

Edgar Filing: ASTRALIS LTD - Form 10QSB

ASTRALIS LTD  
Form 10QSB  
November 14, 2003

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

Form 10-QSB

(Mark One)

- Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 For the quarterly period ended September 30, 2003.
- 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  No

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date: 37,538,189 shares of Common Stock outstanding as of November 14, 2003.

Transitional Small Business Disclosure Format (check one):

Yes  No

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ASTRALIS LTD.

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FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2003

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### PART I. FINANCIAL INFORMATION

#### ITEM 1. FINANCIAL STATEMENTS

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

	ASSETS	September 30, 2003 ----- (Unaudited)
Current Assets		
Cash and cash equivalents		\$ 26,491
Marketable securities		1,972,534
Interest receivable, net		--
Prepaid expense - related party		1,259,375
Prepaid expenses and supplies		168,412 -----
Total Current Assets		3,426,812
Intangible Assets, Net - Related Party		3,690,472
Other Intangible Assets, Net		54,914
Property and Equipment, Net		314,202
Deposits		29,953 -----
		\$ 7,516,353 =====

#### LIABILITIES AND STOCKHOLDERS' EQUITY

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Current Liabilities		
Accounts payable and accrued expenses	\$	165,197
		-----
Total Current Liabilities		165,197
		-----
Commitments and Contingencies		
Stockholders' Equity		
Convertible preferred stock, Series A, \$.001 par value; 2,000,000 shares authorized at 2003 and 2002; 2,000,000 and 1,750,000 issued and outstanding at 2003 and 2002, respectively (liquidation preference - \$21,820,137 at September 30, 2003)		2,000
Common stock; \$.0001 par value; 75,000,000 shares authorized at 2003; 37,538,189 issued and outstanding at 2003 and 2002		3,754
Additional paid-in capital		35,982,442
Deferred compensation		(17,557)
Common stock subscriptions receivable		(36,000)
Accumulated other comprehensive loss		(36,586)
Deficit accumulated in the development stage		(28,546,897)
		-----
Total Stockholders' Equity		7,351,156
		-----
	\$	7,516,353
		=====

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

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

	Three Months Ended September 30,		Nine Mo Ended Septe
	2003	2002	2003
	-----	-----	-----
Revenues	\$       --	\$       --	\$       --
	-----	-----	-----
Operating Expenses			
Research and development - related party	430,447	2,173,761	1,291,341
Research and development	429,244	263,739	1,722,216
Depreciation and amortization	33,523	30,648	98,066
General and administrative	322,741	384,971	956,019
	-----	-----	-----

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Total Operating Expenses	1,215,955	2,853,119	4,067,642
	-----	-----	-----
Loss From Operations	(1,215,955)	(2,853,119)	(4,067,642)
Investment Income	20,080	30,506	105,107
	-----	-----	-----
Net Loss	(1,195,875)	(2,822,613)	(3,962,535)
Preferred Stock Dividends	--	--	--
	-----	-----	-----
Net Loss to Common Stockholders	\$ (1,195,875)	\$ (2,822,613)	\$ (3,962,535)
	=====	=====	=====
Basic and Diluted Loss per Common Share	\$ (0.03)	\$ (0.08)	\$ (0.11)
	=====	=====	=====
Basic and Diluted Weighted Average Common Shares Outstanding	37,538,189	37,538,189	37,538,189
	=====	=====	=====

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

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

	Nine Months Ended September 30, 2003	
	-----	-----
Cash Flows from Operating Activities		
Net loss	\$ (3,962,535)	\$
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	633,782	
Amortization of net premium paid on investments	5,737	
Dividends reinvested	(49,298)	
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	47,903	
Investor relations fee netted against subscription receivable	24,000	
Compensatory common stock	--	
(Gain) loss on sale of marketable securities	(11,874)	
Changes in assets and liabilities		
Prepaid expenses - related party	755,625	

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Prepaid expenses	11,531	
Interest receivable	5,891	
Supplies	(96,455)	
Deposits	--	
Accounts payable - related party	--	
Accounts payable and accrued expenses	(83,806)	
	-----	
Net Cash Used in Operating Activities	(2,719,499)	
	-----	
Cash Flows from Investing Activities		
Purchases of marketable securities	(1,915,369)	
Proceeds from sale of marketable securities	1,184,046	
Expenditures related to patent	(7,203)	
Purchases of property and equipment	(47,677)	
	-----	
Net Cash Used in Investing Activities	(786,203)	
	-----	
Cash Flows from Financing Activities		
Repurchase of common stock	--	
Proceeds from stock subscription receivable	825,000	
Issuance of common stock, net of offering and transaction costs	--	
Issuance of preferred stock, net of research and development service fee, technology option and costs of offering	2,480,000	
	-----	
Net Cash Provided by Financing Activities	3,305,000	
	-----	
Net Increase (Decrease) in Cash and Cash Equivalents	(200,702)	
Cash and Cash Equivalents, Beginning of Period	227,193	
	-----	
Cash and Cash Equivalents, End of Period	\$ 26,491	\$
	=====	=====

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

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

NOTE 1 - BASIS OF PRESENTATION

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

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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 2002 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, 2003.

### 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,		Nine Mo Sept
	2003	2002	2003
Net loss, as reported	\$ (1,195,875)	\$ (2,822,613)	\$ (3,962,535)
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	(7,000)	--	(13,063)
Pro forma net loss	\$ (1,202,875)	\$ (2,822,613)	\$ (3,975,598)
Basic and diluted net loss per share - as reported	(.03)	(.08)	(.11)
Basic and diluted net loss per share - pro forma	(.03)	(.08)	(.11)
Shares used in basic and diluted loss per share amounts	37,538,189	37,538,189	37,538,189

#### NOTE 2 - DESCRIPTION OF BUSINESS

##### Nature of Operations

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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 agent 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 is pursuing opportunities to sell equity securities privately to limited investors in 2003. These funds, in addition to its cash and marketable securities held at September 30, 2003, will be needed in order to finance the Company's currently anticipated needs for operating and capital expenditures for 2004, including the cost to complete Phase II of the FDA testing process for Psoraxine. 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 deposits 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.

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

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specific-identification method.

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

NOTE 4 - MARKETABLE SECURITIES (Continued)

As of September 30, 2003, available-for-sale securities consist of the following:

	Due	Amortized Cost	Gross Unrealized Loss	Gross Unrealized Gains
	-----	-----	-----	-----
Fixed Income Funds	Current	\$ 2,009,120	\$ (36,628)	\$ 42,000
		-----	-----	-----
		\$ 2,009,120	\$ (36,628)	\$ 42,000
		=====	=====	=====

NOTE 5 - STOCK SUBSCRIPTION RECEIVABLE

As of September 30, 2003, a subscription receivable in the amount of \$36,000 will be satisfied via services provided to the Company. For the nine months ended September 30, 2003, \$24,000 of prior year subscription receivable was satisfied with services.

NOTE 6 - CAPITAL STOCK ACTIVITY

Under the terms of a purchase agreement dated December 10, 2001, SkyePharma PLC ("SkyePharma") agreed to purchase 2,000,000 shares of Series A Convertible Preferred Stock of the Company at a price of \$10 per share. On January 31, 2003, the Company sold 250,000 shares of Series A Convertible Preferred Stock to SkyePharma for a purchase price of \$2,500,000, which represented the final installment under the purchase agreement. The Company owed SkyePharma \$20,000 related to the final payment of a service agreement. That amount was deducted from the proceeds of the January 2003 issuance of the preferred stock.

Options

On March 24, 2003, the Board of Directors approved, effective on April 4, 2003, the grant of options to a director to purchase 50,000 shares of common stock at an exercise price of \$0.45 per share. Options to purchase 12,500 shares of common stock vested on April 4, 2003, and options to purchase an additional 12,500 shares will vest each year thereafter for the following three years.

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



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### NOTE 7 - 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,	
	2003	2002	2003	2002
Net loss	\$(1,195,875)	\$(2,822,613)	\$(3,962,535)	\$(8,267,000)
Unrealized loss on securities:				
Unrealized loss arising during period	(18,506)	4,522	(27,062)	(1,000)
Reclassification adjustment for (gain) loss realized in net loss above	(42)	(16,976)	5,657	(1,000)
Unrealized loss, net	(18,548)	(12,454)	(21,405)	(1,000)
Comprehensive loss	\$(1,214,423)	\$(2,835,067)	\$(3,983,940)	\$(8,267,000)

### NOTE 8 - 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 19,645,237 and 14,095,237 at September 30, 2003 and 2002, respectively.

### NOTE 9 - RECLASSIFICATION

For comparability purposes, certain figures for the prior periods have been reclassified where appropriate to conform with the financial statement presentation used in 2003. These reclassifications had no effect on the reported net loss.

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### Notes to Condensed Financial Statements

#### NOTE 10 - SUBSEQUENT EVENTS

The Company intends to raise additional capital through the sale of equity securities under a private placement offering. In order to have a sufficient number of shares of common stock and common stock underlying the warrants that will be issued in the private placement, the Company is in the process of amending its Certificate of Incorporation in order to increase the number of authorized shares.

In November 2003 the Company signed a non-binding term sheet with SkyePharma PLC ("SkyePharma") pursuant to which (upon the execution of a binding agreement) SkyePharma will convert its outstanding shares of the Astralis Series A Preferred Stock into shares of common stock immediately following the closing of a planned private placement. In consideration of the agreement of SkyePharma to convert its shares of Series A Preferred Stock, the Company will adjust the conversion price of the shares of Series A Preferred Stock upon the closing of the private placement. The conversion price will be \$0.80 per share, subject to adjustment based on the price of securities offered in the private placement. The term sheet also provides that the Company will receive a call option on the additional shares of common stock issued to SkyePharma resulting from the conversion price adjustment, subject to certain conditions. The term sheet also contains provisions relating to a voting agreement and the Company having a minimum of two independent members on the board of directors. The term sheet is non-binding and is subject to the negotiation by the Company and SkyePharma of definitive agreements.

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#### SPECIAL CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

We believe that it is important to communicate our future expectations to our investors. However, we may be unable to accurately predict or control events in the future. The factors listed in the 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

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

### Overview

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:

- o Ongoing Phase I clinical trials in the United States, which includes enrolling and treating patients to evaluate the safety of Psoraxine;
- o Review and discussion with the FDA of Phase II clinical trial protocol; and
- o Identification of potential investigators for Phase II clinical trials in the United States.

### Results of Operations

Comparison of the nine months and three months ended September 30, 2003 and September 30, 2002.

Revenues. We did not record any revenues during the nine months or three months ended September 30, 2003 and September 30, 2002.

Operating Expenses. Operating expenses primarily consist of research and development costs and general and administrative expenses. Research and development costs decreased \$4,122,093 and \$1,577,809, or 58% and 65%, to \$3,013,557 and \$859,691, respectively, for the nine and three months ended September 30, 2003 from \$7,135,650 and \$2,437,500, respectively, for the nine

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and three months ended September 30, 2002. Research and development expenditures were higher in the prior period as we incurred the majority of our costs under the terms of our Service Agreement with SkyePharma in 2002. General and administrative expenses decreased \$209,247 and \$62,230, or 18% and 16%, to \$956,019 and \$322,741, respectively, for the nine and three months ended September 30, 2003 from \$1,165,266 and \$384,971, respectively, for the nine and three months ended September 30, 2002. The decrease in general and administrative expenses was primarily due to a significant reduction in investor relation costs and other reductions resulting from cost containment measures implemented by management.

### The Next Twelve Months

At September 30, 2003 we had cash balances of \$26,491 and marketable securities of \$1,972,534.

Based on our current operating plan, we anticipate conducting the following activities and using our cash over the course of the next twelve months as follows:

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- o Our primary focus is to further our development efforts of our initial product candidate, Psoraxine. We have commenced Phase I clinical trials of Psoraxine. We intend to conduct additional clinical trials in the process of obtaining FDA approval of Psoraxine and will also maintain ongoing research and development. We will expend approximately \$3,000,000 in connection with these activities.
- o We intend to implement our business plan and facilitate the operations of our company. We will spend approximately \$1,000,000 to pay management salaries and salaries of employees.
- o We also expect to expend approximately \$1,000,000 for our public relations, general administrative and working capital requirements.

We will need to raise additional funds to continue our operations in 2004. 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 Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2003. Based on this evaluation, our Chief Executive Officer and 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, 2003 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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### 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, had no revenues and had incurred a net loss of approximately \$28,546,897 as of September 30, 2003 which has increased to date. 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

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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 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.

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

Based on our current plans, we believe that we currently have sufficient funds to meet our operating expenses and capital requirements through approximately the first quarter of 2004. 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.

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 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, our initial product candidate, 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

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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, when commenced, expose participating patients to unacceptable health risks, we may suspend such trials. We may encounter problems in our studies which will cause us or the FDA to delay or suspend the studies. Some of the factors that may delay our commencement and rate of completion of clinical trials include:

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

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

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

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

Because our initial product candidate, 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

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product. Further, after granting regulatory approval, regulatory authorities subject a marketed product and its manufacturer to continual review, and discovery of previously unknown problems with a product or manufacturer may result in restrictions on the product, manufacturer and manufacturing facility, including withdrawal of the product from the market. In certain countries, regulatory agencies also set or approve prices.

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

We have not 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.

Dr. Jose Antonio O'Daly has filed a patent application for Psoraxine and has received a notice of allowance in connection with such patent application. 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 license, and do not own, the intellectual property rights to Psoraxine. 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

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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.

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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, Amgen, Genentech, SmithKline Beecham, Protein Design Labs, Ligand Pharmaceuticals, Schering-Plough, Pfizer 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. Our key personnel have no prior experience managing a start-up biotechnology company. We do not currently have sufficient executive management personnel to execute our business plan fully. 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



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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 our initial product candidate, 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 (greater than 5% stockholders) together control approximately 75.75% 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

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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. In the event of a merger or acquisition resulting in a change in control, SkyePharma also has a right to a premium equal to its purchase price for our preferred stock plus an amount equal to 30% of such purchase price per annum (or proportional part thereof if a portion of a year) commencing on the date of issuance of the preferred stock until the change in control.

### PART II. OTHER INFORMATION

#### Item 4. Submission of Matters to a Vote of Security Holders

We held an Annual Meeting of Shareholders on July 16, 2003. At that meeting, our shareholders elected seven directors for a term that will expire at our Annual Meeting in 2004, or until their successors are duly elected and qualified. In addition, our shareholders ratified the appointment of L J Soldinger Associates Ltd. as our independent auditors for the fiscal year ending

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December 31, 2003. The voting results were as follows:

	Votes For	Votes Withheld
Election of Director		
Jose Antonio O'Daly	29,809,003	27,929
Mike Ajnsztajn	29,809,003	27,929
Gaston Liebhaber	29,809,003	27,929
Gina Tedesco	29,809,003	27,929
Michael Ashton	29,809,003	27,929
Steven Fulda	29,809,003	27,929
Fabien Pictet	29,809,003	27,929
	Votes For	Votes Against
Ratification of Auditors	29,809,254	18,403

In addition, there were 671,536 broker non-votes on the above matters.

### Item 5. Other Information

#### Private Placement

Our current cash is expected to be sufficient to fund operations through the fourth quarter of 2003. As a result of discussions regarding our capital requirements, our board of directors and our management determined that we should raise additional capital through the sale of equity securities. Upon the terms and conditions of the private placement, we will offer units consisting of shares of our common stock and warrants to purchase shares of our common stock (the "Units"). We intend to sell an aggregate of up to \$10 million of our securities in connection with the private placement. In order to have a sufficient number of shares of common stock and common stock underlying the warrants that we will issue in the private placement, we must amend our Certificate of Incorporation in order to increase the number of authorized shares. Although we anticipate that the Units will be offered at a discount to the market price of our common stock, the offering price has not yet been determined and once determined may be changed as market conditions and the market price of our common stock fluctuate. As a result, we cannot know with certainty how many shares of common stock we will issue in the private placement. The securities offered in the private placement may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements. There can be no assurance that the private placement will close or, in the event the private placement closes, that proceeds of the private placement will be adequate to sustain our operations.

#### SkyePharma

We have signed a non-binding term sheet with SkyePharma PLC ("SkyePharma") pursuant to which, upon the execution of a binding agreement, SkyePharma will agree to convert its outstanding shares of our Series A Preferred Stock into shares of our common stock immediately following the closing of our private placement. In consideration of the agreement of SkyePharma to convert its shares

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of Series A Preferred Stock, we will adjust the conversion price of the shares of Series A Preferred Stock upon the closing of the private placement. The conversion price will be \$0.80 per share, subject to adjustment based on the price of securities offered in the private placement. The term sheet also provides that in connection with the conversion of the Series A Preferred Stock by SkyePharma, SkyePharma would enter into an agreement with us whereby we would, upon the attainment of certain future milestones, obtain the right to repurchase 12,500,000 shares of our common stock from SkyePharma based on the conversion price. As part of this transaction, we will also amend our Stockholders Agreement dated December 10, 2001 to extend the terms of the agreement to expire three years from the date of such transaction. The amended Stockholders Agreement would require the parties to vote all shares held by such parties for four directors designated by Jose Antonio O'Daly, Mike Ajnsztajn, Gaston Liebhaber and Gina Tedesco, one director designated by SkyePharma and two independent directors. Further, SkyePharma would be required to vote its shares of common stock in favor of certain enumerated transactions approved by the board of directors, including all independent directors. The term sheet is non-binding and is subject to the negotiation by us and SkyePharma of definitive agreements.

### Item 6. Exhibits and Reports on Form 8-K

#### (a) Exhibits

See Exhibit Index.

#### (b) Reports on Form 8-K

On August 13, 2003, we filed a current report on Form 8-K reporting that we issued a press release regarding our earnings for the quarter ended September 30, 2003.

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### SIGNATURES

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

ASTRALIS LTD.  
(Registrant)

Dated: November 14, 2003

By: /s/ Mike Ajnsztajn

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Mike Ajnsztajn  
Chief Executive Officer  
(Principal Executive Officer; Authorized  
Signatory on behalf of Registrant)

Dated: November 14, 2003

By: /s/ Gina Tedesco

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Gina Tedesco  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

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### EXHIBIT INDEX

EXHIBIT NUMBER	DESCRIPTION
31.1	Certification of Mike Ajnsztajn required by Rule 13a-14(a) or Rule 15d-14(a)
31.2	Certification of Gina Tedesco required by Rule 13a-14(a) or Rule 15d-14(a)
32.1	Certification of Mike Ajnsztajn and Gina Tedesco 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