addition, for consulting services provided in connection with the private placement, FPP Capital Advisors and certain other selling stockholders received warrants to purchase an aggregate of 418,394 shares of our common stock at \$0.50 per share and warrants to purchase an aggregate of 418,394 shares of our common stock at \$0.73 per share. One of these other selling stockholders, Manuel Tarabay, received warrants to purchase 72,000 shares of common stock, and became a member of the Board of Directors in August 2005. Upon exercise of the warrants issued in the private placement, we will pay a cash commission equal to 5% of the amounts raised through the exercise of the warrants.

In addition, in consideration for services provided in negotiating our Omnibus Conversion Agreement with SkyePharma, we issued to FPP Capital Advisors units consisting of 150,000 shares of common stock and warrant stock and warrants to purchase 150,000 shares of common stock at an exercise price of \$0.73 per share. We also assigned the right to purchase 1,250,000 shares under our Call Option Agreement with SkyePharma to FPP Capital Advisors.

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### SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth the names and beneficial ownership of our common stock owned as of September 21, 2005, by (i) each of our directors, (ii) each person named in the Summary Compensation Table, (iii) all our directors and executive officers as a group, and, to the best of our knowledge, (iv) all holders of 5% or more of the outstanding shares of our common stock. Unless otherwise noted, the address of all the individuals and entities named below is care of Astralis Ltd. at 75 Passaic Avenue, Fairfield, NJ 07004.

| Name and Address<br>-----   | Number of Shares of Common Stock<br>Beneficially<br>Owned (1) | Percentage of<br>Stock Owned |
|---|---|------------------------------|
| Dr. Jose Antonio O'Daly, MD,<br>Ph.D. (2) (3)   | 14,368,000  | 1                            |
| James Sharpe (4)  | 282,000   |                              |
| Michael Ashton (5)  | 36,413,900  | 3                            |
| Samuel Barnett, Ed.D (6)  | 130,000   |                              |
| Steven Fulda (7)  | 42,500  |                              |
| Fabien Pictet (8)   | 3,677,794   |                              |
| Gordon Schooley, Ph.D. (9)  | 12,500  |                              |
| SkyePharma PLC (3) (5)<br>105 Piccadilly<br>London W1J 7NJ<br>England                     | 36,413,900  | 3                            |
| Blue Cedar Limited (10)<br>P.O. Box 546<br>28-30 The Parade<br>St. Heiler, Jersey JE4 8X9 | 48,484,848  | 3                            |
| Manuel Tarabay (11)   | 734,500   |                              |
| All Officers and Directors<br>as a Group (2) (4) (5) (6) (7) (8) (9)                      | 55,681,194  |                              |

-----  
\* Less than 1%

(1) Beneficial ownership is determined in accordance with Rule 13d-3(a) of the Securities Exchange Act of 1934 and generally includes voting or investment power with respect to securities. Except as indicated by footnotes and subject to community property laws, where applicable, the person named above has sole voting and investment power with respect to all shares of the common stock shown



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as beneficially owned by him. The beneficial ownership percentage is based on 91,354,873 shares of our common stock outstanding as of September 21, 2005.

(2) Includes 13,640,000 shares of common stock and vested options to purchase 728,000 shares of common stock.

(3) Under the terms of Amendment Stockholders' Agreement, dated as of January 20, 2004 by and among us, SkyePharma, Dr. O'Daly and our other original stockholders, the parties agreed to vote all shares held by such parties for (i) one director designated by SkyePharma, (ii) one director designated by Dr. O'Daly, (iii) one director designated by each of the other three original stockholders and (iv) two independent directors. No party to the agreement has the right to dispose (or direct the disposition of) any shares of common stock held by any of the other parties to the agreement. Accordingly, each party disclaims beneficial ownership of the shares held by the other parties. Since the date of such agreement, the other three original stockholders resigned their positions with us and transferred all of their shares of common stock to SkyePharma. As a result, none of them have any rights to designate a director under the Agreement

(4) Includes 100,000 shares of common stock and options to purchase 182,000 shares of common stock that are exercisable within 60 days of September 21, 2005.

(5) Includes 36,393,900 shares of common stock beneficially owned by SkyePharma and warrants to purchase 20,000 shares of common stock beneficially owned by SkyePharma that are exercisable within 60 days of September 21, 2005. Mr. Ashton is Chief Executive Officer of SkyePharma. Under the terms of a Call Option Agreement, dated January 20, 2004, we have the right to repurchase some or all of 12,500,000 shares of our common stock from SkyePharma. In June 2004, we assigned the right to purchase 1,250,000 shares under the Call Option Agreement to FPP Capital Advisors, an entity controlled by Fabien Pictet. The call option will be exercisable by us for a period commencing upon our achievement of a certain milestone event and ending on January 20, 2007.

(6) Includes 100,000 shares of common stock and options to purchase 12,500 shares of common stock that are exercisable within 60 days of September 21, 2005.

(7) Includes 25,000 shares of common stock and options to purchase 12,500 shares of common stock that are exercisable within 60 days of September 21, 2005.

(8) Includes 1,260,000 shares of common stock owned by FPP Emerging Hedge Fund 1, Ltd. and warrants to purchase an aggregate of 632,000 shares of common stock owned by FPP Emerging Hedge Fund 1, Ltd. that are exercisable within 60 days of September 21, 2005. Includes 400,000 shares of common stock and warrants to purchase 500,000 shares of common stock owned by Perly International Ltd. that are exercisable within 60 days of September 21, 2005. Includes 180,000 shares of common stock owned by Pictet Private Equity Investors, S.A. and warrants to purchase 36,000 shares held by Pictet Private Equity Investors S.A. that are exercisable within 60 days of September 21, 2005. Includes 150,000

shares of common stock owned by FPP Capital Advisors and warrants to purchase 519,794 shares held by FPP Capital Advisors that are exercisable within 60 days of September 21, 2005. Mr. Pictet controls Perly International, Ltd and is Group Chairman of Fabien Pictet and Partners Ltd. that controls FPP Emerging Hedge Fund 1, Ltd., Pictet Private Equity Investors, S.A., FPP Capital Advisors. In June 2004, we assigned the right to purchase 1,250,000 shares of our common

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stock under the Call Option Agreement between us and SkyePharma to FPP Capital Advisors, an entity controlled by Fabien Pictet. The shares beneficially owned by Mr. Pictet, as reflected in this table do not include these 1,250,000 shares.

(9) Includes options to purchase 12,500 shares of common stock that are exercisable within 60 days of September 21, 2005.

(10) Includes 18,181,818 shares of common stock owned by Blue Cedar and (i) warrants to purchase 18,181,818 shares of common stock for a period of five years and (ii) warrants to purchase 12,121,212 shares of common stock for a period of twelve months. The warrants may be exercised as of August 17, 2005.

(11) Includes 650,000 shares of common stock, warrants to purchase 72,000 shares of common stock within 60 days of September 21, 2005 and options to purchase 12,500 shares of common stock within 60 days of September 21, 2005.

### SELLING STOCKHOLDERS

An aggregate of up to 47,056,520 shares of our common stock may be offered and sold pursuant to this prospectus by the selling stockholders. SkyePharma acquired its shares of common stock through the conversion of our outstanding Series A Preferred Stock. The other selling stockholders acquired common stock and warrants to purchase common stock by (i) purchasing units consisting of common stock and warrants in a private placement consummated in January and February 2004, (ii) receiving warrants as consideration for consulting services provided in connection with such private placement or (iii) receiving units as consideration for negotiating the Omnibus Conversion Agreement dated January 12, 2004 between us and SkyePharma.

In the private placement consummated in January and February 2004, we issued an aggregate of 10,459,866 shares of our common stock and warrants to purchase an aggregate of 10,459,866 shares of our common stock at an exercise price of \$0.73 per share. We received gross proceeds of \$5,229,933 from the January and February 2004 private placement.

In the event all selling stockholders exercise their warrants to purchase shares of our common stock, we will receive additional gross proceeds of \$8,259,827.

### Relationship with Certain Selling Stockholders

In connection with the January and February 2004 private placement, FPP Capital Advisors received a consulting fee of \$261,496. In addition, FPP Capital Advisors and certain other selling stockholders who assisted FPP Capital Advisors in providing consulting services to us, received warrants to purchase an aggregate of 418,394 shares of our common stock at \$0.50 per share and warrants to purchase an aggregate of 418,394 shares of our common stock at \$0.73 per share. One of these other selling stockholders, Manuel Tarabay, received warrants to purchase 72,000 shares of common stock, and became a member of the Board of Directors in August 2005. Further, in consideration for services rendered in negotiating the Omnibus Conversion Agreement, dated January 12, 2004 between us and SkyePharma, we issued units consisting of 150,000 shares of common stock and warrants to purchase 150,000 shares of common stock at an exercise price of \$0.73 per share to FPP Capital Advisors. We also assigned to FPP Capital Advisors the right to purchase 1,250,000 shares of our common stock from SkyePharma under the Call Option Agreement discussed below. FPP Capital Advisors is controlled by Fabien Pictet, a member of our Board of Directors.

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Under the terms of the Omnibus Conversion Agreement, between us and SkyePharma, on January 20, 2004 SkyePharma converted all of its outstanding shares of our Series A Preferred Stock into 25,000,000 shares of common stock at a conversion price of \$0.80 per share. As a result of its conversion, SkyePharma beneficially owns 26% of our common stock. On January 20, 2004, we and SkyePharma entered into a Call Option Agreement pursuant to which we received the right to repurchase some or all of 12,500,000 shares of our common stock from SkyePharma at a premium to the conversion price. We assigned to FPP Capital Advisors the right to purchase 1,250,000 of these shares. The call option will be exercisable by us for a period commencing upon our achievement of a certain milestone event and ending on January 20, 2007.

On January 20, 2004, we, SkyePharma and our other original stockholders entered into the Amended Stockholders' Agreement to amend the stockholders agreement, dated as of December 10, 2001 to provide for, among other things, the termination of the agreement on the later of (1) January 20, 2007 or (2) the date on which SkyePharma no longer beneficially owns 20% of our outstanding common stock. Under the terms of Amended Stockholders' Agreement, the parties agreed to vote all shares held by such parties for (i) one director designated by SkyePharma, (ii) one director designated by Dr. O'Daly, (iii) one director designated by each of the other three original stockholders and (iv) two independent director. No party to the agreement has the right to dispose (or direct the disposition of) any shares of common stock held by any of the other parties to the agreement. Accordingly, each party disclaims beneficial ownership of the shares held by the other parties. Since the date of the Amended Stockholders' Agreement, the other three original stockholders resigned their positions with us and transferred all of their shares of common stock to SkyePharma. As a result, none of them have any rights to designate a director under the Amended Stockholders' Agreement. In addition, pursuant to the Amended Stockholders' Agreement, SkyePharma is required to vote its shares of our common stock in favor of certain enumerated transactions, where those transactions have been approved by our Board of Directors and all of the independent directors.

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

No other selling stockholders has held any position or office or had a material relationship with us within the past three years other than as a result of the ownership of our common stock and other securities.

The following table sets forth certain information as of June 28, 2004 regarding the sale by the selling stockholders of 47,056,520 shares of common stock in this offering.

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| Selling Stockholder | Shares<br>Beneficially<br>Owned Before the<br>Offering (1) | Shares<br>Currently<br>Outstanding at<br>June 28, 2004<br>Registered in<br>the Offering (1) | Warrant<br>Shares<br>Registered in<br>the Offering | Total<br>Share<br>Registered<br>in the Offering |
|---------------------|--|---|--|---|
| Vieri Bracco        | 305,200 (2)  | 140,000   | 165,200 (2)  | 305,200   |
| ACE Fund Sicav      | 1,600,000  | 800,000   | 800,000  | 1,600,000                                       |

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|  |                    |                |             |            |
|--|--------------------|----------------|-------------|------------|
| Pictet & Cie   | 1,700,000          | 850,000        | 850,000     | 1,700,000  |
| Fidulex Management,<br>Inc.  | 3,600,000          | 1,800,000      | 1,800,000   | 3,600,000  |
| Gesico International<br>S.A.   | 800,000            | 400,000        | 400,000     | 800,000    |
| Epalinges Limited  | 599,928            | 299,964        | 299,964     | 599,928    |
| Bank Morgan Stanley AG   | 3,600,000          | 1,800,000      | 1,800,000   | 3,600,000  |
| S.A.M. Master Fund<br>L.P.   | 1,200,000          | 600,000        | 600,000     | 1,200,000  |
| Mirabaud & Cie   | 200,000            | 100,000        | 100,000     | 200,000    |
| Bank Julius Baer &<br>Co., Ltd.  | 200,000            | 100,000        | 100,000     | 200,000    |
| UBS Private Banking<br>Nominees Ltd.                                       | 1,000,000          | 500,000        | 500,000     | 1,000,000  |
| B.I. Lipworth & Co.<br>Limited   | 200,000            | 100,000        | 100,000     | 200,000    |
| Deborah Jones  | 300,000            | 150,000        | 150,000     | 300,000    |
| FPP Emerging Hedge<br>Fund I   | 1,200,000          | 600,000        | 600,000     | 1,200,000  |
| Vistal International<br>Ltd.   | 200,000            | 100,000        | 100,000     | 200,000    |
| Marcelo M. Fleury  | 200,000            | 100,000        | 100,000     | 200,000    |
| Maran Limited  | 300,000            | 150,000        | 150,000     | 300,000    |
| Newbridge Advisors   | 80,000             | 40,000         | 40,000      | 80,000     |
| Donvale Investments<br>Ltd.  | 400,000            | 200,000        | 200,000     | 400,000    |
| Greenwood Nominees<br>Ltd.   | 200,000            | 100,000        | 100,000     | 200,000    |
| Serica Bank  | 100,000            | 50,000         | 50,000      | 100,000    |
| Bernard Rapoport   | 100,000            | 50,000         | 50,000      | 100,000    |
| Larry Jaynes   | 100,000            | 50,000         | 50,000      | 100,000    |
| Maurice Sydney<br>Lipworth   | 200,000            | 100,000        | 100,000     | 200,000    |
| Graeme Gordon  | 400,000            | 200,000        | 200,000     | 400,000    |
| Nick Wentworth Stanley   | 199,920            | 99,960         | 99,960      | 199,920    |
| Carla Maria Orsi<br>Carbone  | 160,000            | 80,000         | 80,000      | 160,000    |
| Alexandre Stakhovitch  | 769,794 (3)        | 200,000        | 569,794 (3) | 769,794    |
| Raffaele Ricci   | 199,884            | 99,942         | 99,942      | 199,884    |
| Marcos M. Carvalhal<br>and Scott Starkey<br>Joint Tenants                  | 200,000            | 100,000        | 100,000     | 200,000    |
| B.I. Lipworth & Co.<br>Limited as Nominee<br>for BrandNew Group<br>Limited | 200,000            | 100,000        | 100,000     | 200,000    |
| I.S. Twersky   | 400,000            | 200,000        | 200,000     | 400,000    |
| Rhonda Limited   | 400,000            | 200,000        | 200,000     | 400,000    |
| SkyePharma PLC   | 25,220,000 (4) (5) | 25,000,000 (2) | --          | 25,000,000 |
| FPP Capital Advisors   | 669,794 (6)        | 150,000        | 519,794     | 519,794    |
| Manuel Tarabay   | 722,000 (7) (8)    | --             | 72,000 (8)  | 72,000     |

\* Less than 1%.

(1) Beneficial ownership is determined in accordance with rules and regulations of the Securities and Exchange Commission. In computing the number of shares beneficially owned by a person, shares of common stock subject to options or warrants held by that person that are currently exercisable or exercisable within 60 days of the date of this prospectus are deemed

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outstanding. Except as indicated in the footnotes to this table and pursuant to applicable community property laws, each stockholder named in the table has sole voting and investment power with respect to the shares beneficially owned by him. Selling stockholders are deemed to beneficially own the shares of common stock issuable upon the exercise of their warrants.

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(2) Includes warrants to purchase 12,600 shares of common stock at an exercise price of \$0.50 per share and warrants to purchase 12,600 shares of common stock at an exercise price of \$0.73 per share. Such warrants were issued for consulting services provided in connection with our 2004 private placement.

(3) Includes warrants to purchase 184,897 shares of common stock at an exercise price of \$0.50 per share and warrants to purchase 184,897 shares of common stock at an exercise price of \$0.73 per share. Such warrants were issued for consulting services provided in connection with our 2004 private placement and in connection with the conversion of our Series A Preferred Stock by SkyePharma.

(4) Includes 25,200,000 shares of common stock and warrants to purchase 20,000 shares of common stock. Michael Ashton, Chief Executive Officer of SkyePharma and a member of our Board of Directors, exercises voting control over the shares held by SkyePharma.

(5) Under the terms of a Call Option Agreement, dated January 20, 2004, we have the right to repurchase some or all of 12,500,000 shares of our common stock from SkyePharma. In June 2004, we assigned the right to purchase 1,250,000 shares under the Call Option Agreement to FPP Capital Advisors, an entity controlled by Fabien Pictet. The call option will be exercisable for a period commencing upon our achievement of a certain milestone event and ending on January 20, 2007.

(6) Includes warrants to purchase 184,897 shares of common stock at an exercise price of \$0.50 per share and warrants to purchase 184,897 shares of common stock at an exercise price of \$0.73 per share. Such warrants were issued for consulting services provided in connection with our 2004 private placement and in connection with negotiating the Omnibus Conversion Agreement dated January 12, 2004 between us and SkyePharma.

(7) Includes 650,000 shares of common stock beneficially owned by Mr. Tarabay which he acquired prior to our 2004 private placement.

(8) Includes warrants to purchase 36,000 shares of common stock at an exercise price of \$0.50 per share and warrants to purchase 36,000 shares of common stock at an exercise price of \$0.73 per share. Such warrants were issued for consulting services provided in connection with our 2004 private placement.

### PLAN OF DISTRIBUTION

The selling stockholders and any of their pledgees, donees, transferees, assignees or other successors-in-interest may, from time to time, sell any or all of the shares of common stock offered hereby on any stock exchange, market or trading facility on which the shares are traded or in private transactions. Our common stock currently trades on the OTC Bulletin Board. Any sales by the selling stockholders may be at fixed or negotiated prices. The selling stockholders may use any one or more of the following methods when selling shares:

- o ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

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- o block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

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- o purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- o an exchange distribution in accordance with the rules of the applicable exchange;
- o privately negotiated transactions;
- o short sales;
- o broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- o a combination of any such methods of sale; and
- o any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved.

The selling stockholders may from time to time pledge or grant a security interest in any of their warrants or common stock issuable upon conversion of their warrants and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares underlying the warrants from time to time under this prospectus.

The selling stockholders also may transfer their warrants or shares of common stock issuable upon conversion of their warrants in other circumstances, in which case the pledgees, donees, transferees, assignees or other successors-in-interest will be "selling stockholders" for purposes of this prospectus.

The selling stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. The selling stockholders have informed us that they do not have any agreement or understanding, directly or indirectly, with any person to distribute the common stock.

We will not receive any proceeds from sales of any shares by the selling stockholders. However, we may receive an aggregate of \$8,259,827 upon the exercise of all the warrants held by selling stockholders, if such warrants are exercised for cash. We will use such funds, if any, to fund clinical trials and for working capital and general corporate purposes.

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### DESCRIPTION OF CAPITAL STOCK

We are authorized to issue 153,000,000 shares of capital stock divided into (i) 150,000,000 shares of common stock, par value \$0.0001 per share and (ii) 3,000,000 shares of preferred stock par value \$0.001 per share. As of September 21, 2005, there are 91,354,873 shares of our common stock outstanding, held of record by approximately 2,833 stockholders. We do not have any shares of preferred stock outstanding.

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#### Common Stock

The holders of our common stock are entitled to one vote for each share held of record in the election of directors and in all other matters to be voted on by the stockholders. There is no cumulative voting with respect to the election of directors. As a result, the holders of more than 50% of the shares voting for the election of directors can elect all of the directors. Holders of common stock are entitled:

- o to receive any dividends as may be declared by the Board of Directors out of funds legally available for such purpose after payment of accrued dividends on the outstanding shares of preferred stock; and
- o in the event of our liquidation, dissolution, or winding up, to share ratably in all assets remaining after payment of liabilities and after provision has been made for each class of stock having preference over the common stock.

All of the outstanding shares of common stock are validly issued, fully paid and nonassessable. Holders of our common stock have no preemptive right to subscribe for or to purchase additional shares of any class of our capital stock.

Under the terms of Amended Stockholders' Agreement, dated as of January 20, 2004 by and among us, SkyePharma, Dr. O'Daly and our other original stockholders, the parties agreed to vote all shares held by such parties for (i) one director designated by SkyePharma, (ii) one director designated by Dr. O'Daly, (iii) one director designated by each of the other three original stockholders and (iv) two independent director. No party to the Amended Stockholders' Agreement has the right to dispose (or direct the disposition of) any shares of common stock held by any of the other parties to the agreement. Accordingly, each party disclaims beneficial ownership of the shares held by the other parties. Since the date of the Amended Stockholders' Agreement, the other three original stockholders resigned their positions with us and transferred all of their shares of common stock to SkyePharma. As a result, none of them have any rights to designate a director under the Agreement. Further, the Amended Stockholders' Agreement provides, among other things, the termination of the agreement or the later of (1) January 20, 2007 or (2) the date on which SkyePharma no longer beneficially owns 20% of our outstanding common stock. In addition, SkyePharma is required to vote its shares of our common stock in favor of certain enumerated transactions, where those transactions have been approved by our Board of Directors and all of the independent directors. Additionally, pursuant to the Blue Cedar Stockholder's Agreement, dated as of August 17, 2005, Blue Cedar may designate one director to our Board of Directors. The Blue Cedar Stockholder's Amendment will terminate upon the later of the Blue Cedar Termination Date or August 15, 2008. The "Blue Cedar Termination Date" is the date on which Blue Cedar no longer beneficially owns, in the aggregate, at least

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20% of our outstanding common stock.

### Preferred Stock

Our Board of Directors has the authority, within the limitations set forth in our certificate of designations and certificate of incorporation to provide by resolution for the issuance of preferred stock, in one or more classes or series, and to fix the rights, preferences, privileges and restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences and the number of shares constituting any series or the designation of such series.

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### Warrants

As of September 21, 2005, we have outstanding warrants to purchase 140,120,340 shares of our common stock. We issued warrants to purchase 6,300,000 shares of our common stock at an exercise price of \$1.60 per share pursuant to a private placement that occurred in September 2001. We issued warrants to purchase 415,237 shares of our common stock at an exercise price of \$4.00 per share pursuant to a private placement that occurred in November 2001. We issued warrants to purchase 10,459,866 shares of our common stock at an exercise price of \$0.73 per share pursuant to a private placement that occurred in January and February 2004. In connection with a private placement that was completed June 2004, we issued to FPP Capital Advisors and certain other selling stockholders who assisted FPP Capital Advisors in providing consulting services to us warrants to purchase an aggregate of 418,394 shares of our common stock at \$0.50 per share and warrants to purchase an aggregate of 418,394 shares of our common stock at \$0.73 per share. One of these other selling stockholders, Manuel Tarabay, received warrants to purchase 72,000 shares of common stock, and became a member of the Board of Directors in August 2005. In consideration for services rendered in negotiating the Omnibus Conversion Agreement, dated January 12, 2004 between us and SkyePharma, we issued units consisting of 150,000 shares of common stock and warrants to purchase 150,000 shares of common stock to FPP Capital Advisors. FPP Capital Advisors is controlled by Fabien Pictet, a member of our Board of Directors. In connection with our most recent private placement which consummated August 19, 2005, we issued to Blue Cedar warrants to purchase over a 5-year period 18,181,818 shares of common stock with an exercise price of \$0.165 and warrants to purchase over a 12-month period 12,121,212 shares of common stock with an exercise price of \$0.165. In addition, in connection with the August 19, 2005 private placement, as consideration for services rendered, we issued warrants to purchase 1,454,545 shares of common stock with an exercise price of \$0.165, to our placement agent, Lipworth Capital Limited.

### Market for Common Stock

Shares of our common stock are listed on the OTC Bulletin Board under the symbol ASTR.

### Transfer Agent and Registrar

Our transfer agent and registrar is American Stock Transfer and Trust Company, 59 Maiden Lane, Plaza Level, New York, New York 10038.

### Shares Eligible for Future Sale

We currently have 91,354,873 shares of common stock outstanding. Of the 91,354,873 shares of common stock outstanding, up to 11,605,224 shares are freely tradable without restriction or further registration under the Securities



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Act, except for any shares purchased by an "affiliate", which will be subject to the resale limitations of Rule 144 promulgated under the Securities Act.

All of the remaining shares of common stock currently outstanding are "restricted securities" or owned by "affiliates", as those terms are defined in Rule 144, and may not be sold publicly unless they are registered under the Securities Act or are sold pursuant to Rule 144 or another exemption from registration. The restricted securities are not eligible for sale without registration under Rule 144. As of September 21, 2005, there were outstanding options and warrants to purchase 140,120,340 shares of our common stock.

### Lock-Up Agreements

None of the currently outstanding shares of common stock are subject to lock-up agreements.

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### Rule 144

Generally, under Rule 144 as currently in effect, subject to the satisfaction of certain other conditions, a person, including any of our affiliates or persons whose shares are aggregated with an affiliate, who has owned restricted shares of common stock beneficially for at least one year, is entitled to sell, within any three-month period, a number of shares that does not exceed the greater of:

- o 1% of our then outstanding shares of common stock; or
- o the average weekly trading volume of shares of our common stock during the four calendar weeks preceding such sale.

A person who is not an affiliate, has not been an affiliate within three months prior to sale, and has beneficially owned the restricted shares for at least two years is entitled to sell such shares under Rule 144(k) without regard to any of the limitations described above.

### Charter and Bylaws Provisions and Delaware Anti-Takeover Statute

We are subject to Section 203 of the Delaware General Corporation Law regulating corporate takeovers. This section prevents Delaware corporations from engaging under certain circumstances, in a "business combination", which includes a merger or sale of more than 10% of the corporation's assets, with any "interested stockholder", or a stockholder who owns 15% or more of the corporation's outstanding voting stock, as well as affiliates and associates of any such persons, for three years following the date such stockholder became an "interested stockholder", unless (i) the business combination or the transaction in which such stockholder became an "interested stockholder" is approved by the Board of Directors prior to the date the "interested stockholder" attained such status; (ii) upon consummation of the transaction that resulted in the stockholder becoming an "interested stockholder", the "interested stockholder" owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned by (x) persons who are directors and also officers and (y) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or (iii) on or after the date the "interested stockholder" attained such status the business combination is approved by the Board of Directors and authorized at an annual or special meeting of stockholders by the affirmative vote of at least two-thirds of the

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outstanding voting stock that is not owned by the "interested stockholder."

Our certificate of incorporation and bylaws do not provide for cumulative voting in the election of directors. Our bylaws eliminate the right of stockholders to call special meetings of stockholders. The authorization of one million shares of undesignated preferred stock makes it possible for the Board of Directors to issue a class of preferred stock with voting or other rights or preferences that could impede the success of any attempt to effect a change in our control. These and other provisions may have the effect of delaying, deferring or preventing hostile takeovers or changes in the control or management of the Company even if doing so would be beneficial to our stockholders.

### LEGAL MATTERS

The validity of the common stock offered by this prospectus will be passed upon by McCarter & English, LLP.

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### EXPERTS

L J Soldinger Associates, LLC, independent registered public accountants, have audited our financial statements as of December 31, 2004 and 2003, and for the years then ended and the period March 12, 2001 (date of inception) through December 31, 2004, as set forth in their report. We have included our financial statements in the prospectus and elsewhere in this registration statement in reliance on the L J Soldinger Associates, LLC reports, given on their respective authority as experts in accounting and auditing.

### WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the Securities and Exchange Commission, a Registration Statement on Form SB-2 under the Securities Act of 1933 with respect to the common stock offered by this prospectus. This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. For further information with respect to us and the common stock offered by this prospectus, reference is made to the registration statement and the exhibits and schedules filed as a part of the registration statement. Additionally, we file annual, quarterly and current reports, proxy statements and other documents with the Securities and Exchange Commission. You may read and copy any materials we file with the Securities and Exchange Commission at the Securities and Exchange Commission's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the Securities and Exchange Commission at 1-800-SEC-0330. The Securities and Exchange Commission also maintains a World Wide Web site that contains reports, proxy and information statements and other information regarding registrants that file electronically with the Securities and Exchange Commission. The address of the Securities and Exchange Commission's Web site is <http://www.sec.gov>.

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ASTRALIS LTD.  
(A Development Stage Entity)

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### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and  
Stockholders of Astralis Ltd.

We have audited the accompanying balance sheets of Astralis Ltd. (a development stage entity) as of December 31, 2004 and 2003, and the related statements of operations, stockholders' equity and cash flows for the years then ended and the period March 12, 2001 (date of inception) through December 31, 2004. 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 audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Astralis Ltd. as of December 31, 2004 and 2003, and the results of its operations, changes in stockholders' equity and its cash flows for the years then ended and the period March 12, 2001 (date of inception) through December 31, 2004 in conformity with accounting

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principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the financial statements, the Company has incurred net losses since inception, does not have sufficient funds to execute its business plan, estimates its current cash will last through the end of the second quarter of 2005, and reported in 2005 the results from its Phase II testing indicated no statistical difference between the Company's product and a placebo. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans regarding those matters are also described in Note 3. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ L J SOLDINGER ASSOCIATES, LLC

Deer Park, Illinois  
February 16, 2005

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ASTRALIS LTD.  
(A Development Stage Entity)  
Balance Sheets

ASSETS

|  | December 31, |          |
|--|--------------|----------|
|  | 2004         | 2003     |
| Current Assets                         |              |          |
| Cash and cash equivalents              | \$ 2,312,401 | \$ 10    |
| Marketable securities                  | --           | 1,374    |
| Prepaid expense - related party        | --           | 1,007    |
| Prepaid expenses                       | 70,895       | 84       |
| Supplies                               | 55,851       | 87       |
|  | 2,439,147    | 2,564    |
| Total Current Assets                   |              |          |
| Intangible Assets, Net - Related Party | --           | 3,511    |
| Other Intangible Assets, Net           | 117,923      | 94       |
| Property and Equipment, Net            | 214,140      | 293      |
| Deposits                               | 26,763       | 29       |
|  | \$ 2,797,973 | \$ 6,493 |
| LIABILITIES AND STOCKHOLDERS' EQUITY   |              |          |
| Current Liabilities                    |              |          |
| Accounts payable and accrued expenses  | \$ 397,762   | \$ 279   |
|  |              |          |

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|   |              |          |
|---|--------------|----------|
| Total Current Liabilities   | 397,762      | 279      |
| <hr/>   |              |          |
| Commitments and Contingencies   |              |          |
| Stockholders' Equity  |              |          |
| Convertible preferred stock; Series A, \$.001 par value;<br>3,000,000 shares authorized at 2004 and 2003; 0 and<br>2,000,000 issued and outstanding at 2004 and 2003, respectively<br>(liquidation preference - \$0 and \$22,122,600 at 2004 and 2003,<br>respectively) | --           | 2        |
| Common stock; \$.0001 par value; 150,000,000 shares authorized at<br>2004 and 2003; 73,173,055 and 37,538,189 issued and<br>outstanding at 2004 and 2003, respectively  | 7,317        | 3        |
| Additional paid-in capital  | 52,095,251   | 35,929   |
| Deferred compensation   | --           | (4       |
| Common stock subscriptions receivable   | --           | (24      |
| Accumulated other comprehensive loss  | --           | (27      |
| Deficit accumulated in the development stage  | (49,702,357) | (29,664  |
| <hr/>   |              |          |
| Total Stockholders' Equity  | 2,400,211    | 6,214    |
| <hr/>   |              |          |
|   | \$ 2,797,973 | \$ 6,493 |
| <hr/>   |              |          |

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

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

|  | Year Ended December 31, |             | March 12, 2001<br>(Inception) to<br>December 31,<br>2004 |
|--|-------------------------|-------------|--|
|  | 2004                    | 2003        |  |
|  | -----                   | -----       | -----  |
| Revenues                                 | \$ --                   | \$ --       | \$ --  |
| <hr/>                                    |                         |             |  |
| Operating Expenses                       |                         |             |  |
| Research and development - related party | 4,519,400               | 1,721,788   | 16,278,822   |
| Research and development                 | 3,169,660               | 2,323,885   | 6,449,228  |
| Depreciation and amortization            | 30,403                  | 26,062      | 73,024   |
| General and administrative               | 1,860,844               | 1,290,346   | 5,377,454  |
| <hr/>                                    |                         |             |  |
| Total Operating Expenses                 | 9,580,307               | 5,362,081   | 28,178,528   |
| <hr/>                                    |                         |             |  |
| Loss From Operations                     | (9,580,307)             | (5,362,081) | (28,178,528)   |

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|   |                 |                |                 |
|---|-----------------|----------------|-----------------|
| Investment income (loss)  | (722)           | 60,018         | 179,824         |
|   | -----           | -----          | -----           |
| Loss before income tax benefit                                  | (9,581,029)     | (5,302,063)    | (27,998,704)    |
| Income tax benefit  | 293,461         | 221,636        | 515,097         |
|   | -----           | -----          | -----           |
| Net Loss  | (9,287,568)     | (5,080,427)    | (27,483,607)    |
| Preferred Stock Dividends                                       | (10,750,000)    | --             | (22,218,750)    |
|   | -----           | -----          | -----           |
| Net Loss to Common Stockholders                                 | \$ (20,037,568) | \$ (5,080,427) | \$ (49,702,357) |
|   | =====           | =====          | =====           |
| Basic and Diluted Loss per Common Share                         | \$ (0.28)       | \$ (0.14)      | \$ (1.12)       |
|   | =====           | =====          | =====           |
| Basic and Diluted Weighted Average<br>Common Shares Outstanding | 71,073,507      | 37,538,189     | 44,472,789      |
|   | =====           | =====          | =====           |

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

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ASTRALIS LTD.  
(A Development Stage Entity)  
Statements of Stockholders' Equity

|   | Preferred Stock |        | Common Stock |        |
|---|-----------------|--------|--------------|--------|
|   | Shares          | Amount | Shares       | Amount |
|   | -----           | -----  | -----        | -----  |
| Balances, March 12, 2001<br>(Date of Inception)   | --              | \$ --  | --           | \$ --  |
| Members' capital contributions,<br>3/15/2001  | --              | --     | 25,300,000   | 2      |
| Capital contributions received,<br>3/1 - 8/13/2001  | --              | --     | --           | --     |
| Members' contributed services,<br>3/15 - 6/30/2001  | --              | --     | --           | --     |
| Members' capital contributions,<br>9/1/2001   | --              | --     | 2,700,000    | --     |
| Warrants to purchase 6,300,000 shares<br>of common stock at \$1.60 per share<br>issued in private placement | --              | --     | --           | --     |
| Common stock issuable for consulting  |                 |        |              |        |

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|  |           |          |            |       |
|--|-----------|----------|------------|-------|
| services, 9/1/2001; 500,000 shares   | --        | --       | --         |       |
| Common stock issued in private placement net of issuance costs, 11/13/2001; 2,076,179 shares at \$1.60 per share             | --        | --       | 2,076,179  |       |
| Warrants to purchase 415,237 shares of common stock at \$4.00 per share issued in private placement, 11/13/2001              | --        | --       | --         |       |
| Net assets and liabilities acquired in merger with Hercules  | --        | --       | 7,512,000  |       |
| Preferred stock issued, net of issuance costs, 12/10/2001; 1,000,000 shares at \$10.00 per share                             | 1,000,000 | 1,000    | --         |       |
| Preferred stock dividend, 12/10/2001   | --        | --       | --         |       |
| Options to purchase 200,000 shares of common stock at \$1.77 (based on valuation) issued for legal services, 12/31/2001      | --        | --       | --         |       |
| Options to purchase 100,000 shares of common stock at \$1.77 (based on valuation) issued for consulting services, 12/31/2001 | --        | --       | --         |       |
| Amortization of deferred compensation  | --        | --       | --         |       |
| Net loss   | --        | --       | --         |       |
|  | -----     | -----    | -----      | ----- |
| Total Comprehensive Loss   |           |          |            |       |
| Balance, December 31, 2001   | 1,000,000 | \$ 1,000 | 37,588,179 | \$ 3  |
|  | -----     | -----    | -----      | ----- |

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

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ASTRALIS LTD.  
(A Development Stage Entity)  
Statements of Stockholders' Equity

| Subscription<br>Receivable | Deferred<br>Compensation | Accumulated<br>Other<br>Comprehensive<br>Loss | Defici<br>Accumul<br>During<br>Develop<br>Stage |
|----------------------------|--------------------------|---|---|
| -----                      | -----                    | -----   | -----   |

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|   |    |             |    |           |    |       |           |
|---|----|-------------|----|-----------|----|-------|-----------|
| Balances, March 12, 2001<br>(Date of Inception)   | \$ | --          | \$ | --        | \$ | --    | \$        |
| Members' capital contributions,<br>3/15/2001  |    | (33,183)    |    | --        |    | --    |           |
| Capital contributions received,<br>3/1 - 8/13/2001  |    | 33,183      |    | --        |    | --    |           |
| Members' contributed services,<br>3/15 - 6/30/2001  |    | --          |    | --        |    | --    |           |
| Members' capital contributions,<br>9/1/2001   |    | (1,350,000) |    | --        |    | --    |           |
| Warrants to purchase 6,300,000 shares of<br>common stock at \$1.60 per share issued<br>in private placement                           |    | --          |    | --        |    | --    |           |
| Common stock issuable for consulting<br>services, 9/1/2001; 500,000 shares  |    | --          |    | --        |    | --    |           |
| Common stock issued in private placement<br>net of issuance costs, 11/13/2001;<br>2,076,179 shares at \$1.60 per share                |    | --          |    | --        |    | --    |           |
| Warrants to purchase 415,237 shares of<br>common stock at \$4.00 per share issued<br>in private placement, 11/13/2001                 |    | --          |    | --        |    | --    |           |
| Net assets and liabilities acquired in<br>merger with Hercules  |    | --          |    | --        |    | --    |           |
| Preferred stock issued, net of issuance<br>costs, 12/10/2001; 1,000,000 shares<br>at \$10.00 per share                                |    | --          |    | --        |    | --    |           |
| Preferred stock dividend, 12/10/2001  |    | --          |    | --        |    | --    | (2,12)    |
| Options to purchase 200,000 shares of<br>common stock at \$1.77 (based on valuation)<br>issued for legal services, 12/31/2001         |    | --          |    | (354,000) |    | --    |           |
| Options to purchase 100,000 shares of<br>common stock at \$1.77 (based on valuation)<br>issued for consulting services,<br>12/31/2001 |    | --          |    | (177,000) |    | --    |           |
| Amortization of deferred compensation   |    | --          |    | 132,750   |    | --    |           |
| Net loss  |    | --          |    | --        |    | --    | (4,07)    |
|   |    | -----       |    | -----     |    | ----- | -----     |
| Total Comprehensive loss  |    |             |    |           |    |       |           |
| Balance, December 31, 2001  | \$ | (1,350,000) | \$ | (398,250) | \$ | --    | \$ (6,19) |
|   |    | -----       |    | -----     |    | ----- | -----     |

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



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ASTRALIS LTD.  
(A Development Stage Entity)  
Statements of Stockholders' Equity

|  | Preferred Stock |          | Common     |
|--|-----------------|----------|------------|
|  | Shares          | Amount   | Shares     |
| Balances Brought Forward   | 1,000,000       | \$ 1,000 | 37,588,179 |
| Oversubscription of common stock issued<br>in private placement, 11/13/2001; 49,990<br>shares cancelled at \$1.60 per share, 1/24/2002 | --              | --       | (49,990)   |
| Preferred stock issue, net of issuance costs,<br>1/31/2002; 250,000 shares at \$10.00 per share  | 250,000         | 250      | --         |
| Preferred stock issue, net of issuance costs,<br>4/30/2002; 250,000 shares at \$10.00 per share  | 250,000         | 250      | --         |
| Preferred stock dividend, April 30, 2002   | --              | --       | --         |
| Preferred stock issue, net of issuance costs,<br>7/31/2002; 250,000 shares at \$10.00 per share  | 250,000         | 250      | --         |
| Collection of subscription receivable  | --              | --       | --         |
| Options issued for consulting services,<br>9/10/2002; 15,000 options at \$0.38<br>per option, based on valuation                       | --              | --       | --         |
| Preferred stock dividend, 12/10/2002   | --              | --       | --         |
| Amortization of deferred compensation  | --              | --       | --         |
| Fair value adjustment on deferred<br>compensation  | --              | --       | --         |
| COMPREHENSIVE LOSS   |                 |          |            |
| Net loss   | --              | --       | --         |
| Other comprehensive loss:  |                 |          |            |
| Unrealized gain (loss) on available-for-sale<br>securities   | --              | --       | --         |
| Total Comprehensive Loss   |                 |          |            |

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|                            |           |          |            |
|----------------------------|-----------|----------|------------|
| Balance, December 31, 2002 | 1,750,000 | \$ 1,750 | 37,538,189 |
|                            | -----     | -----    | -----      |

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

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ASTRALIS LTD.  
(A Development Stage Entity)  
Statements of Stockholders' Equity

|   | Subscription<br>Receivable | Deferred<br>Compensation | Accumulated<br>Other<br>Comprehensive<br>Loss | Deficit<br>Accumula<br>During t<br>Developm<br>Stage |
|---|----------------------------|--------------------------|---|--|
|   | -----                      | -----                    | -----   | -----  |
| Balances Brought Forward  | \$ (1,350,000)             | \$ (398,250)             | \$ --   | \$ (6,195)   |
| Oversubscription of common stock issued<br>in private placement, 11/13/2001; 49,990<br>shares cancelled at \$1.60 per share,<br>1/24/2002 | --                         | --                       | --  |  |
| Preferred stock issue, net of issuance<br>costs, 1/31/2002; 250,000 shares at<br>\$10.00 per share  | --                         | --                       | --  |  |
| Preferred stock issue, net of issuance<br>costs, 4/30/2002; 250,000 shares at<br>\$10.00 per share  | --                         | --                       | --  |  |
| Preferred stock dividend, April 30, 2002  | --                         | --                       | --  | (270)  |
| Preferred stock issue, net of issuance<br>costs, 7/31/2002; 250,000 shares at<br>\$10.00 per share  | --                         | --                       | --  |  |
| Collection of subscription receivable   | 465,000                    | --                       | --  |  |
| Options issued for consulting services,<br>9/10/2002; 15,000 options at \$0.38<br>per option, based on valuation                          | --                         | (5,700)                  | --  |  |
| Preferred stock dividend, 12/10/2002  | --                         | --                       | --  | (9,078)  |
| Amortization of deferred compensation   | --                         | 34,254                   | --  |  |
| Fair value adjustment on deferred   |                            |                          |   |  |

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|  |              |             |             |             |
|--|--------------|-------------|-------------|-------------|
| compensation                                     | --           | 357,532     | --          |             |
| COMPREHENSIVE LOSS                               |              |             |             |             |
| Net loss   | --           | --          | --          | (9,040)     |
| Other comprehensive loss:                        |              |             |             |             |
| Unrealized loss on available-for-sale securities | --           | --          | (15,181)    |             |
| -----  |              |             |             |             |
| Total Comprehensive Loss                         |              |             |             |             |
| Balance, December 31, 2002                       | \$ (885,000) | \$ (12,164) | \$ (15,181) | \$ (24,584) |
| -----  |              |             |             |             |

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

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ASTRALIS LTD.  
(A Development Stage Entity)  
Statements of Stockholders' Equity

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

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

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

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ASTRALIS LTD.  
(A Development Stage Entity)  
Statements of Stockholders' Equity

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

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

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

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ASTRALIS LTD.  
(A Development Stage Entity)  
Statements of Stockholders' Equity

|  | Preferred Stock |          | Common S   |
|--|-----------------|----------|------------|
|  | Shares          | Amount   | Shares     |
|  | -----           | -----    | -----      |
| Balances Brought Forward   | 2,000,000       | \$ 2,000 | 37,538,189 |
| Common stock issue, net of issuance costs,<br>Jan -Feb 2004 at \$0.50 per unit | --              | --       | 10,459,866 |
| Collection of subscription receivable  | --              | --       | --         |
| Conversion of Preferred Stock, Series A  | (2,000,000)     | (2,000)  | 25,000,000 |
| Preferred stock dividend   | --              | --       | --         |
| Common stock issued,<br>in lieu of payment for services                        | --              | --       | 150,000    |
| Call option assigned,<br>in lieu of payment for services                       | --              | --       | --         |
| Amortization of deferred compensation  | --              | --       | --         |
| Stock options exercised  | --              | --       | 25,000     |
| COMPREHENSIVE LOSS   |                 |          |            |
| Net loss   | --              | --       | --         |
| Other comprehensive loss:  |                 |          |            |
| Unrealized gain (loss) on<br>available-for-sale<br>securities                  | --              | --       | --         |
|  | -----           | -----    | -----      |
| Total Comprehensive Loss   |                 |          |            |
| Balance, December 31, 2004   | --              | \$ --    | 73,173,055 |
|  | =====           | =====    | =====      |

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ASTRALIS LTD.  
(A Development Stage Entity)  
Statements of Stockholders' Equity

|  | Subscription<br>Receivable | Deferred<br>Compensation | Accumulated<br>Other<br>Comprehensive<br>Loss | Deficit<br>Accumulat<br>During th<br>Developme<br>Stage |
|--|----------------------------|--------------------------|---|---|
|  | -----                      | -----                    | -----   | -----   |
| Balances Brought Forward   | \$ (24,000)                | \$ (4,822)               | \$ (27,698)                                   | \$ (29,664,   |
| Common stock issue, net of issuance costs, Jan -Feb 2004 at \$2.00 per share | --                         | --                       | --  |   |
| Collection of subscription receivable,                                       | 24,000                     | --                       | --  |   |
| Conversion of Preferred Stock, Series A                                      | --                         | --                       | --  |   |
| Preferred stock dividend   | --                         | --                       | --  | (10,750,  |
| Common stock issued, in lieu of payment for services                         | --                         | --                       | --  |   |
| Call option assigned, in lieu of payment for services                        | --                         | --                       | --  |   |
| Amortization of deferred compensation  | --                         | 4,822                    | --  |   |
| Stock options exercised  | --                         | --                       | --  |   |
| COMPREHENSIVE LOSS   |                            |                          |   |   |
| Net loss   | --                         | --                       | --  | (9,287,   |
| Other comprehensive loss:  |                            |                          |   |   |
| Unrealized gain (loss) on available-for-sale securities, net                 | --                         | --                       | 27,698  |   |
|  | -----                      | -----                    | -----   | -----   |
| Total Comprehensive Loss   |                            |                          |   |   |
| Balance, December 31, 2004   | \$ --                      | \$ --                    | \$ --   | \$ (49,702,   |
|  | =====                      | =====                    | =====   | =====   |

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

|   | Year Ended December 31 |                    |
|---|------------------------|--------------------|
|   | 2004                   | 2003               |
| <b>Cash Flows from Operating Activities</b>   |                        |                    |
| Net loss  | \$ (9,287,568)         | \$ (5,080,000)     |
| Adjustments to reconcile net loss to net cash used in operating activities                          |                        |                    |
| Depreciation and amortization   | 867,902                | 847,000            |
| Impairment of intangible asset  | 2,797,612              |                    |
| Amortization of net premium paid on investments   | --                     | 5,000              |
| Dividend income reinvested  | (117,219)              | (72,000)           |
| Members' contributed salaries   | --                     |                    |
| Research and development service fee netted against proceeds received from preferred stock issuance | --                     | 20,000             |
| Operating expenses paid by related parties on behalf of company                                     | --                     |                    |
| Amortization of deferred compensation   | 4,822                  | 25,000             |
| Investor relation fees netted against subscription receivable                                       | 24,000                 | 36,000             |
| Compensatory common stock   | 75,000                 |                    |
| Assignment of call option   | 376,508                |                    |
| Loss on sale of available-for-sale securities and fixed asset retirement                            | 129,832                | 23,000             |
| Changes in assets and liabilities   |                        |                    |
| Prepaid expenses  | 1,059,838              | 975,000            |
| Interest receivable   | --                     | 5,000              |
| Supplies  | 31,186                 | (56,000)           |
| Deposits  | 3,190                  |                    |
| Accounts payable and accrued expenses   | 77,228                 | (1,000)            |
| <b>Net Cash Used in Operating Activities</b>  | <b>(3,957,669)</b>     | <b>(3,270,000)</b> |
| <b>Cash Flows from Investing Activities</b>   |                        |                    |
| Purchases of available-for-sale securities  | (4,300,010)            | (1,919,000)        |
| Proceeds from sale of available-for-sale securities   | 5,690,970              | 1,783,000          |
| Expenditures related to patent  | (26,947)               | (36,000)           |
| Insurance proceeds from claim   | 4,113                  |                    |
| Purchases of property and equipment   | (74,157)               | (60,000)           |
| <b>Net Cash Used in Investing Activities</b>  | <b>1,293,969</b>       | <b>(233,000)</b>   |
| <b>Cash Flows from Financing Activities</b>   |                        |                    |
| Repurchase of common stock  | --                     |                    |
| Collection of subscription receivable   | --                     | 825,000            |
| Proceeds from exercise of stock options   | 11,250                 |                    |
| Issuance of common stock, net of offering and transaction costs                                     | 4,954,191              |                    |
| Issuance of preferred stock   | --                     | 2,480,000          |
| Private placement offering costs  | --                     | (17,000)           |

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|  |              |        |
|--|--------------|--------|
| Net Cash Provided by Financing Activities            | 4,965,441    | 3,287, |
| Net Increase (Decrease) in Cash and Cash Equivalents | 2,301,741    | (216,  |
| Cash and Cash Equivalents, Beginning of Period       | 10,660       | 227,   |
| Cash and Cash Equivalents, End of Period             | \$ 2,312,401 | \$ 10, |

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

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

NOTE 1 - DESCRIPTION OF BUSINESS

Nature of Operations

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

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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

Development Stage Enterprise

The Company is a Development Stage Enterprise, as defined in Statement of Financial Accounting Standards ("SFAS") No. 7 "Accounting and Reporting for Development Stage Enterprises." 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 performing research and development activities, fulfilling FDA requirements in order to get approval on Psoraxine(R), and the raising of capital through private placement stock offerings.

Use of Estimates



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

### Cash and Cash Equivalents

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

### Credit Risk

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

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

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

#### Property and Equipment

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

#### Income Taxes

Income taxes are recorded in the period in which the related transactions are recognized in the financial statements, net of the valuation allowances, which have been recorded against deferred tax assets. Deferred tax assets and liabilities are recorded for the expected future tax consequences of temporary differences between the tax basis and the financial reporting of assets and liabilities. Net deferred tax assets and liabilities, relating primarily to federal and state net operating loss carryforwards and research and development credits that have been deferred for tax purposes have also been recorded. A valuation reserve has been recorded to offset a portion of the deferred tax benefit (except for amount realized through the sale of a portion of the Company's New Jersey net operating loss) because management has determined it is more likely than not that the deferred tax assets will not be realized. See Note 7.

#### Fair Value of Financial Instruments

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

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### Stock-Based Compensation Arrangements

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

The following table illustrates the effect on net loss and earnings per share if the Company had applied the fair value recognition provisions of SFAS 123, "Accounting for Stock-Based Compensation," to stock-based compensation.

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

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

|   | Year Ended December |                |
|---|---------------------|----------------|
|   | 2004                | 2003           |
| Net loss, as reported   | \$(20,037,568)      | \$ (5,000,000) |
| Add:  |                     |                |
| Stock-based compensation expense included in reported net loss determined under APB No. 25, net of related tax effects              | --                  |                |
| Deduct:   |                     |                |
| Total stock-based director compensation expense determined under fair-value-based method for all awards, net of related tax effects | 29,495              |                |
| Pro forma net loss  | \$(20,067,063)      | \$ (5,000,000) |
| Loss per share:   |                     |                |
| Basic - as reported   | \$ (0.28)           | \$ (0.28)      |
| Basic - pro forma   | \$ (0.28)           | \$ (0.28)      |

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

|       |       |
|-------|-------|
| 2004  | 2003  |
| ----- | ----- |

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|                               |        |        |
|-------------------------------|--------|--------|
| Risk free rate                | 4.13%  | 2.1%   |
| Expected years until exercise | 9.614  | 3.0    |
| Expected stock volatility     | 100.0% | 100.0% |
| Dividend yield                | --     | --     |
|                               | =====  | =====  |

### Loss Per Share

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

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

|                             | 2004       | 2003       |
|-----------------------------|------------|------------|
|                             | -----      | -----      |
| Options                     | 1,118,000  | 365,000    |
| Warrants                    | 18,151,891 | 6,780,237  |
| Convertible preferred stock | --         | 12,500,000 |
|                             | -----      | -----      |
|                             | 19,269,891 | 19,645,237 |
|                             | =====      | =====      |

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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 SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information."

#### Research and Development Costs

The cost of research, development and product improvement expenditures, which includes depreciation of the Company's laboratory, amortization and impairment of the technology access option, are charged to expense as they are incurred. Research, development and product improvement costs included in operating expenses amounted to \$7,689,060 and \$4,045,673 for the years ending December 31, 2004 and 2003, respectively; and \$22,728,050 for the period from March 12, 2001 (date of inception) to December 31, 2004.

Included in this amount were payments to related parties (see Note 11). Also included in the December 31, 2004 and for the period from March 12, 2001 (date of inception) to December 31, 2004 amount, is an impairment of intangible assets of \$2,797,612. (see Note 5).

#### Recently Issued Accounting Pronouncements

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In December 2004, the Financial Accounting Standards Board issued SFAS No. 123 (revised 2004), Share-Based Payment, which is a revision of SFAS No. 123, Accounting for Stock-Based Compensation. SFAS 123(R) supersedes Accounting Principles Board ("APB") Opinion No. 25, Accounting for Stock Issued to Employees. Generally, the approach in SFAS 123(R) is similar to the approach described in Statement 123. However, Statement 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. Statement 123(R) must be adopted no later than January 1, 2006 and early adoption is permitted in periods in which financial statements have not yet been issued.

As required, the Company will adopt SFAS No. 123(R) no later than January 1, 2006. Under SFAS No. 123(R), the Company may either recognize compensation cost for share-based payments to employees based on the grant-date fair value from the beginning of the period in which the provisions are first applied, without restating periods prior to adoption, or may elect to restate prior periods by recognizing compensation costs in the amounts previously reported in the pro-forma footnote disclosures under the provisions of SFAS 123. The Company is evaluating the impact of the two adoption methods and as yet has not determined which method we will utilize.

The Company cannot estimate the impact of adopting Statement No. 123(R) because it will depend on levels of share-based payments granted in the future but, based solely upon the pro-forma disclosures for prior periods, we believe that the impact will not be material to our results of operations.

### NOTE 3 - GOING CONCERN

The Company incurred net losses to common stockholders of \$20,037,568 and \$49,702,357 for the year ended December 31, 2004 and for the period March 12, 2001 (date of inception) to December 31, 2004, respectively. Included in these net losses were non-cash preferred stock dividends generated from beneficial conversion features of preferred stock in the amounts of \$10,750,000 for the year ended December 31, 2004 and \$22,218,750 in the cumulative net loss (see Note 8).

The Company estimates it has sufficient funds to meet operating expenses and capital requirements through the end of the second quarter of 2005.

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### NOTE 3 - GOING CONCERN (Continued)

Pharmaceutical products must undergo an extensive process, including testing in compliance with U.S. Food and Drug Administration ("FDA") regulations, before they can be commercially sold and distributed in the United States. FDA testing occurs in various phases over a multiple number of years. The Company expects to continue clinical testing of Psoraxine in 2005 and beyond. The Company will need significant additional funds to complete all of the testing required by the FDA. Currently, the Company has no products approved for commercial sale and therefore no means to generate revenue.

On March 14, 2005, the Company issued a press release to disclose the results of its Phase II study for Psoraxine. The Phase II study of our novel

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immuno-stimulatory product for the treatment of Psoriasis did not meet the primary study endpoint upon completion of the treatment phase of the study thereby providing inconclusive results. In the study, Psoraxine was found to be safe and well tolerated.

The Company is currently analyzing the data from our Phase II study to understand why the results differ from the long-term improvement of the more than 2,700 patients who were treated with Psoraxine in pre-clinical studies and whether a different approach, including evaluating a longer course of therapy and/or modifications to the formulation, may yield an outcome that is more consistent with results from pre-clinical studies.

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

Management plans to raise additional capital through private placement equity offerings in 2005. These funds, in addition to its cash held at December 31, 2004, will be needed in order to finance the Company's currently anticipated needs for operating and capital expenditures for 2005, including the cost to evaluate the results of the Phase II study, continue clinical trials of Psoraxine(R) and initiate development of pipeline products to treat arthritis and leishmaniasis. The Company will also need to raise significant additional funds from outside sources in future years in order to complete existing and future phases of FDA required testing.

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

### NOTE 4 - MARKETABLE SECURITIES

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

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

The Company had no available for sale securities as of December 31, 2004.

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NOTE 4 - MARKETABLE SECURITIES (Continued)

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

|                   | Due     | Amortized<br>Cost | Gross<br>Unrealized<br>Loss | Gross<br>Unrealized<br>Gains | Fair Value   |
|-------------------|---------|-------------------|-----------------------------|------------------------------|--------------|
|                   | -----   | -----             | -----                       | -----                        | -----        |
| Fixed Income Fund | Current | \$ 1,401,872      | \$ (27,740)                 | \$ 42                        | \$ 1,374,174 |
|                   |         | -----             | -----                       | -----                        | -----        |
|                   |         | \$ 1,401,872      | \$ (27,740)                 | \$ 42                        | \$ 1,374,174 |
|                   |         | =====             | =====                       | =====                        | =====        |

The Company's investment income (loss) consists of:

|   | Years Ended December 31, |            |
|---|--------------------------|------------|
|   | 2004                     | 2003       |
|   | -----                    | -----      |
| Interest income                           | \$ 127,409               | \$ 120,668 |
| Realized loss from disposal of securities | (128,131)                | (23,760)   |
| Bad debt expense                          | --                       | (36,890)   |
|   | -----                    | -----      |
|   | \$ (722)                 | \$ 60,018  |
|   | =====                    | =====      |

NOTE 5 - INTANGIBLE ASSETS

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

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

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

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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 evaluates this intangible annually for impairment under SFAS 144 "Accounting for the Impairment or Disposal of Long-Lived Assets." The Company has determined that as of December 31, 2004, the technology access option fee exceeded its fair market value and consequently the Company recorded impairment charges in the amount of \$2,797,612 in 2004.

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NOTE 5 - INTANGIBLE ASSETS - (Continued)

The Company has amortized \$6,362 and \$2,892 of patent costs and \$714,288 and \$714,288 of the cost of the technology option license in 2004 and 2003, respectively. The amortization and impairment related to the technology option license is recorded as research and development cost as required by SFAS No. 2.

Intangible assets consisted of the following at December 31,

|                               | 2004        | 2003         |
|-------------------------------|-------------|--------------|
|                               | -----       | -----        |
| Patent                        | \$ 130,109  | \$ 100,464   |
| Technology access fee         | 5,000,000   | 5,000,000    |
| Less impairment               | (2,797,612) | --           |
| Less accumulated amortization | (2,214,574) | (1,493,924)  |
|                               | -----       | -----        |
|                               | \$ 117,923  | \$ 3,606,540 |
|                               | =====       | =====        |

Amortization expense related to the patents is expected to be approximately \$6,400 per year for each of the succeeding five years.

NOTE 6 - PROPERTY AND EQUIPMENT

Property and equipment consisted of the following at December 31,

|   | 2004       | 2003       |
|---|------------|------------|
|   | -----      | -----      |
| Furniture and Fixtures                    | \$ 28,281  | \$ 28,281  |
| Computer Equipment                        | 30,477     | 21,803     |
| Leasehold Improvements                    | 199,741    | 196,544    |
| Lab Equipment                             | 299,066    | 236,781    |
| Automobiles                               | --         | 8,945      |
|   | -----      | -----      |
|   | \$ 557,565 | \$ 492,354 |
| Accumulated depreciation and amortization | (343,425)  | (199,305)  |
|   | -----      | -----      |
|   | \$ 214,140 | \$ 293,049 |
|   | =====      | =====      |

Depreciation expense amounted to \$147,252 and \$130,574 for the years ended

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December 31, 2004 and 2003, respectively. The depreciation related to the Company's laboratory and related equipment is recorded as research and development as required by SFAS No. 2.

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NOTE 7 - INCOME TAXES

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

|   | December 31,<br>2004 | 2003        |
|---|----------------------|-------------|
|   | -----                | -----       |
| Deferred tax assets :   |                      |             |
| Prepaid research and development  | \$ --                | \$ 798,800  |
| Deferred compensation   | 77,000               | 76,500      |
| Accumulated depreciation and amortization   | 332,000              | 1,613,200   |
| Research and development credits carryforward   | 1,974,300            | 1,125,400   |
| Federal and state deferred tax benefit arising from<br>net operating loss carryforwards | 8,370,600            | 5,612,500   |
|   | -----                | -----       |
|   | 12,034,600           | 7,945,700   |
| Less valuation allowance  | (12,034,600)         | (7,945,700) |
|   | -----                | -----       |
| Total deferred tax assets   | \$ --                | \$ --       |
|   | =====                | =====       |

As of December 31, 2004, the Company had losses, which resulted in net operating loss carryforwards for tax purposes amounting to approximately \$22,000,000 that may be offset against future taxable income. These carryforwards start to expire in 2021. The Company generated federal research and development credits of \$1,350,300 that will start to expire in 2021 and state credits of \$624,000 that will start to expire in 2008. However, these carryforwards and credits may be significantly limited due to changes in the ownership of the Company as a result of future equity offerings.

Recognition of the benefits of the deferred tax assets and liabilities will require that the Company generate future taxable income. There can be no assurance that the Company generates any earnings or any specific level of earnings in future years. Therefore, the Company has established a valuation allowance for deferred tax assets (net of liabilities) of approximately \$12,034,600 and \$7,945,700 as of December 31, 2004 and 2003.

In 2004 and 2003, the Company sold \$3,791,489 and \$2,863,511, respectively, of its gross New Jersey net operating loss carryforwards under the State of New



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Jersey's Technology Business Tax Certificate Transfer Program (the "Program"). The Program allows qualified technology and biotechnology businesses in New Jersey to sell unused amounts of net operating loss carryforwards and defined research and development tax credits for cash. The proceeds from the sale of the Company's carryforwards were \$293,461 and \$221,600, respectively (net of fees) and the amount was recorded as a tax benefit in the statements of operations. The State of New Jersey renews the Program annually and limits the aggregate proceeds of the program to \$10,000,000. Due to the uncertainty at any time as to the Company's ability to effectuate the sale of available New Jersey net operating losses, and since the Company has no control or influence over the Program, the benefits are recorded once the agreement with the counterpart is signed and the sale is approved by the State.

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

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ASTRALIS, LTD.  
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NOTE 7 - INCOME TAXES (Continued)

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

|   | December 31, |              |
|---|--------------|--------------|
|   | 2004         | 2003         |
| Federal income tax benefit at statutory rate                | \$ 3,257,550 | \$ 1,802,700 |
| State income tax benefit (net of effect of federal benefit) | 446,600      | 296,300      |
| Non-deductible expenses                                     | (170,650)    | (130,300)    |
| Research and development credit                             | 848,900      | 688,200      |
| Valuation allowance before realization of state benefit     | (4,382,400)  | (2,656,900)  |
| Benefit from sale of state net operating loss               | 293,500      | 221,600      |
|   | \$ 293,500   | \$ 221,600   |
| Income Tax Benefit  | \$ 293,500   | \$ 221,600   |
|   | =====        | =====        |
| Effective Income Tax Rate                                   | (9%)         | (13%)        |
|   | =====        | =====        |

NOTE 8 - CAPITAL STOCK ACTIVITY

Common Stock

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

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ownership and 6,300,000 options to purchase member units.

Prior to the Merger

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.

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

On September 1, 2001, five new members were admitted as members of the LLC through the execution of a subscription agreement. These new members subscribed to units ("Units") from Astralis LLC consisting of an aggregate of 2,700,000 membership interests (the "Membership Interests") in Astralis LLC and 6,300,000 options to purchase additional Membership Interests in Astralis LLC for an exercise price of \$1.60 per Membership Interest.

On November 13, 2001, the aforementioned Units were exchanged for an aggregate of 2,700,000 shares of our common stock and warrants to purchase 6,300,000 shares of common stock at an exercise price of \$1.60 per share. The aggregate purchase price for such Units was \$1,350,000 and was paid with subscription notes. Warrants to purchase 3,150,000 shares of common stock, as amended, were to expire on December 13, 2004 and 3,150,000 expire November 13, 2006. The 3,150,000 warrants that were set to expire on December 13, 2004 were extended to February 18, 2005 and subsequently extended to March 11, 2005 when they expired.

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ASTRALIS, LTD.  
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Notes to Financial Statements

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

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

Subsequent to Merger

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

In January 2002, the Company agreed to amend a subscription agreement with one of the investors who participated in the November 2001 private placement

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offering. The Company consented to reduce the number of shares in the subscription agreement by 49,990 shares of common stock. The Company cancelled the respective shares and returned the corresponding amount of funds to the investor amounting to \$80,000.

In 2002 and 2003, the Company collected \$465,000 and \$825,000 in cash of the subscription receivables, respectively. In April 2003, the Company entered into the Amended Investor Relation Agreement with one of the stockholders who has outstanding subscription receivable with the Company. The Company agreed to receive services in lieu of payment of the outstanding subscription receivable in the amount of \$60,000. In 2004 and 2003, the Company received services valued at \$24,000 and \$36,000, respectively.

On December 15, 2003, the Company amended its Articles of Incorporation to authorize the issuance of 150,000,000 shares of common stock, \$0.0001 par value per share, and 3,000,000 shares of Series A preferred stock, \$0.001 par value of which 73,173,055 shares of common and 0 share of Series A preferred were outstanding as of December 31, 2004.

On January 20, 2004, the Company closed a private placement from which it received gross proceeds of approximately \$4,080,000. The transaction consisted of the sale to accredited investors of units consisting of 8,159,964 shares of common stock and warrants to purchase 8,159,964 shares of common stock. The warrants have an exercise price of \$0.73 and expire in four years.

On February 19, 2004, the Company closed the second round of its private placement from which it received \$1,150,000. The transaction consisted of sales to accredited investors of units consisting of 2,299,902 shares of common stock and warrants to purchase 2,299,902 shares of common stock. The warrants have an exercise price of \$0.73 and expire in four years.

FPP Capital Advisors whose sole stockholder is a director of the Company was paid a consulting fee in the amount of \$261,496 in February 2004 for the consulting services related to the private placement completed in 2004. In addition, the related party and his assignees received warrants to purchase an aggregate of 418,394 shares of the Company's common stock at \$0.50 per share and warrants to purchase an aggregate of 418,394 shares of the Company's common stock at \$0.73 per share. An additional consulting fee equal to 5% of proceeds received will be paid upon exercise of the warrants issued in the private placements. The warrants expire in four years.

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NOTE 8 - CAPITAL STOCK ACTIVITY (Continued)

The Company issued to FPP Capital Advisors (a related party) 150,000 shares of common stock and warrants to purchase 150,000 shares of common stock for consulting services valued at \$75,000. The warrants have an exercise price of \$0.73 and expire in five years. In addition, in connection with the conversion by SkyePharma of its shares of the Company's Series A Preferred Stock, the Company assigned to FPP Capital Advisors, as compensation, 10% of the call option provided to the Company under the call option agreement dated January 20, 2004 between the Company and SkyePharma. Accordingly, the Company recorded a non-cash charge of \$376,508 in June 2004.

On July 9, 2004 a director of the Company exercised options to purchase 25,000

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shares of common stock at \$0.45 a share. The shares issued remain restricted.

### Preferred Stock

On December 13, 2001, the Company authorized 2,000,000 shares of preferred stock to be designated as "Series A Convertible Preferred Stock" ("Series A Preferred Stock") with a \$0.001 par value per share. If the Company declares a dividend, holders of each share of Series A Preferred are entitled to non-cumulative cash dividends which will be the greater of i) 6% of the preferred share purchase price; or ii) the amount such holders would have received had the holders converted to common stock immediately prior to record date for payment of a dividend to holders of common stock. No dividend can be declared or paid on common stock without an equal or greater dividend being paid or declared on the Series A Preferred. Holders of each share of Series A Preferred were entitled to vote on all matters at stockholder meetings. Holders of each share of the Series A Preferred could convert their shares to common stock at an initial conversion price of \$2.50. The conversion price could be adjusted and reset as set forth in the purchase agreement for the Series A Preferred.

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

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

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

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

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

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NOTE 8 - CAPITAL STOCK ACTIVITY (Continued)

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On January 20, 2004, Skyepharma converted all of its outstanding shares of Series A Preferred Stock of the Company into 25,000,000 shares of common stock at a reduced conversion price of \$0.80 per share. Skyepharma agreed that up to 12,500,000 shares of its common stock issued upon conversion of the Series A Preferred Stock will be subject to a call option at the discretion of the Company upon completion of an agreed upon milestone at a premium in excess of the conversion price. The call option can be exercised on or after July 21, 2004. In connection with this transaction and in accordance with SFAS 84, "Induced Conversions of Convertible Debt, an Amendment of APB Opinion No. 26" the Company recorded a non-cash preferred stock dividend in January 2004 amounting to \$10,750,000.

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

In the first quarter of 2005 SkyePharma purchased the outstanding stock, 11,160,000 shares, and related rights from Mike Ajnsztajn and Gaston Liebhaber. Consequently, as of March 3, 2005 SkyePharma owns approximately 49.8% of the Company's outstanding common stock.

### Stock Warrants

At December 31, 2004, the Company had the following outstanding common stock warrants to purchase its securities:

| Number of Warrants<br>Issued | Exercise Price<br>Per Share |
|------------------------------|-----------------------------|
| 18,151,891                   | \$0.50 - \$4.00             |

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

### NOTE 9 - STOCK OPTION PLAN

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

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applicable law.

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NOTE 9 - STOCK OPTION PLAN - (Continued)

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

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

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 stockholders' equity with an offsetting increase to additional paid-in capital. The Company then amortizes deferred compensation into stock-based compensation expense over the performance period, which typically coincides with the vesting period of the stock-based award.

During April 2003, the Company granted options to purchase 50,000 shares of common stock at an exercise price of \$0.45 per share to one of its directors. Options to purchase 12,500 shares of common stock vested on April 4, 2003, and options to purchase an additional 12,500 shares will vest each year thereafter for the following three years. In July 2004, 25,000 vested options were exercised.

On July 2, 2004, the Company granted options to purchase 50,000 shares of common stock at an exercise price of \$1.00 per share to one of its directors. Options to purchase 12,500 shares of common stock vested on grant date and options to purchase an additional 12,500 shares will vest each year thereafter for the following three years. The term of the options is four years.

During December 2004, the Company granted options to purchase 728,000 shares of common stock at an exercise price of \$0.70 per share to one of its officers. The options are vested immediately and expire in ten years.

NOTE 10 - DEFERRED COMPENSATION

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

|  | 2004     | 2003      |
|--|----------|-----------|
|  | -----    | -----     |
| Balance at January 1                     | \$ 4,822 | \$ 12,164 |
| Deferred compensation recorded           | --       | --        |
| Fair value adjustments                   | --       | 18,321    |
| Amortization to stock-based compensation | (4,822)  | (25,663)  |

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|                        |       |          |
|------------------------|-------|----------|
|                        | ----- | -----    |
| Balance at December 31 | \$ -- | \$ 4,822 |
|                        | ===== | =====    |

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NOTE 10 - DEFERRED COMPENSATION - (Continued)

Exercise prices for stock options outstanding as of December 31, 2004 and the weighted average remaining contractual life are as follows:

| Exercise Prices | Options Outstanding | Weighted Average<br>Remaining<br>Contractual Life | Number<br>Exercisable |
|-----------------|---------------------|---|-----------------------|
| -----           | -----               | -----   | -----                 |
| \$ 0.45         | 25,000              | 3.25 years  | --                    |
| \$ 0.70         | 728,000             | 10 years  | 728,000               |
| \$ 1.00         | 50,000              | 3.5 years   | 12,500                |
| \$ 2.50 - 2.75  | 315,000             | 1.08 year   | 315,000               |

In accordance with FAS 123 the fair value of the options were estimated as of the date of the grant or subsequent vesting date, or December 31, 2004 if not vested, using a Black-Scholes option-pricing model. The assumptions used in estimating the fair value of the options ranged as follows:

|                         |              |
|-------------------------|--------------|
| Volatility              | 100% - 130%  |
| Risk-free interest rate | 2.1% - 4.19% |
| Expected life           | 1 - 10 years |
| Dividend yield          | --           |

NOTE 11 - 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.

SkyePharma PLC Agreements

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

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

The Company entered into a technology option agreement whereby it agreed to pay SkyePharma \$5,000,000 in return for the right, for 7 years, to enter into a non-exclusive license agreement with SkyePharma to utilize three drug delivery systems (\$2,000,000, \$2,000,000, and \$1,000,000, respectively per delivery system). The royalty fee in this license

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

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

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 technology option cost basis exceeded its fair value under the FAS No. 144 test as of December 31, 2004 and consequently the Company recorded an impairment charge of \$2,797,612 in relation to the option (see Note 5).

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

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

SkyePharma has the right of first negotiation to acquire the worldwide licensing and distribution rights to Psoraxine up to the completion of the Phase II studies. On completion of Phase II studies, Astralis will offer SkyePharma the



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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.

As of March 7, 2005, SkyePharma owns approximately 49.8% of the Company's outstanding common stock.

### 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.

### NOTE 12 - OPERATING LEASES

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

During 2003 and 2004, the Company leased two apartments and an automobile for two different key employees, one of whom is an officer. One of the leases terminated in August 2004. As of December 31, 2004, the Company had one lease outstanding for an apartment of a key employee and one auto lease outstanding.

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

### NOTE 12 - OPERATING LEASES (Continued)

The Company incurred rent expense in the amount of \$128,443 and \$137,070 for 2004 and 2003, respectively.

The following is a schedule by year of future minimum rental payments required under operating leases, as of December 31, 2004:

| Year Ending December 31: |           |
|--------------------------|-----------|
| 2005                     | \$ 58,835 |
| 2006                     | 1,908     |
| 2007                     | 1,113     |

### NOTE 13 - COMPREHENSIVE LOSS

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

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|  | Year Ended December 31, |                |
|--|-------------------------|----------------|
|  | 2004                    | 2003           |
| Net loss to common stockholders                              | \$ (20,037,568)         | \$ (5,080,427) |
| Unrealized gain (loss) on securities:                        |                         |                |
| Unrealized gain (loss) arising during period                 | --                      | (26,245)       |
| Reclassification adjustment for loss realized<br>in net loss | 27,698                  | 13,728         |
| Unrealized gain (loss), net                                  | 27,698                  | (12,517)       |
| Comprehensive loss   | \$ (20,009,870)         | \$ (5,092,944) |

NOTE 14 - CONCENTRATIONS

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

NOTE 15 - SUPPLEMENTARY DISCLOSURES OF CASH FLOW INFORMATION

The Company did not pay any interest or taxes in 2004 or 2003.

NOTE 16 - SUBSEQUENT EVENTS

In January 2005, the Company entered into an Employment Agreement with the newly hired Chief Executive Officer of the Company. The agreement is for a term of two years and will be automatically renewed for an unlimited number of additional terms of one year each unless either party provides written notice of termination at least ninety days prior to the end of such term.

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

NOTE 16 - SUBSEQUENT EVENTS (Continued)

In January 2005, the Company issued 100,000 shares of the Company's common stock along with 728,000 options to a newly hired officer of the Company. The options were issued with an exercise price of \$0.70 per share and vest equally over four years, with a term of ten years.

On March 14, 2005, the Company issued a press release to disclose the results of its Phase II study for Psoraxine. The Phase II study of our novel immuno-stimulatory product for the treatment of Psoriasis did not meet the primary study endpoint upon completion of the treatment phase of the study

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thereby providing inconclusive results. In the study, Psoraxine was found to be safe and well tolerated.

The Company is currently analyzing the data from the Phase II study to understand why the results differ from the long-term improvement of the more than 2,700 patients who were treated with Psoraxine in pre-clinical studies and whether a different approach, including evaluating a longer course of therapy and/or modifications to the formulation, may yield an outcome that is more consistent with results from pre-clinical studies.

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### INTERIM FINANCIAL STATEMENTS

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### FINANCIAL INFORMATION

ASTRALIS LTD.  
(A Development Stage Entity)  
Condensed Balance Sheets

#### ASSETS

|                              | June 30,<br>2005     | December<br>2004 |
|------------------------------|----------------------|------------------|
|                              | -----<br>(Unaudited) | -----<br>(Audit) |
| Current Assets               |                      |                  |
| Cash and cash equivalents    | \$ 483,809           | \$ 2,312         |
| Accrued interest receivable  | 580                  |                  |
| Prepaid expenses             | 80,516               | 70               |
| Supplies                     | 36,121               | 55               |
|                              | -----                | -----            |
| Total Current Assets         | 601,026              | 2,439            |
| Other Intangible Assets, Net | 118,593              | 117              |
| Property and Equipment, Net  | 147,031              | 214              |
| Deposits                     | 26,763               | 26               |
|                              | -----                | -----            |
|                              | \$ 893,413           | \$ 2,797         |
|                              | =====                | =====            |

#### LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)

|                                       |            |        |
|---------------------------------------|------------|--------|
| Current Liabilities                   |            |        |
| Accounts payable and accrued expenses | \$ 983,147 | \$ 397 |
|                                       | -----      | -----  |
| Total Current Liabilities             | 983,147    | 397    |
|                                       | -----      | -----  |
| Commitments and Contingencies         |            |        |

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|  |              |          |
|--|--------------|----------|
| Stockholders' Equity (Deficit)   |              |          |
| Common stock; \$.0001 par value; 150,000,000 shares authorized<br>at 2005 and 2004; 73,173,055 issued and outstanding at 2005<br>and 2004, 100,000 and 0 issuable at 2005 and 2004, respectively | 7,327        | 7        |
| Additional paid-in capital   | 52,160,241   | 52,095   |
| Deficit accumulated in the development stage   | (52,257,302) | (49,702) |
|  | (89,734)     | 2,400    |
| Total Stockholders' Equity (Deficit)   | (89,734)     | 2,400    |
|  | \$ 893,413   | \$ 2,797 |
|  | 893,413      | 2,797    |

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

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

|  | Three Months Ended June 30, |             | Six Months Ended |
|--|-----------------------------|-------------|------------------|
|  | 2005                        | 2004        | 2005             |
| Revenues                                 | \$ --                       | \$ --       | \$ --            |
| Operating Expenses                       |                             |             |                  |
| Research and development - related party | --                          | 430,447     | --               |
| Research and development                 | 507,708                     | 689,800     | 1,594,372        |
| Depreciation and amortization            | 6,724                       | 7,530       | 14,646           |
| General and administrative               | 365,288                     | 762,317     | 961,797          |
|  | 879,720                     | 1,890,094   | 2,570,815        |
| Total Operating Expenses                 | 879,720                     | 1,890,094   | 2,570,815        |
| Loss From Operations                     | (879,720)                   | (1,890,094) | (2,570,815)      |
| Investment Income                        | 4,972                       | 15,349      | 15,870           |
| Loss Before Income Tax Benefit           | (874,748)                   | (1,874,745) | (2,554,945)      |
| Income Tax Benefit                       | --                          | --          | --               |
| Net Loss                                 | (874,748)                   | (1,874,745) | (2,554,945)      |
| Preferred Stock Dividends                | --                          | --          | --               |

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|   |              |                |                |
|---|--------------|----------------|----------------|
| Net Loss to Common Stockholders                                 | \$ (874,748) | \$ (1,874,745) | \$ (2,554,945) |
|   | =====        | =====          | =====          |
| Basic and Diluted Loss per Common Share                         | \$ (0.01)    | \$ (0.03)      | \$ (0.03)      |
|   | =====        | =====          | =====          |
| Basic and Diluted Weighted Average<br>Common Shares Outstanding | 73,273,055   | 73,042,560     | 73,248,746     |
|   | =====        | =====          | =====          |

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

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

|   | Six Months Ended |                |
|---|------------------|----------------|
|   | June 30, 2005    | June 30, 2004  |
|   | -----            | -----          |
| Cash Flows from Operating Activities  |                  |                |
| Net loss  | \$ (2,554,945)   | \$ (3,622,718) |
| Adjustments to reconcile net loss to net cash used in operating activities                          |                  |                |
| Depreciation and amortization   | 73,005           | 430,716        |
| Impairment of intangible asset  | --               | --             |
| Amortization of net premium paid on investments   | --               | --             |
| Dividends reinvested  | --               | (75,970)       |
| Members' contributed salaries   | --               | --             |
| Research and development service fee netted against proceeds received from preferred stock issuance | --               | --             |
| Operating expenses paid by related parties on behalf of Company                                     | --               | --             |
| Amortization of deferred compensation   | --               | 2,576          |
| Investor relations fee netted against subscription receivable                                       | --               | 24,000         |
| Compensatory common stock   | 65,000           | 75,000         |
| Assignment of call options as compensation  | --               | 376,508        |
| (Gain) loss on sale of available-for-sale securities  | --               | 50,317         |
| Changes in assets and liabilities   |                  |                |
| Prepaid expenses  | (9,621)          | 518,071        |
| Interest receivable   | (580)            | --             |
| Supplies  | 19,730           | 18,487         |
| Deposits  | --               | --             |
| Accounts payable and accrued expenses   | 585,385          | (68,303)       |
|   | -----            | -----          |
| Net Cash Used in Operating Activities   | (1,822,026)      | (2,271,316)    |
|   | -----            | -----          |
| Cash Flows from Investing Activities  |                  |                |
| Purchases of available-for-sale securities  | --               | (4,300,010)    |

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|   |             |             |
|---|-------------|-------------|
| Proceeds from sale of available-for-sale securities             | --          | 1,902,407   |
| Expenditures related to patent                                  | (4,113)     | (19,135)    |
| Insurance proceeds from fixed asset retirement                  | --          | --          |
| Purchases of property and equipment                             | (2,453)     | (35,425)    |
|   | -----       | -----       |
| Net Cash Used in Investing Activities                           | (6,566)     | (2,452,163) |
|   | -----       | -----       |
| Cash Flows from Financing Activities                            |             |             |
| Repurchase of common stock                                      | --          | --          |
| Proceeds from stock subscription receivable                     | --          | --          |
| Proceeds from exercise of stock options                         | --          | --          |
| Issuance of common stock, net of offering and transaction costs | --          | 4,954,191   |
| Issuance of preferred stock                                     | --          | --          |
| Private placement offering costs                                | --          | --          |
|   | -----       | -----       |
| Net Cash Provided by Financing Activities                       | --          | 4,954,191   |
|   | -----       | -----       |
| Net Increase in Cash and Cash Equivalents                       | (1,828,592) | 230,712     |
| Cash and Cash Equivalents, Beginning of Period                  | 2,312,401   | 10,660      |
|   | -----       | -----       |
| Cash and Cash Equivalents, End of Period                        | \$ 483,809  | \$ 241,372  |
|   | =====       | =====       |

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

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

NOTE 1 - BASIS OF PRESENTATION

The unaudited condensed financial statements included herein have been prepared by Astralis, Ltd. (the "Company"), without audit, pursuant to the rules and regulations of the Securities and Exchange Commission. The financial statements reflect all adjustments that are, in the opinion of management, necessary to fairly present such information. All such adjustments are of a normal recurring nature. Although the Company believes that the disclosures are adequate to make the information presented not misleading, certain information and footnote disclosures, including a description of significant accounting policies normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America, have been condensed or omitted pursuant to such rules and regulations.

These financial statements should be read in conjunction with the financial statements and the notes thereto included in the Company's 2004 Annual Report on Form 10-KSB filed with the Securities and Exchange Commission. The results of operations for interim periods are not necessarily indicative of the results for any subsequent quarter or the entire fiscal year ending December 31, 2005.

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### Stock Based Compensation

On April 4, 2003, the Company granted stock-based director compensation options to one member of the Board of Directors. The Company accounts for those options under the recognition and measurement principles of Accounting Principles Board (APB) Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. No stock-based director compensation cost is included in net loss, as all the options granted had an exercise price equal to the market value of the stock on the date of grant. The following table illustrates the effect on net loss and earnings per share if the Company had applied the fair value recognition provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation," to stock-based compensation.

|   | Three Months Ended<br>June 30, |                |        |
|---|--------------------------------|----------------|--------|
|   | 2005                           | 2004           |        |
| Net loss to common stockholders, as reported  | \$ (874,748)                   | \$ (1,874,745) | \$ (2) |
| Add: Stock-based employee/ director compensation included in reported net loss  | --                             | --             |        |
| Deduct: Total stock-based employee/director compensation expense under the fair value based method for all awards, net of tax | (154,826)                      | (1,014)        |        |
| Pro forma net loss  | (1,029,574)                    | \$ (1,875,759) | (2)    |
| Loss per share basic and diluted - as reported  | \$ (0.01)                      | \$ (0.03)      | \$     |
| Loss per share basic and diluted - pro forma  | \$ (0.01)                      | \$ (0.03)      | \$     |
| Shares used in basic and diluted loss per share amounts   | 73,273,055                     | 73,042,560     | 73     |

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

#### NOTE 2 - DESCRIPTION OF BUSINESS

##### Nature of Operations

Astralix, Ltd. (the "Company") is an emerging stage biotechnology company, based in New Jersey and incorporated under the laws of the State of Delaware, which primarily engages in research and development of treatments for immune system disorders and skin diseases. The Company is currently developing two products. Its primary product, Psoraxine(R), administered by intramuscular injection, is an innovative immunotherapeutic product under development for the treatment of psoriasis. The Company's second product is for the treatment of arthritis. The Company is engaged in on-going research and development of Psoraxine(R) and expects to recommence clinical trials to obtain the approval of the United States Food and Drug Administration for the marketing of Psoraxine(R), and

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development of the technology underlying the Psoraxine(R), for the treatment of other indications, such as eczema, leishmaniasis and seborrheic dermatitis.

### NOTE 3 - GOING CONCERN

The Company incurred net losses to common stockholders of \$2,554,945 and \$52,257,302 for the six-month period ended June 30, 2005 and for the period March 12, 2001(date of inception) to June 30, 2005, respectively. Included in the cumulative net losses was non-cash preferred stock dividend generated from beneficial conversion features of preferred stock in the amount of \$22,218,750.

The Company estimates it has sufficient funds to meet operating expenses and capital requirements through the end of January 2006.

Pharmaceutical products must undergo an extensive process, including testing in compliance with U.S. Food and Drug Administration ("FDA") regulations, before they can be commercially sold and distributed in the United States. FDA testing occurs in various phases over a multiple number of years. The Company expects to continue clinical testing of Psoraxine in 2005 and beyond. The Company will need significant additional funds to complete all of the testing required by the FDA. Currently, the Company has no products approved for commercial sale and therefore no means to generate revenue.

On March 14, 2005, the Company issued a press release to disclose the results of its Phase II study for Psoraxine. The Phase II study of its novel immuno-stimulatory product for the treatment of Psoriasis indicated no statistical difference between the Company's product and a placebo. In the study, Psoraxine was found to be safe and well tolerated.

The Company is currently analyzing the data from its Phase II study to understand why the results differ from the long-term improvement of the more than 2,700 patients who were treated with Psoraxine in pre-clinical studies and whether a different approach, including evaluating a longer course of therapy and/or modifications to the formulation, may yield an outcome that is more consistent with results from pre-clinical studies.

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

The Company raised \$2,000,000 additional capital in August 2005 through a private placement equity offering. These funds, in addition to its cash held at June 30, 2005, are sufficient to finance the Company's needs for operating and capital expenditures through January 2006, including the cost to evaluate the results of the Phase II study, recommence clinical trials of Psoraxine(R) and initiate development of pipeline products to treat arthritis and leishmaniasis. The Company will also need to raise significant additional funds from outside sources in future years in order to complete existing and future phases of FDA required testing.

The Company's ability to continue as a going concern is dependent upon raising capital through debt and equity financing. There can be no assurance that the Company will successfully raise the required future financing on terms desirable to the Company or that the FDA will approve Psoraxine for use in the United

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States. If the Company does not obtain the needed funds, it will likely be required to delay development of its products, alter its business plan, or in the extreme situation, cease operations.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets and amounts and classifications of liabilities that might result from the outcome of this uncertainty.

### NOTE 4 - CAPITAL STOCK ACTIVITY

In the first quarter of 2005 SkyePharma purchased the outstanding stock, 11,160,000 shares, and related rights from Mike Ajnsztajn and Gaston Liebhaber. Consequently, as of March 3, 2005 SkyePharma owns approximately 49.7% of the Company's outstanding common stock.

In January 2005, the Company issued 100,000 shares of the Company's common stock along with 728,000 options to a newly hired officer of the Company. The options were issued with an exercise price of \$0.70 per share and vest equally over three years, with a term of ten years.

On February 2, 2005, the Company issued 20,000 options to a director. The options were issued with an exercise price of \$0.69 and with a term of 10 years. The options vest over three years, with the first twenty-five percent vesting on the date of grant.

On April 11, 2005, the Company issued 50,000 options to a newly elected director. The options were issued with an exercise price of \$0.26 and with a term of 10 years. The options vest over three years, with the first twenty-five percent vesting on the date of grant.

On June 4, 2005, the Company issued 20,000 options to a director. The options were issued with an exercise price of \$0.28 and with a term of 10 years. The options vest over three years, with the first twenty-five percent vesting on the date of grant.

### NOTE 5 - NET LOSS PER SHARE

Basic and diluted net loss per common share are presented in accordance with Statement of Financial Accounting Standards No. 128, Earnings Per Share ("FAS 128"), for all periods presented. In accordance with FAS 128, basic and diluted net loss per common share have been computed using the weighted-average number of shares of common stock outstanding during the period. Shares associated with stock options, stock warrants, and convertible preferred stock are not included because the inclusion would be anti-dilutive (i.e., reduce the net loss per share). The total number of such shares excluded from diluted net loss per common share were 17,007,891 and 18,576,891 at June 30, 2005 and 2004, respectively.

### NOTE 6 - SUPPLEMENTARY DISCLOSURE OF CASH FLOW INFORMATION

In April 2005, the Company financed \$24,184 of its business liability insurance premiums by entering into a short-term note payable. The note matures on February 16, 2006 and bears interest at a rate of 6.75% per annum. As of June 30, 2005, this note had an outstanding balance of \$19,455.

In January 2005, the Company financed \$33,516 of its directors and officers liability insurance premiums by entering into a short-term note payable. The note matures on November 10, 2005 and bears interest at a rate of 5.75% per annum. As of June 30, 2005, this note had an outstanding balance of \$13,599.

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In December 2004, the Company financed \$28,280 of its directors and officers liability insurance premiums by entering into a short-term note payable. The note matures on October 10, 2005 and bears interest at a rate of 6.65% per annum. As of June 30, 2005 and December 31, 2004, this note had an outstanding balance of \$9,583 and \$28,280, respectively.

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

### NOTE 7 - RECLASSIFICATION

For comparability purposes, certain figures for the prior periods have been reclassified where appropriate to conform with the financial statement presentation used in 2004. These reclassifications had no effect on the reported net loss.

### NOTE 8 - SUBSEQUENT EVENTS

On August 19, 2005, we closed a private placement of securities from which we received gross proceeds of approximately \$2,000,000. The transaction consisted of the sale to one accredited investor, Blue Cedar Limited ("Blue Cedar"), of units consisting of: (i) 18,181,818 shares of common stock, (ii) warrants to purchase over a 5-year period 18,181,818 shares of common stock with an exercise price of \$0.165 and (iii) warrants to purchase over a 12-month period 12,121,212 shares of common stock with an exercise price of \$0.165. We relied upon the exemption from registration provided under Section 4(2) of the Securities Act of 1933, as amended (the "Securities Act") and Rule 506 of Regulation D promulgated thereunder. The private placement was only made available to one "accredited investor" as defined in Rule 501 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. Lipworth Capital Limited acted as our placement agent in connection with the private placement. We paid an 8% fee to our placement agent and issued warrants to purchase 1,454,545 shares of common stock with an exercise price of \$0.165, in connection with the financing in addition to other costs. Additionally, we granted Blue Cedar certain registration rights pursuant to a registration rights agreement, dated as of August 17, 2005, in connection with this transaction. The registration rights agreement requires the Company to file a registration statement within approximately 30 days of the final closing of our private placement covering the resale of all shares included therein, as well as the shares underlying the warrants. If the registration statement is not filed or effective by the dates specified in the agreement, the Company is subject to a penalty of 0.5% per month of the aggregate purchase price .

In August 2005 the Board of Directors approved a resolution, subject to stockholder approval, to increase the authorized number of common stock by 200,000,000 shares.

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## PART II

### INFORMATION NOT REQUIRED IN PROSPECTUS

Item 24. Indemnification of Directors and Officers

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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 includes 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 proceedings 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 our officers, directors, employees and agents 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 Delaware law.

### Item 25. Other Expenses of Issuance and Distribution

Expenses payable in connection with the issuance and distribution of the securities being registered (estimated except in the case of the registration fee) are as follows:

|                              | Amount<br>----- |
|------------------------------|-----------------|
| Printing                     | N/A             |
| Legal Fees and Expenses      | \$ 60,000       |
| Accounting Fees and Expenses | \$ 20,000       |
| Miscellaneous                | \$160,000       |
| TOTAL                        | \$240,000       |

The above fees will be paid by us and not by the selling stockholders.

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### Item 26. Recent Sales of Unregistered Securities

On August 19, 2005, we completed a private placement of securities from which we received gross proceeds of approximately \$2,000,000. The transaction consisted of the sale to an accredited investor, Blue Cedar Limited ("Blue Cedar"), of units consisting of: (i) 18,181,818 shares of common stock, (ii) warrants to purchase over a 5-year period 18,181,818 shares of common stock with an exercise price of \$0.165 and (iii) warrants to purchase over a 12-month period 12,121,212 shares of common stock with an exercise price of \$0.165. We relied upon the exemption from registration provided under Section 4(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder. The private placement was only made available to one "accredited investor" as defined in Rule 501 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.

In June 2004, we issued units consisting of 150,000 shares of common stock and warrants to purchase 150,000 shares of common stock to FPP Capital Advisors in consideration for services rendered in negotiating the Call Option Agreement dated January 12, 2004 between us and SkyePharma. In addition, we assigned to FPP Capital Advisors the right to purchase 1,250,000 shares of our common stock pursuant to the Call Option Agreement dated January 12, 2004 between us and SkyePharma. We relied on the exemption from registration with the Securities and Exchange Commission provided under Section 4(2) and Rule 506 of Regulation D

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under the Securities Act of 1933.

On January 20, 2004 and February 19, 2004, we sold to accredited investors units consisting of an aggregate of 10,459,866 shares of common stock and warrants to purchase 10,459,866 shares of common stock for an aggregate purchase price of approximately \$5.23 million. In connection with this transaction, FPP Capital Advisors and certain other persons who assisted FPP Capital Advisors in providing consulting services to us received a consulting fee of \$261,496, warrants to purchase an aggregate of 418,394 shares of our common stock at \$0.50 per share and warrants to purchase an aggregate of 418,394 shares of our common stock at \$0.73 per share. One of these other selling stockholders, Manuel Tarabay, received warrants to purchase 72,000 shares of common stock, and became a member of the Board of Directors in August 2005. 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 entered into a Purchase Agreement dated as of December 10, 2001 with SkyePharma PLC, a company incorporated under the laws of England and Wales. Pursuant to the Purchase Agreement, SkyePharma purchased, during a thirteen month period ending January 31, 2003, 2,000,000 shares of our Series A Preferred Stock, par value \$.001 per share, at a purchase price of \$10.00 per share, or an aggregate purchase price of \$20.0 million. We relied on the exemption from registration with the Securities and Exchange Commission provided under Section 4(2) and Rule 506 of Regulation D under the Securities Act of 1933. On January 20, 2004, pursuant to an Omnibus Conversion Agreement dated January 12, 2004 between us and SkyePharma, SkyePharma converted all of its shares of our Series A Preferred Stock into 25,000,000 shares of common stock at a conversion price of \$0.80 per share. We relied on the exemption from registration with the Securities and Exchange Commission provided under Section 4(2) and Rule 506 of Regulation D under the Securities Act of 1933.

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

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

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

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

During May 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. We relied on the exemption from registration afforded by Section 4(2) of the Securities Act of 1933.

### Item 27. Exhibits

| Exhibit Number | Description   |
|----------------|---|
| -----          | -----   |
| 3.1 *          | Certificate of Incorporation of Astralis Ltd.   |
| 3.2 **         | Bylaws of Astralis Ltd.   |
| 4.1 +++        | Specimen Stock Certificate  |
| 5.1 @          | Opinion of McCarter & English, LLP  |
| 10.1 **        | Agreement and Plan of Merger  |
| 10.2 #         | Contribution Agreement dated September 10, 2001   |
| 10.3 ##        | Purchase Agreement dated December 10, 2001  |
| 10.4 ##        | Stockholder Agreement dated December 10, 2001   |
| 10.5 +         | 2001 Stock Option Plan  |
| 10.6 ***       | Sub-Lease Agreement   |
| 10.7 ***       | License Agreement dated April 26, 2001 between Jose Antonio O'Daly and Astralis LLC   |
| 10.8 ***       | Assignment of License   |
| 10.9 ***       | Form of Warrant   |
| 10.10 ++       | Agreement for Services dated December 10, 2001 between SkyePharma Inc. and Astralis Ltd.  |
| 10.11 ++       | Technology Access Option Agreement dated December 10, 2001 by and among SkyePharma Inc., SkyePharma Holding AG and Astralis Ltd.  |
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| 10.12 ###      | Employment Agreement dated December 10, 2001, between Dr. Jose Antonio O'Daly and Astralis Ltd.   |
| 10.13 ###      | Amendment #1 to Agreement for Services dated March 18, 2003 between SkyePharma Inc. and Astralis Ltd.   |
| 10.14 +        | Omnibus Conversion Agreement dated January 12, 2004 between Astralis Ltd. and SkyePharma PLC  |
| 10.15 +        | Call Option Agreement dated January 20, 2004 between Astralis Ltd. and SkyePharma PLC   |
| 10.16 +        | Amendment No. 1 to Stockholders Agreement dated January 20, 2004 by and among Astralis Ltd., SkyePharma PLC, Jose Antonio O'Daly, Mike Ajnsztajn, Gaston Liebhaber and Gina Tedesco |
| 10.17 @@       | Securities Purchase Agreement, dated August 17, 2005, by and between Astralis Ltd. and Blue Cedar Limited.  |
| 10.18 @@       | Registration Rights Agreement, dated August 17, 2005, by and  |

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between Astralis Ltd. and Blue Cedar Limited.  
10.19 @@ Stockholder's Agreement, dated August 17, 2005, by and between Astralis Ltd. and Blue Cedar Limited.  
10.20 @@ Long-term Common Stock Purchase Warrant, issued to Blue Cedar Limited by Astralis Ltd.  
10.21 @@ Short-term Common Stock Purchase Warrant, issued to Blue Cedar Limited by Astralis Ltd.  
10.22 @@ Long-term Common Stock Purchase Warrant, issued to Lipworth Capital Limited by Astralis Ltd.  
23.1 Consent of McCarter & English, LLP (included in Exhibit 5.1)  
23.2 Consent of L J Soldingier & Associates, LLC  
24.1 Powers of Attorney (included on the signature page)

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\* Previously filed with the Securities and Exchange Commission as an Exhibit to the Annual Report on Form 10-KSB on March 30, 2004.

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

\*\*\* Previously filed with the Securities and Exchange Commission as an Exhibit to the 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 14, 2001.

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

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

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

+++ Previously filed with the Securities and Exchange Commission as an Exhibit to the Registration Statement on Form SB-2 for Astralis Ltd. on May 28, 2004.

@ Previously filed with the Securities and Exchange Commission as an Exhibit to the Registration Statement on Form SB-2 for Astralis Ltd. on June 28, 2004.

@@ Previously filed with the Securities and Exchange Commission as an Exhibit on Form 10-QSB on August 19, 2005.

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### Item 28. Undertakings

The undersigned registrant hereby undertakes:

(1) To file, during any period in which it offers or sells securities, a post-effective amendment to this registration statement to:

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(i) Include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) Reflect in the prospectus any facts or events which, individually or together, represent a fundamental change in the information in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) Include any additional or changed material information on the plan of distribution.

(2) For determining liability under the Securities Act, to treat each post-effective amendment as a new registration statement of the securities offered, and the offering of the securities at that time to be the initial bona fide offering.

(3) To file a post-effective amendment to remove from registration any of the securities which remain unsold at the end of the offering.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

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SIGNATURES

In accordance with the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form SB-2 and authorized this registration statement to be signed on its behalf by the undersigned, in the City of Fairfield, State of New Jersey, on October 12, 2005.

ASTRALIS LTD.

By: /s/ James Sharpe

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James Sharpe  
Chief Executive Officer

In accordance with the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates stated.

| Signature<br>-----  | Title<br>-----   | Date<br>-----    |
|---|--|------------------|
| /s/ Jose Antonio O'Daly<br>-----<br>Dr. Jose Antonio O'Daly | Chairman of the Board  | October 12, 2005 |
| /s/ James Sharpe<br>-----<br>James Sharpe                   | Chief Executive Officer and<br>Director<br>(principal executive officer)   | October 12, 2005 |
| /s/ Michael Garone<br>-----<br>Michael Garone               | Chief Financial Officer<br>(principal financial and<br>accounting officer) | October 12, 2005 |
| -----<br>Michael Ashton                                     | Director   | October 12, 2005 |
| /s/ Samuel Barnett<br>-----<br>Samuel Barnett               | Director   | October 12, 2005 |
| -----<br>Steven Fulda                                       | Director   | October 12, 2005 |
| /s/ Fabien Pictet<br>-----<br>Fabien Pictet                 | Director   | October 12, 2005 |
| /s/ Gordon Schooley<br>-----<br>Gordon Schooley             | Director   | October 12, 2005 |
| -----<br>Manuel Tarabay                                     | Director   | October 12, 2005 |