ASTRALIS LTD
Form 10QSB
November 15, 2004

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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 September 30, 2004.

|_| 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: 73,171,055 shares of Common Stock outstanding as of November 15, 2004.

Transitional Small Business Disclosure Format (check one):

Yes |_| No |X|

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ASTRALIS LTD.

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FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2004

PART I
FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

ASSETS

	September 30, 2004 (Unaudited)	D
Current Assets		
Cash and cash equivalents	$ 250,148	$
Marketable securities	2,694,679	
Prepaid expense - related party	251,875	
Prepaid expenses and supplies	168,863	
Total Current Assets	3,365,565	
Intangible Assets, Net - Related Party	2,976,184	
Other Intangible Assets, Net	115,736	
Property and Equipment, Net	243,862	
Deposits	29,452	
	$ 6,730,799	$

LIABILITIES AND STOCKHOLDERS' EQUITY

Current Liabilities		
Accounts payable and accrued expenses	$ 329,076	$

Total Current Liabilities	329,076
Commitments and Contingencies	
Stockholders' Equity	
Convertible preferred stock, Series A, $.001 par value; (authorized - 3,000,000 shares authorized at 2004 and 2003; issued and outstanding - 0 and 2,000,000 at 2004 and 2003) liquidation preference - $0 and $22,122,600 at 2004 and 2003	--
Common stock; $.0001 par value (authorized - 150,000,000 shares at 2004 and 2003; issued and outstanding - 73,173,055 and 37,538,189 at 2004 and 2003)	7,317
Additional paid-in capital	52,095,251
Deferred compensation	(1,039)
Stock subscriptions receivable	--
Accumulated other comprehensive loss	(31,272)
Deficit accumulated in the development stage	(45,668,534)
Total Stockholders' Equity	6,401,723
	$ 6,730,799

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

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

	Three Months Ended September 30,		Nine Months September
	2004	2003	2004
Revenues	$ --	$ --	$ --
Operating Expenses			
Research and development - related party	430,447	430,447	1,291,341
Research and development	886,006	429,244	2,476,500
Depreciation and amortization	7,774	33,523	22,814
General and administrative	307,329	322,741	1,491,544
Total Operating Expenses	1,631,556	1,215,955	5,282,199

Loss From Operations	(1,631,556)	(1,215,955)	(5,282,199)
Investment Income	529	20,080	28,454
Loss Before Income Tax Benefit	(1,631,027)	(1,195,875)	(5,253,745)
Income Tax Benefit	--	--	--
Net Loss	(1,631,027)	(1,195,875)	(5,253,745)
Preferred Stock Dividends	--	--	(10,750,000)
Net Loss to Common Stockholders	$ (1,631,027)	$ (1,195,875)	$(16,003,745)
Basic and Diluted Loss per Common Share	$ (0.02)	$ (0.03)	$ (0.23)
Basic and Diluted Weighted Average Common Shares Outstanding	73,171,132	37,538,189	70,488,807

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

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

	Nine Months Ended September 30,	
	2004	20
Cash Flows from Operating Activities		
Net loss	$ (5,253,745)	$ (3,9
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	649,199	6
Amortization of net premium paid on investments	--	
Dividends reinvested	(108,654)	(
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	3,783	
Investor relations fee netted against subscription receivable	24,000	
Compensatory common stock	75,000	
Assignment of call options as compensation	376,508	
(Gain) loss on fixed asset retirement	1,403	

(Gain) loss on sale of available-for-sale securities	83,329	(
Changes in assets and liabilities		
Prepaid expenses	797,537	7
Interest receivable	--	
Supplies	(38,836)	(
Deposits	501	
Accounts payable and accrued expenses	49,571	(
Net Cash Used in Operating Activities	(3,340,404)	(2,7
Cash Flows from Investing Activities		
Purchases of available-for-sale securities	(4,300,010)	(1,9
Proceeds from sale of available-for-sale securities	3,001,256	1,1
Expenditures related to patent	(25,676)	
Insurance proceeds from fixed asset retirement	4,113	
Purchases of property and equipment	(65,232)	(
Net Cash Used in Investing Activities	(1,385,549)	(7
Cash Flows from Financing Activities		
Repurchase of common stock	--	
Proceeds from stock subscription receivable	--	8
Proceeds from exercise of stock options	11,250	
Issuance of common stock, net of offering and transaction costs	4,954,191	
Issuance of preferred stock, net of research and development service fee, technology option and costs of offering	--	2,4
Net Cash Provided by Financing Activities	4,965,441	3,3
Net Increase (Decrease) in Cash and Cash Equivalents	239,488	(2
Cash and Cash Equivalents, Beginning of Period	10,660	2
Cash and Cash Equivalents, End of Period	$ 250,148	$

The accompanying notes are an integral part of
these 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 2003 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, 2004.

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 September 30,		
	2004	2003	
Net loss to common stockholders, as reported	$ (1,631,027)	$ (1,195,875)	$(16
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	(1,024)	(7,000)	
Pro forma net loss	$ (1,632,051)	$ (1,202,875)	$(16
Loss per share basic and diluted - as reported	(0.02)	(0.03)	
Loss per share basic and diluted - pro forma	(0.02)	(0.03)	
Shares used in basic and diluted loss per share amounts	73,171,132	37,538,189	70

NOTE 2 - DESCRIPTION OF BUSINESS

Nature of Operations

Astralis Ltd. is an emerging biotechnology company based in New Jersey and engaged primarily in the research and development of novel treatments for immune system disorders and skin diseases. The Company is currently developing two products. Its primary product, Psoraxine, is an innovative immunotherapeutic product under development for the treatment of psoriasis. The Company's second product is for the treatment of leishmaniasis.

NOTE 3 - GOING CONCERN

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 several years. The Company commenced clinical testing of Psoraxine in the third quarter of 2003. 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. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

Management estimates that its current cash and marketable securities held at September 30, 2004, will be needed in order to finance the Company's currently anticipated needs for operating and capital expenditures through the first quarter of 2005, including the cost to complete Phase II of the FDA testing process for Psoraxine. Based on our current plans, we will need to raise additional funds to continue our operations in the period following the first quarter of 2005. The Company is evaluating various options to raise additional funds necessary to continue our operations following that period. The Company will also need to raise significant additional funds from outside sources in future years in order to complete future phases of FDA required testing.

The Company's ability to adhere to its current business plan 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. Continuing as a going concern is dependent upon successfully obtaining additional working capital as described above. 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 - MARKETABLE SECURITIES

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

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

NOTE 4 - MARKETABLE SECURITIES (Continued)

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

As of September 30, 2004, available-for-sale securities consist of the following:

	Due	Amortized Cost	Gross Unrealized Loss	Gross Unrealized Gains
Fixed Income Funds	Current	$ 2,725,951	$ (86,556)	$ 55,284
		$ 2,725,951	$ (86,556)	$ 55,284

NOTE 5 - CAPITAL STOCK ACTIVITY

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

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

On the closing date of conversion, January 20, 2004, the Company and other original stockholders amended the stockholders agreement dated as of December 10, 2001. The board of directors is now required to be comprised of at least seven directors and include at least two independent directors. The agreement will terminate upon the later of (i) the date on which SkyePharma no longer beneficially owns, in the aggregate, at least 20% of the outstanding common stock of the Company or (ii) January 20, 2007. Further, this agreement may be

terminated by mutual written consent of the Company and SkyePharma.

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

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

NOTE 5 - CAPITAL STOCK ACTIVITY (Continued)

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

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

Warrants issued in April 2001 to purchase 75,000 shares of the Company's common stock expired in April 2004.

On July 9, 2004 a director of the Company exercised options to purchase 25,000 shares of common stock at $0.45 a share. The shares issued remain restricted.

NOTE 6 - COMPREHENSIVE LOSS

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net loss	$ (1,631,027)	$ (1,195,875)	$(16,003,745)	$ (3,962
Unrealized gain (loss) arising				

during period	87,851	(18,506)	24,043	(27
Reclassification adjustment for (gain) loss realized in net loss	(35,242)	(42)	(27,617)	5
Unrealized gain (loss)	52,609	(18,548)	(3,574)	(21
Comprehensive loss	$ (1,578,418)	$ (1,214,423)	$(16,007,319)	$ (3,983

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

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 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 18,491,891 and 19,645,237 at September 30, 2004 and 2003, respectively.

NOTE 8 - 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.

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 sections 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 OPERATIONS

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

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

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

- Ongoing research and development of Psoraxine, including conducting Phase II clinical trials in the U.S.; and

- Development of the technology underlying Psoraxine for the treatment of indications other than psoriasis, such as eczema, seborrheic dermatitis, leishmaniasis and psoriatic arthritis.

Results of Operations

Comparison of the three and nine months ended September 30, 2004 and September 30, 2003.

Revenues. We did not record any revenues during the three and nine months ended September 30, 2004 and September 30, 2003.

Operating Expenses. Operating expenses primarily consist of research and development costs and general and administrative expenses. Research and development costs increased $456,762 and $754,284, or 53% and 25% to $1,316,453 and $3,767,841, respectively, for the three and nine months ended September 30, 2004 from $859,691 and $3,013,557, respectively, for the three and nine months ended September 30, 2003. Research and development expenditures increased primarily due to milestone payments to the clinical research organization related to patient recruitment in continuing Phase II clinical trials. General

and administrative expenses decreased $15,412 and increased $535,525, or 5% and 56%, to $307,329 and $1,491,544, respectively, for the three and nine months ended September 30, 2004 from $322,741 and $956,019, respectively, for the three and nine months ended September 30, 2003. The decrease in general and administrative expenses for the three months ended September 30, 2004 was primarily due to a decrease in management salary expense with the departure of

our prior Chief Executive Officer and Chief Financial Officer. The increase in general and administrative expense for the nine months ended September 30, 2004 was primarily due to a non-cash expense related to our assignment to FPP Capital Advisors of 10% of the call option provided to us under the Call Option Agreement dated January 20, 2004 between us and SkyePharma. We assigned 10% of the call option to FPP Capital Advisors for consulting services. FPP Capital Advisors is an entity whose sole shareholder is Fabien Pictet, one of our directors. As a result of the assignment, we recorded in general and administrative expenses a non-cash charge of $376,508. The remaining increase in general and administrative expenses for the nine months ended September 30, 2004 is attributable to increased legal and accounting costs associated with the preparation and filing of a registration statement on Form SB-2 for shares issued in a private placement offering during the first quarter of 2004.

The Next Twelve Months

At September 30, 2004 we had cash balances of $250,148 and marketable securities of $2,694,679.

Based on our current operating plan, we anticipate conducting the following activities and using our cash through the third quarter of 2005 as follows:

- Our primary focus is to further our development efforts of our initial product candidate, Psoraxine. We expect to spend $2,000,000 on research and development, of which we expect to pay approximately $950,000 to third parties.

- We intend to proceed with the implementation of our business plan and continue the operations of our company. We will spend approximately $950,000 to pay management salaries and salaries of employees, a portion of which is treated as research and development expense and reflected in the paragraph above.

- In preparation for meeting the increasing need for supplies for Phase III clinical studies and commercialization we intend to scale up manufacturing capabilities for our lead product candidate in collaboration with a third party. We anticipate the costs associated with this activity to be approximately $1,200,000.

- We also expect to expend approximately $1,100,000 for our general administrative and working capital requirements.

We will need to raise additional funds to continue our operations in the period following the first quarter of 2005. Furthermore, substantial additional funds will be needed in order to fund our continued efforts to obtain FDA approval of Psoraxine. 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, or in the extreme situation, cease operations.

ITEM 3. CONTROLS AND PROCEDURES

Our management, with the participation of our interim Chief Executive Officer and interim Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2004. Based on this evaluation, our interim Chief Executive Officer and interim Chief Financial Officer concluded that our disclosure controls and procedures are effective for

recording, processing, summarizing and reporting the information the company is required to disclose in the reports it files under the Securities Exchange Act of 1934, within the time periods specified in the SEC's rules and forms. Such evaluation did not identify any change in our internal control over financial reporting that occurred during the quarter ended September 30, 2004 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

RISK FACTORS

We have no sales; we will not have sales in the foreseeable future; we are in an early stage of development and we may never sell products or become 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, have no revenues and have incurred a cumulative net loss of $45,668,534 through September 30, 2004 which has increased to date. The cumulative net loss through September 30, 2004 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, 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 and 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.

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

Based on our current plans, we will need to raise additional funds to continue our operations in the period following the first quarter of 2005. We will need 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. 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.

In addition, the Independent Auditors' Report on our annual financial statements includes a paragraph indicating doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

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. Our ability to implement our business strategy may be adversely affected if we 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.

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. 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 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.

Our initial product candidate, Psoraxine, will require the commitment of substantial resources to move it towards commercialization. Before obtaining regulatory approvals for the commercial sale of Psoraxine, 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 FDA 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

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.

Because Psoraxine 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. 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 in Venezuela, we have not sought, nor have we obtained, regulatory approval for the commercialization of Psoraxine 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 completed clinical trials of Psoraxine. If Psoraxine emerges successfully from clinical trials, we will either commercialize products resulting from our proprietary programs directly or through licensing arrangements with other companies. We have no experience in manufacturing and marketing, and we currently do not have the resources or capability to manufacture, market or sell our products on a commercial scale. In order to commercialize Psoraxine directly, we would need to develop or obtain through outsourcing arrangements the capability to manufacture, market and sell

products. We have an agreement with SkyePharma PLC ("SkyePharma") under which SkyePharma will provide development, pre-clinical and clinical development services for Psoraxine until December 31, 2004. However, we do not currently have a written agreement covering any period after December 31, 2004 and we may not be able to enter into such an agreement on commercially reasonable terms, or at all. In addition, we currently do not have any agreements for the marketing or sale of any of our products and we may not be able to enter into such agreements on commercially reasonable terms, or at all.

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. Dr. Jose Antonio O'Daly is the owner of the patent for Psoraxine. 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 and 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 loss of whose services would adversely impact the achievement of our objectives. In addition, we have recently hired an interim Chief Executive Officer and interim Chief Financial Officer. We do not currently have sufficient executive management personnel to execute our business plan fully. Also, 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 executive officers and 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 and the development of additional expertise by existing management personnel. The inability to acquire or develop this expertise could impair the growth 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 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 may not make decisions that further the best interests of all stockholders.

Our officers, directors and principal stockholders owning at least 5% of our common stock together control approximately 71.94% 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 November 14, 2004, the range of our stock price has been between $0.22 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 73,173,055 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 91,664,946 shares of common stock outstanding. Of the outstanding shares, up to 73,148,055 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 INFOMATION

Item 6. Exhibits

See Exhibit Index.

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: November 15, 2004

By: /s/ Peter Golikov

Peter Golikov
Interim Chief Executive Officer
(Principal Executive Officer;
Authorized Signatory on behalf
of Registrant)

Dated: November 15, 2004

By: /s/ Michael Garone

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

EXHIBIT INDEX

EXHIBIT NUMBER	DESCRIPTION
31.1	Certification of Peter Golikov required by Rule 13a-14(a) or Rule 15d-14(a)
31.2	Certification of Michael Garone required by Rule 13a-14(a) or Rule 15d-14(a)
32.1	Certification of Peter Golikov and Michael Garone required by Rule 13a-14(b) or Rule 15d-14(b) and Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350