

ASTRALIS LTD
Form 424B3
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Registration Statement
333-115974

PRELIMINARY PROSPECTUS

ASTRALIS LTD.

47,056,520 Shares of Common Stock

The stockholders named in this prospectus are selling up to 47,056,520 shares of our common stock. 11,446,654 of the shares we are registering are issuable upon the exercise of outstanding warrants. The selling stockholders may offer and sell their shares on a continuous or delayed basis in the future. These sales may be conducted in the open market or in privately negotiated transactions and at market prices, fixed prices or negotiated prices. We will not receive any of the proceeds from the sale of shares by the selling stockholders, but we will receive funds from the exercise of their warrants.

Our common stock is currently listed on the OTC Bulletin Board under the symbol "ASTR." On June 25, 2004, the last reported sale price of our common stock on the OTC Bulletin Board was \$1.10 per share.

Investing in our common stock involves risks. Please read the "Risk Factors" section beginning on page 4 to read about certain risks that you should consider before purchasing shares of our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this Prospectus is July 6, 2004

No dealer, salesperson or other person has been authorized to give any information or to make any representations other than those contained in this prospectus, and if given or made, such information or representations must not be relied upon as having been authorized by us, the selling stockholders or any underwriter. You should rely only on the information contained in this prospectus. This prospectus does not constitute an offer to sell or the solicitation of an offer to buy any security other than the common stock offered by this prospectus, or an offer to sell or a solicitation of an offer to buy any security by any person in any jurisdiction in which such offer or solicitation would be unlawful. Neither the delivery of this prospectus nor any sale made hereunder shall, under any circumstances, imply that the information in this prospectus is correct as of any time subsequent to the date of this prospectus.

TABLE OF CONTENTS

Page
SUMMARY.....2

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RISK FACTORS.....	4
CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS.....	10
USE OF PROCEEDS.....	11
MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.....	11
MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATIONS.....	12
BUSINESS.....	16
MANAGEMENT.....	24
EXECUTIVE COMPENSATION.....	28
CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.....	30
SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT.....	32
SELLING STOCKHOLDERS.....	34
PLAN OF DISTRIBUTION.....	37
DESCRIPTION OF CAPITAL STOCK.....	39
LEGAL MATTERS.....	42
EXPERTS.....	42
WHERE YOU CAN FIND ADDITIONAL INFORMATION.....	42
INDEX TO FINANCIAL STATEMENTS.....	F-1

-i-

SUMMARY

You should read this summary together with the more detailed information, including our financial statements and related notes, appearing elsewhere in this prospectus.

Our Company

We are a development-stage biotechnology company, which primarily engages in research and development of treatments for immune system disorders and skin diseases. Our current activities focus on the development of a product candidate named Psoraxine(R) for the treatment of the skin disease psoriasis. Currently, we are engaged in ongoing research and development of Psoraxine. We are also engaged in research on the possible development of the technology underlying Psoraxine for the treatment of other indications, such as eczema, seborrheic dermatitis and psoriatic arthritis.

We are incorporated under the laws of the State of Delaware. Our principal executive offices are located at 75 Passaic Avenue, Fairfield, New Jersey 07004 and our telephone number is (973) 227-7168. Our Internet address is www.astralisltd.com. The information on our web site is not incorporated by reference into, and does not constitute part of, this prospectus.

The Offering

Shares of common stock offered	47,056,520
Use of Proceeds	We will not receive any proceeds from the sale of the common stock offered by the selling stockholders. However, we may receive an aggregate of approximately \$8,259,827 upon the exercise of all the warrants held by selling stockholders, if such warrants are exercised for cash. We will use such funds, if any, to fund clinical trials and for working capital and general corporate purposes.
OTC Bulletin Board Symbol	ASTR

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2

Summary Financial Information

The summary financial data is derived from the historical financial statements of Astralis Ltd. This summary financial data should be read in conjunction with "Management's Discussion and Analysis or Plan of Operations" as well as our historical financial statements and the related notes thereto, included elsewhere in this prospectus.

Statement of operations data:

	Three Months Ended March 31,		Year Ended De
	2004	2003	2003
Revenues	\$ --	\$ --	\$ --
Operating Expenses			
Research and development - related party	430,447	430,447	1,721,788
Research and development	900,694	731,058	2,323,885
Depreciation and amortization	7,510	31,549	26,062
General and administrative	421,898	318,769	1,290,346
Total Operating Expenses	1,760,549	1,511,823	5,362,081
Loss From Operations	(1,760,549)	(1,511,823)	(5,362,081)
Investment Income	12,576	37,109	60,018
Loss before income tax benefit	(1,747,973)	(1,474,714)	(5,302,063)
Income tax benefit	--	--	221,636
Net Loss	(1,747,973)	(1,474,714)	(5,080,427)
Preferred Stock Dividends	(10,750,000)	--	--
Net Loss to Common Stockholders	(12,497,973)	(1,474,714)	\$ (5,080,427)
Basic and Diluted Loss per Common Share	\$ (0.19)	\$ (0.04)	\$ (0.14)
Basic and Diluted Weighted Average Common Shares Outstanding	64,861,411	37,575,404	37,538,189

Balance sheet data:

	Three Months Ended March 31, 2004	Year Ended December 31, 2003
Total current assets	6,358,323	2,564,273
Total assets	10,093,467	6,493,815
Total current liabilities	633,760	279,506
Deficit accumulated in the development stage	(42,162,762)	(29,664,789)
Total stockholders' equity	9,459,707	6,214,309

RISK FACTORS

Prospective investors should carefully consider the following factors, in addition to the other information contained in this prospectus, in connection with an investment in our common stock. This prospectus contains certain forward-looking statements, which involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of certain factors, including those set forth below and elsewhere in this prospectus. An investment in our common stock involves a high degree of risk and is suitable only for investors who can afford to lose their entire investment.

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

We commenced our current operations in 2001 and such operations remain in an early stage of development. We have no products approved for sale and therefore, no means to generate revenue. We have not commercialized any products, have no revenues and have incurred a cumulative net loss of \$42,162,762 through March 31, 2004 which has increased to date. The cumulative net loss through March 31, 2004 includes preferred stock dividends of \$22,218,750. We expect that substantial losses will continue for the foreseeable future. In order to obtain revenue from the sales of our product candidate, Psoraxine, we must successfully develop, test, obtain regulatory approval for, manufacture, market and eventually sell such product candidate. Our expenses have consisted principally of costs incurred in research and development and from general and administrative costs associated with our operations. We expect our expenses to increase and to continue to incur operating losses for the next several years as we continue our research and development efforts for Psoraxine and 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 second quarter of 2005. We will need additional funds to continue our operations following that period. Furthermore, substantial additional funds will be needed in order to fund our continued efforts to obtain U.S. Food and Drug Administration ("FDA") approval of Psoraxine. No assurance can be given that we will be able to obtain financing, or successfully sell assets or stock, or, even if such transactions are possible, that they will be on terms reasonable to us or that they will enable us to satisfy our cash requirements. In addition, raising additional funds by selling additional shares of our capital stock will dilute the ownership interest of our stockholders. If we do not obtain additional funds, we will likely be required to eliminate programs, delay development of our products, alter our business plans, or in the extreme situation, cease operations.

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

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might be necessary if we are unable to continue as a going concern.

4

We may not be successful in the development and commercialization of products.

We may not develop products that prove to be safe and effective, that meet applicable regulatory standards or that we can manufacture at reasonable costs or market successfully. Successful products will require significant development and investment, including testing, to demonstrate their safety and efficacy prior to their commercialization. We have not proven our ability to develop and commercialize products. We must conduct a substantial amount of additional research and development before any regulatory authority will approve our initial product candidate, Psoraxine. Our research and development and clinical trials may not confirm the safety and efficacy of our products, in which case regulatory authorities may not approve them. In addition, even if we successfully complete our research and development efforts, Psoraxine may not perform in the manner we anticipate, and may not be accepted for use by the public.

Substantial additional funds and effort will be necessary for further development and commercialization of Psoraxine.

Our initial product candidate, Psoraxine, will require the commitment of substantial resources to move it towards commercialization. Before obtaining regulatory approvals for the commercial sale of Psoraxine, we must demonstrate the safety and efficacy of our product candidate through preclinical testing and clinical trials. Conducting clinical trials involves a lengthy, expensive and uncertain process. Completion of clinical trials may take several years or more. The length of time generally varies substantially according to the type, complexity, novelty and intended use of the product. If we or the FDA believe that our clinical trials expose participating patients to unacceptable health risks, we may suspend such trials. We may encounter problems in our studies which will cause us or the FDA to delay or suspend the studies. Some of the factors that may delay our commencement and rate of completion of clinical trials include:

- 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.

5

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

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

Because Psoraxine involves the application of new technologies and may be used upon new therapeutic approaches, government regulatory authorities may subject this product to more rigorous review and may grant regulatory approvals more slowly for this product than for products using more conventional technologies. We have not received approval from the FDA to market or commercialize Psoraxine. The regulatory agencies of foreign governments must also approve any therapeutic product we may develop before the product can be sold in those countries. To date, although we have obtained regulatory approval for clinical testing of Psoraxine in Venezuela, we have not sought, nor have we obtained, regulatory approval for the commercialization of Psoraxine in Venezuela because, among other things, we do not have manufacturing facilities in that country and such facilities are required by regulatory authorities in Venezuela before granting commercial approval for a proposed drug.

Even after investing significant time and resources, we may not obtain regulatory approval for our product. If we do not receive regulatory approval, we cannot sell the product. Even if we receive regulatory approval, this approval may place limitations on the indicated uses for which we can market the product. Further, after granting regulatory approval, regulatory authorities subject a marketed product and its manufacturer to continual review, and discovery of previously unknown problems with a product or manufacturer may result in restrictions on the product, manufacturer and manufacturing facility, including withdrawal of the product from the market. In certain countries, regulatory agencies also set or approve prices.

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

We have not completed clinical trials of Psoraxine. If Psoraxine emerges successfully from clinical trials, we will either commercialize products resulting from our proprietary programs directly or through licensing arrangements with other companies. We have no experience in manufacturing and marketing, and we currently do not have the resources or capability to manufacture, market or sell our products on a commercial scale. In order to commercialize Psoraxine directly, we would need to develop or obtain through

outsourcing arrangements the capability to manufacture, market and sell products. We have an agreement with SkyePharma PLC ("SkyePharma") under which SkyePharma will provide development, pre-clinical and clinical development services for Psoraxine until December 31, 2004. However, we do not currently have a written agreement covering any period after December 31, 2004 and we may not be able to enter into such an agreement on commercially reasonable terms, or

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at all. In addition, we currently do not have any agreements for the marketing or sale of any of our products and we may not be able to enter into such agreements on commercially reasonable terms, or at all.

We license and do not own our intellectual property. Any inability to protect our proprietary technologies adequately could harm our competitive position.

We license, and do not own, the intellectual property rights to Psoraxine. Dr. Jose Antonio O'Daly is the owner of the patent for Psoraxine. Under the terms of a license agreement and assignment of license agreement, we have the right to use any patent issued pursuant to Dr. O'Daly's patent application. We also have rights to other patents filed by Dr. O'Daly under the terms of our employment agreement with him. Our success will depend in part on our ability to obtain patents and maintain adequate protection of other intellectual property for our technologies and products in the United States and other countries. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate our competitive advantage. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these foreign countries.

The patent positions of biotechnology companies, including our patent positions, involve complex legal and factual questions and, therefore, validity and enforceability cannot be predicted with certainty. Patents may be challenged, deemed unenforceable, invalidated or circumvented. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that we cover our proprietary technologies with valid and enforceable patents or we effectively maintain such proprietary technologies as trade secrets. We will apply for patents covering both our technologies and product candidates as we deem appropriate. However, we may fail to apply for patents on important technologies or products in a timely fashion, or at all, and in any event, the applications we do file may be challenged and may not result in issued patents. Any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative technologies or design around our patented technologies. In addition, others may challenge or invalidate our patents, or our patents may fail to provide us with any competitive advantages. If we encounter challenges to the use or validity of any of our patents, resulting in litigation or administrative proceedings, we would incur substantial costs and the diversion of management in defending the patent. In addition, we do not control the patent prosecution of technology that we license from others. Accordingly, we cannot exercise the same degree of control over this intellectual property as we would over technology we own.

We rely upon trade secrets protection for our confidential and proprietary information. We have taken measures to protect our proprietary information. These measures may not provide adequate protection for our trade secrets or other proprietary information. We seek to protect our proprietary information by

7

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

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than we do may develop products and technologies that could make ours obsolete.

Companies in the biotechnology industry face rapid technological change in a rapidly evolving field. Our future success will depend on our ability to maintain a competitive position with respect to technological advances. Rapid technological development by others may result in our products and technologies becoming obsolete.

We face, and will continue to face, intense competition from organizations such as large biotechnology and pharmaceutical companies, as well as academic and research institutions and government agencies. Our competitors may include Biogen, Genentech/Xoma, Amgen and Wyeth, Abbott Laboratories and Novartis. These organizations may develop technologies that provide superior alternatives to our technologies. Further, our competitors may be more effective at implementing their technologies to develop commercial products.

Any products that we develop through our technologies will compete in multiple, highly competitive markets. Many of the organizations competing with us in the markets for such products have greater capital resources, research and development and marketing staffs, facilities and capabilities, and greater experience in obtaining regulatory approvals, product manufacturing and marketing. Accordingly, our competitors may be able to develop technologies and products more easily, which would render our technologies and products obsolete and noncompetitive.

If we lose our key personnel or fail to attract and retain additional personnel, we may be unable to discover and develop our products.

We depend on the services of Dr. Jose Antonio O'Daly, the loss of whose services would adversely impact the achievement of our objectives. 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.

8

If we face claims in clinical trials of a drug candidate, these claims will divert our management's time and we will incur litigation costs.

We face an inherent business risk of clinical trial liability claims in the event that the use or misuse of Psoraxine results in personal injury or death. We may experience clinical trial liability claims if our drug candidates are misused or cause harm before regulatory authorities approve them for marketing. Although we currently maintain clinical liability insurance coverage, it may not sufficiently cover any claims made against us and may not be available in the future on acceptable terms, if at all. Any claims against us, regardless of their merit, could strain our financial resources in addition to consuming the time and attention of our management. Law suits for any injuries

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caused by our products may result in liabilities that exceed our total assets.

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

Our officers, directors and principal stockholders owning at least 5% of our common stock together control approximately 71.94% of our outstanding common stock. As a result, these stockholders, if they act individually or together, may exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. Furthermore, the interests of this concentration of ownership may not always coincide with our interests or the interests of other stockholders and accordingly, they could cause us to enter into transactions or agreements which we would not otherwise consider. In addition, this concentration of ownership may delay or prevent a merger or acquisition resulting in a change in control of us and might affect the market price of our common stock, even when such a change in control may be in the best interest of all stockholders.

The market price of our common stock may be highly volatile.

The market price of our common stock has been and will likely continue to be highly volatile. From the date trading of our common stock commenced until June 25, 2004, the range of our stock price has been between \$0.22 and \$7.15. Factors including announcements of technological innovations by us or other companies, regulatory matters, new or existing products or procedures, concerns about our financial position, operating results, government regulation, developments or disputes relating to agreements, patents or proprietary rights may have a significant impact on the market price of our stock. In addition, potential dilutive effects of future sales of shares of common stock by us or our stockholders, including the selling stockholders pursuant to this prospectus, 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

9

73,173,055 shares of our common stock outstanding. If all options and warrants currently outstanding to purchase shares of our common stock are exercised, there will be approximately 91,514,946 shares of common stock outstanding. Of the outstanding shares, up to 37,538,189 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 and we are registering an additional 47,056,520 shares with this Registration Statement. 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.

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Our common stock trades on the OTC Bulletin Board. As a result, the holders of our common stock may find it more difficult to obtain accurate quotations concerning the market value of the stock. Stockholders also may experience greater difficulties in attempting to sell the stock than if it were listed on a stock exchange or quoted on the Nasdaq National Market or the Nasdaq Small-Cap Market. Because our common stock does not trade on a stock exchange or on the Nasdaq National Market or the Nasdaq Small-Cap Market, and the market price of the common stock is less than \$5.00 per share, the common stock qualifies as a "penny stock." SEC Rule 15c-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.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus 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 in the importance of communicating 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" and "Management's Discussion and Analysis or Plan of Operations," as well as any other cautionary language in this prospectus, 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.

10

USE OF PROCEEDS

We will not receive any proceeds from the sale of common stock by the selling stockholders. We will receive proceeds upon the exercise of any warrants. If all of the selling stockholders exercise all of their warrants for cash, we will receive an aggregate of approximately \$8,259,827. We will use such funds, if any, to fund clinical trials and for working capital and general corporate purposes.

MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock is traded on the OTC Bulletin Board under the symbol ASTR. The closing price for our common stock on June 25, 2004 was \$1.10.

The following table sets forth, for the periods indicated, the range of high and low bid quotations for shares of our common stock as quoted on the OTC Bulletin Board. The reported bid quotations reflect inter-dealer prices, without retail markup, markdown or commissions, and may not necessarily represent actual transactions.

	High	Low
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2002

First Quarter	\$2.75	\$1.50
Second Quarter	\$3.35	\$0.91
Third Quarter	\$1.06	\$0.32
Fourth Quarter	\$0.66	\$0.22

2003

First Quarter	\$0.72	\$0.34
Second Quarter	\$1.01	\$0.40
Third Quarter	\$1.41	\$0.36
Fourth Quarter	\$0.87	\$0.42

2004

First Quarter	\$1.66	\$0.80
Second Quarter through June 25, 2004	\$1.46	\$1.05

11

Holders of common stock

As of June 25, 2004, there were approximately 2,385 holders of record of our common stock.

Dividends

We have never paid or declared a cash dividend on our common stock. We intend, for the foreseeable future, to retain all future earnings for use in our business. The amount of dividends we pay in the future, if any, will be at the discretion of our board of directors and will depend upon our earnings, capital requirements, financial condition and other relevant factors.

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

Overview

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

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

- o Ongoing research and development of Psoraxine; and

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

Three months ended March 31, 2004 compared to three months ended March 31, 2003

For three months ended March 31, 2004:

On January 20, 2004, we completed the first closing of a private placement of our securities from which we received gross proceeds of approximately \$4.08

12

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

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

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

- o Research and development costs of \$1,331,141, including \$430,447 that we incurred in connection with services provided by SkyePharma under our Service Agreement with them and amortization of approximately \$178,572 under our technology option license which is being amortized over a seven year period.
- o General and administrative costs of approximately \$421,898, including professional fees and our general corporate expenditures.

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

For the three months ended March 31, 2003:

On January 31, 2003, we sold to SkyePharma pursuant to a Purchase Agreement dated December 10, 2001, 250,000 shares of our Series A 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:

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- o 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.

13

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

As a result, during the three months ended March 31, 2003, we incurred a net loss of \$1,474,714.

Fiscal year ended December 31, 2003 compared to fiscal year ended December 31, 2002

For fiscal year ended December 31, 2003:

In January 2003, pursuant to a Purchase Agreement dated as of December 10, 2001, we sold 250,000 shares of our Series A Convertible Preferred Stock to SkyePharma for an aggregate purchase price of \$2,500,000. We received proceeds of \$2,480,000 after we netted out from the proceeds \$20,000 due to SkyePharma in connection with the Service Agreement.

During the fiscal year ended December 31, 2003, we received \$825,000 outstanding under subscription notes. In April 2003, we entered into an Amended Investor Relation Agreement with a stockholder who had outstanding subscription notes. In exchange for services rendered, we reduced the outstanding amount by \$36,000. In 2004, the stockholder will provide services valued at \$24,000 in lieu of payment of the outstanding subscription receivable balance.

For the fiscal year ended December 31, 2003, we had no revenue from operations and incurred operating expenses of \$5,362,081 which consisted primarily of:

- o Research and development costs of \$4,045,673, including \$1,007,500 that we incurred in connection with services provided by SkyePharma under our Service Agreement with them and amortization of approximately \$714,288 under our technology option license which is being amortized over a seven year period.
- o General and administrative costs of approximately \$1,290,346, including professional fees and our general corporate expenditures.

As a result, during the fiscal year ended December 31, 2003, we incurred a net loss of \$5,080,427.

In December 2003, we received \$221,636 in cash from the sale of a portion of our tax related net operating losses ("NOLS") under the State of New Jersey's Technology Business Tax Certificate Transfer Program. The program is an initiative passed by the New Jersey State legislature that allows qualified technology and biotechnology businesses in New Jersey to sell unused amounts of NOLS and defined research and development tax credits for cash.

For the fiscal year ended December 31, 2002:

In 2002, we sold to SkyePharma pursuant to the Purchase Agreement dated as of December 10, 2001, an aggregate of 750,000 shares of our Series A Convertible

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Preferred Stock for an aggregate purchase price of \$7,500,000. We received net

14

proceeds of approximately \$5,505,000 from this placement after we netted out from the proceeds \$1,995,000 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 fiscal year ended December 31, 2002, we had no revenue and incurred operating expenses of \$9,151,521 which consisted primarily of:

- o Research and development costs of \$7,761,542, including \$5,985,000 that was paid to SkyePharma for services provided under our Service Agreement with them and amortization of approximately \$714,288 under our technology option license which is being amortized over a seven year period.
- o General and administrative costs of approximately \$1,374,251, including professional fees and our general corporate expenditures.

We also had a non-cash preferred stock dividend in April 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.

We recorded an additional preferred stock dividend in December 2002 in the amount of \$9,078,750. The contingent beneficial conversion feature arose because of the reset of the conversion price of our preferred stock on December 10, 2002 from \$2.50 per share of preferred stock to \$1.60 per share. EITF No. 98-5 and EITF No. 00-27 "Application of Issue No. 98-5 to Certain Convertible Instruments" required that we record this preferred stock dividend.

As a result, during the fiscal year ended December 31, 2002, we incurred a net loss of \$18,388,998.

In March 2003, we amended our Service Agreement with SkyePharma, effective as of January 1, 2003, to extend the term of the agreement and modify the services to be provided by SkyePharma. The amended service agreement provides that, in consideration for payments we previously made to SkyePharma, it will continue to provide services to us through December 31, 2004. Consequently, as of December 31, 2002, we recorded a prepaid expense in the amount of \$1,995,000 which was a portion of what we paid to SkyePharma during 2002 in connection with the Service Agreement. This prepaid amount will be incurred during the remaining period of the amended service agreement.

The Next Twelve Months

At March 31, 2004 we had cash balances of \$708,223 and marketable securities of \$4,709,681.

15

Based on our current operating plan, we anticipate conducting the

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following activities and using our cash 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 expect to spend \$2,753,000 on research and development, of which we expect to pay approximately \$1,645,000 to third parties in connection with our Phase II clinical trials.
- o We intend to implement our business plan and facilitate the operations of our company. We will spend approximately \$945,000 to pay management salaries and salaries of employees, a portion of which is treated as research and development expense.
- o We also expect to expend approximately \$960,000 for our general administrative and working capital requirements.

We will need to raise additional funds to continue our operations for the period following the second quarter of 2005. Furthermore, substantial additional funds will be needed in order to fund our continued efforts to attempt to obtain FDA approval for the marketing 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.

BUSINESS

You should read the following description of our business in conjunction with the information included elsewhere in this prospectus. This description contains certain forward-looking statements that involve risk and uncertainties. Our actual results could differ significantly from the results discussed in the forward-looking statements as a result of certain of the factors set forth in the "Risk Factors" section and elsewhere in this prospectus.

General

We are a development-stage biotechnology company primarily engaged in research and development of treatments for immune system disorders and skin diseases. Our current activities focus on the development of a product candidate named Psoraxine(R) for the treatment of the skin disease psoriasis. Currently, we are engaged in ongoing research and development of Psoraxine. We are also engaged in research on the possible development of the technology underlying Psoraxine for the treatment of other indications, such as eczema, seborrheic dermatitis and psoriatic arthritis.

We were originally incorporated under the laws of the State of Colorado in 1999 under the name Hercules Development Group, Inc. We subsequently changed our name to Astralis Pharmaceuticals Ltd. and, in November 2001, reincorporated under the laws of the State of Delaware under our present name.

Psoriasis

Psoriasis is a chronic inflammatory skin disorder of currently unknown origins that generally lasts a lifetime and for which there is presently no

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known cure. Researchers believe that psoriasis may be caused by the immune system sending faulty signals that affect the growth cycle of skin cells. As a result, skin cells accumulate on the surface of the body faster than normal. In people without psoriasis, skin cells mature and are shed approximately every 28 days. In psoriatic skin, the skin cells mature over a period of approximately three to six days.

The symptoms of psoriasis include scaly skin and inflammation occurring on a cyclical basis, with periods of remission and relapse. There are five types of psoriasis. The most common form, appearing in approximately 80% of individuals suffering from the disease, is plaque psoriasis. The other forms are guttate, inverse, erythrodermic and pustular psoriasis. Psoriasis typically does not prevent individuals with the condition from functioning normally. However, the pain, discomfort and emotional effects may be extensive.

Market Opportunity

According to the National Psoriasis Foundation, psoriasis affects approximately 2.1% of the United States population, or more than 4.5 million people in the United States. Psoriasis also affects approximately 1% to 3% of the world's population. Approximately 150,000 to 260,000 new cases of psoriasis are diagnosed each year. In addition, each year approximately 350 people in the United States die due to complications caused by psoriasis. Primarily, such complications occur in relation to severe, extensive forms of psoriasis such as erythrodermic or pustular psoriasis, where large areas of skin are shed. Because the skin plays an important role in regulating body temperature and serving as a barrier to infection, when a person's skin is severely compromised, secondary infections may occur. These serious forms of psoriasis may also cause complicating factors, such as fluid loss and strain on the circulatory system.

The National Psoriasis Foundation also indicates that between 10% and 30% of people who have psoriasis will also develop psoriatic arthritis, which is similar to rheumatoid arthritis, but generally milder. Psoriatic arthritis causes inflammation and stiffness in the soft tissue around joints, and frequently affects the fingers and toes. Psoriatic arthritis may also affect other areas of the body such as the wrists, neck, lower back, knees and ankles.

Psoriasis is a chronic illness that, in many cases, requires continuous treatment. Patients with psoriasis often pay for costly medications and face ongoing visits with physicians. Severe cases may require periods of hospitalization. The National Psoriasis Foundation estimates that the costs of treating psoriasis may exceed \$3.0 billion annually.

17

Psoraxine

Psoraxine was developed by Dr. Jose Antonio O'Daly, our chairman of the board and president of research and development. In 1991, Dr. O'Daly was conducting trials for a vaccine for leishmaniasis in Caracas, Venezuela. One patient involved in the leishmaniasis vaccine trials, who also suffered from psoriasis for 12 years, experienced complete remission of psoriasis after receiving the vaccine. As a result of this discovery, Dr. O'Daly focused his efforts on developing a product for the treatment of psoriasis. From 1992 through 2001, Dr. O'Daly developed Psoraxine, an improved version of the original product that is an immunotherapeutic agent presented in liquid form and packed in 0.5 milligram ampules for intra-muscular injection. Dr. O'Daly tested the original product that was a precursor of Psoraxine in approximately 2,900 patients in several clinical trials in Venezuela. The results from the studies provided evidence of remission of psoriasis lesions as a result of treatment

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with the product. In addition, individuals in the studies did not present severe side effects as a result of treatment. In one clinical study, of the 2,770 patients, 648, or 28%, experienced complete remission of psoriasis. In addition, almost half of the patients experienced psoriasis reduction of between 70% to 99% as measured by the Psoriasis Area and Severity Index ("PASI"). Additional studies yielded average PASI reductions of between 73% and 92%.

Dr. O'Daly licensed Psoraxine to us in 2001 and moved to the United States in 2002. We made capital investments to our research and development facility of approximately \$500,000 in 2002 and we filed an Investigational New Drug application with the FDA for Psoraxine in March 2003. On August 4, 2003 the FDA allowed us to commence our Phase I clinical trials for Psoraxine.

The purpose of Phase I studies is to test the safety of a drug. We have completed our Phase I studies, which involved the administration by intramuscular injection of a single dose of 50, 150 or 300 micrograms of Psoraxine or a placebo in a controlled setting to groups of psoriatic patients. We spent approximately \$130,000 on our Phase I studies in 2003 and anticipate spending an additional \$150,000 on Phase I studies in 2004. We have commenced Phase II studies. The purpose of Phase II studies is to test the safety and efficacy of a drug. We anticipate that it will take at least one year to complete the Phase II studies at a cost of not less than \$2,500,000. For the year ended December 31, 2003, we incurred \$4,045,673 in research and development expenses, including \$1,721,788 related to SkyePharma. For the year ended December 31, 2002, we incurred \$7,761,542 in research and development expenses, including \$6,699,288 related to SkyePharma.

Current Psoriasis Therapies

The topical treatment for psoriasis has been based on the use of emollients, keratolytic agents, coal tar, anthralin, corticosteroids of medium to strong potency and calcipotriene. UVB phototherapy has been used in the treatment of moderate cases of psoriasis. For severe cases, systemic treatments include methotextrate, cyclosporine and oral retinoids. Each of these treatments has variable efficacy, with side effects and cosmetic problems in addition to the failure to prevent frequent relapses.

18

Competition and Psoriasis Treatments in Development

The pharmaceutical and biotechnology industries are intensely competitive. Many companies, including biotechnology, chemical and pharmaceutical companies, are actively engaged in activities similar to ours, including research and development of drugs for the treatment of the same disease as Psoraxine. The FDA has approved Amevive, manufactured by Biogen, Raptiva, manufactured by Genentech/Xoma, and Embrel, manufactured by Amgen and Wyeth, for the treatment of moderate-to-severe chronic plaque psoriasis in adult patients. If we succeed in obtaining FDA approval of Psoraxine, Amevive, Raptiva and Embrel may compete directly with our product. In addition to Biogen, Genentech/Xoma, Amgen and Wyeth, our competitors may include Centocor, Abbott Laboratories and Novartis. Many of these companies have substantially greater financial and other resources, larger research and development staffs, and more extensive marketing and manufacturing organizations than we have. In addition, some of these companies have considerable experience in preclinical testing, clinical trials and other regulatory approval procedures. There are also academic institutions, governmental agencies and other research organizations that are conducting research in areas in which we are working. They may also market commercial products, either on their own or through collaborative efforts.

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We expect to encounter significant competition for any of the pharmaceutical products we develop. Companies that complete clinical trials, obtain required regulatory approvals and commence commercial sales of their products before their competitors may achieve a significant competitive advantage.

Developments by others may render our product obsolete or noncompetitive. We will face intense competition from other companies for collaborative arrangements with pharmaceutical and biotechnology companies, for establishing relationships with academic and research institutions and for licenses to additional technologies. These competitors may succeed in developing technologies or products that are more effective than Psoraxine.

Government Regulation

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and testing, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our potential products.

The process required by the FDA before our product candidate, Psoraxine, may be marketed in the United States generally involves the following:

- o preclinical laboratory and animal tests;
- o submission of an Investigational New Drug application, which must become effective before clinical trials may begin;

19

- o adequate and well controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use; and
- o FDA approval of a new drug application or biologics license application.

The testing and approval process requires substantial time, effort and financial resources, and there can be no assurance that any approvals for Psoraxine or any other potential products will be granted on a timely basis, if at all.

Prior to commencing clinical trials, which are typically conducted in three sequential phases, a company must submit an Investigational New Drug application to the FDA. In March 2003, we filed our Investigational New Drug application for Psoraxine with the FDA. In August 2003, the FDA informed us that we could commence our clinical trials of Psoraxine. We have completed Phase I clinical trials and have commenced Phase II clinical trials.

We may not successfully complete clinical trials of Psoraxine within any specific time period, if at all. Furthermore, the FDA or an institutional review board or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The results of product development, pre-clinical studies and clinical studies are submitted to the FDA as part of a new drug application or biologics license application. The FDA may deny a new drug application or biologics license application if the applicable regulatory criteria are not satisfied or

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may require additional clinical data. Even if such data is submitted, the FDA may ultimately decide that the new drug application or biologics license application does not satisfy the criteria for approval. Once issued, the FDA may withdraw product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches market. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Satisfaction of FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or indication. Government regulation may delay or prevent marketing of potential products or new indications for a considerable period of time and impose costly procedures upon our activities. Success in early stage clinical trials does not assure success in later stage clinical trials.

Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations which could delay, limit or prevent regulatory approval. Even if a product receives regulatory approval, the approval may be significantly limited to specific indications and dosages. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delays in obtaining, or failures to obtain, additional regulatory approvals for any of our product candidates would have a material adverse effect on our business.

20

Any products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with good manufacturing practices, which impose certain procedural and documentation requirements upon us and any third party manufacturers we may utilize. We cannot be certain that our present or future suppliers will be able to comply with the good manufacturing practices, regulations and other FDA regulatory requirements.

Outside the United States, our ability to market a product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within the European Union, registration procedures are available to companies wishing to market a product in more than one EU Member State. If the regulatory authority is satisfied that adequate evidence of safety, quality and efficacy has been presented, a marketing authorization will be granted. This foreign regulatory approval process involves all of the risks associated with FDA clearance. To date, we have obtained regulatory approval for clinical testing of Psoraxine in Venezuela, but we have not obtained final regulatory approval for commercial distribution of Psoraxine in Venezuela because we do not have manufacturing facilities in that country and such facilities are required by regulatory authorities in Venezuela before granting commercial approval for a proposed drug.

Intellectual Property

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In January 2004 the United States Patent and Trademark Office ("PTO") issued a patent to Dr. Jose O'Daly for the "Compositions and Methods for the Treatment and Clinical Remission of Psoriasis." Under the terms of a license agreement and assignment of license agreement, we have the exclusive right and license to use and exploit this patent. Dr. O'Daly will continue to maintain ownership rights with respect to the patent and patent application. However, Dr. O'Daly has granted us a perpetual, royalty free license to his patent under the agreements, which will terminate only upon the expiration of the patent, or upon the commencement of a bankruptcy or insolvency proceeding involving our company or upon our dissolution or liquidation.

In March 2002, Akiva LLC, an entity controlled by Dr. O'Daly, also filed an application to obtain patent protection internationally under the Patent Cooperation Treaty. In addition, in August 2003, Akiva LLC filed patent applications in the European Union, Australia, Brazil, Canada, Mexico and Japan. We have rights to these applications, which are currently pending, pursuant to the license and assignment of license agreements described above.

In January 2004, Dr. O'Daly filed a patent application with the PTO focusing on the mechanism of action of Psoraxine, expanding the claims to include medical indications other than psoriasis, such as Atopic Dermatitis, Psoriatic Arthritis and Rheumatoid Arthritis. In addition, the patent elaborates

21

further on the mechanism of action of leishmania extracts, which are believed to induce T-cell activation. In January 2004, Dr. O'Daly also filed a second patent relating to a culture medium for parasitic organisms, which is part of our technology platform. Dr. O'Daly has assigned to us the rights in the patent applications. Also, in January 2004, the PTO granted us a federal trademark registration for the mark Psoraxine.

Agreements with SkyePharma

We entered into a Purchase Agreement dated as of December 10, 2001 with SkyePharma pursuant to which SkyePharma purchased an aggregate of 2,000,000 shares of our Series A Preferred Stock for an aggregate purchase price of \$20.0 million. On January 20, 2004, pursuant to an Omnibus Conversion Agreement dated January 12, 2004 between us and SkyePharma ("Omnibus Conversion Agreement"), SkyePharma converted all of its outstanding shares of Series A Preferred Stock into 25,000,000 shares of common stock at a conversion price of \$0.80 per share. As a result of its conversion, SkyePharma beneficially owns 34.52% of our common stock.

On January 20, 2004, we and SkyePharma entered into a Call Option Agreement pursuant to which we received the right to repurchase some or all of 12,500,000 shares of our common stock from SkyePharma at a premium to the \$0.80 conversion price. In the event we exercise the call option, the exercise price will be between \$1.28 and \$1.52 per share, depending on the date of exercise. The call option will be exercisable by us for a period commencing upon our achievement of a certain milestone event and ending on January 20, 2007. In June 2004, we assigned the right to purchase 1,250,000 shares under the Call Option Agreement to FPP Capital Advisors as consideration for services it provided in negotiating the Omnibus Conversion Agreement. FPP Capital Advisors is controlled by Fabien Pictet, a member of our board of directors.

On January 20, 2004, we, SkyePharma and other stockholders who are parties to a Stockholders Agreement dated December 10, 2001, entered into an amendment to the Stockholders Agreement to provide for, among other things, the

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termination of the agreement on the later of (1) January 20, 2007 or (2) the date on which SkyePharma no longer beneficially owns 20% of our outstanding common stock. The amended Stockholders Agreement provides that each party thereto will vote all shares held by such parties for one director designated by Mike Ajnsztajn, one director designated by Jose O'Daly, one director designated by Gaston Liebhaber, one director designated by Gina Tedesco, one director designated by SkyePharma and two independent directors. In addition, SkyePharma is required to vote its shares of our common stock in favor of certain enumerated transactions, where those transactions have been approved by our board of directors and all of the independent directors. These transactions include (i) the amendment of our certificate of incorporation solely to increase authorized capital stock, (ii) the adoption or amendment of an employee benefit plan applicable to all employees, (iii) the issuance of additional securities for cash and (iv) the sale of all of our outstanding capital stock, sale of all or substantially all of our assets or merger with another entity provided that SkyePharma will receive the same consideration for its shares as other holders of common stock and will be able to participate in the transaction on the same terms as Messrs. O'Daly, Ajnsztajn and Liebhaber and Ms. Tedesco and the total consideration for the transaction is greater than \$135 million.

We also entered into two agreements concerning the formulation and development of our initial injectable product candidate, Psoraxine, with SkyePharma. Under the terms of the Technology Access Option Agreement, dated December 10, 2001, we paid to SkyePharma a \$5 million fee for the option to

22

acquire a license for DepoFoam and other relevant drug delivery technologies owned by SkyePharma. Under the terms of the Technology Access Option Agreement, if we exercise our option, we must pay a royalty of 5% of net sales of all products manufactured or sold that use or exploit the drug delivery technologies that we license from SkyePharma. In addition, if we exercise our option, SkyePharma retains the right during the term of the Technology Access Option Agreement to undertake the manufacture of all of our products that incorporate or utilize the drug delivery technologies. The option we received under the Technology Access Option Agreement expires on December 10, 2008. The Technology Access Option Agreement may be terminated by either party if (i) the other party commits any irreparable breach of the agreement, (ii) the other party commits any remediable breach and fails to remedy such breach within sixty days of service of notice of the breach, (iii) a court makes an administration order with respect to the other party or any composition in satisfaction of the debts of, or scheme of arrangement of the affairs of, the other party, or (iv) the other party becomes insolvent, has a receiver appointed over any of its assets, enters into any composition with creditors generally or has an order made or resolution passed for it to be wound up. SkyePharma has the right of first negotiation to acquire the worldwide marketing rights to Psoraxine.

In addition, we entered into a Service Agreement, dated December 10, 2001, pursuant to which SkyePharma will provide us with development, manufacturing, pre-clinical and clinical development services in consideration of \$11 million of which \$3 million was paid in 2001 with the remaining \$8 million paid primarily during 2002 for second generation Psoraxine. The Service Agreement terminated on December 31, 2002. We have entered into an Amendment to the Service Agreement with SkyePharma, effective as of January 1, 2003, to extend the term of the Service Agreement and modify the services to be provided by SkyePharma such that SkyePharma will continue to provide certain services to us through December 31, 2004 in consideration for payments made during 2002. In addition, the amendment sets forth milestones expected to be reached during the 24 month period following January 1, 2003.

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Other Research and Development Efforts

In addition to our development of Psoraxine for the treatment of psoriasis, we are researching its possible application for the treatment of other conditions, such as eczema, seborrheic dermatitis and psoriatic arthritis. We are also developing a second product for the treatment of leishmaniasis. Since leishmaniasis is not prevalent in the United States, we intend to market this product primarily in other countries. We have not named this product yet and we do not have any approvals from, nor has any application been filed with, the FDA or any foreign governmental regulatory authority for this product. Currently, we do not have any collaborators for this product. However, our Technology Access Option Agreement permits us to use the technology we may license from SkyePharma for our leishmaniasis treatment. We are also engaged in preliminary research of a treatment for transplant rejection.

Employees and Consultants

As of June 25, 2004, we employed nine full-time employees, including four scientists and a laboratory technician. We also have 14 consultants. We have no part-time employees. None of our employees are covered by a collective bargaining agreement and we believe that our employee relations are good.

23

Legal Proceedings

We are not currently a party to any material legal proceedings.

Property

We lease our executive offices and research laboratory located at 75 Passaic Avenue, Fairfield, New Jersey 07004. The yearly rent for such office and laboratory space is \$77,500.

MANAGEMENT

Executive Officers and Directors

The names, ages and positions of our current directors and executive officers are as follows:

Name	Age	Position
Jose Antonio O'Daly, M.D., Ph.D.	62	Chairman of the Board of Directors; President of Research and Development
Mike Ajnsztajn	39	Chief Executive Officer; Director
Gaston Liebhaber	69	Director
Gina Tedesco	41	Chief Financial Officer; Director
Michael Ashton	58	Director
Steven Fulda	71	Director
Fabien Pictet	46	Director
Sam Barnett, Ed.D.	57	Director

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Phillipe Magistretti, M.D., Ph.D. 47 Director

With the exception of Mr. Ajnsztajn and Ms. Tedesco who are husband and wife, and Mr. Liebhaber who is Mr. Ajnsztajn's uncle, there are no familial relationships among our directors and/or officers. Directors hold office until the next annual meeting of our stockholders or until their respective successors have been elected and qualified. Officers serve at the pleasure of the board of directors.

24

Jose Antonio O'Daly, M.D., Ph.D. Dr. O'Daly has served as our Chairman of the Board of Directors and President of Research and Development since November 13, 2001. Dr. O'Daly is the sole founder of Center for Research and Treatment for Psoriasis in Caracas, Venezuela and has served as its president since 1998. From 1972 to 1998, Dr. O'Daly served as Director and Head of Research of the Microbiology Center of the Venezuelan Institute of Scientific Investigations. Dr. O'Daly attended the Central University of Venezuela, Caracas receiving his Doctorate of Medical Sciences in 1968. In 1971, Dr. O'Daly earned a Doctorate of Philosophy from the Johns Hopkins University in Baltimore, Maryland. Dr. O'Daly is an honorary member of the Venezuelan Medical Academy.

Mike Ajnsztajn. Mr. Ajnsztajn has served as our Chief Executive Officer and as a director since November 13, 2001. From 1986 to 1992, Mr. Ajnsztajn worked for Rhone Poulenc as both an Export Manager for the Far East based in France, and as the Marketing Director in China. From 1992 to 2001, Mr. Ajnsztajn was the president of Blowtex, a Brazilian condom manufacturer. Mr. Ajnsztajn is also co-founder of Opus International, a New Jersey based import/export company that distributes hospital examination gloves and raw materials for the latex industry. Opus International also provides business-consulting services.

Gaston Liebhaber. Mr. Liebhaber has served as our Director of International Affairs since November 13, 2001 and as a director since January 31, 2002. Mr. Liebhaber has 35 years of experience in the pharmaceutical industry. Mr. Liebhaber founded Fundafarmacia in Caracas, Venezuela, a non-profit organization that distributes medicine, at discounted prices, to the poor and homeless. Since 1982, Mr. Liebhaber has served as the Managing Director of Latin America of Sankyo Pharmaceutical. Since 1987, Mr. Liebhaber also has served on the Board of Directors of the Venezuelan Association of Pharmaceutical Companies.

Gina Tedesco. Ms. Tedesco has served as our Chief Financial Officer since November 13, 2001 and as a director since January 31, 2002. Ms. Tedesco is a co-founder of Opus International and has served as its President since 1997. Ms. Tedesco has extensive experience in the pharmaceutical industry and in finance and business planning. From 1989 to 1996, Ms. Tedesco held various positions with Rhone Poulenc ranging from controller for the European pharmaceutical subsidiaries to Director of Finance and Investor Relations for a Brazilian subsidiary. Ms. Tedesco earned a MBA from George Washington University in International Business.

Michael Ashton. Mr. Ashton has served as one of our directors since January 31, 2002. Since 1977, Mr. Ashton has been employed by SkyePharma PLC, a London based drug delivery technology provider. Since 1999, Mr. Ashton has served as the Chief Executive Officer of SkyePharma PLC. Mr. Ashton is a member of the board of directors of Transition Inc. Mr. Ashton has thirty years of experience in the pharmaceutical industry. Mr. Ashton has a Bachelor of Pharmacy Degree from Sydney University and a MBA Degree from Rutgers University.

25

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Steven Fulda. Mr. Fulda has served as one of our directors since February 6, 2002. Since 1989, Mr. Fulda has served as Managing Director of Fulda Business Planners. Mr. Fulda has forty years of management and consulting experience including business strategy, planning, development and financing. Since 1992, Mr. Fulda has been an Adjunct Professor of Entrepreneurship and Director of the Small Business Institute at Fairleigh Dickinson University. Mr. Fulda holds a Master's Degree in Quantitative Business Analysis from New York University and a Master's Degree in Systems Engineering from Bell Laboratories' New York University Graduate Program.

Fabien Pictet. Mr. Pictet has served as one of our directors since February 6, 2002. Since 1998, Mr. Pictet has served as Chairman of Fabien Pictet and Partners, a London based firm which invests in the emerging markets arena. Mr. Pictet has twenty years of experience in investing in emerging markets. During his eleven year tenure with Pictet and Cie, from 1986 to 1997, Mr. Pictet held various positions ranging from Manager responsible for U.S. equity investments to Partner responsible for all of the firm's institutional activities in Geneva, Zurich and London. Mr. Pictet has a Master's Degree in International Management from American Graduate School of International Management and a Bachelor's Degree in Economics from the University of San Francisco.

Sam Barnett. Mr. Barnett has served as one of our directors since June 2004. In 1979, Mr. Barnett founded Barnett International, a consulting firm where he served as chief consultant. Mr. Barnett subsequently served as head of the Americas Pharmaceutical Practice of PricewaterhouseCoopers Consulting and head of the Americas Life Sciences Consulting Practice for IBM, Business Consulting Services. Mr. Barnett received his Bachelor's Degree from Wesleyan University and received both his Master's and Doctorate Degrees from Temple University.

Phillipe Magistretti, M.D., Ph.D. Dr. Magistretti has served as one of our directors since June 2004. He is currently the Chief Executive Officer of Translign Inc., a company focused on technology transfer in the life sciences industry. He previously served as Chief Executive Officer of Credit Agricole Lazard Financial Products Bank and as Managing Director of Lazard & Co., Ltd. He has previously served as President of Bank AIG and as a Vice President of Credit Suisse First Boston. Dr. Magistretti received his M.D. and Ph.D. from the University of Genova.

Advisors

Scientific Advisory Board

James Leyden, MD. Dr. Leyden has served as the Chairman of our Medical Advisory Board since November 31, 2001. Dr. Leyden has been a Professor of Dermatology at the Hospital of the University of Pennsylvania in Philadelphia since 1983. He has served on the boards of many of the nation's key dermatological committees, including those of the American Academy of Dermatology and the Dermatology Foundation. Dr. Leyden has also served as a consultant to the U.S. Food and Drug Administration and the Federal Trade Commission, and to drug regulation agencies in England, Germany and Austria. Dr. Leyden has also assisted in the development, testing and commercialization of Accutane, Bactroban, Nizoral, Cleocin, Benzamycin, Benzaclin, Minocin and the use of bicarbonate to control body odor. Dr. Leyden has a Bachelor's Degree from Saint Joseph's College and a MD for the University of Pennsylvania School of Medicine.

Gerald Krueger, MD. Dr. Krueger has served on our Medical Advisory Board since December 2, 2003. Dr. Krueger is a professor of dermatology at the University of Utah School of Medicine. Dr. Krueger consults for the U.S. Food and Drug Administration on psoriasis and serves on the executive committee of the Dermatology Foundation. In addition, he recently completed a ten year term as

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chairman of the Medical Advisory Board of the National Psoriasis Foundation. Dr. Krueger has been elected into the Alpha Omega Honor Society of Medicine. He has received the Taub International Award for psoriasis research, the American Skin Association Award for psoriasis research and the National Psoriasis Foundation's Lifetime Achievement Award and Founders Award.

26

Our Scientific Advisory Board does not hold any formal meetings. However, management consults with the Scientific Advisory Board from time to time.

Marketing Advisor

Bruce Epstein. Mr. Epstein has served as our Marketing Affairs Advisor since November 13, 2001. Since 2000, Mr. Epstein has served as the General Manager of Noesis Healthcare Interactions, a full-service healthcare communications company managing a creative and support staff focused on the marketing and advertising of multiple pharmaceutical brands with leading pharmaceutical companies. Mr. Epstein specializes in strategic planning and tactical implementation of pharmaceutical products. From 1996 to 2000, Mr. Epstein worked at Klemner Advertising, the healthcare division of Saatchi and Saatchi. From 1986 to 1996, Mr. Epstein worked for Roche Laboratories, a Swiss pharmaceutical company with a U.S. division based in Nutley, New Jersey. Mr. Epstein obtained a MBA from New York University, Stern School of Business, and a Registered Pharmacist Degree from Rutgers, College of Pharmacy.

Board Composition

We currently have nine directors, each serving a term until the next annual meeting of stockholders. Pursuant to an Amendment to Stockholders' Agreement dated January 20, 2004 between us, SkyePharma, Jose O'Daly, Mike Ajnsztajn, Gina Tedesco and Gaston Liebhaber, the parties agreed to vote all shares held by such parties for (i) one director designated by Jose O'Daly, (ii) one director designated by Mike Ajnsztajn, (iii) one director designated by Gaston Liebhaber, (iv) one director designated by Gina Tedesco, (v) one director designated by SkyePharma and (vi) two independent directors. The agreement terminates on the later of (i) January 20, 2007 or (ii) the date on which SkyePharma no longer beneficially owns 20% of our outstanding common stock.

Compensation of Directors

Our directors do not receive compensation pursuant to any standard arrangement for their services as directors. We reimburse all outside directors for travel and lodging expenses related to scheduled board meetings. During the fiscal year ended December 31, 2003, we paid \$1,000 to each outside director for each board meeting attended and paid an additional \$4,500 to the chairman of our audit committee.

Indemnification Matters

Our Certificate of Incorporation eliminates the personal liability of directors to the fullest extent permitted by the provisions of paragraph (7) of subsection (b) of Section 102 of the General Corporation Law of Delaware. In addition, our Certificate of Incorporation includes provisions to indemnify our officers and directors and other persons against expenses, judgments, fines and amounts paid in settlement in connection with threatened, pending or completed suits or proceedings against those persons by reason of serving or having served as officers, directors or in other capacities to the fullest extent permitted by Section 145 of the General Corporation Law of Delaware.

Our bylaws provide the power to indemnify our officers, directors, employees and agents or any person serving at our request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise to the fullest extent permitted by Delaware law.

EXECUTIVE COMPENSATION

The following table sets forth certain information regarding compensation paid by us and our predecessors during each of the last three fiscal years to our Chief Executive Officer and any other executive officer who received compensation greater than \$100,000 during any of the last three fiscal years.

Summary Compensation Table

Name and Principal Position	Year	Annual Compensation	
		Salary (\$)	Other Annual Compensation (\$)
Mike Ajnsztajn, Chief Executive Officer (1)	2003	154,375	4,613 (3)
	2002	150,000	4,613
	2001	81,164	--
Jose Antonio O'Daly, Chairman of the Board of Directors and President of Research and Development (2)	2003	158,750	73,740 (4)
	2002	150,000	56,671
	2001	63,500	--

- (1) Mr. Ajnsztajn became our Chief Executive Officer on November 13, 2001.
- (2) Dr. O'Daly became one of our employees on July 1, 2002. Prior to July 1, 2002, Dr. O'Daly provided services as a consultant to the company.
- (3) For the fiscal year ended December 31, 2003, this amount includes \$4,613 in health insurance premiums paid by us for Mr. Ajnsztajn's benefit.
- (4) For the fiscal year ended December 31, 2003, this amount includes \$9,929 in health insurance premiums paid by us for Dr. O'Daly's benefit, an automobile allowance of \$6,317, \$37,494 for a furnished apartment and \$20,000 for tax payments.

Employment Agreement

Pursuant to an Employment Agreement dated December 10, 2001, Dr. O'Daly receives a salary of \$150,000 per year for his services as Chairman of the Board and President of Research and Development. The agreement has a term of three years and requires Dr. O'Daly to refrain from competing with us for a period of one year following termination of his employment. The agreement does not contain

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any change of control provisions. None of our other executive officers receive compensation pursuant to any standard arrangement for their services as executive officers.

2001 Stock Option Plan

Our 2001 Stock Option Plan ("2001 Plan") was unanimously adopted by the board of directors on November 1, 2001 and approved by our stockholders at a special meeting held on November 1, 2001. The 2001 Plan provides for the issuance of 5,000,000 shares of common stock underlying stock options available for grant thereunder. The purpose of the 2001 Plan is to provide additional incentive to our directors, officers, employees and consultants who are primarily responsible for our management and growth. Each option will be designated at the time of grant as either an incentive stock option (an "ISO") or as a non-qualified stock option (a "NQSO"). As of December 31, 2003, options to purchase 365,000 shares of common stock have been granted under the 2001 Plan.

The 2001 Plan will be administered by our board of directors, or by any committee that we may in the future form and to which the board of directors may delegate the authority to perform such functions (in either case, the "Administrator").

Every person who at the date of grant of an option is an employee of ours or any affiliate of ours is eligible to receive NQSOs or ISOs under the 2001 Plan. Every person who at the date of grant is a consultant to, or non-employee director of, ours or any affiliate of ours is eligible to receive NQSOs under the 2001 Plan.

The exercise price of a NQSO will be not less than 85% of the fair market value of the stock subject to the option on the date of grant. To the extent required by applicable laws, rules and regulations, the exercise price of a NQSO granted to any person who owns, directly or by attribution under the Code (currently Section 424(d)), stock possessing more than 10% of the total combined voting power of all classes of our stock or stock of any of our affiliates (a "10% Shareholder") will not be less than 110% of the fair market value of the stock covered by the option at the time the option is granted. The exercise price of an ISO will be determined in accordance with the applicable provisions of the Code and will not be less than the fair market value of the stock covered by the option at the time the option is granted. The exercise price of an ISO granted to any 10% Shareholder will not be less than 110% of the fair market value of the stock covered by the option at the time the option is granted.

The Administrator, in its sole discretion, will fix the term of each option, provided that the maximum term of an option will be ten years. ISOs granted to a 10% Shareholder will expire not more than five years after the date of grant. The 2001 Plan provides for the earlier expiration of options in the event of certain terminations of employment of the holder.

29

Options may be granted and exercised under the 2001 Plan only after there has been compliance with all applicable federal and state securities laws. The 2001 Plan will terminate within ten years from the date of its adoption by the board of directors.

If for any reason other than death or permanent and total disability, an optionee ceases to be employed by us or any of our affiliates (such event being called a "Termination"), options held at the date of Termination (to the extent then exercisable) may be exercised in whole or in part at any time within three

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months of the date of such Termination, or such other period of not less than thirty days after the date of such Termination as is specified in the Option Agreement or by amendment thereof (but in no event after the expiration date of the option (the "Expiration Date")); provided, however, that if such exercise of the option would result in liability for the optionee under Section 16(b) of the Exchange Act, then such three-month period automatically will be extended until the tenth day following the last date upon which the optionee has any liability under Section 16(b) (but in no event after the Expiration Date).

The board of directors may at any time amend, alter, suspend or discontinue the 2001 Plan. Without the consent of an optionee, no amendment, alteration, suspension or discontinuance may adversely affect outstanding options except to conform the 2001 Plan and ISOs granted under the 2001 Plan to the requirements of federal or other tax laws relating to ISOs. No amendment, alteration, suspension or discontinuance will require shareholder approval unless (i) shareholder approval is required to preserve incentive stock option treatment for federal income tax purposes or (ii) the board of directors otherwise concludes that shareholder approval is advisable.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

General

Centro Para La Investigacion y Tratamiento De La Psoriasis ("CITP"), a research entity owned by Helen O'Daly, the spouse of Dr. Jose Antonio O'Daly, provided assistance in the research and development of Psoraxine in Venezuela commencing in November 2001 and terminating in May 2002. We paid approximately \$275,000 to CITP for the services it provided.

Relationship with SkyePharma

We entered into a Purchase Agreement dated as of December 10, 2001 with SkyePharma pursuant to which SkyePharma purchased an aggregate of 2,000,000 shares of our Series A Preferred Stock, for an aggregate purchase price of \$20.0 million. On January 20, 2004, pursuant to an Omnibus Conversion Agreement dated

30

January 12, 2004 between us and SkyePharma ("Omnibus Conversion Agreement"), SkyePharma converted all of its outstanding shares of Series A Preferred Stock into 25,000,000 shares of our common stock at a conversion price of \$0.80 per share. As a result of its conversion, SkyePharma beneficially owns 34.54% of our common stock on a fully diluted basis.

On January 20, 2004, we and SkyePharma entered into a Call Option Agreement ("Call Option Agreement") pursuant to which we received the right to repurchase some or all of 12,500,000 shares of our common stock from SkyePharma at a premium to the conversion price. The call option will be exercisable by us upon our achievement of a certain milestone event and ending on January 20, 2007.

On January 20, 2004, we, SkyePharma and other stockholders who are parties to the Stockholders Agreement dated December 10, 2001, entered into an amendment of the Stockholders Agreement to provide for, among other things, the termination of the agreement on the later of (1) January 20, 2007 or (2) the date on which SkyePharma no longer beneficially owns 20% of our outstanding common stock. The amended Stockholders Agreement requires the parties to agree to vote all shares held by such parties for one director designated by Mike Ajnsztajn, one director designated by Jose O'Daly, one director designated by Gaston Liebhaber, one director designated by Gina Tedesco, one director

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designated by SkyePharma and two independent directors. In addition, SkyePharma is required to vote its shares of our common stock in favor of certain enumerated transactions, where those transactions have been approved by our board of directors and all of the independent directors.

On December 10, 2001, we entered into a Technology Access Option Agreement and a Service Agreement with SkyePharma. Also, effective as of January 1, 2003, we entered into an Amendment to the Service Agreement with SkyePharma. These agreements are described under "Business - Agreements with SkyePharma."

Relationship with FPP Capital Advisors

In connection with private placements of units consisting of common stock and warrants that occurred in 2004, FPP Capital Advisors, an entity controlled by our board member, Fabien Pictet, received a consulting fee of \$261,496. In addition, for consulting services provided in connection with the private placement, FPP Capital Advisors and certain other selling stockholders received warrants to purchase an aggregate of 418,394 shares of our common stock at \$0.50 per share and warrants to purchase an aggregate of 418,394 shares of our common stock at \$0.73 per share. Upon exercise of the warrants issued in the private placement, we will pay a cash commission equal to 5% of the amounts raised through the exercise of the warrants.

In addition, in consideration for services provided in negotiating the Omnibus Conversion Agreement, we issued to FPP Capital Advisors units consisting of 150,000 shares of common stock and warrants to purchase 150,000 shares of common stock at an exercise price of \$0.73 per share. We also assigned the right to purchase 1,250,000 shares under the Call Option Agreement to FPP Capital Advisors.

31

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth the names and beneficial ownership of our common stock owned as of June 25, 2004, by (i) each of our directors, (ii) each person named in the Summary Compensation Table, (iii) all our directors and executive officers as a group, and, to the best of our knowledge, (iv) all holders of 5% or more of the outstanding shares of our common stock. Unless otherwise noted, the address of all the individuals and entities named below is care of Astralis Ltd. at 75 Passaic Avenue, Fairfield, NJ 07004.

Name and Address	Number of Shares of common stock Beneficially Owned (1)	Percentage of Outstanding Common Stock
Dr. Jose Antonio O'Daly (2)	13,640,000	
Mike Ajnsztajn (2) (3)	8,680,000	
Gina Tedesco (2) (3)	8,680,000	
Gaston Liebhaber (2)	2,480,000	
Michael Ashton (4)	25,220,000	
Fabien Pictet (5)	4,211,794	

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Steven Fulda (6)	29,700
SkyePharma PLC (2) (7) 105 Piccadilly London W1J 7NJ England	25,220,000
All Officers and Directors as a Group	54,261,494

* Less than 1%

(1) Beneficial ownership is determined in accordance with Rule 13d-3(a) of the Securities Exchange Act of 1934 and generally includes voting or investment power with respect to securities. Except as indicated by footnotes and subject to community property laws, where applicable, the person named above has sole voting and investment power with respect to all shares of the common stock shown as beneficially owned by him. The beneficial ownership percentage is based on 73,173,055 shares of our common stock outstanding as of June 25, 2004.

32

(2) Under the terms of Amendment No. 1 to the Stockholders' Agreement dated as of January 20, 2004 by and among SkyePharma, Jose O'Daly, Mike Ajnsztajn, Gaston Liebhaber, Gina Tedesco and us, the parties agreed to vote all shares held by such parties for (i) one director designated by Mike Ajnsztajn, (ii) one director designated by Jose O'Daly, (iii) one director designated by Gaston Liebhaber, (iv) one director designated by Gina Tedesco, (v) one director designated by SkyePharma and (vi) two independent directors. No party to the agreement has the right to dispose (or direct the disposition of) any shares of common stock held by any of the other parties to the agreement. Accordingly, each party disclaims beneficial ownership of the shares held by the other parties.

(3) Ms. Tedesco, our Chief Financial Officer, may be deemed to be the beneficial owner of the 8,680,000 shares of common stock owned as of June 25, 2004 by her husband, Mike Ajnsztajn. Ms. Tedesco disclaims beneficial ownership of such shares.

(4) Includes 25,200,000 shares of common stock beneficially owned by SkyePharma and warrants to purchase 20,000 shares of common stock beneficially owned by SkyePharma. Mr. Ashton is Chief Executive Officer of SkyePharma. Under the terms of a Call Option Agreement dated January 20, 2004, we have the right to repurchase some or all of 12,500,000 shares of our common stock from SkyePharma. The call option will be exercisable by us for a period commencing upon our achievement of a certain milestone event and ending on January 20, 2007.

(5) Includes 1,260,000 shares of common stock owned by FPP Emerging Hedge Fund and warrants to purchase an aggregate of 1,176,000 shares of common stock owned by FPP Emerging Hedge Fund. Includes 390,000 shares of common stock and warrants to purchase 500,000 shares of common stock owned by Perly International Ltd. Includes 180,000 shares of common stock owned by Pictet Private Equity Investors and warrants to purchase 36,000 shares held by Pictet Private Equity Investors. Also includes 150,000 shares of common stock owned by FPP Capital Advisors and warrants to purchase 519,794 shares held by FPP Capital Advisors. Does not include 1,250,000 shares of common stock held by SkyePharma which FPP Capital

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Advisors has the right to purchase under the term of (i) the Call Option Agreement dated January 20, 2004 between us and SkyePharma and (ii) the Assignment and Assumption Agreement dated as of June 24, 2004 between us and FPP Capital Advisors.

(6) Includes 4,700 shares of common stock owned as of June 25, 2004 by Mr. Fulda's spouse. Mr. Fulda disclaims beneficial ownership of such shares.

(7) Includes 25,200,000 shares of common stock and warrants to purchase 20,000 shares of common stock held by SkyePharma. Michael Ashton, Chief Executive Officer of SkyePharma and a member of our board of directors, exercises voting control over the shares held by SkyePharma. Under the terms of a Call Option Agreement dated January 20, 2004, we have the right to repurchase some or all of 12,500,000 shares of our common stock from SkyePharma. In June 2004, we assigned the right to purchase 1,250,000 shares under the Call Option Agreement to FPP Capital Advisors, an entity controlled by Fabien Pictet. The call option will be exercisable for a period commencing upon our achievement of a certain milestone event and ending on January 20, 2007.

33

SELLING STOCKHOLDERS

An aggregate of up to 47,056,520 shares of our common stock may be offered and sold pursuant to this prospectus by the selling stockholders. SkyePharma acquired its shares of common stock through the conversion of our outstanding Series A Preferred Stock. The other selling stockholders acquired common stock and warrants to purchase common stock by (i) purchasing units consisting of common stock and warrants in a private placement, consummated in January and February 2004, (ii) receiving warrants as consideration for consulting services provided in connection with such private placement or (iii) receiving units as consideration for negotiating the Omnibus Conversion Agreement dated January 12, 2004 between us and SkyePharma.

In the private placement, we issued an aggregate of 10,459,866 shares of our common stock and warrants to purchase an aggregate of 10,459,866 shares of our common stock at an exercise price of \$0.73 per share. We received gross proceeds of \$5,229,933 from the private placement.

In the event all selling stockholders exercise their warrants to purchase shares of our common stock, we will receive additional gross proceeds of \$8,259,827.

Relationship with Certain Selling Stockholders

In connection with the private placement, FPP Capital Advisors received a consulting fee of \$261,496. In addition, FPP Capital Advisors and certain other selling stockholders who assisted FPP Capital Advisors in providing consulting services to us, received warrants to purchase an aggregate of 418,394 shares of our common stock at \$0.50 per share and warrants to purchase an aggregate of 418,394 shares of our common stock at \$0.73 per share. Further, in consideration for services rendered in negotiating the Omnibus Conversion Agreement dated January 12, 2004 between us and SkyePharma, we issued units consisting of 150,000 shares of common stock and warrants to purchase 150,000 shares of common stock at an exercise price of \$0.73 per share to FPP Capital Advisors. We also assigned to FPP Capital Advisors the right to purchase 1,250,000 shares of our common stock from SkyePharma under the Call Option Agreement discussed below. FPP Capital Advisors is controlled by Fabien Pictet, a member of our board of directors.

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In addition to FPP Capital Advisors, Fabien Pictet controls FPP Emerging Hedge Fund I and Pictet & Cie, both of which were investors in the private placement and are selling stockholders.

Under the terms of the Omnibus Conversion Agreement between us and SkyePharma, on January 20, 2004, SkyePharma converted all of its outstanding shares of our Series A Preferred Stock into 25,000,000 shares of common stock at a conversion price of \$0.80 per share. As a result of its conversion, SkyePharma beneficially owns 34.54% of our common stock. On January 20, 2004, we and SkyePharma entered into a Call Option Agreement pursuant to which we received the right to repurchase some or all of 12,500,000 shares of our common stock from SkyePharma at a premium to the conversion price. We assigned to FPP Capital Advisors the right to purchase 1,250,000 of these shares. The call option will be exercisable for a period commencing upon our achievement of a certain milestone event and ending on January 20, 2007.

On January 20, 2004, we, SkyePharma and other stockholders who are parties to a Stockholders Agreement dated December 10, 2001, entered into an amendment to the Stockholders Agreement to provide for, among other things, the termination of the agreement on the later of (1) January 20, 2007 or (2) the date on which SkyePharma no longer beneficially owns 20% of our outstanding common stock. The amended Stockholders Agreement provides that each party thereto will vote all shares held by such parties for one director designated by

34

Mike Ajnsztajn, one director designated by Jose O'Daly, one director designated by Gaston Liebhaber, one director designated by Gina Tedesco, one director designated by SkyePharma and two independent directors. In addition, SkyePharma is required to vote its shares of our common stock in favor of certain enumerated transactions, where those transactions have been approved by our board of directors and all of the independent directors.

Further, on December 10, 2001, we entered into a Technology Access Option Agreement and a Service Agreement with SkyePharma. Also, effective as of January 1, 2003, we entered into an Amendment to the Service Agreement with SkyePharma. These agreements are described under "Business -- Agreements with SkyePharma."

No other selling stockholders has held any position or office or had a material relationship with us within the past three years other than as a result of the ownership of our common stock and other securities.

The following table sets forth certain information as of June 25, 2004 regarding the sale by the selling stockholders of 47,056,520 shares of common stock in this offering.

Selling Stockholder	Shares Beneficially Owned Before the Offering (1)	Shares Currently Outstanding and Being Registered in the Offering (1)	Warrant Shares Being Registered in the Offering	Total Shares Bei Registered the Offeri
Vieri Bracco	305,200 (2)	140,000	165,200 (2)	305,200 (
ACE Fund Sicav	1,600,000	800,000	800,000	1,600,000
Pictet & Cie	1,700,000	850,000	850,000	1,700,000
Fidulex Management,	3,600,000	1,800,000	1,800,000	3,600,000

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Inc.				
Gesico International S.A.	800,000	400,000	400,000	800,000
Epalinges Limited	599,928	299,964	299,964	599,928
Bank Morgan Stanley AG	3,600,000	1,800,000	1,800,000	3,600,000
S.A.M. Master Fund L.P.	1,200,000	600,000	600,000	1,200,000
Mirabaud & Cie	200,000	100,000	100,000	200,000
Bank Julius Baer & Co., Ltd.	200,000	100,000	100,000	200,000
UBS Private Banking Nominees Ltd.	1,000,000	500,000	500,000	1,000,000
B.I. Lipworth & Co. Limited	200,000	100,000	100,000	200,000
Deborah Jones	300,000	150,000	150,000	300,000
FPP Emerging Hedge Fund I	1,200,000	600,000	600,000	1,200,000
Vistal International Ltd.	200,000	100,000	100,000	200,000
Marcelo M. Fleury	200,000	100,000	100,000	200,000
Maran Limited	300,000	150,000	150,000	300,000
Newbridge Advisors	80,000	40,000	40,000	80,000
Donvale Investments Ltd.	400,000	200,000	200,000	400,000
Greenwood Nominees Ltd.	200,000	100,000	100,000	200,000
Serica Bank	100,000	50,000	50,000	100,000
Bernard Rapoport	100,000	50,000	50,000	100,000

35

Larry Jaynes	100,000	50,000	50,000	100,000
Maurice Sydney Lipworth	200,000	100,000	100,000	200,000
Graeme Gordon	400,000	200,000	200,000	400,000
Nick Wentworth Stanley	199,920	99,960	99,960	199,920
Carla Maria Orsi Carbone	160,000	80,000	80,000	160,000
Alexandre Stakhovitch	769,794 (3)	200,000	569,794 (3)	769,794 (3)
Raffaele Ricci	199,884	99,942	99,942	199,884
Marcos M. Carvalhal and Scott Starkey Joint Tenants	200,000	100,000	100,000	200,000
B.I. Lipworth & Co. Limited as Nominee for BrandNew Group Limited	200,000	100,000	100,000	200,000
I.S. Twersky	400,000	200,000	200,000	400,000
Rhonda Limited	400,000	200,000	200,000	400,000
SkyePharma PLC	25,220,000 (4) (5)	25,000,000 (2)	--	25,000,000 (4) (5)
FPP Capital Advisors	669,794 (6)	150,000	519,794	519,794
Manuel Tarabay	722,000 (7) (8)	--	72,000 (8)	72,000

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* Less than 1%.

(1) Beneficial ownership is determined in accordance with rules and regulations of the Securities and Exchange Commission. In computing the number of shares beneficially owned by a person, shares of common stock subject to options or warrants held by that person that are currently exercisable or exercisable within 60 days of the date of this prospectus are deemed outstanding. Except as indicated in the footnotes to this table and pursuant to applicable community property laws, each stockholder named in the table has sole voting and investment power with respect to the shares beneficially owned by him. Selling stockholders are deemed to beneficially own the shares of common stock issuable upon the exercise of their warrants.

(2) Includes warrants to purchase 12,600 shares of common stock at an exercise price of \$0.50 per share and warrants to purchase 12,600 shares of common stock at an exercise price of \$0.73 per share. Such warrants were issued for consulting services provided in connection with our 2004 private placement.

(3) Includes warrants to purchase 184,897 shares of common stock at an exercise price of \$0.50 per share and warrants to purchase 184,897 shares of common stock at an exercise price of \$0.73 per share. Such warrants were issued for consulting services provided in connection with our 2004 private placement and in connection with the conversion of our Series A Preferred Stock by SkyePharma.

(4) Includes 25,200,000 shares of common stock and warrants to purchase 20,000 shares of common stock. Michael Ashton, Chief Executive Officer of SkyePharma and a member of our board of directors, exercises voting control over the shares held by SkyePharma.

(5) Under the terms of a Call Option Agreement dated January 20, 2004, we have the right to repurchase some or all of 12,500,000 shares of our common stock from SkyePharma. In June 2004, we assigned the right to purchase 1,250,000 shares under the Call Option Agreement to FPP Capital Advisors, an entity controlled by Fabien Pictet. The call option will be exercisable for a period commencing upon our achievement of a certain milestone event and ending on January 20, 2007.

36

(6) Includes warrants to purchase 184,897 shares of common stock at an exercise price of \$0.50 per share and warrants to purchase 184,897 shares of common stock at an exercise price of \$0.73 per share. Such warrants were issued for consulting services provided in connection with our 2004 private placement and in connection with negotiating the Omnibus Conversion Agreement dated January 12, 2004 between us and SkyePharma.

(7) Includes 650,000 shares of common stock beneficially owned by Mr. Tarabay which he acquired prior to our 2004 private placement.

(8) Includes warrants to purchase 36,000 shares of common stock at an exercise price of \$0.50 per share and warrants to purchase 36,000 shares of common stock at an exercise price of \$0.73 per share. Such warrants were issued for consulting services provided in connection with our 2004 private placement.

PLAN OF DISTRIBUTION

The selling stockholders and any of their pledgees, donees, transferees, assignees or other successors-in-interest may, from time to time, sell any or all of the shares of common stock offered hereby on any stock exchange, market or trading facility on which the shares are traded or in private transactions.

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Our common stock currently trades on the OTC Bulletin Board. Any sales by the selling stockholders may be at fixed or negotiated prices. The selling stockholders may use any one or more of the following methods when selling shares:

- o ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- o block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- o purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- o an exchange distribution in accordance with the rules of the applicable exchange;
- o privately negotiated transactions;
- o short sales;
- o broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- o a combination of any such methods of sale; and
- o any other method permitted pursuant to applicable law.

37

The selling stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved.

The selling stockholders may from time to time pledge or grant a security interest in any of their warrants or common stock issuable upon conversion of their warrants and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares underlying the warrants from time to time under this prospectus.

The selling stockholders also may transfer their warrants or shares of common stock issuable upon conversion of their warrants in other circumstances, in which case the pledgees, donees, transferees, assignees or other successors-in-interest will be "selling stockholders" for purposes of this prospectus.

The selling stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. The selling stockholders have informed us that they do not have any agreement or understanding, directly or

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indirectly, with any person to distribute the common stock.

We will not receive any proceeds from sales of any shares by the selling stockholders. However, we may receive an aggregate of \$8,259,827 upon the exercise of all the warrants held by selling stockholders, if such warrants are exercised for cash. We will use such funds, if any, to fund clinical trials and for working capital and general corporate purposes.

38

DESCRIPTION OF CAPITAL STOCK

We are authorized to issue 153,000,000 shares of capital stock divided into (i) 150,000,000 shares of common stock, par value \$0.0001 per share and (ii) 1,000,000 shares of preferred stock. As of June 25, 2004, there are 73,173,055 shares of our common stock outstanding, held of record by approximately 2,385 stockholders. We do not have any shares of preferred stock outstanding.

Common Stock

The holders of our common stock are entitled to one vote for each share held of record in the election of directors and in all other matters to be voted on by the stockholders. There is no cumulative voting with respect to the election of directors. As a result, the holders of more than 50% of the shares voting for the election of directors can elect all of the directors. Holders of common stock are entitled:

- o to receive any dividends as may be declared by the board of directors out of funds legally available for such purpose after payment of accrued dividends on the outstanding shares of preferred stock; and
- o in the event of our liquidation, dissolution, or winding up, to share ratably in all assets remaining after payment of liabilities and after provision has been made for each class of stock having preference over the common stock.

All of the outstanding shares of common stock are validly issued, fully paid and nonassessable. Holders of our common stock have no preemptive right to subscribe for or to purchase additional shares of any class of our capital stock.

Pursuant to an Amendment to Stockholders' Agreement dated January 20, 2004 between us, SkyePharma, Jose O'Daly, Mike Ajnsztajn, Gina Tedesco and Gaston Liebhaber, the parties agreed to vote all shares held by such parties for (i) one director designated by Jose O'Daly, (ii) one director designated by Mike Ajnsztajn, (iii) one director designated by Gaston Liebhaber, (iv) one director designated by Gina Tedesco, (v) one director designated by SkyePharma and (vi) two independent directors. The agreement terminates on the later of (i) January 20, 2007 or (ii) the date on which SkyePharma no longer beneficially owns 20% of our outstanding common stock.

Preferred Stock

Our board of directors has the authority, within the limitations set forth in our certificate of designations and certificate of incorporation to provide by resolution for the issuance of preferred stock, in one or more classes or series, and to fix the rights, preferences, privileges and restrictions thereof, including dividend rights, conversion rights, voting rights, terms of

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redemption, liquidation preferences and the number of shares constituting any series or the designation of such series.

39

Warrants

As of June 25, 2004, we have outstanding warrants to purchase 18,011,891 shares of our common stock. We issued warrants to purchase 6,300,000 shares of our common stock at an exercise price of \$1.60 per share pursuant to a private placement that occurred in September 2001. We issued warrants to purchase 415,237 shares of our common stock at an exercise price of \$4.00 per share pursuant to a private placement that occurred in November 2001. We issued warrants to purchase 10,459,866 shares of our common stock at an exercise price of \$0.73 per share pursuant to a private placement that occurred in January and February 2004. In connection with our most recent private placement, we also issued to FPP Capital Advisors and certain other selling stockholders who assisted FPP Capital Advisors in providing consulting services to us warrants to purchase an aggregate of 418,394 shares of our common stock at \$0.50 per share and warrants to purchase an aggregate of 418,394 shares of our common stock at \$0.73 per share. In consideration for services rendered in negotiating the Omnibus Conversion Agreement dated January 12, 2004 between us and SkyePharma, we issued units consisting of 150,000 shares of common stock and warrants to purchase 150,000 shares of common stock to FPP Capital Advisors. FPP Capital Advisors is controlled by Fabien Pictet, a member of our board of directors.

Market for Common Stock

Shares of our common stock are listed on the OTC Bulletin Board under the symbol ASTR.

Transfer Agent and Registrar

Our transfer agent and registrar is American Stock Transfer and Trust Company, 59 Maiden Lane, Plaza Level, New York, New York 10038.

Shares Eligible for Future Sale

We currently have 73,173,055 shares of common stock outstanding. Of the 73,173,055 shares of common stock outstanding, up to 37,538,189 shares are freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by an "affiliate", which will be subject to the resale limitations of Rule 144 promulgated under the Securities Act.

All of the remaining shares of common stock currently outstanding are "restricted securities" or owned by "affiliates", as those terms are defined in Rule 144, and may not be sold publicly unless they are registered under the Securities Act or are sold pursuant to Rule 144 or another exemption from registration. The restricted securities are not eligible for sale without registration under Rule 144. As of June 25, 2004, there were outstanding options and warrants to purchase 18,566,891 shares of our common stock.

Lock-Up Agreements

None of the currently outstanding shares of common stock are subject to lock-up agreements.

40

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Rule 144

Generally, under Rule 144 as currently in effect, subject to the satisfaction of certain other conditions, a person, including any of our affiliates or persons whose sha