ASTRALIS LTD
Form 10QSB
May 13, 2003

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 March 31, 2003

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, NJ 07004
(Address of principal executive office)

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

The number of shares of the Issuer's Common Stock outstanding as of May 12, 2003 was 37,538,189.

Transitional Small Business Disclosure Format (check one):

Yes |_| No |X|

ASTRALIS LTD.

INDEX

FOR QUARTERLY PERIOD ENDED MARCH 31, 2003

Part I.	Financial Information	3
Item 1.	Condensed Balance Sheets as of March 31, 2003 (unaudited) and December 31, 2002	3
	Condensed Statements of Operations (unaudited)	4
	Condensed Statements of Cash Flows (unaudited)	5
	Notes to Condensed Financial Statements	6
Item 2.	Management's Discussion and Analysis or Plan of Operations	9
Item 3.	Controls and Procedures	11
	Risk Factors	11

Part II.	Other Information	11
Item 2.	Changes in Securities and Use of Proceeds	16
Item 5	Other Information	17
Item 6.	Exhibits and Reports on Form 8-K	17

PART I
FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

ASSETS

	March 31, 2003	December 2002
	(Unaudited)	(Audit
Current Assets		
Cash and cash equivalents	$ 370,777	$ 227
Marketable securities	2,720,108	1,207
Interest receivable, net	9,154	5
Prepaid expense - related party	1,763,125	1,995
Prepaid expenses and supplies	90,918	103
Total Current Assets	4,954,082	3,538
Intangible Assets, Net - Related Party	4,047,616	4,226
Other Intangible Assets, Net	44,356	43
Property and Equipment, Net	358,901	362
Deposits	29,953	29
	$ 9,434,908	$ 8,201

LIABILITIES AND STOCKHOLDERS' EQUITY

Current Liabilities		
Accounts payable and accrued expenses	$ 237,446	$ 263
Total Current Liabilities	237,446	263
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 - $21,218,494 at 2002)	2,000	1
Common stock; $.0001 par value; 75,000,000 shares authorized at 2003; 37,538,189 and 37,588,179 issued and outstanding at 2003 and 2002, respectively	3,754	3
Additional paid-in capital	35,937,651	33,429
Deferred compensation	(17,325)	(12
Common stock subscriptions receivable	(652,685)	(885
Accumulated other comprehensive loss	(16,857)	(15
Deficit accumulated in the development stage	(26,059,076)	(24,584
Total Stockholders' Equity	9,197,462	7,938
	$ 9,434,908	$ 8,201

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

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

	Three Months Ended March 31, 2003	Three Months Ended March 31, 2002	Mar (In Mar
Revenues	$ --	$ --	$
Operating Expenses			
Research and development - related party	430,447	2,295,534	
Research and development	731,058	--	
Depreciation and amortization	31,549	1,235	
General and administrative	318,769	529,585	
Total Operating Expenses	1,511,823	2,826,354	
Loss From Operations	(1,511,823)	(2,826,354)	(
Investment Income	37,109	30,425	
Net Loss	(1,474,714)	(2,795,929)	(
Preferred Stock Dividends	--	--	(

Net Loss to Common Stockholders	$ (1,474,714)	$ (2,795,929)	$(
Basic and Diluted Loss per Common Share	$ (0.04)	$ (0.07)	
Basic and Diluted Weighted Average Common Shares Outstanding	37,538,189	37,551,373	

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

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

	Three Months Ended March 31, 2003	Three En March
Cash Flows from Operating Activities		
Net loss	$ (1,474,714)	$ (2,
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	210,121	
Amortization of net premium paid on investments	2,978	
Dividends reinvested	(11,586)	
Members' contributed salaries	--	
Research and development service fee netted against proceeds received from preferred stock issuance	--	
Operating expenses paid by related parties on behalf of Company	--	
Amortization of deferred compensation	3,345	
Compensatory common stock	--	
Loss on sale of marketable securities	--	
Changes in assets and liabilities		
Prepaid expenses	250,246	
Interest receivable	(3,263)	
Supplies	(5,802)	
Deposits	--	
Accounts payable - related party	--	(
Accounts payable and accrued expenses	(5,799)	
Net Cash Used in Operating Activities	(1,034,474)	(2,
Cash Flows from Investing Activities		
Purchases of marketable securities	(1,665,997)	(4,
Proceeds from sale of marketable securities	160,000	
Expenditures related to patent	(1,113)	
Purchases of property and equipment	(27,147)	

Net Cash Used in Investing Activities	(1,534,257)	(3,
Cash Flows from Financing Activities		
Repurchase of common stock	--	
Proceeds from stock subscription receivable	232,315	
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	1,
Net Cash Provided by Financing Activities	2,712,315	1,
Net Increase (Decrease) in Cash and Cash Equivalents	143,584	(4,
Cash and Cash Equivalents, Beginning of Period	227,193	4,
Cash and Cash Equivalents, End of Period	$ 370,777	$

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

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 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.

NOTE 2 - DESCRIPTION OF BUSINESS

Nature of Operations

Astralis Ltd. is an emerging biotechnology company based in New Jersey and engaged primarily in the research and development of novel treatments for immune

system disorders and skin diseases. The Company is currently developing two products. Its primary product, Psoraxine, is an innovative vaccine 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 expects to commence clinical testing of Psoraxine in 2003; however, the IND application to commence clinical trials is currently on hold until the Company provides the FDA with additional information and addresses certain issues regarding the design of the pre-clinical studies. No assurance can be given that the FDA will release the hold placed on the study or that clinical trials will commence. 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 plans to pursue opportunities to sell equity securities privately to limited investors in 2003. These funds, in addition to its cash and marketable securities held at March 31, 2003, will be needed in order to finance the Company's currently anticipated needs for operating and capital expenditures for 2003, 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.

NOTE 3 - GOING CONCERN (Continued)

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, 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 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 March 31, 2003, available-for-sale securities consist of the following:

	Due	Amortized Cost	Gross Unrealized Loss	Gro Unrea Ga
Certificate of Deposits *	7/2003 to 10/2014	$ 1,015,582	$ (8,234)	$ 2
Fixed Income Funds	Current	1,721,368	(10,886)	
		$ 2,736,950	$ (19,120)	$ 2

*It will be necessary for the Company to utilize the proceeds from these certificates of deposits to fund its operations in 2003 and therefore they have been classified as short-term investments.

NOTE 5 - STOCK SUBSCRIPTION RECEVIABLE

Certain stockholders owed $1,350,000 to the Company, under stock subscription agreements, which was due February 13, and May 13, 2002. This money was not paid to the Company causing the notes to become in default. As of March 31, 2003, the stockholders were late on the scheduled payments in the amount of $652,685.

The board of directors of the Company have voted to cancel, effective June 1, 2003, the proportionate shares of common stock for which the related subscription receivables are not paid in full by May 31, 2003.

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 the 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.

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 March 31, 2003	Three Months Ended March 31, 2002
Net loss	$(1,474,714)	$(2,795,929)
Unrealized gain (loss), net	(1,676)	(56,158)
Comprehensive loss	$(1,476,390)	$(2,852,087)

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 19,595,237 and 12,080,239 at March 31, 2003 and 2002, respectively.

NOTE 9 - SUBSEQUENT EVENTS

On April 1, 2003, the Company amended an investor relation agreement with one of its shareholders. The agreement was amended to provide that in lieu of paying $4,000 per month in consideration for services provided, the Company would credit the shareholder's subscription note receivable for said amount until the receivable is paid in full. At March 31, 2003, the balance on the note was $60,000.

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, 2004, and options to purchase an additional 12,500 shares will vest each year thereafter for the following three years.

SPECIAL CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This filing contains many forward-looking statements that involve substantial risks and uncertainties. You can identify these statements by forward-looking words such as "may," "will," "expect," "anticipate," "believe," "estimate" and "continue" or similar words. You should read statements that

contain these words carefully because they discuss our future expectations, contain projections of our future operating results or of our financial condition or state other "forward-looking" information.

We believe that it is important to communicate our future expectations to our investors. However, we may be unable to accurately predict or control events in the future. The factors listed in the sections captioned Risk Factors, as well as any other cautionary language in this filing, provide examples of risks, uncertainties and events that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. Before you invest in our common stock, you should be aware that the occurrence of certain of the events described in the Risk Factors section could seriously harm our business.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATIONS

The following discussion of our financial condition and plan of operation should be read in conjunction with our financial statements and the related notes included elsewhere in this quarterly report on Form 10-QSB. This quarterly report contains certain statements of a forward-looking nature relating to future events or our future financial performance. We caution prospective investors that such statements involve risks and uncertainties, and that actual events or results may differ materially. In evaluating such statements, prospective investors should specifically consider the various factors identified in this quarterly report, including the matters set forth under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We disclaim any obligation to update information contained in any forward-looking statement.

Overview

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

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

- Ongoing research and development of Psoraxine;
- Production of drug supply for use in clinical trials in the United States; and
- Doctor and site enrollment for clinical trials in the United States.

Three months ended March 31, 2003 compared to the three months ended March 31, 2002.

For the three months ended March 31, 2003:

On January 31, 2003, we sold to SkyePharma PLC ("SkyePharma") pursuant to a Purchase Agreement dated December 10, 2001, 250,000 shares of our Series A Convertible Preferred Stock for an aggregate purchase price of $2,500,000. We received net proceeds of approximately $2,480,000 after we netted out from the proceeds $20,000 due to SkyePharma for services they provided under our Service Agreement with them which was treated as an expense at the time of payment.

For the three months ended March 31, 2003, we had no revenue and incurred operating expenses of $1,511,823 which consisted primarily of:

- Research and development costs of $1,161,505, including $430,447 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.

- General and administrative costs of approximately $318,769, including professional fees and our general corporate expenditures.

For the three months ended March 31, 2002:

On January 31, 2002, we sold to SkyePharma pursuant to a Purchase Agreement dated December 10, 2001, 250,000 shares of our Series A Convertible Preferred Stock for 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 was treated as an expense at the time of payment.

For the three months ended March 31, 2002, we had no revenue and incurred operating expenses of $2,826,534 which consisted primarily of:

- Research and development costs of $2,295,534, including $1,995,000 that was paid to SkyePharma for services provided under our Service Agreement with them and amortization of approximately $178,000 under our technology option license which is being amortized over a seven year period.

- General and administrative costs of approximately $529,585, including professional fees related to our merger with Astralis, LLC and our general corporate expenditures.

The Next Twelve Months

At March 31, 2003 we had cash balances of $370,777 and marketable securities of $2,720,108.

We anticipate collecting a portion of our outstanding amounts on our subscription notes receivable. These subscription notes receivable were originally due in two installments during 2002. We did not receive all of the amounts due under the installment payments. We entered into a payment plan agreement with the note holders of the subscription notes receivable. As of March 31, 2003, the note holders failed to make scheduled payments in the aggregate amount of $652,685. In accordance with the terms of the payment plan agreement, we have decided that on June 1, 2003, we will cancel any shares of common stock corresponding to any unpaid balance.

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:

- Our primary focus is to further our development efforts of our initial product candidate, Psoraxine. Upon receiving approval of our Investigational New Drug application, we will 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 $2,700,000 in connection with these activities.

- We intend to implement our business plan and facilitate the operations of our company. We will spend approximately $750,000 to pay management salaries and salaries of employees.

- We also expect to expend approximately $1,250,000 for our public relations, general administrative and working capital requirements.

We will need to raise additional funds to continue our operations for the period following the third quarter of 2003. 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

(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, our chief executive officer and chief financial officer have concluded that our 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 us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

(b) Changes in internal controls.

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

RISK FACTORS

We 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 $26,059,076 as of March 31, 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 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 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 third quarter of 2003. 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.

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. Before obtaining regulatory approvals for the commercial sale of Psoraxine, we must demonstrate the safety and efficacy of our product candidate through preclinical testing and clinical trials. Conducting clinical trials involves a lengthy, expensive and uncertain process. Completion of clinical trials may take several years or more. The length of time generally

varies substantially according to the type, complexity, novelty and intended use of the product. If we or the 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:

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

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

Our Potential Therapeutic Products Face A Lengthy And Uncertain Regulatory Process. If We Do Not Obtain Regulatory Approval Of Our Potential Products, We Will Not Be Able To Commercialize These Products.

The FDA must approve any therapeutic product before it can be marketed in the United States. Before we obtain FDA approval of a new drug application or biologics license application, the product must undergo extensive testing, including animal and human clinical trials, which can take many years and requires substantial expenditure.

Data obtained from such testing may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. In addition, changes in regulatory policy for product approval during the period of product development and regulatory agency review of each submitted new drug application may cause delays or rejections. We must devote a substantial amount of time and resources in the regulatory process in order to obtain regulatory approval of our initial product candidate, Psoraxine.

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 received approval from the FDA or any other regulatory authority to test any potential products in humans or to market any product candidate. Although we have filed an Investigational New Drug application with the FDA, a representative of the FDA has informed us that, before clinical trials may proceed, we must provide the FDA with additional information and address certain issues regarding the design of the pre-clinical studies. As a result, the FDA has indicated that we will be receiving a letter instructing us not to proceed with any clinical studies unless and until these matters have been resolved to the satisfaction of the FDA. No assurance can be given that the FDA will release the hold placed on our study or whether or when

we may commence clinical trials. In addition, we may not 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.

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.

We Are Exposed To International Risks As A Result Of Our Conduct Of Clinical Studies In Venezuela.

We are continuing clinical trials of Psoraxine in Venezuela. During recent months, Venezuela has suffered from political instability and popular unrest. As a result, at times, participants in our clinical trials were unable to reach the facilities where our studies are conducted. This may have impaired the results of our studies. Since the FDA requires that we report all studies conducted on human subjects, in the event our Investigational New Drug application is approved, we must include our Venezuela studies as previous human experience in our annual reporting to the FDA. This data will be used only as supporting information and will not likely increase the chance of faster FDA approval of Psoraxine.

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, 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 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 prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative technologies or design around our patented technologies. In addition, others may challenge or invalidate our patents, or our patents may fail to provide us with any competitive advantages. If we encounter challenges to the use or validity of any of our patents, resulting in litigation or administrative proceedings, we would incur substantial costs and the diversion of management in defending the patent. In addition, we do not control the patent prosecution of technology that we license from others. Accordingly, we cannot exercise the same degree of control over this intellectual property as we would over technology we own.

We rely upon trade secrets protection for our confidential and proprietary information. We have taken measures to protect our proprietary information. These measures may not provide adequate protection for our trade secrets or other proprietary information. We seek to protect our proprietary information by entering into confidentiality agreements with employees, collaborators and consultants. Nevertheless, employees, collaborators or consultants may still disclose our proprietary information, and we may not be able to meaningfully protect our trade secrets. In addition, others may independently develop substantially equivalent proprietary information or techniques or otherwise gain access to our trade secrets.

Many Potential Competitors Which Have Greater Resources And Experience Than We Do May Develop Products And Technologies That 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 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 that 5% stockholders) together control approximately 75.75% of our outstanding common stock. In addition, as a result of the application of certain preferred stock adjustment rights, SkyePharma's percentage ownership may increase substantially

from its current 25.41% and may result in it having control of the company. As a result, these stockholders, if they act individually or together, may exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. Furthermore, the interests of this concentration of ownership may not always coincide with our interests or the interests of other stockholders and accordingly, they could cause us to enter into transactions or agreements which we would not otherwise consider. In addition, this concentration of ownership may delay or prevent a merger or acquisition resulting in a change in control of us and might affect the market price of our common stock, even when such a change in control may be in the best interest of all stockholders. 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 the preferred stock plus 30% of such purchase price per annum commencing on the date of issuance of the preferred stock.

The Market Price Of Our Common Stock May Be Highly Volatile.

The market price of our common stock has been and will likely continue to be highly volatile. From the date trading of our common stock commenced until May 12, 2003, 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 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 current conversion price of $1.60, there will be approximately 57,233,416 shares of common stock outstanding. The conversion price of preferred stock may be further adjusted through 2004, increasing substantially the number of shares of common stock that may be outstanding. Of the outstanding shares, up to 13,163,114 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

result, the holders of our common stock may find it more difficult to obtain accurate quotations concerning the market value of the stock. Stockholders also may experience greater difficulties in attempting to sell the stock than if it were listed on a stock exchange or quoted on the Nasdaq National Market or the Nasdaq Small-Cap Market. Because our common stock does not trade on a stock exchange or on the Nasdaq National Market or the Nasdaq Small-Cap Market, and the market price of the common stock is less than $5.00 per share, the common stock qualifies as a "penny stock." SEC Rule 15g-9 under the Securities Exchange Act of 1934 imposes additional sales practice requirements on broker-dealers that recommend the purchase or sale of penny stocks to persons other than those who qualify as an "established customer" or an "accredited investor." This includes the requirement that a broker-dealer must make a determination on the appropriateness of investments in penny stocks for the customer and must make special disclosures to the customer concerning the risks of penny stocks. Application of the penny stock rules to our common stock could adversely affect the market liquidity of the shares, which in turn may affect the ability of holders of our common stock to resell the stock.

PART II. OTHER INFORMATION

Item 2. Changes in Securities and Use of Proceeds

We entered into a Purchase Agreement dated as of December 10, 2001 with SkyePharma PLC, a company incorporated under the laws of England and Wales. The Purchase Agreement provides that SkyePharma would make a total equity investment of $20 million. Pursuant to the Purchase Agreement, as of December 31, 2002, SkyePharma purchased 1,750,000 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 $17.5 million. The remaining $2.5 million investment involved the sale of an additional 250,000 shares of preferred stock to SkyePharma on January 31, 2003. Each share of preferred stock issued pursuant to the Purchase Agreement was initially convertible into four shares of common stock at the option of SkyePharma at a conversion price of $2.50 per share of common stock (an aggregate of 8 million shares of common stock). The conversion price is subject to multiple adjustments for three years from the date of the Purchase Agreement depending on our stock price maintaining certain levels. The conversion price is also subject to anti-dilution protection. However, the conversion price will not adjust to a level greater than approximately 50 shares of common stock for each share of preferred stock (an equivalent conversion price of $0.20 per share). On December 10, 2001, the conversion price was reset to $1.60 per share of common stock (convertible into an aggregate of 12,500,000 shares of common 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 was only made available to "Accredited Investors" as defined in Rule 501 of Regulation D, the offering of preferred stock pursuant to the Purchase Agreement was made available to less than 35 purchasers as required by Rule 506(a)(2) 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 5. Other Information

The FDA has reviewed the IND Application for Psoraxine that we filed on March 28, 2003. A representative of the FDA has informed us that, before clinical trials may proceed, we must provide the FDA with additional information

and address certain issues regarding the design of the pre-clinical studies. As a result, the FDA has indicated that we will be receiving a letter instructing us not to proceed with any clinical studies unless and until these matters have been resolved to the satisfaction of the FDA. No assurance can be given that the FDA will release the hold placed on our study or whether or when we may commence clinical trials.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

Exhibit Number	Description
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.
10.12+++	Employment Agreement dated December 10, 2001, between Dr. Jose Antonio O'Daly and Astralis Ltd.
10.13+++	Amendment #1 to Agreement for Services dated March 18, 2003 between SkyePharma Inc. and Astralis Ltd.
99.1	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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* 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.

\+ 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.

+++ Previously filed with the Securities and Exchange Commission as an Exhibit to the Annual Report on Form 10-KSB for Astralis Ltd. on March 31, 2003.

(b) Reports on Form 8-K

On March 31, 2003, we filed a current report on Form 8-K reporting that we issued a press release regarding our earnings for the fiscal year ended December 31, 2002.

SIGNATURES

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

ASTRALIS LTD.
(Registrant)

Dated: May 13, 2003 By: /s/ Mike Ajnsztajn

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

Dated: May 13, 2003 By: /s/ Gina Tedesco

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

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):

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: May 13, 2003

/s/ Mike Ajnsztajn

Name: Mike Ajnsztajn
Title: Chief Executive Officer

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 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: May 13, 2003

/s/ Gina Tedesco

Name: Gina Tedesco
Title: Chief Financial Officer