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ASTRALIS LTD  
Form 10QSB  
August 22, 2005

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

FORM 10-QSB

(Mark One)

- Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 For the quarterly period ended June 30, 2005.
- Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 000-30997

ASTRALIS LTD.

(Exact name of small business issuer as specified in its charter)

Delaware 84-1508866  
(State or Other Jurisdiction of (I.R.S. Employer Identification No.)  
Incorporation or Organization)

75 Passaic Avenue  
Fairfield, New Jersey 07004  
(Address of principal executive offices)

(973) 227-7168  
(Issuer's telephone number)

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date: 91,454,873 shares of Common Stock outstanding as of August 19, 2005.

Transitional Small Business Disclosure Format (check one):

Yes  No

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ASTRALIS LTD.

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FOR THE QUARTERLY PERIOD ENDED June 30, 2005

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### PART I

#### FINANCIAL INFORMATION

#### ITEM 1. FINANCIAL STATEMENTS

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                                                                                                 |            |        |
| 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 |            |        |

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|                                                                 |              |          |
|-----------------------------------------------------------------|--------------|----------|
| 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) |
|                                                                 | -----        | -----    |
| Total Stockholders' Equity (Deficit)                            | (89,734)     | 2,400    |
|                                                                 | -----        | -----    |
|                                                                 | \$ 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          |
|                                          | -----                       | -----          | -----            |
| 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                | --                          | --             | --               |
|                                          | -----                       | -----          | -----            |
| Net Loss to Common Stockholders          | \$ (874,748)                | \$ (1,874,745) | \$ (2,554,945)   |
|                                          | =====                       | =====          | =====            |

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|                                                                 |            |            |            |
|-----------------------------------------------------------------|------------|------------|------------|
| 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)    |
| 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                                                      | --               | --             |

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|                                                                 |             |             |
|-----------------------------------------------------------------|-------------|-------------|
| 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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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.

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

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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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### NOTE 2 - 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 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 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.

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

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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.

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.

### 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.



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### 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 will be 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 shareholder approval, to increase the authorized number of common stock by 200,000,000 shares.

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### SPECIAL CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

### ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

The following discussion of our financial condition and plan of operation should be read in conjunction with our financial statements and the related notes included elsewhere in this quarterly report on Form 10-QSB. This quarterly

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report contains certain statements of a forward-looking nature relating to future events or our future financial performance. We caution prospective investors that such statements involve risks and uncertainties, and that actual events or results may differ materially. In evaluating such statements, prospective investors should specifically consider the various factors identified in this quarterly report, including the matters set forth under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We disclaim any obligation to update information contained in any forward-looking statement.

### Overview

#### 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.

#### 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 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 the Company to file a registration statement no later than December 31, 2005 covering the shares issued in connection with this private placement transaction and the shares underlying the warrants which were also issued in the transaction. 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

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aggregate purchase price.

Concurrently with the closing of the private placement, the Company and Blue Cedar entered into a stockholder's agreement, dated as of August 17, 2005 (the "Stockholder's Agreement"). Pursuant to the Stockholder's Agreement, Blue Cedar may designate one director to the Board of Directors of the Company. Further, we agreed not to enter into any service agreement, distribution arrangement or transfer of personnel with any shareholder of the Company 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 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 the outstanding common stock of the Company.

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 February 2006 is contingent upon the success of efforts to raise additional capital.

The Board of Directors has approved an amendment to the Certificate of Incorporation of the Company, pursuant to which the Company will be authorized to issue an additional 200,000,000 shares of Common Stock. The Amendment will be subject to the approval of the stockholders of the Company 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 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 \$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

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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.

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- 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, 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.

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 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.

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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.

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- 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 Convertible 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.

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.

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.

### 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 February 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

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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, the Company announced that the Phase II study of its 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.

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- o We also expect to expend approximately \$1,280,000 for our general administrative and working capital requirements.

We will need to raise additional funds to continue our operations for the period following February 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.

### ITEM 3. CONTROLS AND PROCEDURES

- (a) Evaluation of disclosure controls and procedures.

Based on their evaluation as of the end of the period covered by this Quarterly Report on Form 10-QSB, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")) are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is

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recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

(b) Changes in internal controls.

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

### RISK FACTORS

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 February 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.

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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 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

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at all. As a result, we may never become profitable.

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 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.



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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 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 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,

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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.

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

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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.

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

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secrets. We will apply for patents covering both our technologies and product candidates as we deem appropriate. However, we may fail to apply for patents on important technologies or products in a timely fashion, or at all, and in any event, the applications we do file may be challenged and may not result in issued patents. Any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative technologies or design around our patented technologies. In addition, others may challenge or invalidate our patents, or our patents may fail to provide us with any competitive advantages. If we encounter challenges to the use or validity of any of our patents, resulting in litigation or administrative proceedings, we would incur substantial costs and the diversion of management in defending the patent. In addition, we do not control the patent prosecution of technology that we license from others. Accordingly, we cannot exercise the same degree of control over this intellectual property as we would over technology we own.

We rely upon trade secrets protection for our confidential and 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.

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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 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

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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.

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.

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 August 19, 2005, the range of our stock price has been between \$.16 and \$7.15. On August 19, 2005 we completed a private placement of common stock at a price \$.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

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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 91,454,873 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 140,220,340 shares of common stock outstanding. Of the outstanding shares, up to 73,248,055 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 be obligated 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. 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 holders of our common stock to resell the stock.

### PART II. OTHER INFORMATION

#### Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

##### Recent Sales of Unregistered Securities

On April 11, 2005, we issued to a newly-elected director options to purchase 50,000 shares of our common stock, with an exercise price of \$0.26 per share of common stock and a term of 10 years. The options shall vest over three years, with the first twenty-five percent vesting on the date of grant. The options were granted to this non-executive director pursuant to our 2001 Stock

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Option Plan as a one-time grant upon election to our Board of Directors.

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On February 2, 2005 and June 4, 2005, we issued to two of our directors options to purchase 20,000 shares of our common stock, with an exercise price of \$0.69 and \$0.28 respectively per share of common stock and a term of 10 years. The options shall vest over three years, with the first twenty-five percent vesting on the date of grant. The options were granted pursuant to our 2001 Stock Option Plan as compensation for serving on our Board of Directors.

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 will be 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.

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### Item 5. Other Information.

On August 16, 2005, Manuel Tarabay was elected to serve as a Member of the Board of Directors of the Company. Mr. Tarabay is an investment banker and has held positions at Merrill Lynch, J.P. Morgan and Credit Suisse First Boston. Mr. Tarabay is Blue Cedar's designated director to the Board of Directors of the Company. Mr. Tarabay has not been appointed to serve on any committees of the Board of Directors. Mr. Tarabay currently acts as an advisor to Blue Cedar.

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### Item 6. Exhibits

#### EXHIBIT INDEX

| EXHIBIT<br>NUMBER | DESCRIPTION |
|-------------------|-------------|
|-------------------|-------------|

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- 10.1 Securities Purchase Agreement, dated August 17, 2005, by and between Astralis Ltd. and Blue Cedar Limited.
- 10.2 Registration Rights Agreement, dated August 17, 2005, by and between Astralis Ltd. and Blue Cedar Limited.
- 10.3 Stockholder's Agreement, dated August 17, 2005, by and between Astralis Ltd. and Blue Cedar Limited.
- 10.4 Long-term Common Stock Purchase Warrant, issued to Blue Cedar Limited by Astralis Ltd.
- 10.5 Short-term Common Stock Purchase Warrant, issued to Blue Cedar Limited by Astralis Ltd.
- 10.6 Long-term Common Stock Purchase Warrant, issued to Lipworth Capital Limited by Astralis Ltd.
- 31.1 Certification by the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification by the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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SIGNATURES

In accordance with the requirements of the Securities Exchange Act of 1934, as amended, the Registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ASTRALIS LTD.  
(Registrant)

Dated: August 22, 2005

By: /s/ JAMES SHARPE

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James Sharpe  
President and Chief Executive Officer  
(Principal Executive Officer; Authorized  
Signatory on behalf of Registrant)

Dated: August 22, 2005

By: /s/ MICHAEL GARONE

-----  
Michael Garone  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

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