ASTRALIS LTD
Form 10QSB
May 16, 2005

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-QSB

(Mark One)

|X| Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 For the quarterly period ended March 31, 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 Incorporation or Organization)	(I.R.S. Employer Identification No.)

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 |X| No |_|

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date: 73,273,055 shares of Common Stock outstanding as of May 13, 2005.

Transitional Small Business Disclosure Format (check one):

Yes |_| No |X|

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ASTRALIS LTD.

INDEX

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2005

Part I Financial Information..... 3
Item 1 Condensed Balance Sheets..... 3

		Condensed Statements of Operations (Unaudited).....	4
		Condensed Statements of Cash Flows (Unaudited).....	5
		Notes to Condensed Financial Statements.....	6
	Item 2	Management's Discussion and Analysis or Plan of Operation....	10
	Item 3	Controls and Procedures.....	13
		Risk Factors.....	13
Part II		Other Information.....	19
	Item 2	Unregistered Sales of Equity Securities and Use of Proceeds..	19
	Item 6	Exhibits.....	

PART I
FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

ASSETS

	March 31, 2005	December 2004
	(Unaudited)	(Audit
Current Assets		
Cash and cash equivalents	$ 1,014,876	$ 2,312
Accrued interest receivable	1,032	
Prepaid expenses	79,464	70
Supplies	48,924	55
Total Current Assets	1,144,296	2,439
Other Intangible Assets, Net	120,402	117
Property and Equipment, Net	178,175	214
Deposits	26,763	26
	$ 1,469,636	$ 2,797

LIABILITIES AND STOCKHOLDERS' EQUITY

Current Liabilities		
Accounts payable and accrued expenses	$ 684,622	$ 397
Total Current Liabilities	684,622	397
Commitments and Contingencies		
Stockholders' Equity		
Common stock; $.0001 par value; 150,000,000 shares authorized		

at 2005 and 2004; 73,173,055 issued and outstanding at 2005 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	(51,382,554)	(49,702
Total Stockholders' Equity	785,014	2,400
	$ 1,469,636	$ 2,797

See the accompanying notes to condensed financial statements.

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

	Three Months Ended March 31,		March 12, 2001 (Inception) to March 31,
	2005	2004	2005
Revenues	$ --	$ --	$ --
Operating Expenses			
Research and development - related party	--	430,447	16,278,822
Research and development	1,086,664	900,694	7,535,892
Depreciation and amortization	7,922	7,510	80,946
General and administrative	596,509	421,898	5,973,963
Total Operating Expenses	1,691,095	1,760,549	29,869,623
Loss From Operations	(1,691,095)	(1,760,549)	(29,869,623)
Investment income	10,898	12,576	190,722
Loss before income tax benefit	(1,680,197)	(1,747,973)	(29,678,901)
Income tax benefit	--	--	515,097
Net Loss	(1,680,197)	(1,747,973)	(29,163,804)
Preferred Stock Dividends	--	(10,750,000)	(22,218,750)
Net Loss to Common Stockholders	$ (1,680,197)	$(12,497,973)	$(51,382,554)

Basic and Diluted Loss per Common Share	$ (0.02)	$ (0.19)	$ (1.11)
Basic and Diluted Weighted Average Common Shares Outstanding	73,224,166	64,861,411	46,234,871

See the accompanying notes to condensed financial statements.

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

	Three Months Ended Marc	
	2005	200
Cash Flows from Operating Activities		
Net loss	$ (1,680,197)	$ (1,74
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	40,052	21
Impairment of intangible asset	--	
Amortization of net premium paid on investments	--	
Dividend income reinvested	--	(2
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	--	
Investor relation fees netted against subscription receivable	--	
Compensatory common stock	65,000	1
Assignment of call option	--	
Loss on sale of available-for-sale securities and fixed asset retirement	--	1
Changes in assets and liabilities		
Prepaid expenses	(8,569)	27
Interest receivable	(1,032)	
Supplies	6,927	(3
Deposits	--	
Accounts payable and accrued expenses	286,860	33
Net Cash Used in Operating Activities	(1,290,959)	(95
Cash Flows from Investing Activities		
Purchases of available-for-sale securities	--	(3,80
Proceeds from sale of available-for-sale securities	--	50
Expenditures related to patent	(4,113)	(
Insurance proceeds from claim	--	
Purchases of property and equipment	(2,453)	(

Net Cash Used in Investing Activities	(6,566)	(3,30
Cash Flows from Financing Activities		
Repurchase of common stock	--	
Collection of subscription receivable	--	
Proceeds from exercise of stock options	--	
Issuance of common stock, net of offering and transaction costs	--	4,95
Issuance of preferred stock	--	
Private placement offering costs	--	
Net Cash Provided by Financing Activities	--	4,95
Net Increase (Decrease) in Cash and Cash Equivalents	(1,297,525)	69
Cash and Cash Equivalents, Beginning of Period	2,312,401	1
Cash and Cash Equivalents, End of Period	$ 1,014,876	$ 70

See the accompanying notes to condensed financial statements.

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

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 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 March 31,	
	2005	2004
	(Unaudited)	(Unaudited)
Net loss to common stockholders, as reported	$ (1,680,197)	$(12,497,973
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)	(3,914
Pro forma net loss	$ (1,849,127)	$(12,501,887
Loss per share basic and diluted - as reported	$ (0.02)	$ (0.19
Loss per share basic and diluted - pro forma	$ (0.03)	$ (0.19
Shares used in basic and diluted loss per share amounts	73,224,166	64,861,411

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

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 also engaged in research on the possible development of the technology underlying Psoraxine(R) for the treatment of other indications, such as eczema and leishmaniasis.

NOTE 3 - GOING CONCERN

The Company incurred net losses to common stockholders of $1,680,197 and $51,382,554 for the three-month period ended March 31, 2005 and for the period March 12, 2001(date of inception) to March 31, 2005, respectively. Included in

the cumulative net losses was non-cash preferred stock dividend generated from beneficial conversion features of preferred stock in the amount of $22,218,750.

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

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.

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

NOTE 3 - GOING CONCERN (Continued)

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. Among the shares owned by SkyePharma, up to 12,500,000 shares issued upon conversion of the Series A preferred stock will be subject to a call option at the discretion of the Company upon completion of an agreed upon milestone, prior to January 2007, at a premium in excess of the conversion price.

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 with a term of ten years. The first 182,000 shares vested immediately at grant date and then an additional 182,000 shares per year on a cumulative basis until all options have vested.

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 numbers of such shares excluded from diluted net loss per common share 16,847,891 and 18,441,891 at March 31, 2005 and 2004, respectively.

NOTE 6 - SUPPLEMENTARY DISCLOSURE OF CASH FLOW INFORMATION

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 March 31, 2005, this note had an outstanding balance of $26,941.

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 March 31, 2005 and December 31, 2004, this note had an outstanding balance of $19,009 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.

NOTE 8 - SUBSEQUENT EVENTS

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 shall vest over four years, with the first twenty-five percent vesting on the date of grant.

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 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:

- Ongoing research and development of Psoraxine(R);
- Conducting 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 Psoraxine(R) for the treatment of indications other than psoriasis, such as eczema, seborrheic dermatitis and leishmaniasis.

Recent Developments

Deferral of 10% of Salary by Executive Officers.

Based on our current plans, we believe that we have sufficient funds to meet our operating expenses and capital requirements through approximately July 2005. We will need to raise additional funds to continue our operations following that period. Substantial additional funds will also be needed in order to fund our continued efforts to obtain approval from the Food and Drug Administration for the marketing of Psoraxine(R), especially given the failure of our Phase II clinical study for Psoraxine(R) to meet its primary endpoint. In

response to our limited working capital and our substantial need for funds to continue testing Psoraxine(R) to obtain FDA approval, our executive officers have agreed to defer 10% of their salaries until such time as appropriate funding can be raised. As a result, the annual salary of Dr. Jose Antonio O'Daly, our Chairman of the Board and Chief Scientific Officer, will be reduced from $231,000 to $207,900, the annual salary of James Sharpe, our President and Chief Executive Officer, will be reduced from $231,000 to $207,900 and the minimum monthly salary of Michael Garone, our Chief Financial Officer, will be reduced from $15,600 to $14,040.

Astralis Phase II Study of Psoraxine(R) for Psoriasis Did Not Meet Primary Study Endpoint.

On March 14, 2005, we issued a press release to disclose the results of our Phase II study for Psoraxine(R). The Phase II study of our novel immuno-stimulatory product for the treatment of Psoriasis did not meet the primary study endpoint upon completion of the treatment phase of the study. In the study, Psoraxine(R) was found to be safe and well-tolerated. The Phase II randomized, double-blind, placebo-controlled study involved 120 patients with moderate to severe psoriasis who received intramuscular injections of Psoraxine(R). The primary endpoint of the study was a specified level of improvement of symptoms as measured in accordance with the Psoriasis Area and Severity Index (PASI), a measurement scale that ranks the severity of symptoms of patients suffering from psoriasis. Initial analysis of the preliminary data showed no statistically significant clinical improvement compared to placebo following six injections over twelve weeks of treatment.

We entered into an Employment Agreement with our new Chief Executive Officer.

In January 2005, pursuant to the terms of the Employment Agreement we entered into with James Sharpe, our President and Chief Executive Officer, and a member of Board of Directors, we granted Mr. Sharpe options to purchase 728,000 shares of our common stock, which vested to the extent of 182,000 immediately and thereafter an additional 182,000 shares will vest each year on a cumulative basis until all options have vested. The options have an initial exercise price of $0.70 per share and have a term of ten years. In addition, Mr. Sharpe was issued 100,000 shares of our common stock, which were fully vested and considered fully paid when issued.

Plan of Operation

Three months ended March 31, 2005 compared to three months ended March 31, 2004

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:

- 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 Services Agreement with SkyePharma, which expired in December 2004.

- General and administrative costs of approximately $596,509, including professional fees, rents, salaries for management and our general corporate expenditures.

As a result, during the three months ended March 31, 2005, we incurred a net loss of $1,680,197.

For the three months ended March 31, 2004:

On January 20, 2004 we completed the first closing of a private placement of our securities from which we received gross proceeds of approximately $4.08 million. The transaction consisted of the sale to accredited investors of units consisting of 8,159,964 shares of common stock and warrants to purchase 8,159,964 shares of common stock. Concurrently with this transaction, SkyePharma PLC ("SkyePharma") converted all of its outstanding shares of our Series A Preferred Stock into 25,000,000 shares of common stock at a reduced conversion price of $0.80 per share. SkyePharma has agreed that 12,500,000 shares of the common stock issued upon conversion of the Series A Preferred Stock will be subject to a right of repurchase by us under certain circumstances at a premium to the conversion price. In connection with this transaction and in accordance with Statement of Financial Auditing Standard 84, "Induced Conversions of Convertible Debt, an Amendment of APB Opinion No. 26" we have recorded a non-cash preferred stock dividend in January 2004 amounting to $10,750,000.

On February 19, 2004, we held a second closing for the private placement from which we received gross proceeds of approximately $1.15 million. The transaction consisted of the sale to accredited investors of units consisting of 2,299,902 shares of common stock and warrants to purchase 2,299,902 shares of common stock.

For the three months ended March 31, 2004, we had no revenue from operations and incurred operating expenses of $1,760,549 which consisted primarily of:

- Research and development costs of $1,331,141, including $430,447 that we incurred in connection with services provided by SkyePharma under our Service Agreement with them and amortization of approximately $178,572 under our technology option license which is being amortized over a seven year period.

- General and administrative costs of approximately $421,898, including professional fees and our general corporate expenditures.

As a result, during the three months ended March 31, 2004, we incurred a net loss of $12,497,973.

Comparison

Although our research and development expenses declined from $1,331,141 during the three months ended March 31, 2004 to $1,086,664 during the three months ended March 31, 2005, the 2004 period included $251,875 of costs related to our Services Agreement with SkyePharma and $178,572 of costs related to our Technology Access Option Agreement with SkyePharma. In fact, because of the increased costs relating to the Phase II trials for Psoraxine(R) during the period, the Company's expenses without giving effect to the SkyePharma Services Agreement and/or Technology Access Option Agreement increased during the period ended March 31, 2005 by $185,970.

General and administrative costs increased by $174,611, reflecting increased professional fees and increased management salaries as a result of our need to retain a new Chief Executive Officer and Chief Financial Officer.

Net loss for the three months ended March 31, 2004 was $12,497,973, which included $10,750,000 of costs relating to a non-cash preferred stock dividend resulting from our preferred stock conversion to common stock completed during such three-month period. Without giving effect to such transactions, we would have had losses of $1,747,973 during the three months ended March 31, 2004, which included $430,447 of costs associated with our Services Agreement and Technology Access Option Agreement with SkyePharma. As a result, due to the costs relating to our Phase II trials for Psoraxine(R), during the period ended March 31, 2005, although we had losses of $1,680,197 for such period, our losses, excluding the non-cash preferred stock dividend, Services Agreement and Technology Access Option expenses, actually increased by $362,670 for the period ended March 31, 2005 compared to the same period ended March 31, 2004.

The Next Twelve Months

At March 31, 2005 we had cash balances of $1,014,876, which we estimate will last us through approximately July 2005, and no marketable securities.

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:

- Our primary focus is to further our 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 are implementing cost containment measures and realigning development activities to focus on such things as formulation, manufacturing, analytical protocols and potency. We remain committed to Psoraxine(R) and its future development, and expect to redesign and recommence Phase II 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.

- We intend to implement our business plan and facilitate the continuing operations of our company. We will spend approximately $1,690,000 to pay management salaries and salaries of employees, a portion of which is treated as research and development expense.

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

We will need to raise additional funds immediately to continue our operations for the period following July 2005 and to fund any of the activities described above. If we are able to identify additional capital to fund its operating and capital expenditures for 2005, such funds will be required to cover the cost to evaluate the results from our Phase II clinical studies for Psoraxine(R), to continue clinical trials for Psoraxine(R) and to initiate development of products for 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 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 immediately 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 July 2005. We will need to raise additional funds to continue our operations following that period. Furthermore, substantial additional funds will be needed in order to fund our continued efforts to obtain FDA approval of Psoraxine(R), especially given the failure of our Phase II study to meet its primary endpoint. No assurance can be given that we will be able to obtain financing, or successfully sell assets or stock, or, even if such transactions are possible, that they will be on terms reasonable to us or that they will enable us to satisfy our cash requirements. In addition, raising additional funds by selling additional shares of our capital stock will dilute the ownership interest of our

stockholders. If we do not obtain additional funds, we will likely be required to eliminate programs, delay development of our products, alter our business plans, or in the extreme situation, cease operations.

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

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

We commenced our current operations in 2001 and such operations remain in an early stage of development. We have no products approved for sale and therefore, no means to generate revenue. We have not commercialized any products, had no revenues and had incurred a cumulative net loss of $51,382,554 as of March 31, 2005 which has increased to date. The cumulative net loss through March 31, 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 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 and we would have to identify new potential products to develop.

Recent and future changes in senior management may affect our ability to implement our business plan.

On July 28, 2004, we accepted the resignations of Mike Ajnsztajn and Gina Tedesco, effective immediately with respect to their positions as members of our Board of Directors and effective as of August 26, 2004 with respect to their

positions as our Chief Executive Officer and Chief Financial Officer, respectively. On October 13, 2004, we retained Peter Golikov as interim Chief Executive Officer and Michael Garone as interim Chief Financial Officer. On November 24, 2004, Mr. Golikov ceased being our interim Chief Executive Officer. On January 27, 2005, we retained James Sharpe as our Chief Executive Officer. On February 21, 2005, we retained Michael Garone as our Chief Financial Officer. 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.

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

SkyePharma acquired 11,160,000 additional shares of our common stock on March 3, 2005, in a privately negotiated transaction, increasing its ownership of our common stock from 34.5% to 49.7%. 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 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.

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.

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:

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

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, 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.

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 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.

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 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.

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 13, 2005, the range of our stock price has been between $.16 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 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 73,273,055 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 90,170,946 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.

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 15g-9 under the Securities Exchange Act of 1934 imposes additional sales practice requirements on broker-dealers that recommend the purchase or sale of penny stocks to persons other than those who qualify as an "established customer" or an "accredited investor." This includes the requirement that a broker-dealer must make a determination on the appropriateness of investments in penny stocks for the customer and must make special disclosures to the customer concerning the risks of penny stocks. Application of the penny stock rules to our common stock could adversely affect the market liquidity of the shares, which in turn may affect the ability of holders of our common stock to resell the stock.

PART II. OTHER INFORMATION

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

Recent Sales of Unregistered Securities

On January 27, 2005, we entered into an Employment Agreement with James Sharpe, our President and Chief Executive Officer, and a member of Board of Directors. Pursuant to the terms of the Employment Agreement, we granted Mr. Sharpe options to purchase 728,000 shares of our common stock, which will vest to the extent of 182,000 immediately and then an additional 182,000 shares per year on a cumulative basis until all options have vested. The options have an initial exercise price of $0.70 per share and have a term of ten years. In addition, Mr. Sharpe was issued 100,000 shares of our common stock, which were fully vested and considered fully paid when issued. These 100,000 shares are restricted securities and were issued in reliance on an exemption from registration with the Securities and Exchange Commission provided under Section 4(2) of the Securities Act of 1933, as amended.

Item 6. Exhibits

EXHIBIT INDEX

EXHIBIT NUMBER	DESCRIPTION
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

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 16, 2005 By: /s/ JAMES SHARPE

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

Dated: May 16, 2005 By: /s/ MICHAEL GARONE

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