ASTRALIS LTD Form 10KSB/A May 02, 2005

U.S. SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM 10-KSB/A

(Mark One)

IXI ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2004

|_| TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to ____

Commission file number 000-30997

ASTRALIS LTD. (Name of small business issuer in its charter)

Delaware (State or other jurisdiction of Incorporation or organization) 84-1508866 (I.R.S. Employer Identification No.)

07004

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

(Zip Code)

Issuer's telephone number (973) 227-7168

Securities registered under Section 12(b) of the Exchange Act: None

Securities registered under Section 12(g) of the Exchange Act:

Common Stock, \$.0001 par value (Title of class)

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes |X| No $|_{}|$

Check whether disclosure of delinquent filers in response to Item 405 of Regulation S-B is not contained in this form, and no disclosure will be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB/A or any amendment to this Form 10-KSB/A.

State issuer's revenues for its most recent fiscal year. --

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of April 29, 2005, was approximately \$5.04 million.

As of April 29, 2005, there were 73,273,055 shares of the registrant's common stock outstanding.

Transitional Small Business Disclosure Format (check one):

Yes |_| No |X|

DOCUMENTS INCORPORATED BY REFERENCE

None.

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EXPLANATORY NOTE

The Registrant is amending its Annual Report on Form 10-KSB for the year ended December 31, 2004 to include the information required by Part III (Items 9, 10, 11, 12 and 14), which was omitted in the original filing pursuant to General Instruction E(3) of Form 10-KSB. This Form 10-KSB/A also includes new Certificates by our President and Chief Executive Officer and our Chief Financial Officer under Item 13 of Part III, as required by Rule 12b-15 of the Securities Exchange Act of 1934, as amended, for amendments to an Annual Report on Form 10-KSB. Except for the foregoing matters, no other information included in our original Form 10-KSB for the year ended December 31, 2004, is amended by this Form 10-KSB/A.

PART III

Item 9. Directors and Executive Officers of the Registrant.

Directors and Executive Officers

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. | 63 | Chairman of the Board of Directors and Chief Scientific Officer |
| James Sharpe | 53 | President, Chief Executive Officer and Director |

| Michael Garone | 46 | Chief Financial Officer |
|------------------------|----|-------------------------|
| Michael Ashton | 59 | Director |
| Samuel Barnett, Ed.D. | 57 | Director |
| Steven Fulda | 72 | Director |
| Fabien Pictet | 46 | Director |
| Gordon Schooley, Ph.D. | 58 | Director |

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.

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Jose Antonio O'Daly, M.D., Ph.D. Dr. O'Daly has served as our Chairman of the Board of Directors since November 2001, and was appointed our Chief Scientific Officer on December 22, 2004. From November 2001 to December 22, 2004, Dr. O'Daly served as our President of Research and Development. Dr. O'Daly is the sole founder of the 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.

James Sharpe. Mr Sharpe has served as our President and Chief Executive Officer and as one of our Directors since January 27, 2005. From 1999 to 2005, Mr. Sharpe served as President and founder of Ankyr Consulting, L.L.C, an independent consulting company for healthcare and biotechnology companies. In early 1999, he served as President of Small Molecule Therapeutics, a privately-owned drug discovery company. From 1997 to 1998, Mr. Sharpe served as Chief Operating Officer of FEI Technologies, Inc., a privately-owned drug delivery company. From 1991 to 1996, Mr. Sharpe served as President and co-founder of GX BioSystems A/S, a privately-owned biotechnology company focused on vaccines and biopesticides. Mr. Sharpe recently founded Metacine, Inc., a cancer vaccine company, and co-founded Optigenix, Inc., a directed evolution company. He was a founding member of the Pennsylvania Biotechnology Association, where he served as President from 1990 to 1992 and was a member of the Board of Directors from 1989 to 1997. From 1993 to 1996 he served as a member of the Board of Governors of the Emerging Company Section of the Biotechnology Industry Association. Mr. Sharpe holds a B.S. in Chemistry from Union College and an M.B.A. in Marketing and Finance from the University of Rochester.

Michael Garone. Mr. Garone has served as our Chief Financial Officer since February 21, 2005. From October 13, 2004 to February 21, 2005, Mr. Garone served as our Interim Chief Financial Officer. During 2004, Mr. Garone founded Gar-1 Business Advisory Services, L.L.C., an independent consulting company for information movement and management companies. From 1983 to 2003, Mr. Garone was employed by AT&T, Inc. where he held various positions of increasing responsibilities, including Chief Financial Officer of AT&T Alascom and Financial Planning Vice President, Broadband and Internet Services. Mr. Garone began his career in finance as an Over-the-Counter stock trader specializing in

high technology start-up companies. Mr. Garone holds a B.A. in Mathematics from Colgate University and an M.B.A. from Columbia University.

Michael Ashton. Mr. Ashton has served as one of our Directors since January 2002. Since 1997 Mr. Ashton has held the position of Chief Executive Officer of SkyePharma PLC, a London-based drug delivery technology provider. Mr. Ashton has 30 years of experience in the pharmaceutical industry, having worked prior to SkyePharma for Merck, Pfizer, Purepac and Faulding, where he served as Chairman, President and Chief Executive Officer. Mr. Ashton holds a Bachelor of Pharmacy Degree from Sydney University and an M.B.A. from Rutgers University.

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Samuel Barnett, Ed.D. Mr. Barnett has served as one of our Directors and a member of our audit committee since June 2004. In 1979, Mr. Barnett founded Barnett International, a consulting firm, and served as Chief Consultant from 1979 to 1999. From 1999 to 2000, Mr. Barnett served as Lead Partner of the Americas Pharmaceutical Practice of PricewaterhouseCoopers Consulting. From 2000 to 2005, he served as Lead Partner of the Americas Life Sciences Consulting Practice for IBM Business Consulting Services. Mr. Barnett holds a Bachelor's Degree from Wesleyan University and received both his Master's and Doctorate Degrees from Temple University.

Steven Fulda. Mr. Fulda has served as one of our Directors and a member of our audit committee since February 2002. Since 1989, Mr. Fulda has served as Managing Director of Fulda Business Planners. Mr. Fulda has 40 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 2002. Since 1998, Mr. Pictet has served as Chairman of Fabien Pictet and Partners, a London-based investment firm. Mr. Pictet has 20 years of experience in investing in emerging markets. During his 11 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 holds a Bachelor's Degree in Economics from the University of San Francisco and a Master's Degree in International Management from American Graduate School of International Management.

Gordon Schooley, Ph.D. Dr. Schooley has served as one of our Directors and a member of our Medical Advisory Board since April 11, 2005. Dr. Schooley has over 33 years of experience in the pharmaceutical field, including extensive experience in clinical and product development. Since 1999, Dr. Schooley has served as Chief Scientific Officer of SkyePharma PLC. From 1989 to 1998, Dr. Schooley served as Vice President of Clinical and Regulatory Affairs for Alliance Pharmaceutical Corp. From 1987 to 1989, Dr. Schooley served as Vice President of Clinical and Regulatory Affairs for Newport Pharmaceuticals International, Inc. From 1979 to 1987, Dr. Schooley served as Director of Clinical Research, Biostatistics and Computing Services for Allergan Pharmaceuticals. Dr. Schooley currently serves as a member of the Scientific Advisory Boards of Topigen Pharmaceuticals, Inc., Progen Ltd., and Seacology Foundation. Dr. Schooley holds a B.S. and an M.S. in Business and Statistics from Brigham Young University and received his Doctorate of Philosophy in Biostatistics from the University of Michigan School of Public Health. Advisors

Medical Advisory Board

James Leyden, M.D. Dr. Leyden has served as the Chairman of our Medical Advisory Board since November 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

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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 holds a Bachelor's Degree from Saint Joseph's College and an M.D. from the University of Pennsylvania School of Medicine.

Gerald Krueger, M.D. Dr. Krueger has served on our Medical Advisory Board since December 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 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.

On April 11, 2005, we also appointed Dr. Schooley to serve on our Medical Advisory Board.

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

Committees of the Board of Directors

The Board of Directors has an Audit Committee, a Compensation and Nominating Committee and a Corporate Strategy Committee. The members of the Audit Committee are Steven Fulda and Samuel Barnett. The members of the Compensation and Nominating Committee are Steven Fulda, Samuel Barnett and Michael Ashton.

Audit Committee Financial Expert

The Board of Directors has determined that Steven Fulda has the financial knowledge, business experience and independent judgment necessary for service on the Audit Committee and that Mr. Fulda is an "audit committee financial expert" as defined by Item 401(e) of Regulation S-B of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). As Corporate Division Manager of one of two business planning divisions of AT&T, Mr. Fulda was responsible for the creation and development of business plans for five

AT&T subsidiaries. Each business plan included a financial plan incorporating past performance and future expectations of the subsidiary, as well as actual and pro forma financial statements. Mr. Fulda collaborated daily with the controller and treasury department of AT&T. In addition, Mr. Fulda holds a Master's Degree in Quantitative Business Analysis from New York University and has served as an Adjunct Professor at Fairleigh Dickinson University in the College of Business and as Director of their Small Business Institute since 1992, teaching courses related to management and business planning, including detailed financial planning and analysis.

Audit Committee

The Audit Committee of our Board of Directors is an "Audit Committee" for the purposes of Section 3(a) (58) of the Securities Exchange Act of 1934. The Audit Committee recommends to the Board of Directors the independent public accountants to be selected to audit our annual financial statements, evaluates internal accounting controls, reviews the adequacy of the internal audit budget, personnel and plan, and determines that all audits and exams required by law are performed fully, properly, and in a timely fashion. The members of that Committee are Steven Fulda and Samuel Barnett. Other than in their capacities as members of the Audit Committee, our Board of Directors or any of our other Board committees, neither Mr. Fulda nor Mr. Barnett has accepted from us, directly or indirectly, any consulting, advisory or other compensatory fee. In addition, neither Mr. Fulda nor Mr. Barnett has direct or indirect beneficial ownership of over 10% of our common stock or is one of our executive officers. Our Board of Directors has determined that both Mr. Fulda and Mr. Barnett are "independent" under NASD Rule 4200 and Item 7(d)(3)(iv) of Schedule 14A, promulgated under the Exchange Act.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our executive officers and directors and persons who own more than 10% of our common stock ("Reporting Persons") to file reports of ownership and changes in ownership of our common stock with the SEC. Reporting Persons are required by SEC regulations to furnish us with copies of all reports they file pursuant to Section 16(a).

Based solely on our review of the copies of such forms received or written representations from Reporting Persons, we believe that with respect to the fiscal year ended December 31, 2004, all the Reporting Persons complied with all applicable filing requirements, except that Fabien Pictet failed to timely file Form 4s during the year relating to his purchases of our stock.

Code of Business Conduct and Ethics

We have a Code of Business Conduct and Ethics that applies to all directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer. You can find our Code of Business and Ethics on our website by going to the following address:

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www.astralisltd.com. We will post any amendments to the Business Code of Conduct and Ethics as well as any waivers that are required to be disclosed by the rules of the Securities and Exchange Commission on our website.

Our Board of Directors has adopted Corporate Governance Guidelines and Charters for the Audit, Compensation and Nominating, and Corporate Strategy Committees of the Board of Directors.

You can also obtain a printed copy of any of the materials referred to above by contacting us at the following address: 75 Passaic Avenue, Fairfield, New Jersey 07004, Attention: Secretary. Telephone number (973) 227-7168.

Item 10. 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

| | | Annual | Compensation |
|--|----------------------|-------------------------------|-----------------------------------|
| Name and Principal Position | Year | Salary (\$) | Other Annual Compensation (\$) |
| James Sharpe, | 2004 | | |
| President and Chief Executive | 2003 | | |
| Officer (1) | 2002 | | |
| Mike Ajnsztajn Prior Chief Executive Officer (2) | 2004 2003 2002 | 109,875 154,375 150,000 | 2,437(4) 4,613 4,613 |
| Jose Antonio O'Daly, Chairman of the Board of Directors and Chief Scientific Officer (3) | 2004 2003 2002 | 188,487 158,750 150,000 | 41,004(5) 73,740 56,671 |

(1) Mr. Sharpe became our President and Chief Executive Officer on January 27, 2005.

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(2) On July 28, 2004, we accepted the resignation of Mr. Ajnsztajn, effective immediately with respect to his position as a member of our Board of Directors and effective August 26, 2004 with respect to his position as our Chief Executive Officer.

(3) 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.

(4) For the fiscal year ended December 31, 2004, this amount includes \$2,437 in health insurance premiums paid by us for Mr. Ajnsztajn's benefit.

(5) For the fiscal year ended December 31, 2004, this amount includes \$8,707 in health insurance premiums paid by us for Dr. O'Daly's benefit, an automobile allowance of \$5,729 and \$26,568 for a furnished apartment.

Employment Agreements

On December 22, 2004, we entered into an employment agreement with Jose Antonio O'Daly, the Chairman of our Board of Directors and our Chief Scientific Officer. Under the terms of his employment agreement, Dr. O'Daly is entitled to an annual base salary of \$231,000 payable in arrears in bi-monthly installments,

less statutory deductions (the "Base Salary") and an annual bonus of up to 25% of his Base Salary and based upon achievement of such goals and subject to such additional terms as may be determined by the Board of Directors. As a member of our senior management team, Dr. O'Daly has been granted the option to purchase 728,000 shares of our common stock with an initial exercise price of \$0.70 per share. The options are fully vested and have a term of ten years. In the event of a voluntary termination for "good reason" or if Dr. O'Daly is terminated following a change in control or without "cause," he generally will receive, among other things, the following severance benefits: (a) an amount equal to two times his annual Base Salary established for the fiscal year in which the date of termination occurs and (b) an amount equal to two times his annual bonus award established for the fiscal year in which his date of termination occurs. In the event of a voluntary termination by Dr. O'Daly without good reason, or if Dr. O'Daly is terminated by us for cause, he will receive the following severance benefits: (a) an amount equal to his Base Salary for one year and (b) an amount equal to one times his annual bonus award established for the fiscal year in which his date of termination occurs. The employment agreement includes certain non-competition and confidentiality provisions.

On January 27, 2005, we entered into an employment agreement with James Sharpe, our President and Chief Executive Officer until January 15, 2007, and a member of Board of Directors. Under the terms of his employment agreement, Mr. Sharpe is entitled to an annual base salary of \$231,000 payable in arrears in bi-monthly installments, less statutory deductions (the "Base Salary") and an annual bonus of up to 25% of his Base Salary and based upon achievement of such goals and subject to such additional terms as may be determined by the Board of Directors. As a member of our senior management team, Mr. Sharpe has been granted the option to purchase 728,000 shares of our common stock, which will vest to the extent of 182,000 immediately and then an additional 182,000 shares per year on a cumulative basis until all options have vested. The options have an initial exercise price of \$0.70 per share and have a term of ten years. In addition, on the first date of employment, Mr. Sharpe shall be issued 100,000 shares of common stock and on the date that is one year following the first date of employment, an additional 100,000 shares, which will be fully vested and fully paid on the date of issuance. Also, pursuant to the agreement, we will

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make the following payments to Mr. Sharpe: (a) \$35,000, no later than January 15, 2006 and (b) an additional amount of not less than \$35,000 and not more than \$65,000 no later than January 15, 2007, provided however, that if prior to January 15, 2007, our cash balance falls below \$350,000, we will immediately pay the minimum remaining amount to Mr. Sharpe. In the event that Mr. Sharpe is terminated after a change of control, he generally will receive, among other things, the following severance benefits: (a) an amount equal to two times his annual Base Salary established for the fiscal year in which the date of termination occurs and (b) an amount equal to two times his annual bonus award established for the fiscal year in which his date of termination occurs. In the event Mr. Sharpe is terminated for good reason, without cause, or non-renewal, he will generally receive the following severance benefits: (a) an amount equal to one times his annual Base Salary established for the fiscal year in which the date of termination occurs and (b) an amount equal to one times his annual bonus award established for the fiscal year in which the date of termination occurs. The employment agreement includes certain non-competition and confidentiality provisions.

On February 21, 2005, we entered into a consultant agreement with Michael Garone, whereby Mr. Garone was retained on a full-time, exclusive basis to serve as our Chief Financial Officer. As Chief Financial Officer, Mr. Garone will report to our Chief Executive Officer and will be responsible for, among other

things, our financial planning and funding and will assist our Chief Executive Officer lead and implement our long-term strategy and vision to provide successful growth in value for our investors and shareholders. Under the terms of the consultant agreement, Mr. Garone is entitled to a monthly fee of at least \$15,600. We have agreed to indemnify Mr. Garone against any claims that may arise as a result of the performance of his duties as our Chief Financial Officer under the consultant agreement and to include him, at our cost, as an insured party under our current directors' and officer' liability insurance policy. The term of the consultant agreement will continue until terminated by either party without cause upon 30 days written notice or with cause upon 10 days written notice.

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, 2004, options to purchase 1,143,000 shares of common stock have been granted under the 2001 Plan.

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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 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 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.

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 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 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.

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Board Composition

We currently have seven Directors, each serving a term until the next annual meeting of stockholders. On January 20, 2004, we, SkyePharma, Dr. O'Daly and our other original shareholders amended the Stockholders Agreement (the "Amended Agreement"), dated as of December 10, 2001. Pursuant to the Amended Agreement, our Board of Directors is now required to be comprised of at least seven Directors and must include at least two independent Directors. Per the Amended Agreement, SkyePharma has the right to nominate one Director. Michael Ashton is SkyePharma's initial and current nominated Director. Until January 20, 2007, Dr. O'Daly has the right to nominate one Director. The Amended Agreement will terminate upon the later of (i) the date on which SkyePharma no longer beneficially owns, in the aggregate, at least 20% of our outstanding common stock or (ii) January 20, 2007. Further, the Amended Agreement may be terminated by the mutual written consent of the parties.

Compensation of Directors

We reimburse all outside directors for travel and lodging expenses related to scheduled board meetings. Our Board of Directors authorized the following payments for non-executive Directors during the fiscal year-ended December 31, 2004: \$1,000 for each board meeting attended in person and \$400 for each meeting attended by teleconference; an annual retainer of \$4,000 paid to the Chairman of the Audit Committee; \$1,000 paid to each Audit Committee member per financial filing; an annual retainer of \$2,500 paid to the Chairman of the Compensation Committee; an annual retainer of \$1,500 paid to each Compensation Committee member, other than the Chairman; an annual retainer of \$3,000 paid to the Chairman of the Strategic Planning Committee; an annual retainer of \$1,000 paid

to each Strategic Planning Committee member, other than the Chairman; and \$1,000 paid to each Strategic Planning Committee member for each half-day strategic planning meeting attended in person. In addition, each non-executive Director will receive a one-time grant upon election to the Board of stock options to purchase 50,000 shares of our common stock, vesting over a four-year period with the first 25% vesting on the date of grant, and an annual grant upon the anniversary of election to the Board of stock options to purchase 20,000 shares of our common stock, vesting over a four-year period with the first 25% vesting over a four-year period with the first 25% vesting over a four-year period with the first 25% vesting on the date of grant.

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.

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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.

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Item 11. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table sets forth the names and beneficial ownership of our common stock owned as of April 29, 2005, 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 Common Stock Owned |
|---|---|-------------------------------------|
| Dr. Jose Antonio O'Daly, M.D., Ph.D. (2) (3) | 14,368,000 | 19.4% |
| James Sharpe (4) | 282,000 | * |
| Michael Ashton (5) | 36,413,900 | 49.7% |
| Samuel Barnett, Ed.D. (6) | 112,500 | * |
| Steven Fulda (7) | 42,200 | * |
| Fabien Pictet (8) | 5,377,794 | 7.1% |

| Gordon Schooley, Ph.D. (9) | 12,500 | * |
|---|------------|-------|
| SkyePharma PLC (3) (5) 105 Piccadilly London W1J 7NJ England | 36,413,900 | 49.7% |
| All Officers and Directors as a Group (2) (4) (5) (6) (7) (8) (9) | 56,608,894 | 73.7% |

* 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 73,273,055 shares of our common stock outstanding as of April 29, 2005.

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(2) Includes 13,640,000 shares of common stock and vested options to purchase 728,000 shares of common stock.

(3) Under the terms of Amendment No. 1 to the Stockholders' Agreement dated as of January 20, 2004 by and among us, SkyePharma, Dr. O'Daly and our other original shareholders, the parties agreed to vote all shares held by such parties for (i) one director designated by SkyePharma, (ii) one director designated by Dr. O'Daly, (iii) one director designated by each of the other three original shareholders and (iv) two independent director. 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. Since the date of such agreement, the other three original shareholders resigned their positions with us and transferred all of their shares of common stock to SkyePharma. As a result, none of them have any rights to designate a director under the Agreement.

(4) Includes 100,000 shares of common stock and options to purchase 182,000 shares of common stock that are exercisable within 60 days of April 29, 2005.

(5) Includes 36,393,900 shares of common stock beneficially owned by SkyePharma and warrants to purchase 20,000 shares of common stock beneficially owned by SkyePharma that are exercisable within 60 days of April 29, 2005. 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. 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 by us for a period commencing upon our achievement of a certain milestone event and ending on January 20, 2007.

(6) Includes 100,000 shares of common stock and options to purchase 12,500 shares of common stock that are exercisable within 60 days of April 29, 2005.

(7) Includes 4,700 shares of common stock owned by Mr. Fulda's spouse. Mr. Fulda disclaims beneficial ownership of such shares. Also includes 25,000 shares of common stock owned by Mr. Fulda and options to purchase 12,500 shares of common stock that are exercisable within 60 days of April 29, 2005.

(8) Includes 1,260,000 shares of common stock owned by FPP Emerging Hedge Fund 1, Ltd. and warrants to purchase an aggregate of 632,000 shares of common stock owned by FPP Emerging Hedge Fund 1, Ltd. that are exercisable within 60 days of April 29, 2005. Includes 390,000 shares of common stock and warrants to purchase 500,000 shares of common stock owned by Perly International Ltd. that are exercisable within 60 days of April 29, 2005. Includes 180,000 shares of common stock owned by Pictet Private Equity Investors, S.A. and warrants to purchase 36,000 shares of common stock held by Pictet Private Equity Investors, S.A. that are exercisable within 60 days of April 29, 2005. Includes 150,000 shares of common stock owned by FPP Capital Advisors and warrants to purchase 519,794 shares of common stock held by FPP Capital Advisors that are exercisable within

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60 days of April 29, 2005. Includes 10,000 shares of common stock owned by Perly Ltd. Also includes 850,000 shares of common stock owned by Pictet & Cie and warrants to purchase 850,000 shares of common stock held by Pictet & Cie that are exercisable within 60 days of April 29, 2005. Mr. Pictet controls FPP Emerging Hedge Fund 1, Ltd., Perly International Ltd., Pictet Private Equity Investors, S.A., FPP Capital Advisors, Perly Ltd. and Pictet & Cie. In June 2004, we assigned the right to purchase 1,250,000 shares of our common stock under the Call Option Agreement between us and SkyePharma to FPP Capital Advisors. The shares beneficially owned by Mr. Pictet, as reflected in this table do not include these 1,250,000 shares.

(9) Includes options to purchase 12,500 shares of common stock that are exercisable within 60 days of April 29, 2005.

Item 12. Certain Relationships and Related Transactions

Relationship with Dr. Jose Antonio O'Daly

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" (the "Psoriasis Formula"). 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 for the Psoriasis Formula 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 primarily on the mechanism of action of our initial injectable product candidate, Psoraxine(R), expanding the claims to include medical indications other than psoriasis, such as Atopic Dermatitis, Psoriatic Arthritis and Rheumatoid Arthritis. 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 these patent applications.

Centro Para La Investigacion y Tratmiento 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(R) in Venezuela commencing in November 2001 and terminating in May 2002. We paid approximately \$275,000 to CITP for the services it provided.

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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 January 12, 2004 between us and SkyePharma ("Omnibus Conversion Agreement"), SkyePharma converted all of its 2,000,000 shares of Series A Preferred Stock into 25,000,000 shares of our common stock at a conversion price of \$0.80 per share. On March 3, 2005, SkyePharma acquired 11,160,000 additional shares of our common stock in a privately negotiated transaction. As a result, as of April 29, 2005 SkyePharma beneficially owns 49.7% of our common stock on a fully diluted basis.

On January 20, 2004, in connection with SkyePharma's conversion of our Series A Preferred Stock, we entered into a Call Option Agreement ("Call Option Agreement") with SkyePharma, 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 upon our achievement of a certain milestone event and ending on January 20, 2007.

On January 20, 2004, we, SkyePharma, Dr. O'Daly and our other original shareholders amended the Stockholders Agreement (the "Amended Agreement"), dated as of December 10, 2001. Pursuant to the Amended Agreement, our Board of Directors is now required to be comprised of at least seven Directors and must include at least two independent Directors. Per the Amended Agreement, SkyePharma has the right to nominate one Director. Michael Ashton is SkyePharma's initial and current nominated Director. Until January 20, 2007, Dr. O'Daly has the right to nominate one Director. The Amended Agreement will terminate upon the later of (i) the date on which SkyePharma no longer beneficially owns, in the aggregate, at least 20% of our outstanding common stock or (ii) January 20, 2007. Further, the Amended Agreement may be terminated by the mutual written consent of the parties. Pursuant to the Amended Agreement, 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 our 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 or all or substantially all of our assets, or our 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 sale or merger on the same terms as the most favorable terms available to any of our other stockholders and the total consideration for the transaction is greater than \$135 million.

We also entered into two agreements concerning the formulation and development of Psoraxine(R) with SkyePharma. Under the terms of the Technology Access Option Agreement ("Technology Access Option Agreement"), dated December 10, 2001, we paid to SkyePharma a \$5.0 million technology access fee for the option to acquire a license for certain 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

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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, unless terminated sooner pursuant to the terms of the Technology Access Option Agreement. Pursuant to the Technology Access Option Agreement, SkyePharma also has the right of first negotiation to acquire the worldwide marketing rights to Psoraxine(R). Based on an evaluation of the technology access option fee we paid under the Technology Access Option Agreement, which we have been capitalizing as a research and development intangible asset over a seven-year period, we have determined that as of December 31, 2004, the technology access option fee exceeded its fair market value. Consequently, we recorded as additional research and development costs in 2004 a charge of \$2,797,612 to reflect an impairment of this intangible asset.

On December 10, 2001, we entered into a Service Agreement ("Service Agreement") with SkyePharma pursuant to which SkyePharma was to provide us with development, manufacturing, pre-clinical and clinical development services in consideration of \$11 million. The Service Agreement terminated on December 31, 2002. We 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 continued to provide certain services to us through December 31, 2004, in consideration for payments made during 2002. The agreement expired on December 31, 2004.

Relationship with FPP Capital Advisors

In connection with private placements of units consisting of common stock and warrants that occurred in 2004, FPP 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 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 our Omnibus Conversion Agreement with SkyePharma, we issued to FPP Capital Advisors units consisting of 150,000 shares of common stock and warrant 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 our Call Option Agreement with SkyePharma to FPP Capital Advisors.

In addition to FPP Capital Advisors, Fabien Pictet controls FPP Emerging Hedge Fund I, Ltd. and Pictet & Cie, both of which were investors in our private

placements in early 2004.

Item 13. Exhibits, List and Reports on Form 8-K

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

31.1 Certification by the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

31.2 Certification by the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

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Item 14. Principal Accountant Fees and Services

The following disclosure presents fees billed for professional services rendered by L J Soldinger Associates, LLC, our independent auditors, for 2004 and 2003.

Audit Fees

The aggregate fees billed for professional services in connection with the audit of our annual financial statements, and the reviews of our quarterly financial statements and audit services provided in connection with regulatory filings, were approximately \$168,000 and \$133,000 for 2004 and 2003, respectively.

Audit-Related Fees

Audit-related fees for fiscal 2004 totaled \$25,000, which represents fees billed primarily for assurance and related services in connection with registration statements and offerings of securities. There were no audit-related fees billed by our independent auditor in 2003.

Tax Fees

There were no tax related services provided by our independent auditors in 2004 or 2003.

All Other Fees

There were no other services provided by our independent auditors in 2004 or 2003.

Pre-Approval of Audit and Permissible Non-Audit Services

The Audit Committee pre-approves all audit and permissible non-audit services provided by the independent auditors. These services may include audit services, audit-related services, tax services and other services. The Audit Committee has adopted a policy for the pre-approval of services provided by the independent auditors. Under the policy, pre-approval is generally provided for up to one year and any pre-approval is detailed as to the particular service or category of services. In addition, the Audit Committee may pre-approve particular services on a case-by-case basis. All audit and permissible non-audit services provided by L J Soldinger Associates, LLC to us for 2004 and 2003 were approved by the Audit Committee.

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SIGNATURES

In accordance with Section 13 and 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ASTRALIS LTD. (Registrant)

Date: April 29, 2005

By: /s/ James Sharpe

James Sharpe President and Chief Executive Officer

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