

Edgar Filing: ASTRALIS LTD - Form 10QSB

ASTRALIS LTD  
Form 10QSB  
November 14, 2002

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

-----  
FORM 10-QSB

Quarterly report under section 13 or 15(d) of the Securities Exchange Act of  
1934 for the quarterly period ended September 30, 2002

Commission file number: 000-30997

ASTRALIS LTD.  
(exact name of small business issuer as specified in its charter)

Delaware  
(State or Other Jurisdiction of  
Incorporation or Organization)

84-1508866  
(I.R.S. Employer Identification No.)

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

(973) 227-7168  
(Issuer's telephone number, including area code)

Check whether the issuer (1) filed all reports required to be filed by Section  
13 or 15(d) of the Securities 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:

(1) Yes  No   
(2) Yes  No

The number of shares of the Issuer's Common Stock outstanding as of  
November 14, 2002 was 37,538,189.

Transitional Small Business Disclosure Format (check one):

Yes  No

ASTRALIS LTD.

INDEX

FOR QUARTERLY PERIOD ENDED SEPTEMBER 30, 2002

Part I.	Financial Information	3
Item 1.	Condensed Balance Sheets as of September 30, 2002 (unaudited) and December 31, 2001	3
	Condensed Statements of Operations (unaudited)	4
	Condensed Statements of Stockholders' Equity (unaudited)	5

## Edgar Filing: ASTRALIS LTD - Form 10QSB

	Condensed Statements of Cash Flows (unaudited)	9
	Notes to Condensed Financial Statements	10
Item 2.	Management's Discussion and Analysis or Plan of Operations	16
Item 3.	Controls and Procedures	19
	Risk Factors	19
Part II.	Other Information	25
Item 2.	Changes in Securities and Use of Proceeds	25
Item 6.	Exhibits and Reports on Form 8-K	25

2

### PART I FINANCIAL INFORMATION

#### ITEM 1. FINANCIAL STATEMENTS

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

#### ASSETS

	September 30, 2002	December 2001
	----- (Unaudited)	----- (Audit)
Current Assets		
Cash and cash equivalents	\$ 1,675,521	\$ 4,451
Marketable securities - current	1,723,277	
Interest receivable	18,832	
Prepaid expenses	13,748	38
	-----	-----
Total Current Assets	3,431,378	4,490
Marketable Securities - Noncurrent	495,870	
Intangible Assets, Net - Related Party	4,404,760	4,940
Other Intangible Assets, Net	41,687	25
Property and Equipment, Net	417,720	1
Deposits	29,953	
	-----	-----
	\$ 8,821,368	\$ 9,457
	=====	=====

#### LIABILITIES AND STOCKHOLDERS' EQUITY

Current Liabilities

Edgar Filing: ASTRALIS LTD - Form 10QSB

Accounts payable - related party	\$	--	\$	142
Accounts payable and accrued expenses		95,634		240
		-----		-----
Total Current Liabilities		95,634		383
		-----		-----
Commitments and Contingencies				
Stockholders' Equity				
Convertible preferred stock, Series A, \$.001 par value; 2,000,000 shares authorized; 1,750,000 and 1,000,000 issued and outstanding at 2002 and 2001, respectively (liquidation preference - \$15,418,767 at 2002)		1,750		1
Common stock; \$.0001 par value; 75,000,000 shares authorized; 37,538,189 and 37,588,179 issued and outstanding at 2002 and 2001, respectively		3,754		3
Additional paid-in capital		24,708,178		17,013
Deferred compensation		(304,148)		(398)
Common stock subscriptions receivable		(957,000)		(1,350)
Accumulated other comprehensive loss		(9,136)		
Deficit accumulated in the development stage		(14,717,664)		(6,195)
		-----		-----
Total Stockholders' Equity		8,725,734		9,074
		-----		-----
	\$	8,821,368	\$	9,457
		=====		=====

See notes to condensed financial statements.

3

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2002	2001	2002	
	-----	-----	-----	
Revenues	\$	--	\$	--
	-----	-----	-----	
Operating Expenses:				
Research and development - related party	2,173,761	--	6,653,542	
Research and development	211,671	17,571	341,290	
Depreciation and amortization	30,648	465	46,273	
General and administrative	437,039	160,954	1,306,084	
	-----	-----	-----	
Total Operating Expenses	2,853,119	178,990	8,347,189	
	-----	-----	-----	

Edgar Filing: ASTRALIS LTD - Form 10QSB

Loss From Operations	(2,853,119)	(178,990)	(8,347,189)
Investment Income	30,506	6	94,889
Net Loss	(2,822,613)	(178,984)	(8,252,300)
Preferred Stock Dividends	--	--	(270,000)
Net Loss to Common Stockholders	\$ (2,822,613)	\$ (178,984)	\$ (8,522,300)
Pro Forma Information			
Net loss		\$ (178,984)	
Pro forma tax provision		--	
Pro forma net loss		\$ (178,984)	
Basic and Diluted Loss per Common Share	\$ (0.08)	\$ --	\$ (0.23)
Basic and Diluted Weighted Average Common Shares Outstanding	37,538,189	26,190,110	37,542,401

See notes to condensed financial statements.

ASTRALIS LTD.  
(A Development Stage Entity)  
Condensed Statements of Stockholders' Equity  
(Unaudited)

	Preferred Stock		Common Stock		Additi Paid Capi
	Shares	Amount	Shares	Amount	
Balances, March 12, 2001 (Date of Inception)	--	\$ --	--	\$ --	\$ --
Members' capital contributions, 3/15/2001	--	--	25,300,000	2,530	3
Capital contributions received, 3/1 - 8/13/2001	--	--	--	--	--
Members' contributed services, 3/15 - 6/30/2001	--	--	--	--	1
Members' capital contributions, 9/1/2001	--	--	2,700,000	270	1,34

Edgar Filing: ASTRALIS LTD - Form 10QSB

Warrants to purchase 6,300,000 shares of common stock at \$1.60 per share issued in private placement	--	--	--	--	
Common stock issuable for consulting services, 9/1/2001; 500,000 shares	--	--	--	--	13
Common stock issued in private placement net of issuance costs, 11/13/2001; 2,076,179 shares at \$1.60 per share	--	--	2,076,179	208	3,19
Warrants to purchase 415,237 shares of common stock at \$4.00 per share issued in private placement, 11/13/2001	--	--	--	--	
Net assets and liabilities acquired in merger with Hercules	--	--	7,512,000	751	(30
Preferred stock issued, net of issuance costs, 12/10/2001; 1,000,000 shares at \$10.00 per share	1,000,000	1,000	--	--	9,94
Preferred stock dividend, 12/10/2001	--	--	--	--	2,12
Options to purchase 200,000 shares of common stock at \$1.77 (based on valuation) issued for legal services, 12/31/2001	--	--	--	--	35
Options to purchase 100,000 shares of common stock at \$1.77 (based on valuation) issued for consulting services, 12/31/2001	--	--	--	--	17
Amortization of deferred compensation	--	--	--	--	
Net loss	--	--	--	--	
	-----	-----	-----	-----	-----
Balance, December 31, 2001	1,000,000	\$ 1,000	37,588,179	\$ 3,759	\$ 17,01
	-----	-----	-----	-----	-----

See notes to condensed financial statements.

ASTRALIS LTD.  
(A Development Stage Entity)  
Condensed Statements of Stockholders' Equity  
(Unaudited)

	Accumulated	Deficit
	Other	Accumulated
		During the

Edgar Filing: ASTRALIS LTD - Form 10QSB

	Comprehensive Loss	Development Stage	Total	Com
	-----	-----	-----	---
Balances, March 12, 2001 (Date of Inception)	\$ --	\$ --	\$ --	\$
Members' capital contributions, 3/15/2001	--	--	--	
Capital contributions received, 3/1 - 8/13/2001	--	--	33,183	
Members' contributed services, 3/15 - 6/30/2001	--	--	12,986	
Members' capital contributions, 9/1/2001	--	--	--	
Warrants to purchase 6,300,000 shares of common stock at \$1.60 per share issued in private placement	--	--	--	
Common stock issuable for consulting services, 9/1/2001; 500,000 shares	--	--	135,000	
Common stock issued in private placement net of issuance costs, 11/13/2001; 2,076,179 shares at \$1.60 per share	--	--	3,190,637	
Warrants to purchase 415,237 shares of common stock at \$4.00 per share issued in private placement, 11/13/2001	--	--	--	
Net assets and liabilities acquired in merger with Hercules	--	--	(302,320)	
Preferred stock issued, net of issuance costs, 12/10/2001; 1,000,000 shares at \$10.00 per share	--	--	9,947,496	
Preferred stock dividend, 12/10/2001	--	(2,120,000)	--	
Options to purchase 200,000 shares of common stock at \$1.77 (based on valuation) issued for legal services, 12/31/2001	--	--	--	
Options to purchase 100,000 shares of common stock at \$1.77 (based on valuation) issued for consulting services, 12/31/2001	--	--	--	
Amortization of deferred compensation	--	--	132,750	
Net loss	--	(4,075,364)	(4,075,364)	
	-----	-----	-----	---
Balance, December 31, 2001 (audited)	\$ --	\$ (6,195,364)	\$ 9,074,368	\$
	-----	-----	-----	---

See notes to condensed financial statements.

ASTRALIS LTD.  
(A Development Stage Entity)  
Condensed Statements of Stockholders' Equity  
(Unaudited)

	Preferred Stock		Common Stock		Additi Paid- Capit
	Shares	Amount	Shares	Amount	
Balances Brought Forward	1,000,000	\$ 1,000	37,588,179	\$ 3,759	\$ 17,01
Oversubscription of common stock issued in private placement, 11/13/2001; 49,990 shares cancelled at \$1.60 per share, 1/24/2002	--	--	(49,990)	(5)	(7)
Preferred stock issue, net of issuance costs, 1/31/2002; 250,000 shares at \$10.00 per share	250,000	250	--	--	2,49
Preferred stock issue, net of issuance costs, 4/30/2002; 250,000 shares at \$10.00 per share	250,000	250	--	--	2,49
Preferred stock dividend, April 30, 2002	--	--	--	--	27
Preferred stock issue, net of issuance costs, 7/31/2002; 250,000 shares at \$10.00 per share	250,000	250	--	--	2,49
Collection of subscription receivable, July 2002	--	--	--	--	
Collection of subscription receivable, August 2002	--	--	--	--	
Collection of subscription receivable, September 2002	--	--	--	--	
Options issued for consulting services, 9/10/2002; 15,000 options at \$0.38 per option, based on valuation	--	--	--	--	
Amortization of deferred compensation	--	--	--	--	
COMPREHENSIVE LOSS					
Net loss	--	--	--	--	
Other comprehensive loss:					
Unrealized gain (loss) on available-for-sale securities	--	--	--	--	
Total Comprehensive Loss					

Edgar Filing: ASTRALIS LTD - Form 10QSB

Balance, September 30, 2002 (unaudited)    1,750,000    \$    1,750    37,538,189    \$    3,754    \$ 24,700  
=====    =====    =====    =====    =====

See notes to condensed financial statements.

7

Page 4 of 4

ASTRALIS LTD.  
(A Development Stage Entity)  
Condensed Statements of Stockholders' Equity  
(Unaudited)

	Accumulated Other Comprehensive Loss -----	Deficit Accumulated During the Development Stage -----	Total -----
Balances Brought Forward	\$            --	\$ (6,195,364)	\$ 9,074,368
Oversubscription of common stock issued in private placement, 11/13/2001; 49,990 shares cancelled at \$1.60 per share, 1/24/2002	--	--	(80,000)
Preferred stock issue, net of issuance costs, 1/31/2002; 250,000 shares at \$10.00 per share	--	--	2,500,000
Preferred stock issue, net of issuance costs, 4/30/2002; 250,000 shares at \$10.00 per share	--	--	2,500,000
Preferred stock dividend April 30, 2002	--	(270,000)	--
Preferred stock issue, net of issuance costs, 7/31/2002; 250,000 shares at \$10.00 per share	--	--	2,500,000
Collection of subscription receivable, July 2002	--	--	280,000
Collection of subscription receivable, Aug. 2002	--	--	65,000
Collection of subscription receivable, Sept. 2002	--	--	48,000
Options issued for consulting services, 9/10/2002; 15,000 options at \$0.38 per option, based on valuation	--	--	--
Amortization of deferred compensation	--	--	99,802
COMPREHENSIVE LOSS			
Net loss	--	(8,252,300)	(8,252,300)
Other comprehensive loss:			

Edgar Filing: ASTRALIS LTD - Form 10QSB

Unrealized gain (loss) on available-for-sale securities	(9,136)	--	(9,136)
	-----	-----	-----
Total Comprehensive Loss			
Balance, September 30, 2002 (unaudited)	\$ (9,136)	\$ (14,717,664)	\$ 8,725,734
	=====	=====	=====

See notes to condensed financial statements.

8

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

	Nine Months Ended September 30, 2002	March 12, 2001 (Inception) September 30, 2001
	-----	-----
Cash Flows from Operating Activities		
Net loss	\$ (8,252,300)	\$ (208,310)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	581,988	64,000
Amortization of net premium paid on investments	44,900	--
Dividends reinvested	(1,998)	--
Members' contributed salaries	--	12,980
Research and development service fee netted against proceeds received from preferred stock issuance	1,995,000	--
Operating expenses paid by related parties on behalf of Company	--	23,800
Amortization of deferred compensation	99,802	--
Compensatory common stock	--	135,000
Loss on sale of available-for-sale securities	737	--
Changes in assets and liabilities		
Prepaid expenses	24,713	--
Interest receivable	(18,832)	--
Deposits	(29,953)	--
Accounts payable - related party	(145,003)	--
Accounts payable and accrued expenses	(142,446)	36,570
	-----	-----
Net Cash Used in Operating Activities	(5,843,392)	69,000
	-----	-----
Cash Flows from Investing Activities		
Purchases of marketable securities	(7,213,234)	--
Proceeds from sale of marketable securities	4,941,313	--
Expenditures related to patent	(18,192)	--
Purchases of property and equipment	(460,848)	--

Edgar Filing: ASTRALIS LTD - Form 10QSB

	-----	-----
Net Cash Used in Investing Activities	(2,750,961)	-
	-----	-----
Cash Flows from Financing Activities		
Repurchase of common stock	(80,000)	-
Proceeds from stock subscription receivable	393,000	-
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	5,505,000	-
	-----	-----
Net Cash Provided by Financing Activities	5,818,000	-
	-----	-----
Net Increase (Decrease) in Cash and Cash Equivalents	(2,776,353)	69
Cash and Cash Equivalents, Beginning of Period	4,451,874	-
	-----	-----
Cash and Cash Equivalents, End of Period	\$ 1,675,521	\$ 69
	=====	=====

See notes to condensed financial statements.

9

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

NOTE 1 - BASIS OF PRESENTATION

The accompanying unaudited financial statements have been prepared in accordance with the instructions to Form 10-QSB as prescribed by the Securities and Exchange Commission ("SEC"). These financial statements, in the opinion of management, include all adjustments (consisting only of normal recurring items) necessary for their fair presentation in conformity with accounting principles generally accepted in the United States.

These financial statements should be read in conjunction with the financial statements and notes included in the Astralis Ltd. (the "Company") Annual Report on Form 10-KSB for the year ended December 31, 2001, for an expanded discussion of the financial disclosures and accounting policies of the Company. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted pursuant to the SEC rules and regulations. Interim results are not necessarily indicative of results for the full year.

The amortization related to the technology option license is recorded as research and development cost as required by Financial Accounting Standard No. 2 - Research and Development Costs.

NOTE 2 - DESCRIPTION OF BUSINESS

Nature of Operations

## Edgar Filing: ASTRALIS LTD - Form 10QSB

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 vaccine under development for the treatment of psoriasis. The Company's second product is for the treatment of leishmaniasis.

### History and Basis of Financial Information

In November 2001, the Company was a public shell company, defined as an inactive, publicly quoted company with nominal assets and liabilities.

The operations and financial statements of the Company prior to November 13, 2001 are those of Astralis, LLC, ("Astralis, LLC") a New Jersey limited liability company formed on March 12, 2001. Astralis, LLC was merged into the Company on November 13, 2001. The combination of the Company and Astralis, LLC has been treated as a recapitalization of the Company. The Company was the legal acquirer and the surviving legal entity in the merger. Astralis, LLC was the accounting acquirer since the former members of Astralis, LLC acquired a majority ownership interest in the Company. Consequently, the historical financial information included in the financial statements of the Company prior to November 2001 is that of Astralis, LLC. Pro forma financial information relating to the merger is not presented since the combination is a recapitalization and not a business combination.

### Pro Forma Financial Information

As discussed above, Astralis, LLC was originally organized in the form of a Limited Liability Company. Upon the Merger, its capital structure changed to that of a corporation. The change resulted in the Company retaining the tax benefit for the portion of the losses generated subsequent to November 13, 2001, whereas the previous losses were passed through to the Astralis, LLC members. Pursuant to SEC Staff Accounting Bulletin Number 1B.2 "Pro Forma Financial Statements and Earnings per Share", a pro forma income statement has been presented which reflects the impact of the Company's change in capital structure as if it had occurred March 12, 2001 (Astralis LLC's inception). This presentation reflects the Company generating a tax benefit, which has been offset with a valuation allowance, which includes the net operating losses incurred by Astralis, LLC during the period from March 12, 2001 to November 13, 2001, the operating period prior to Astralis, LLC's termination.

10

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

### NOTE 3 - MARKETABLE SECURITIES

The Company's marketable equity securities consisted of certificates of deposits, government securities and corporate bonds 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

## Edgar Filing: ASTRALIS LTD - Form 10QSB

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 specific-identification method.

As of September 30, 2002, available-for-sale securities consist of the following:

	Due -----	Amortized Cost -----	Gross Unrealized Loss -----	
Certificate of Deposits	10/2002 to 2/2003	\$ 994,172	\$ (267)	\$
Corporate Bonds	9/2005	500,000	(4,130)	
Fixed Income Funds	Current	701,803	(5,701)	
Government Securities	11/2002	32,308	--	
		-----	-----	
		\$ 2,228,283	\$ (10,098)	\$
		-----	-----	
Less Current Portion		\$ 1,723,277	\$ --	\$
		-----	-----	
Non-Current Portion		\$ 505,006	\$ (10,098)	\$
		=====	=====	=

### NOTE 4 - INCOME TAXES

Recognition of the benefits of the deferred tax assets and liabilities will require that the Company generate future taxable income. There can be no assurance that the Company will generate any earnings or any specific level of earnings in future years. Therefore, the Company has established a valuation allowance for all deferred assets (net of liabilities).

11

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

### NOTE 5 - CAPITAL STOCK ACTIVITY

#### Common Stock

In January 2002, the Company agreed to amend a subscription agreement with one of the investors who participated in the November 2001 private placement offering. The Company consented to reduce the number of shares in the subscription agreement by 49,990 shares of common stock. The Company cancelled the respective shares and returned the corresponding amount of funds to the investor amounting to \$80,000.

## Edgar Filing: ASTRALIS LTD - Form 10QSB

Certain stockholders owed \$1,350,000 to the Company, under stock subscription agreements, which were due February 13, and May 13, 2002. This money was not paid to the Company causing the notes to become in default. On June 3, 2002 the Company entered into a payment plan agreement with a representative of the stockholders, whereby the stockholders will pay the amounts due, in approximately equal amounts, over a nine-month period commencing in June 2002. The stockholders will be subject to forfeiture of a percentage of their shares if they do not make the required payments. The Company has also agreed to extend the expiration date of warrants to purchase 3,150,000 shares of common stock from December 13, 2003 to December 13, 2004.

As of September 30, 2002, the stockholders were late on the scheduled payments in the amount of \$257,000.

### Preferred Stock

On December 10, 2001, the Company and SkyePharma PLC ("SkyePharma") entered into a purchase agreement whereby SkyePharma agreed to purchase 2,000,000 shares of Series A Convertible Preferred Stock ("Series A Preferred") at a price of \$10 per share over a 13-month period with five separate closings. On December 10, 2002, the one-year anniversary of the agreement, SkyePharma will receive registration rights on the common stock underlying its Series A Preferred shares. The first closing occurred in December 2001 and the Company sold 1,000,000 shares of Series A Preferred for a purchase price of \$10,000,000. The second closing occurred in January 2002 and the Company sold 250,000 shares of Series A Preferred for a purchase price of \$2,500,000. The third closing occurred in April 2002 and the Company sold 250,000 shares of Series A Preferred for a purchase price of \$2,500,000. The fourth closing occurred in July 2002 and the Company sold 250,000 shares of Series A Preferred for a purchase price of \$2,500,000. The remaining 250,000 shares of Series A Preferred totaling \$2,500,000 are contracted to be sold on January 31, 2003.

The Company's stock price on April 30, 2002 was \$2.77; consequently, pursuant to the requirements of EITF 98-5 "Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios", the issuance of the Series A Preferred, which are convertible initially at \$2.50 per share at any time, resulted in a beneficial conversion feature recorded as a preferred stock dividend in the amount of \$270,000.

Since the conversion price of the Series A Preferred is subject to reset provisions as described above, there is a contingent beneficial conversion feature applicable to the Series A Preferred. Using the potential conversion price of \$1.60 for the first anniversary date as limited in the purchase agreement, ignoring any other price adjustments described above, the contingent beneficial conversion feature would result in an additional preferred stock dividend of \$9,100,000 in December 2002.

12

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

### NOTE 6 - DEFERRED COMPENSATION

The components of deferred compensation are as follows:

Consultants  
-----

## Edgar Filing: ASTRALIS LTD - Form 10QSB

Balance at December 31, 2001	\$ 398,250
Deferred compensation recorded	5,700
Amortization to stock-based compensation	(99,802)
	-----
Balance at September 30, 2002	\$ 304,148
	=====

In July 2002, the Company granted 15,000 stock options with a strike price of \$2.50, as compensation to a consultant.

### NOTE 7 - OPERATING LEASES

On March 13, 2002, the Company entered into a lease agreement for laboratory and office space. The lease period is for three years and rent will be \$77,500 annually. The Company also entered into a concurrent service agreement with the lessor of the laboratory space on a time and material basis.

On March 15, 2002, the Company leased an apartment for one key employee and officer for one year. The lease commenced on April 15, 2002 and ends on April 14, 2003. Monthly rent will be \$2,865, which will be paid by the Company.

On June 26, 2002, the Company leased an apartment for a key employee for one year. The lease commenced on July 1, 2002 and ends on June 30, 2003. Monthly rent will be \$1,175, which will be paid by the Company.

On June 22, 2002, the Company leased an automobile for an officer of the Company for 39 months. The lease commenced on June 22, 2002 and ends on September 22, 2005. Monthly payments will be \$477, which will be paid by the Company.

13

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

### NOTE 8 - 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, 2002	March (Ince Septem
	2002	2001		
Net loss	\$ (2,822,613)	\$ (178,984)	\$ (8,252,300)	\$
Unrealized gain on securities:				
Unrealized gain arising during period	4,522	--	962	
Less: Reclassification				

Edgar Filing: ASTRALIS LTD - Form 10QSB

adjustment for loss realized in net loss	(16,976)	--	(10,098)
Unrealized gain (loss), net	(12,454)	--	(9,136)
Comprehensive loss	\$ (2,835,067)	\$ (178,984)	\$ (8,261,436)

NOTE 9 - 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 are 14,095,237 and 0 at September 30, 2002 and 2001, respectively. Such securities, had they been dilutive, would have been included in the computations of diluted loss per share using the treasury stock method, or the if-converted method, depending on the type of security.

NOTE 10 - RELATED PARTY TRANSACTIONS

A research entity owned by the spouse of the majority shareholder provided research and development services to the Company totaling \$132,826.

On December 10, 2001, the Company entered into a services agreement whereby it agreed to pay \$11,000,000 to SkyePharma in return for SkyePharma providing all development, manufacturing, pre-clinical and clinical development services for the Company's primary product, second generation Psoraxine, until December 31, 2002. The contract recognized that SkyePharma performed \$3,000,000 of these services in the fourth quarter of 2001 and that SkyePharma will perform and be paid for the remaining \$8,000,000 of services in 2002. The payment terms for the services agreement are fixed. \$3,000,000 was required to be paid on December 10, 2001 and was expensed in 2001.

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

NOTE 10 - RELATED PARTY TRANSACTIONS (Continued)

The remaining \$8,000,000 is required to be paid in eleven equal monthly installments of \$665,000, and a final payment of \$685,000 in 2002. For the nine months ended September 30, 2002, the Company expensed \$5,985,000 in connection with this agreement.

NOTE 11 - CONCENTRATIONS

The Company currently has two products that are under development. Lack of product development or customer interest could have a materially adverse effect on the Company. Further, significant changes in technology could lead to new products or services that compete with the product to be offered by the Company.

## Edgar Filing: ASTRALIS LTD - Form 10QSB

These changes could materially affect the price of the Company's products or render them obsolete.

In 2002, the Company's funding is expected to be generated from sales of its Series A Preferred shares under a purchase agreement with SkyePharma and collection of the subscription receivables. Should the remaining purchases of shares not occur as specified by the purchase contract, the Company would need to find alternative sources of financing, alter its business plan or curtail its operations.

### NOTE 12 - LIQUIDITY AND CONTINGENCIES NOT DESCRIBED ELSEWHERE

There are many steps to the process that pharmaceutical products must undergo before they can be commercially sold and distributed in the United States. Drugs must undergo testing in compliance with US Food and Drug Administration ("FDA") regulations and ultimately receive FDA approval. The Company's Psoraxine product is expected to enter initial FDA testing in 2002. FDA testing occurs in various phases over a multiple number of years.

The Company anticipates that their current liquid resources at September 30, 2002, together with the \$2,500,000 in proceeds, contractually to be received from the sale of their Series A Preferred (see Note 5) will be sufficient to finance its currently anticipated needs for operating and capital expenditures for 2002 and through the completion of Phase II of the FDA testing process in connection with its Psoraxine drug. However, the Company will need to raise additional funds from outside sources in order to complete future phases of FDA required testing.

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.

### NOTE 13 - SUPPLEMENTARY DISCLOSURE OF CASH FLOW INFORMATION

Payment of the January 2002, April 2002 and July 2002 service fees totaling \$1,995,000 were netted against the SkyePharma January 31, 2002 and April 30, 2002 installment purchases of Company's Series A Preferred stock.

The Company recorded an unrealized loss on its securities available-for-sale in the amount of \$12,454 and \$9,136 for the three months and nine months ended September 30, 2002, respectively.

### 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

## Edgar Filing: ASTRALIS LTD - Form 10QSB

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 Plan Of Operations 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" Contained Elsewhere In This Quarterly Report, 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.

#### Plan of Operations

##### Overview

We were formerly named Astralis Pharmaceuticals Ltd. and Hercules Development Group, Inc., and were incorporated under the laws of the state of Colorado on June 30, 1999. Subsequently we were reincorporated in the state of Delaware on December 10, 2001 and changed our name to Astralis Ltd. In November 2001, we were a public shell company, defined as an inactive, publicly quoted company with nominal assets and liabilities.

Our operations and financial statements prior to November 2001 are those of Astralis LLC, a New Jersey limited liability company formed on March 12, 2001. Astralis LLC was merged into us on November 13, 2001 pursuant to the terms of the Contribution Agreement.

The effect of our combination with Astralis LLC was a reverse merger. We were the legal acquirer in the merger. Astralis LLC was the accounting acquirer since its members acquired a majority ownership interest in us. Consequently, the historical financial information included in our financial statements prior to November 2001 are those of the accounting acquirer, Astralis LLC. The stockholders' equity of the merged company was recapitalized to reflect the capital structure of the legal entity (Astralis Ltd.) and the retained earning of Astralis LLC. Pro forma financial information is not presented since the combination is a recapitalization and not a business combination.

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.

16

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

- o Ongoing research and development of Psoraxine;
- o Doctor and site enrollment for clinical trials of Psoraxine in the United States; and

## Edgar Filing: ASTRALIS LTD - Form 10QSB

- o Preparation of an Investigational New Drug application to obtain approval from the United States Food and Drug Administration for the commencement of clinical trials of Psoraxine in the United States.

Three months ended September 30, 2002 compared to the three months ended September 30, 2001.

For the three months ended September 30, 2002:

On July 30, 2002, we sold to SkyePharma pursuant to a Purchase Agreement dated December 10, 2001, an aggregate of 250,000 shares of our Series A Convertible Preferred Stock, par value \$.001 per share at a purchase price of \$10.00 per share, or an aggregate purchase price of \$2,500,000. We received net proceeds of approximately \$1,835,000 from this placement after we netted out from the proceeds \$665,000 due to SkyePharma for services they provided under our Service Agreement with them which were treated as an expense at the time of payment.

For the three months ended September 30, 2002, we had no revenue and incurred operating expenses of \$2,853,119 which consisted primarily of:

- o Research and development costs of \$2,385,432, including \$1,995,000 that was paid to SkyePharma for services provided under our Service Agreement with them and amortization of approximately \$178,572 under our technology option license which is being amortized over a seven year period.
- o General and administrative costs of approximately \$437,089, including professional fees and our general corporate expenditures.

As a result, during the three months ended September 30, 2002, we incurred a net loss of \$2,822,613.

For the three months ended September 30, 2001:

For the three months ended September 30, 2001, we had no revenue and incurred operating expenses of \$208,322 which consisted primarily of:

- o Research and development costs of \$17,571.
- o General and administrative costs of approximately \$160,954, including professional fees and our general corporate expenditures.

As a result, during the three months ended September 30, 2001, we incurred a net loss of \$178,984.

Nine months ended September 30, 2002 compared to the period from March 12, 2001, which was the date of our inception through September 30, 2001.

For the nine months ended September 30, 2002:

On July 30, 2002, we sold to SkyePharma pursuant to a Purchase Agreement dated December 10, 2001, an aggregate of 250,000 shares of our Series A Convertible Preferred Stock, par value \$.001 per share at a purchase price of \$10.00 per share, or an aggregate purchase price of \$2,500,000. We received net proceeds of approximately \$1,835,000 from this placement after we netted out from the proceeds \$665,000 due to SkyePharma for services they provided under our Service Agreement with them which were treated as an expense at the time of payment.

## Edgar Filing: ASTRALIS LTD - Form 10QSB

For the nine months ended September 30, 2002, we had no revenue and incurred operating expenses of \$8,347,189 which consisted primarily of:

- o Research and development costs of \$6,994,832, including \$5,985,000 that was paid to SkyePharma for services provided under our Service Agreement with them and amortization of approximately \$535,716 under our technology option license which is being amortized over a seven year period.
- o General and administrative costs of approximately \$1,306,084, including professional fees and our general corporate expenditures.

We also had a non-cash preferred stock dividend in 2002 in the amount of \$270,000. The April 30, 2002 sale of convertible preferred stock to SkyePharma had a conversion rate to our common stock which was lower than the market price of our common stock on that date. Therefore, under the requirements of Emerging Issues Task Force No. 98-5 "Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios", the issuance of this preferred stock with a beneficial conversion feature resulted in a preferred stock dividend.

As a result, during the nine months ended September 30, 2002, we incurred a net loss of \$8,522,300.

For the period from March 12, 2001, which was the date of our inception through September 30, 2001, we had no revenue and incurred operating expenses of \$208,322 which consisted primarily of:

- o Research and development costs of \$23,376.
- o General and administrative costs of approximately \$184,299, including professional fees and our general corporate expenditures.

As a result, during the period from March 12, 2001 through September 30, 2001, we incurred a net loss of \$208,316.

The Next Twelve Months

At September 30, 2002 we had cash balances of \$1,675,521 and marketable securities of \$2,219,147.

SkyePharma has agreed to purchase for \$2,500,000 an additional 250,000 shares of preferred stock on January 31, 2003.

We anticipate collecting our subscription notes receivable. These subscription notes receivable were due in two installments, with \$850,000 having been due on February 13, 2002 and the remaining \$500,000 due on May 13, 2002. We entered into a payment plan agreement with the note holders of the subscription notes receivable. The note holders agreed to pay a \$200,000 initial payment and will make payments of \$150,000 per month from July 2002 until January 2003 and a payment of \$100,000 in February 2003. Upon any default by a note holder, such note holder will forfeit the number of shares equal to the remaining amount of his note divided by \$0.50. We received the initial payment of \$200,000 and the \$150,000 payment due in July 2002. We have received \$91,000 of the \$150,000 payment due in August 2002. We have not received the \$150,000 payment due in September 2002 and the \$150,000 payment due in October 2002. The total amount outstanding as of November 14, 2002 is \$909,000.

Based on our current operating plan, we anticipate conducting the following activities and using our cash and expected net proceeds of the

## Edgar Filing: ASTRALIS LTD - Form 10QSB

Purchase Agreement over the course of the next twelve months as follows:

- o Our primary focus is to further our development efforts of our initial product candidate, Psoraxine. We are preparing an Investigational New Drug application to obtain approval from the United States Food and Drug Administration for the commencement of clinical trials of Psoraxine in the United States. Upon receiving approval, we will commence doctor and site enrollment for these clinical trials and then conduct clinical trials in the process of obtaining FDA approval of Psoraxine. We will maintain ongoing research and development of Psoraxine. We will expend approximately \$4,500,000 in connection with these activities. Included in this amount are payments required under our Service Agreement with SkyePharma which will amount to \$2,015,000 for the last quarter of 2002 and are required to be paid in equal monthly amounts.

18

- o We intend to implement our business plan and facilitate the operations of our company. We will spend approximately \$1.3 million to pay for professional services, management salaries and salaries of new employees.
- o We also expect to expend approximately \$700,000 for our public relations, general administrative and working capital requirements.

Based on the current operating plan, we anticipate that our existing capital resources, together with the net proceeds we receive from the Purchase Agreement and the proceeds of the subscription notes receivable, will be adequate to satisfy our capital requirements for approximately the twelve month period ending September 30, 2003. However, our plans may change as we reach milestones and as our circumstances may change.

We also expect to record an additional preferred stock dividend in December 2002. We are subject to the requirements of EITF No. 00-27 "Application of Issue No. 98-5 to Certain Convertible Instruments" and EITF 98-5. Since the conversion price of our preferred stock is subject to reset provisions, there is a contingent beneficial conversion feature. Using the potential conversion price, as limited in the purchase agreement, of \$1.60 for the December 2002 anniversary date and ignoring any other price adjustments, the contingent beneficial conversion feature will result in a \$9,100,000 preferred stock dividend in December 2002. In December 2003 we may record an additional preferred dividend of \$8,510,000.

### ITEM 3. CONTROLS AND PROCEDURES

- (a) Evaluation of disclosure controls and procedures.

Based on their evaluation as of a date within 90 days of the filing date of this Quarterly Report on Form 10-QSB, the Company's chief executive officer and chief financial officer have concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-14(c) and 15d-14(c) under the Securities Exchange Act of 1934 (the "Exchange Act")) are effective to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

- (b) Changes in internal controls.

## Edgar Filing: ASTRALIS LTD - Form 10QSB

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

### RISK FACTORS

We 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 \$14,717,664 as of September 30, 2002 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 administrative costs associated with our operations. We expect our expenses to increase and to continue to incur operating losses for at least 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 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

19

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.

The Development Of Our Initial Product Remains In An Early Stage Of Development And Substantial Additional Funds And Effort Will Be Necessary For Further Development And Commercialization.

Our initial product candidate, Psoraxine, remains in an early stage of development and will require the commitment of substantial resources to move it towards commercialization. Psoraxine will require extensive preclinical and clinical testing before we can submit any applications for regulatory approval. 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

## Edgar Filing: ASTRALIS LTD - Form 10QSB

lengthy, expensive and uncertain process. Completion of clinical trials may take several years or more. The length of time generally varies substantially according to the type, complexity, novelty and intended use of the product. If we or the U.S. Food and Drug Administration believe that our clinical trials, 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 conducted any clinical trials for Psoraxine in the United States, nor have we submitted any applications with the FDA or any other regulatory authority to test any potential products in humans or to market any product candidate. We may not be able to conduct clinical testing or obtain the necessary

approvals from the FDA or other regulatory authorities to market our product. 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 obtained final regulatory approval for the manufacture or commercial distribution of Psoraxine in Venezuela.

## Edgar Filing: ASTRALIS LTD - Form 10QSB

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 development of our initial product candidate, Psoraxine, and we have not received approval for its use in clinical trials in the United States. 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 under which SkyePharma will provide development, manufacturing, pre-clinical and clinical development services for Psoraxine until December 31, 2002. However, we do not currently have a written agreement covering any period after December 31, 2002 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.

Any Inability To Adequately Protect Our Proprietary Technologies Could Harm Our Competitive Position.

Dr. Jose Antonio O'Daly has filed a patent application for Psoraxine, and under the terms of a license agreement and assignment of license agreement, we have the right to use any patent issued pursuant to that application. We license, and do not own, the intellectual property rights to Psoraxine. In addition, we do not have any protection from issued patents covering any of our technology. 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

## Edgar Filing: ASTRALIS LTD - Form 10QSB

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

21

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 Who Have Greater Resources And Experience Than We Do May Develop Products And Technologies That 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.

We Will Need To Obtain Additional Funds To Support Our Future Operation Expenses.

Based on our current plans, we believe that we currently have sufficient funds to meet our operating expenses and capital requirements through at least the next 12 months. However, the actual amount of funds that we will need during or after the next 12 months will be determined by many factors, including those

## Edgar Filing: ASTRALIS LTD - Form 10QSB

discussed in this section. We will need additional funds to commence Phase III studies, which is the final phase of clinical trials in humans. An inability to obtain needed funds or to obtain them on terms favorable to us may cause us to delay, scale back or eliminate some or all of our research and development programs or to license third parties to develop or market products or technologies that we would otherwise seek to develop or market ourselves. Raising additional funds by selling additional shares of our capital stock will dilute the ownership interest of our stockholders.

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

22

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. We currently do not maintain clinical liability insurance coverage. Even if we obtain such an insurance policy, it may not sufficiently cover any claims made against us. Clinical trial liability insurance may be expensive, difficult to obtain 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 73.17% 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. In addition, this concentration of ownership may delay or prevent a change in control of us and might affect the market price of our common stock, even when a change in control

## Edgar Filing: ASTRALIS LTD - Form 10QSB

may be in the best interest of all stockholders. 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.

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 12, 2002, 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, 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 stockholders and by us, including the selling stockholders pursuant to this prospectus and subsequent sale of common stock by SkyePharma and 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 37,538,189 shares of our common stock outstanding. If all options and warrants currently outstanding to purchase shares of our common stock are exercised and all of the 2,000,000 shares of preferred stock are converted into common stock at the initial conversion rate of four shares of common stock for each share of preferred stock, there will be approximately 52,618,416 shares of common stock outstanding. The conversion ratio for the preferred stock is subject to multiple adjustments for three years depending on our stock price maintaining certain levels. The ratio is also subject to anti-dilution protection. However, the conversion ratio will not adjust to a level greater than approximately 50 shares of common stock for each share of preferred stock. At the current stock price on November 12, 2002 of \$0.43 per share, the conversion ratio would adjust, subject to limitations in the purchase agreement, to 6.25 shares of common stock for each share of preferred stock. The first date for determining an adjustment based on stock price is December 10, 2002. Subsequent adjustments may be made on December 10, 2003 and December 10, 2004. Of the outstanding shares, up to 9,931,415

23

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 Over-The-Counter Bulletin Board. As a

## Edgar Filing: ASTRALIS LTD - Form 10QSB

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.

24

### PART II. OTHER INFORMATION

#### Item 2. Changes in Securities and Use of Proceeds

We entered into a Purchase Agreement ("Purchase Agreement") dated as of December 10, 2001 with SkyePharma PLC, a company incorporated under the laws of England and Wales ("SkyePharma"). As of November 11, 2002, pursuant to the Purchase Agreement, SkyePharma purchased 1,750,000 shares of our Series A Convertible Preferred Stock, \$.001 par value per share ("Preferred Stock"), at a purchase price of \$10.00 per share, or an aggregate purchase price of \$17,500,000. Pursuant to the Purchase Agreement, SkyePharma will make a total equity investment in our company of up to \$20,000,000. SkyePharma has agreed to purchase for \$2,500,000 an additional 250,000 shares of Preferred Stock on January 31, 2003. Each share of Preferred Stock issued pursuant to the Purchase Agreement is initially convertible into four shares of Common Stock at the option of SkyePharma initially at a conversion rate of \$2.50 per share of Common Stock. The conversion ratio for the Preferred Stock is subject to multiple adjustments for three years depending on our stock price maintaining certain levels. The ratio is also subject to anti-dilution protection. However, the conversion ratio will not adjust to a level greater than approximately 50 shares of Common Stock for each share of Preferred Stock. At the current stock price on November 12, 2002 of \$0.43 per share, the conversion ratio would adjust, subject to limitations in the Purchase Agreement, to 6.25 shares of Common Stock for each share of Preferred Stock. The first date for determining an adjustment based on stock price is December 10, 2002. Subsequent adjustments may be made on December 10, 2003 and December 10, 2004. In connection with the sale of Preferred Stock, we relied on the exemption from registration with the Securities and Exchange Commission provided under Section 4(2) and Rule 506 of Regulation D under the Securities Act of 1933. We relied on the fact that the offering of Preferred Stock was only made available to "Accredited Investors" as defined in Rule 501 of Regulation D and the required number of manually executed originals and true copies of Form D were duly and timely filed with the Securities and Exchange Commission. No underwriter was used in connection with the offering.

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

##### (a) Exhibits

Exhibit Number	Description
----------------	-------------

Edgar Filing: ASTRALIS LTD - Form 10QSB

-----

3.1 *	Certificate of Incorporation of Astralis Ltd.
3.2 *	Bylaws of Astralis Ltd.
10.1 *	Agreement and Plan of Merger
10.2 #	Contribution Agreement dated September 10, 2001
10.3 ##	Purchase Agreement dated December 10, 2001
10.4 ##	Stockholder Agreement dated December 10, 2001
10.5 +	2001 Stock Option Plan
10.6 **	Sub-Lease Agreement
10.7 **	License Agreement dated April 26,2001 between Jose Antonio O'Daly and Astralis LLC
10.8 **	Assignment of License
10.9 **	Form of Warrant
10.10 ++	Agreement for Services dated December 10, 2001 between SkyePharma Inc. and Astralis Ltd.
10.11 ++	Technology Access Option Agreement dated December 10, 2001 by and among SkyePharma Inc., SkyePharma Holding AG and Astralis Ltd.

-----

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

# Previously filed with the Securities and Exchange Commission as an Exhibit to the Current Report on Form 8-K for Astralis Pharmaceuticals Ltd. on November 14, 2001.

## Previously filed with the Securities and Exchange Commission as an Exhibit to the Current Report on Form 8-K for Astralis Ltd. on December 14, 2001.

25

+ Previously filed with the Securities and Exchange Commission as an Exhibit to the Preliminary Proxy Statement for Hercules Development Group Inc. on October 4, 2001.

\*\* Previously filed with the Securities and Exchange Commission as an Exhibit to the Registration Statement on Form SB-2 for Astralis Ltd. on March 14, 2002.

++ Previously filed with the Securities and Exchange Commission as an Exhibit to the Amendment to the Registration Statement on Form SB-2 for Astralis Ltd. on July 23, 2002.

(b) Reports on Form 8-K

On August 9, 2002, we filed a current report on Form 8-K reporting that we submitted to the Securities and Exchange Commission the certification of our report on Form 10-QSB for the quarter ended June 30, 2002 by our chief executive officer and chief financial officer as required pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

26

SIGNATURES

## Edgar Filing: ASTRALIS LTD - Form 10QSB

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, 2002

By: /s/ Mike Ajnsztajn

-----  
Mike Ajnsztajn  
Chief Executive Officer  
(Principal Executive Officer)

Dated: November 14, 2002

By: /s/ Gina Tedesco

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

27

### Certification of Quarterly Report

I, Mike Ajnsztajn, certify that:

1. I have reviewed this quarterly report on Form 10-QSB of Astralis Ltd.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

Edgar Filing: ASTRALIS LTD - Form 10QSB

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 14, 2002

/s/ Mike Ajnsztajn

-----  
Name: Mike Ajnsztajn  
Title: Chief Executive Officer

28

Certification of Quarterly Report

I, Gina Tedesco, certify that:

1. I have reviewed this quarterly report on Form 10-QSB of Astralis Ltd.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  - c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent

Edgar Filing: ASTRALIS LTD - Form 10QSB

functions):

a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 14, 2002

/s/ Gina Tedesco

-----  
Name: Gina Tedesco  
Title: Chief Financial Officer