

Edgar Filing: ASTRALIS LTD - Form 10QSB

ASTRALIS LTD  
Form 10QSB  
May 22, 2006

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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 March 31, 2006.
- 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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

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 May 15, 2006.

Transitional Small Business Disclosure Format (check one):

Yes  No

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ASTRALIS LTD.

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FOR THE QUARTERLY PERIOD ENDED March 31, 2006

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## PART I FINANCIAL INFORMATION

### ITEM 1. FINANCIAL STATEMENTS

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

#### ASSETS

|                             | March 31,<br>2006    | Dece  |
|-----------------------------|----------------------|-------|
|                             | -----<br>(Unaudited) | ----- |
| Current Assets              |                      |       |
| Cash and cash equivalents   | \$ 276,789           | \$    |
| Prepaid expenses            | 125,933              |       |
| Supplies                    | 32,110               |       |
|                             | -----                | ----- |
| Total Current Assets        | 434,832              |       |
| Property and Equipment, Net | 80,075               |       |
| Deposits                    | 25,000               |       |
|                             | -----                | ----- |
|                             | \$ 539,907           | \$    |
|                             | =====                | ===== |

#### LIABILITIES AND STOCKHOLDERS' EQUITY

|                                       |            |       |
|---------------------------------------|------------|-------|
| Current Liabilities                   |            |       |
| Accounts payable and accrued expenses | \$ 300,990 | \$    |
|                                       | -----      | ----- |
| Total Current Liabilities             | 300,990    |       |
|                                       | -----      | ----- |

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|   |              |       |          |
|---|--------------|-------|----------|
| Convertible notes, net - related party, \$250,000 face value (see Note 5)   | --           | ----- | -----    |
| Total Liabilities   | 300,990      | ----- | -----    |
| Commitments and Contingencies   |              |       |          |
| Stockholders' Equity  |              |       |          |
| Common stock; \$.0001 par value; 150,000,000 shares authorized at 2006 and 2005; 91,454,873 issued and outstanding at 2006 and 2005 | 9,145        | ----- | 53       |
| Additional paid-in capital  | 54,273,531   | ----- | (53)     |
| Deficit accumulated in the development stage  | (54,043,759) | ----- | -----    |
| Total Stockholders' Equity  | 238,917      | ----- | -----    |
|   | \$ 539,907   | ===== | \$ ===== |

See the accompanying notes to condensed financial statements.

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

|  | Three Months Ended March 31, |             | March 12, 2001<br>(Inception) to<br>March 31,<br>2006 |
|--|------------------------------|-------------|---|
|  | 2006                         | 2005        | 2006  |
|  | -----                        | -----       | -----   |
| Revenues                                 | \$ --                        | \$ --       | \$ --   |
|  | -----                        | -----       | -----   |
| Operating Expenses                       |                              |             |   |
| Research and development - related party | --                           | --          | 16,278,822  |
| Research and development                 | 164,027                      | 1,086,664   | 9,123,776   |
| Share based compensation                 | 35,108                       | --          | 35,108  |
| Depreciation and amortization            | 3,097                        | 7,922       | 101,466   |
| General and administrative               | 227,910                      | 596,509     | 7,237,950   |
|  | -----                        | -----       | -----   |
| Total Operating Expenses                 | 430,142                      | 1,691,095   | 32,777,122  |
|  | -----                        | -----       | -----   |
| Loss From Operations                     | (430,142)                    | (1,691,095) | (32,777,122)  |
| Other (income) expense                   |                              |             |   |
| Investment (income) loss                 | (2,899)                      | (10,898)    | (213,095)   |
| Registration rights penalty              | --                           | --          | 83,000  |
|  | -----                        | -----       | -----   |

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|   |              |                |                 |
|---|--------------|----------------|-----------------|
| Loss before income tax benefit                                  | (427,243)    | (1,680,197)    | (32,647,027)    |
| Income tax benefit  | ---          | ---            | 822,018         |
|   | -----        | -----          | -----           |
| Net Loss  | (427,243)    | (1,680,197)    | (31,825,009)    |
| Preferred Stock Dividends                                       | ---          | ---            | (22,218,750)    |
|   | -----        | -----          | -----           |
| Net Loss to Common Stockholders                                 | \$ (427,243) | \$ (1,680,197) | \$ (54,043,759) |
|   | =====        | =====          | =====           |
| Basic and Diluted Loss per Common Share                         | \$ --        | \$ (0.02)      | \$ (1.00)       |
|   | =====        | =====          | =====           |
| Basic and Diluted Weighted Average<br>Common Shares Outstanding | 91,454,873   | 73,224,166     | 53,805,172      |
|   | =====        | =====          | =====           |

See the accompanying notes to condensed financial statements.

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

|   | Three Months Ended March |                |
|---|--------------------------|----------------|
|   | 2006                     | 2005           |
|   | -----                    | -----          |
| Cash Flows from Operating Activities  |                          |                |
| Net loss  | \$ (427,243)             | \$ (1,680,197) |
| Adjustments to reconcile net loss to net cash used in operating activities                          |                          |                |
| Depreciation and amortization   | 21,296                   | 4,000          |
| Impairment of intangible asset  | --                       | --             |
| Amortization of net premium paid on investments   | --                       | --             |
| Dividend income reinvested  | --                       | --             |
| 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   | 35,108                   | --             |
| Investor relation fees netted against subscription receivable                                       | --                       | --             |
| Compensatory common stock   | --                       | 6,000          |
| Assignment of call option   | --                       | --             |
| Loss on sale of available-for-sale securities and fixed asset retirement                            | --                       | --             |
| Changes in assets and liabilities   |                          |                |
| Prepaid expenses  | 5,216                    | (1,000)        |
| Interest receivable   | --                       | (1,000)        |
| Supplies  | --                       | --             |
| Deposits  | --                       | --             |

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|   |            |         |
|---|------------|---------|
| Accounts payable and accrued expenses                           | (241,056)  | 28      |
|   | -----      | -----   |
| Net Cash Used in Operating Activities                           | (606,679)  | (1,29   |
|   | -----      | -----   |
| Cash Flows from Investing Activities                            |            |         |
| Purchases of available-for-sale securities                      | --         |         |
| Proceeds from sale of available-for-sale securities             | --         |         |
| Expenditures related to patent                                  | --         | (       |
| Insurance proceeds from claim                                   | --         |         |
| Purchases of property and equipment                             | --         | (       |
|   | -----      | -----   |
| Net Cash Used in Investing Activities                           | --         | (       |
|   | -----      | -----   |
| Cash Flows from Financing Activities                            |            |         |
| Proceeds from convertible debenture                             | 250,000    |         |
| Repurchase of common stock                                      | --         |         |
| Collection of subscription receivable                           | --         |         |
| Proceeds from exercise of stock options                         | --         |         |
| Issuance of common stock, net of offering and transaction costs | --         |         |
| Issuance of preferred stock                                     | --         |         |
| Private placement offering costs                                | --         |         |
|   | -----      | -----   |
| Net Cash Provided by Financing Activities                       | 250,000    |         |
|   | -----      | -----   |
| Net Increase (Decrease) in Cash and Cash Equivalents            | (356,679)  | (1,29   |
| Cash and Cash Equivalents, Beginning of Period                  | 633,468    | 2,31    |
|   | -----      | -----   |
| Cash and Cash Equivalents, End of Period                        | \$ 276,789 | \$ 1,01 |
|   | =====      | =====   |

See the accompanying notes to 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 2005 Annual Report on Form 10-KSB filed with the Securities and Exchange Commission. The results of

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operations for interim periods are not necessarily indicative of the results for any subsequent quarter or the entire fiscal year ending December 31, 2006.

For comparability purposes, certain figures for the prior periods have been reclassified where appropriate to conform with the financial statement presentation used in 2006. These reclassifications had no effect on the reported net loss.

### NOTE 2 - DESCRIPTION OF BUSINESS

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 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 \$427,243 and \$54,043,759 for the three-month period ended March 31, 2006 and for the period March 12, 2001 (date of inception) to March 31, 2006, 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.

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 2006 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.

Based on an analysis of the data from its Phase II study the Company has developed a hypothesis to explain why the results differed from the long-term improvement of the more than 2,700 patients who were treated with Psoraxine in pre-clinical studies in Venezuela. The Company intends to reformulate the product and reproduce the clinical studies performed in Venezuela. The Company hopes to demonstrate an outcome that is more consistent with results from pre-clinical studies.

The Company raised an additional \$250,000 through a private placement in March of 2006. These funds, in addition to its cash on hand at that time are sufficient to meet the Company's needs for operating and capital expenditures through mid-June 2006. The Company will need to raise significant additional funds from outside sources immediately and in future years in order to complete existing and future phases of FDA required testing and continue operations.

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

Management is seeking to identify additional capital immediately so that it may continue its operations. These funds will be needed in order to finance the Company's currently anticipated needs for operating and capital expenditures for the remainder of 2006, including the cost to 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 it raising capital immediately through debt and/or 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 be required to cease operations. The Company is actively seeking sources of financing. The Company is considering and will implement further dramatic cost reduction measures to extend the availability of its capital. 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 - STOCK BASED COMPENSATION

Effective January 1, 2006, we adopted the provisions of Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-Based Payment" (SFAS No.123R) requiring that compensation cost relating to share-based payment transactions be recognized under fair value accounting and recorded in the financial statements. The cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense over the employee's requisite service period (generally the vesting period of the equity award). Prior to January 1, 2006, we accounted for share-based compensation to employees in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" (APB No. 25), and related interpretations. We also followed the disclosure requirements of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation", as amended by Statement of Financial Accounting Standards No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure". We adopted SFAS No. 123R using the modified prospective method and, accordingly, financial statement amounts for prior periods presented in this Form 10-Q have not been restated to reflect the fair value method of recognizing compensation cost relating to non-qualified stock options.

There was \$35,108 of compensation cost related to non-qualified stock options recognized in operating results for the three months ended March 31, 2006. Since the Company has generated losses from its inception, no associated future income tax benefit was recognized for the three months ended March 31, 2006.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model. Historical volatilities based on the historical stock trading prices of Astralis, Ltd. are used to calculate the expected volatility. We used the simplified method as defined under the SEC Staff Accounting Bulletin No. 107, Topic 14: "Share-based Payment," to derive an expected term. The expected term represents an estimate of the time options are expected to remain outstanding. The risk-free rate for periods within the contractual life of the option is based on the U.S. treasury yield curve in

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effect at the time of grant. The following table sets forth the assumptions used to determine compensation cost for our stock options consistent with the requirements of SFAS No. 123R:

|                                | Three Months Ended<br>March 31, 2006 |
|--------------------------------|--------------------------------------|
| Expected volatility            | 108.00 % - 128.00 %                  |
| Expected annual dividend yield | 0.00 %                               |
| Risk free rate of return       | 4.45 %                               |
| Expected option term (years)   | 5.00                                 |

If the Company had accounted for share based compensation in accordance with SFAS No. 123R for the three months ended March 31, 2005, then \$168,930 would have been recorded as share based compensation expense. 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 Standards No. 123, Accounting for Stock-Based Compensation," to stock-based compensation in the first quarter of 2005.

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|   | Three Months<br>Ended<br>March 31, 2005 |
|---|---|
|   | (Unaudited)                             |
| Net loss to common stockholders, as reported  | \$ (1,680,197)                          |
| 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 | (168,930)                               |
|   | -----                                   |
| Pro forma net loss  | \$ (1,849,127)                          |
|   | -----                                   |
| Loss per share basic and diluted - as reported  | \$ (0.02)                               |
| Loss per share basic and diluted - pro forma  | \$ (0.03)                               |
| Shares used in basic and diluted loss per share amounts   | 73,224,166                              |
|   | -----                                   |

At March 31, 2006, there was \$245,043 of total unrecognized compensation cost related to non-vested non-qualified stock option awards which is expected to be recognized over a weighted-average period of 8.00 years. The total fair value of options vested during the three months ended March 31, 2006 was approximately \$4,353.

The effect of applying SFAS No. 123R in the first quarter of 2006 was an additional \$35,108 of compensation expense was recorded which increased the net loss by a corresponding amount and had no effect on earnings per share.

Other than stock options covered by the Stock Incentive Plan, the Company has no outstanding options to purchase shares of its common stock.

NOTE 5 - CONVERTIBLE NOTES - RELATED PARTY



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On March 31, 2006, the Company issued to Blue Cedar Limited ("Blue Cedar"), an accredited investor and currently a stockholder of the Company; (i) a convertible promissory note in the principal amount of \$250,000, convertible into shares of the Company's common stock at \$0.09 per share at any time prior to the redemption date (March 31, 2009), interest will be charged on the note at 6% per annum and (ii) a warrant to purchase 2,777,778 shares of common stock at an exercise price of \$0.135 per share. The warrants expire five years from the date of issuance.

The Company may at any time and from time to time, on 45 day's written notice to Blue Cedar, redeem all or any part of the principal balance of this Note at a price equal to (i) the "Interest Amount," determined pursuant to the note, of the principal amount of the Notes to be prepaid, plus (ii) the principal amount of Notes to be prepaid. The Interest Amount shall be equal to: (a) if such prepayment occurs on or prior to the first anniversary of the date of the note, six percent (6%) of the principal amount thereof; (b) if such prepayment occurs after the first anniversary date and prior to the second anniversary date, twelve percent (12%) of the aggregate principal amount thereof; and (c) if such prepayment occurs after the second anniversary date, eighteen percent (18%) of the aggregate principal price thereof.

Pursuant to EITF 98-5 "Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios" and EITF 00-27 "Application of Issue No. 98-5 to Certain Convertible Instruments", the Company has recorded a discount to the convertible note in the amount of \$250,000 based on the relative fair value of the debt and warrants in addition to the beneficial conversion feature (the conversion price into common shares being less than the market price of common shares on the date the loan was issued). The discount will be amortized as interest expense over the life of the note.

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For a period ending four years from March 31, 2006, Blue Cedar shall have the right to cause the Company to register the shares of Common Stock issuable upon conversion or exercise of the Notes or Warrants under the Act, as amended, at the Company's expense (exclusive of underwriting discounts and commissions and fees of counsel to such Subscribers), subject to certain restrictions.

Also during the same period set forth above, Blue Cedar shall have the right, to participate on a "piggyback basis" in a registration by the Company under the Act, subject to certain restrictions, including underwriter hold-backs.

The Company evaluated its convertible debt instruments for possible application of derivative accounting under Statement of Financial Accounting Standard ("SFAS") No 133: Accounting for Derivative Instruments and Hedging Activities, Emerging Issues Task Force ("EITF") 00-19: Accounting for Derivative Financial Instrument Indexed to, and Potentially Settled in, a Company's Own Stock, EITF 01-6: The Meaning of "Indexed to a Company's Own Stock" and EITF 05-2: The Meaning of "Conventional Convertible Debt Instrument" in Issue No. 00-19. The Company determined its convertible debt was deemed "conventional" and therefore not subject to derivative accounting.

### NOTE 6 - CAPITAL STOCK ACTIVITY

On January 27, 2006, the Company issued 182,000 options to a former Chief Executive Officer ("CEO"). The options were issued with an exercise price equal to the market price on the date of issuance (\$0.03 on January 27, 2006) and with a term of 5 years and vested immediately. Additionally, on January 27, 2007 an additional 182,000 options will become vested exercisable at the market price on that date for a term of 5 years. The options were issued pursuant to a

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Separation Agreement and General Release, by and between the Company and former CEO, which was signed on January 25, 2006.

### NOTE 7 - 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 debt are not included because the inclusion would be anti-dilutive (i.e., reduce the net loss per share). The total numbers of such shares excluded from diluted net loss per common share were 53,769,022 and 16,847,891 at March 31, 2006 and 2005, respectively.

### NOTE 8 - SUPPLEMENTARY DISCLOSURE OF CASH FLOW INFORMATION

In March 2006, the Company financed \$66,944 of certain insurance premiums by entering into a short-term note payable. The notes mature on September 10, 2006 and have an interest rate of 7.75% per annum. As of March 31, 2006, these notes had an outstanding balance of \$48,456.

### NOTE 9 - SUBSEQUENT EVENTS

On May 5, 2006, the Company received the resignation of Fabien Pictet as a member of the Board of Directors. Mr. Pictet's resignation was effective as of May 4, 2006.

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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 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

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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.

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

Based on our current plans we believe that we have sufficient funds to meet our operating needs through approximately mid-June 2006. We will be able to continue our operations beyond mid-June 2006 only if we can raise additional capital immediately. We are actively seeking sources of financing. We are considering and will implement further dramatic cost reduction measures to extend the availability of our capital.

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#### Recent Developments

##### Blue Cedar March 2006 Private Placement

On March 31, 2006, the Company closed a private placement of securities from which it received proceeds of \$250,000. In connection with this private placement, the Company issued to Blue Cedar Limited ("Blue Cedar"), an accredited investor and currently a stockholder of the Company, (i) a convertible promissory note in the principal amount of \$250,000, convertible into shares of the Company's common stock at \$0.09 per share, and (ii) a warrant to purchase 2,777,778 shares of common stock. Lipworth Capital Limited acted as the placement agent in connection with the private placement. The securities offered and sold in this private placement were sold in reliance on an exemption from the registration requirements under Regulation D of the Securities Act of 1933, as amended (the "Securities Act").

##### Departure of Directors and Principal Officer

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On December 11, 2005, Steven Fulda, a member of the Board of Directors and Audit Committee of the Company, announced his resignation from the Board and Audit Committee, effective December 30, 2005. Mr. Fulda's announcement did not reference a disagreement with the Company on any matter relating to the Company's operations. In addition, on May 5, 2006 Fabien Pictet resigned as a member of the Board of Directors of the Company. Mr. Pictet's effective date of resignation was May 4, 2006. Mr. Pictet's resignation did not reference a disagreement with the Company on any matter relating to the Company's operations.

Additionally, on January 25, 2006, James Sharpe resigned as a member of the Board of Directors, Chief Executive Officer and President of the Company, pursuant to a Separation Agreement and General Release, by and between the Company and Mr. Sharpe ("Separation Agreement"). Mr. Sharpe, whose resignation was effective as of December 31, 2005, did not resign due to a disagreement with the Company on any matter relating to the Company's operations. Michael Garone, the Company's Chief Financial Officer, currently is serving as the Company's interim President until the Company's Board of Directors elects a new Chief Executive Officer and President to replace Mr. Sharpe.

### Proposed Amendment to the Certificate of Incorporation

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 during the second quarter of 2006.

### Plan of Operation

Three months ended March 31, 2006 compared to three months ended March 31, 2005.

For three months ended March 31, 2006:

For the three months ended March 31, 2006, we had no revenue from operations and incurred operating expenses of \$430,142 which consisted primarily of:

- o Research and development costs of \$164,027 including evaluation of clinical trial results, reformulation of Psoraxine(R) and activity testing in animals.

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- o General and administrative costs of \$227,910 , including professional fees, rent, salaries for management and our general corporate expenditures.

As a result, during the three months ended March 31, 2006, we incurred a net loss of \$427,243.

For three months ended March 31, 2005:

For the three months ended March 31, 2005, we had no revenue from operations and incurred operating expenses of \$1,691,095 which consisted primarily of:

- o Research and development costs of \$1,086,664, including \$861,526 of costs relating to the Phase II study for Psoraxine(R). Research and development costs did not include any allocation of costs under our

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Services Agreement with SkyePharma, which expired in December 2004.

- o General and administrative costs of \$596,509, including professional fees, rents, salaries for management and our general corporate expenditures.
- o As a result, during the three months ended March 31, 2005, we incurred a net loss of \$1,680,197.

### Comparison

Our research and development expenses declined from \$1,086,664 during the three months ended March 31, 2005 to \$164,027 during the three months ended March 31, 2006, primarily due to the completion of the clinical trial of Psoraxine(R) during the first quarter of 2005.

By comparison to the three months ended March 31, 2005, our general and administrative costs for the three months ended March 31, 2006 decreased by \$368,599 primarily due to management's cost control initiatives and downsizing.

Losses of \$427,243 for the three months ended March 31, 2006 were \$1,252,954 less than losses for the three months ended March 31, 2005, reflecting the completion of the Psoraxine(R) clinical trial and management's cost control initiatives implemented during 2006.

### The Next Twelve Months

At March 31, 2006 we had cash balances of \$276,789, and accounts payable of \$107,810 which we estimate will last us through approximately mid-June 2006 and no marketable securities. If we do not obtain additional funds before June 15, 2006, we will have to cease operations. To the extent that we raise additional funds, 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. Accordingly, we analyzed the data and developed a hypothesis that may explain why we received these unexpected results. In this regard, we are implementing cost containment measures; realigning development activities to focus on such things as formulation, manufacturing, analytical protocols and potency; and we are testing the hypothesis to explain unexpected results and determine the best course for future development. We remain committed to Psoraxine(R) and its future development, and hope to see it return to Phase II clinical trials in 2006.

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- o We intend to implement our business plan and facilitate the operations of our company. The business plan will be implemented in phases: during the first phase we expect to test the hypothesis developed recently to assess causes for unexpected results in the Phase II trial. During the second phase, test results will be used to design and begin a new Phase II trial. We expect that we would be

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required to incur expenses of approximately \$750,000 to third parties in connection with continuing development of Psoraxine(R).

- o We will spend approximately \$450,000 to pay management salaries and salaries of employees, a portion of which is treated as research and development expense.
- o We also expect to expend approximately \$700,000 for our general administrative and working capital requirements.
- o In connection with the August 2005 Blue Cedar private placement, because a registration statement covering the resale of the Blue Cedar shares was not filed or effective by December 31, 2005, we are required to pay liquidated damages payments of \$10,000 per month, commencing in January 2006 being 0.5% of the aggregate purchase price plus 10% annum interest until such time as a registration statement covering the resale of securities sold to Blue Cedar is declared effective by the Securities and Exchange Commission.
- o We will need to raise additional funds immediately to continue our operations for the period following the first quarter of 2006 and to fund any of the activities described above. Furthermore, substantial additional funds will be needed in order to fund our continued efforts to obtain FDA approval of Psoraxine(R). 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. Presently, neither our management nor our bankers have identified new sources of capital. If we do not obtain additional funds, we will likely be required to 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 interim Chief Executive Officer, interim president and Chief Financial Officer has concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) under the Exchange Act) are not effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms for the following reasons:

As a result of the audit of our 2005 financial statements and the review of our 2006 quarterly financial statements by our independent auditors we have become aware of certain deficiencies that exist in the design and operation of our internal controls over financial reporting that our independent auditors consider to be material weaknesses under standards of the Public Company Accounting Oversight Board (PCAOB).

1. Our independent auditors identified certain errors in the 2005 financial statements that were not initially identified by the Company's internal control over financial reporting. The aggregate amount of these errors was material to our financial statements and therefore represent a material weakness in our internal control over financial reporting. Upon being notified of these errors we corrected the information included in the financial statements before such statements were filed with the Securities and Exchange Commission or disclosed publicly to any parties.

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2. In connection with their review of our 2006 quarterly financial statements our independent auditors identified certain errors and departures from generally accepted accounting principles in the financial statements that were not initially identified by the Company's internal control over financial reporting. Upon being notified of these errors we corrected the information included in the financial statements before such statements were filed with the Securities and Exchange Commission or disclosed publicly to any parties.
3. The Company did not file its 2005 Form 10KSB - Annual Report within the time prescribed by regulations of the Securities and Exchange Commission.

### (b) Changes in internal controls.

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

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### RISK FACTORS

You should carefully consider each of the following risk factors and all of the other information in this report. The following risks relate principally to the Company's business. If any of the following risks actually occur, the business, financial condition or results of operations of the Company could be materially adversely affected. As a result, the market price of shares of the Company's common stock could decline significantly

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

As of May 15, 2006, we have \$128,444 in available cash and accounts payable of \$75,803. Based on our current plans, we believe that we have sufficient funds to meet our operating expenses and capital requirements through approximately mid-June 2006. We will need to raise additional funds immediately 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 immediately we will have to cease operations. We are actively seeking sources of financing. We are considering and will implement further dramatic cost reduction measures to extend the availability of our capital. If we are able to identify funds immediately, but not additional funds thereafter, 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 \$54,043,759 as of March 31, 2006 which has increased to date. The cumulative net loss through March 31, 2006 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 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

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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 week 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



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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.

Recent and future changes in senior management and board composition may affect our ability to implement our business plan. In addition we only have one member of our Audit Committee.

On January 25, 2006, we accepted the resignation James Sharpe, effective as of December 31, 2005 with respect to his position as Chief Executive Officer, President and member of the Board of Directors. Michael Garone, our Chief Financial Officer, currently serves as the interim Chief Executive Officer and interim President. Mr. Sharpe is our third Chief Executive Officer and President to resign in an 18 month period. Our ability to implement our business strategy may be adversely affected if we continue to experience unplanned senior management changes in the future or if we are unable to successfully integrate our current and future senior management personnel into our organization. Additionally there have been changes to the composition of our Board of Directors. On May 5, 2006 The Company received the resignation of Fabien Pictet as a member of the Board of Directors. Mr. Pictet's resignation was effective as of May 4, 2006. Further, in December 2005, Steven Fulda resigned as a member of the Audit Committee and member of the Board of Directors. As a result of Mr. Fulda's resignation, we only have one member of the Audit Committee. Moreover, our Audit Committee does not contain a member that qualifies as a financial "expert" as defined by Item 401(e) of Regulation S-B of the Exchange Act.

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

SkyePharma owns approximately 39.8% of our outstanding common stock. As a result, SkyePharma 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 SkyePharma 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 our control 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.

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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

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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 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

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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.

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

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the extent that we cover our proprietary technologies with valid and enforceable patents or we effectively maintain such proprietary technologies as trade secrets. We will apply for patents covering both our technologies and product candidates as we deem appropriate. However, we may fail to apply for patents on important technologies or products in a timely fashion, or at all, and in any event, the applications we do file may be challenged and may not result in issued patents. Any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative technologies or design around our patented technologies. In addition, others may challenge or invalidate our patents, or our patents may fail to provide us with any competitive advantages. If we encounter challenges to the use or validity of any of our patents, resulting in litigation or administrative proceedings, we would incur substantial costs and the diversion of 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 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.

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We depend on the services of Dr. Jose Antonio O'Daly, the Chairman of our Board of Directors and our Chief Scientific Officer, and Michael Garone, interim Chief Executive Officer, interim President and Chief Financial Officer, the loss of whose services would adversely impact the achievement of our objectives. 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.

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Our officers, directors and principal stockholders (greater than 5% stockholders) together control approximately 77.7% 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 May 15, 2006, the range of our stock price has been between \$0.02 and \$7.15. Factors including announcements of technological innovations by us or other companies, regulatory matters, new or existing products or procedures, concerns about our financial position, operating results, government regulation, or

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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 91,454,873 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 145,223,895 shares of common stock outstanding. Of the outstanding shares, up to 73,173,055 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.

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### PART II.

#### OTHER INFORMATION

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

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On March 31, 2006, the Company closed a private placement of securities from which it received proceeds of \$250,000. In connection with this private placement, the Company issued to Blue Cedar, an accredited investor and currently a stockholder of the Company, (i) a convertible promissory note in the principal amount of \$250,000, convertible into shares of the Company's common stock at \$0.09 per share, and (ii) a warrant to purchase 2,777,778 shares of common stock. Lipworth Capital Limited acted as the placement agent in connection with the private placement. The securities offered and sold in this private placement were sold in reliance on an exemption from the registration requirements under Regulation D of the Securities Act.

### Item 6. Exhibits

| Exhibit Number | Description  |
|----------------|--|
| 3.1 (1)        | Certificate of Incorporation of Astralis Ltd.  |
| 3.2 (2)        | Bylaws of Astralis Ltd.  |
| 4.1 (9)        | Specimen Stock Certificate   |
| 10.1 (2)       | Agreement and Plan of Merger   |
| 10.2 (4)       | Contribution Agreement dated September 10, 2001  |
| 10.3 (5)       | Purchase Agreement dated December 10, 2001   |
| 10.4 (5)       | Stockholder Agreement dated December 10, 2001  |
| 10.5 (7)       | 2001 Stock Option Plan   |
| 10.6 (3)       | Sub-Lease Agreement  |
| 10.7 (3)       | License Agreement dated April 26, 2001 between Jose Antonio O'Daly and Astralis LLC  |
| 10.8 (3)       | Assignment of License  |
| 10.9 (3)       | Form of Warrant  |
| 10.10 (8)      | Agreement for Services dated December 10, 2001 between SkyePharma Inc. and Astralis Ltd.   |
| 10.11 (8)      | Technology Access Option Agreement dated December 10, 2001 by and among SkyePharma Inc., SkyePharma Holding AG and Astralis Ltd.                                   |
| 10.12 (6)      | Employment Agreement dated December 10, 2001, between Dr. Jose Antonio O'Daly and Astralis Ltd.  |
| 10.13 (6)      | Amendment #1 to Agreement for Services dated March 18, 2003 between SkyePharma Inc. and Astralis Ltd.  |
| 10.14 (7)      | Omnibus Conversion Agreement dated January 12, 2004 between Astralis Ltd. and SkyePharma PLC   |
| 10.15 (7)      | Call Option Agreement dated January 20, 2004 between Astralis Ltd. and SkyePharma PLC  |
| 10.16 (7)      | 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 |

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and Gina Tedesco

- 10.17 (11) Securities Purchase Agreement, dated August 17, 2005, by and between Astralis Ltd. and Blue Cedar Limited.
- 10.18 (11) Registration Rights Agreement, dated August 17, 2005, by and between Astralis Ltd. and Blue Cedar Limited.

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- 10.19 (11) Stockholder's Agreement, dated August 17, 2005, by and between Astralis Ltd. and Blue Cedar Limited.
- 10.20 (11) Long-term Common Stock Purchase Warrant, issued to Blue Cedar Limited by Astralis Ltd.
- 10.21 (11) Short-term Common Stock Purchase Warrant, issued to Blue Cedar Limited by Astralis Ltd.
- 10.22 (11) Long-term Common Stock Purchase Warrant, issued to Lipworth Capital Limited by Astralis Ltd.
- 10.23 (12) Separation Agreement and General Release, dated January 25, by and between James Sharpe and the Registrant.
- 10.24 (13) Form of Subscription Agreement, dated March 31, 2006, by and between Astralis Ltd. and Blue Cedar Limited.
- 10.25 (13) Form of Warrant, dated March 31, 2006, issued to Blue Cedar Limited by Astralis Ltd.
- 10.26 (13) Form of Convertible Promissory Note in the principal amount of \$250,000, dated March 31, 2006, issued to Blue Cedar Limited by Astralis Ltd.
- 14.1 (1) Code of Ethics for Chief Executive Officer and Senior Financial Officers
- 31.1 Certification by the Interim Chief Executive Officer and 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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(1) Previously filed with the Securities and Exchange Commission as an Exhibit to the Annual Report on Form 10-KSB on March 30, 2004.

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

(3) 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.

(4) 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.



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(5) 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.

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

(7) 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.

(8) 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.

(9) 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.

(10) 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.

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

(12) Previously filed with the Securities and Exchange Commission as an Exhibit on Form 8-K on March 30, 2006.

(13) Previously filed with the Securities and Exchange Commission as an Exhibit on Form 8-K on April 6, 2006.

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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: May 22, 2006

By: /s/ Michael Garone

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Michael Garone  
Interim Chief Executive Officer & Chief  
Financial Officer (Principal Executive  
Officer; Principal Financial and  
Accounting Officer, Authorized Signatory  
on behalf of Registrant)

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