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ASTRALIS LTD
Form 8-K
December 17, 2002

Securities and Exchange Commission
Washington, DC 20549

Form 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported) December 16, 2002

ASTRALIS LTD.

(Exact Name of Registrant as Specified in its Charter)

Delaware

000-30997

84-1508866

(State or Other
Jurisdiction of Incorporation)

(Commission File Number)

(IRS Employer
Identification No.)

75 Passaic Avenue, Fairfield, New Jersey

07004

(Address of Principal Executive Offices)

(Zip Code)

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

(Former Name or Former Address, if Changed Since Last Report)

ITEM 9. REGULATION FD DISCLOSURE.

On December 16, 2002, the registrant mailed to its shareholders a brochure containing the following information:

About Astralis

Astralis Ltd, an emerging biotechnology company based in New Jersey, focuses on the research and development of novel treatments for immune system disorders and skin diseases. Astralis has developed a viable technology platform, enabling the further development of PSORAXINE(TM) as well as other promising therapeutics.

Versatile Research & Development Platform

"Astralis is now better positioned to develop its research in other therapeutic areas from our new U. S. based facility using the technology platform developed in Venezuela over the last 15 years" commented Mike Ajnsztajn, Astralis' Chief Executive Officer.

180 million people around the world suffer from Psoriasis - National Psoriasis Foundation

Psoraxine(TM) (AS 210)

Psoraxine(TM), the company's first product candidate, is an innovative drug under development for the treatment of psoriasis, and is based on the company's discovery of a new gene sequence of proteins. To date, clinical trial data

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suggests remission of psoriasis in approximately 3000 patients in Venezuela.

Characteristics of Psoraxine(TM)

Psoraxine(TM) is believed to induce a cellular response. Preliminary studies have indicated that there is no antibody creation, no immunosuppression, no programmed cell death, and no killing of T-cells.

Corporate Information
OTC Bulletin Board: ASTR

Internet Address
www.astralisltd.com

Recent Share Price
(2 December 2002)
US \$0.65

Shares Outstanding
(2 December 2002)
37.5 million Common Shares

Market Capitalization
(2 December 2002)
\$24.4 Million

52-week Trading Range
\$0.22 - \$3.35

Board of Directors

Jose Antonio O'Daly, MD, PhD,
Chairman of the Board and President of R&D

Mike Ajnsztajn
Chief Executive Officer

Gina Tedesco
Chief Financial Officer

Gaston Liebhaber
Director of International Affairs

Michael Ashton
CEO SkyePharma

Fabien Pictet
CEO Fabien Pictet & Partners Global Holdings

Steve Fulda
Fairleigh Dickenson University

Advisory Board

Medical Advisor
Dr. James Leyden
Professor
Department of Dermatology
University of Pennsylvania Hospital

Marketing Advisor

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Bruce Epstein
President Noesis Healthcare

Contact Information:
Gina Tedesco,
Chief Financial Officer / Head of IR
75 Passaic Avenue, Fairfield, N.J. 07004 U.S.A.
Tel: 1 973 227 7168
Fax: 1 973 227 7169
Email: info@astralisltd.com

Technology Transfer Update

The transfer of the technology platform and manufacturing process to the New Jersey R&D facility was finalized in August 2002. The Psoraxine(TM) preliminary production process has been standardized, and continuous production has been established for clinical supplies.

Psoraxine(TM) manufacturing upscaling is currently under development.

Strong R&D Base

With approximately \$500K of capital investment in the R&D facility, Astralis has built a strong base on which to continue research in other therapeutic areas.

Summary of Financial Information
Astralis Ltd
(A Development Stage Entity)
Selected Statement of Operation Information (Unaudited)
January 1st, 2002 to September 30th, 2002

| | |
|---|---------------|
| Revenues | -- |
| Total Operating Expenses | \$ 8,347,189 |
| Loss from Operations | \$(8,347,189) |
| Other Income - Interest Income | \$ 94,889 |
| Net Loss to Common Stockholder | \$(8,522,300) |
| Basic and diluted loss per common share | \$ (0.23) |

Recent Highlights

November 2002

Continuing Pre-IND discussions with the FDA

October 2002

Manufacturing process standardized for U.S. clinical supply production for Phase I and Phase II clinical trials. Implemented preliminary Standard Operating Procedures and Good Manufacturing Practices

August 2002

Completed Transfer of Technology from Venezuela to Fairfield, New Jersey R&D Facility

July 2002

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SkyePharma purchases an additional \$2.5 million of preferred shares bringing the total capital injected to \$17.5 million dollars, \$10 million in Dec 2001, \$2.5 million in Jan 2002, \$2.5 million in April 2002, \$2.5 million in July 2002.

June 2002

Initiated transfer of Venezuelan R&D Team to Fairfield, New Jersey R&D Facility. The Petition to Make Special for the Psoraxine(TM) Patent was granted by the United States Patent and Trademark Office, expediting the process

May 2002

Completed Capital Investment of approximately \$500K for clean room technology and state of the art equipment for continued R&D into other therapeutic areas

April 2002

Astralis Ltd US Corporate Headquarters transferred to Fairfield, New Jersey

February 2002

Patent application filed under Patent Cooperation Treaty (PCT) for international protection

December 2001

Purchase Agreement signed with SkyePharma to purchase up to \$20 million in convertible preferred shares. Service Agreement with SkyePharma agreed upon to provide development, pre-clinical and clinical development services. Technology Transfer Agreement with SkyePharma for access to drug delivery technology

November 2001

Raised an initial round of funding via a private placement of \$3.2 million in conjunction with a merger into a public shell company to form Astralis Ltd.

May 2001

Pre Investigational New Drug Application (IND) meeting with the FDA to discuss United States IND filing

March 2001

Astralis filed patent with United States Patent and Trademark office for first product candidate, Psoraxine

March 2001

Astralis LLC founded in the US based on 15 years of work in Venezuela by Dr. Jose Antonio O'Daly

Information or opinions in this fact sheet are presented solely for informative purposes and are not intended nor should be construed as investment advice. Astralis may carry a high investment risk. We encourage you to carefully review the company with your investment advisor and that you verify any information that is important to your investment decision. This fact sheet may contain forward-looking statements regarding Astralis Ltd. Actual results may differ materially from those described in the fact sheet as a result of a number of factors, including but not limited to the following: There can be no assurance that PSORAXINE(TM) will be successfully developed or manufactured, or that final

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results of human clinical trials will result in the regulatory approvals required to market products, or that final regulatory approval will be received in a timely manner, if at all, or that patient and physician acceptance of this product will be achieved. Astralis will continue its research and development effort to the extent that we do not experience any cash shortfalls, adverse developments in our drug development or competitive or other impediments that an early stage company in our industry may face. Astralis Ltd undertakes no obligation to revise or update any such forward-looking statement to reflect events or circumstances after the date of this fact sheet.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ASTRALIS LTD.

Date: December 16, 2002

By: /s/ Mike Ajnsztajn

Mike Ajnsztajn
Chief Executive Officer