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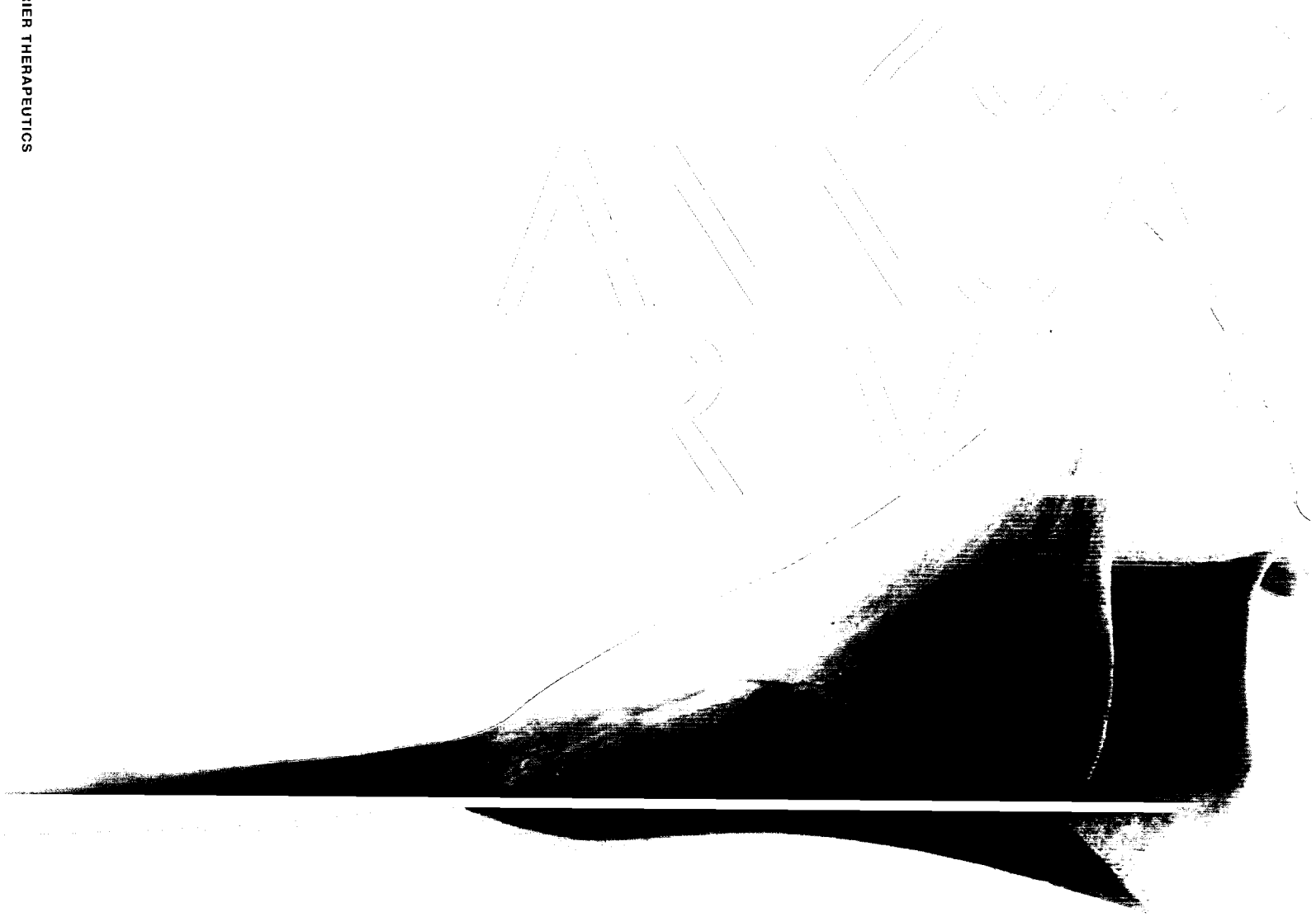


Barrier Therapeutics is a pharmaceutical compan

focused on the discovery, development an

commercialization of pharmaceutical products in th

field of dermatology. Our goal is to develop innovativ

products that address major medical needs in th

treatment of dermatological diseases and disorders

**Barrier** Therapeutics

**Turning Science into Practice**

April 28, 2006

Dear Stockholder:

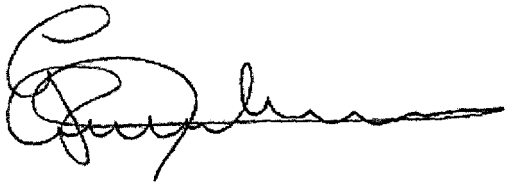
It is my pleasure to invite you to the 2006 Annual Meeting of Stockholders of Barrier Therapeutics, Inc. We will hold the meeting on Wednesday, June 21, 2006 at 11:00 a.m., local time, at the Doral Forrestal Conference Center located at 100 College Road East in Princeton, New Jersey 08540.

During the Annual Meeting, we will discuss each item of business described in the Notice of Annual Meeting and Proxy Statement that follows, update you on important developments in our business and respond to any questions that you may have about Barrier Therapeutics.

Your vote is important. Whether or not you expect to attend the meeting, please vote your shares following the instructions on the proxy card; sign and return the proxy card in the enclosed envelope; or vote in person at the meeting.

On behalf of your Board of Directors, thank you for your continued support and interest in Barrier Therapeutics. I look forward to seeing you at the meeting on June 21, 2006.

Very truly yours,



Geert Cauwenbergh, Ph.D.
*Chairman of the Board*
*and Chief Executive Officer*

**600 College Road East, Princeton , NJ 08540** **Telephone 609.945.1200 Facsimile 609.945.1212**

**BARRIER THERAPEUTICS, INC.**

**NOTICE OF ANNUAL MEETING OF STOCKHOLDERS**

**To be held on June 21, 2006**

TO THE STOCKHOLDERS OF BARRIER THERAPEUTICS, INC.:

NOTICE IS HEREBY GIVEN that the Annual Meeting of Stockholders (the "Annual Meeting") of BARRIER THERAPEUTICS, INC., a Delaware corporation (the "Company"), will be held at the Doral Forrestal Conference Center located at 100 College Road East in Princeton, New Jersey 08540 on Wednesday, June 21, 2006 at 11:00 a.m. local time. At the meeting, the holders of the Company's outstanding Common Stock will act upon the following matters:

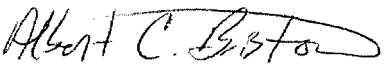
1. To elect three Class II directors;

2. To ratify the appointment of Ernst & Young LLP as the independent registered public accounting firm of the Company for the fiscal year ending December 31, 2006; and

3. To transact such other business as may properly come before the Annual Meeting or any postponements or adjournments thereof.

All stockholders of record as of the close of business on April 24, 2006 are entitled to notice of the Annual Meeting and to vote at the Annual Meeting and any postponements or adjournments thereof. A list of stockholders of the Company entitled to vote at the Annual Meeting will be available for inspection by any stockholder at the Annual Meeting and during normal business hours at the Company's corporate offices during the 10-day period immediately prior to the date of the Annual Meeting.

By Order of the Board of Directors,



ALBERT C. BRISTOW
*Secretary*

Princeton, New Jersey
April 28, 2006

**EACH STOCKHOLDER IS URGED TO COMPLETE, SIGN AND RETURN THE ENCLOSED PROXY CARD IN THE ENVELOPE PROVIDED, WHICH REQUIRES NO POSTAGE IF MAILED IN THE UNITED STATES. IF A STOCKHOLDER DECIDES TO ATTEND THE MEETING, HE OR SHE MAY, IF SO DESIRED, REVOKE THE PROXY AND VOTE THE SHARES IN PERSON.**

**BARRIER THERAPEUTICS, INC.**
**600 COLLEGE ROAD EAST, SUITE 3200**
**PRINCETON, NEW JERSEY 08540**

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# PROXY STATEMENT

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## INTRODUCTION

This Proxy Statement is furnished in connection with the solicitation of proxies by the Board of Directors of Barrier Therapeutics, Inc., referred to herein as the "Company", "Barrier", "we", "us" and "our", for use at the 2006 Annual Meeting of Stockholders, referred to herein as the "Annual Meeting", to be held at the Doral Forrestal Conference Center located at 100 College Road East, in Princeton, New Jersey 08540 on Wednesday, June 21, 2006 at 11:00 a.m., local time, and any postponements or adjournments thereof. This Proxy Statement and the accompanying proxy card are being distributed on or about April 28, 2006.

### Matters for Consideration at the Annual Meeting

At the Annual Meeting, our stockholders will be asked to consider and to vote upon the following:

1. To elect three Class II directors. Our Board of Directors, or the Board, has nominated the following candidates: Carl W. Ehmann, M.D., Peter Ernster and Carol Raphael; and

2. To ratify the appointment of Ernst & Young LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2006.

**THE BOARD UNANIMOUSLY RECOMMENDS THAT STOCKHOLDERS VOTE "FOR" EACH OF THE FOREGOING PROPOSALS.**

## GENERAL INFORMATION

### Persons Making the Solicitation

Execution and return of the enclosed proxy card are being solicited by and on behalf of the Board for the purposes set forth in the notice of meeting. The costs incidental to the solicitation and obtaining of proxies, including the cost of reimbursing banks and brokers for forwarding proxy materials to their principals, will be borne by us. Proxies may be solicited, without extra compensation, by our officers and employees, both in person and by mail, telephone, telefax and other methods of communication.

Our Annual Review (10-K Wrap) and Form 10-K (Annual Report) for the fiscal year ended December 31, 2005, including consolidated financial statements and other information with respect to us and our subsidiaries, is being mailed to our stockholders with this Proxy Statement. Our Annual Report is not part of this Proxy Statement.

## Voting Securities of the Company

Only our stockholders of record at the close of business on April 24, 2006 are entitled to notice of the Annual Meeting and to vote at the Annual Meeting. As of April 24, 2006, we had outstanding 24,135,804 shares of our Common Stock. The holders of a majority of such shares, represented in person or by proxy, shall constitute a quorum at the Annual Meeting. A quorum is necessary before business may be transacted at the Annual Meeting except that, even if a quorum is not present, the stockholders present in person or by proxy shall have the power to adjourn the meeting from time to time until a quorum is present. Each stockholder entitled to vote shall have the right to one vote for each share of Common Stock outstanding in such stockholder's name.

The shares of Common Stock represented by each properly executed proxy card will be voted at the Annual Meeting in the manner directed therein by the stockholder signing such proxy card. The proxy card provides spaces for a stockholder to vote for the Board's nominees, or to withhold authority to vote for either or both of such nominees, for election as directors. Directors are to be elected by a plurality of the votes cast at the Annual Meeting. With respect to any other matter that may properly be brought before the Annual Meeting, the affirmative vote of a majority of the votes cast by stockholders entitled to vote thereon is required to take action, unless a greater percentage is required either by law or by our amended and restated certificate of incorporation or our second amended and restated bylaws. In determining the number of votes cast with respect to any voting matter, only those cast "for" or "against" are included. Abstentions will be considered present and entitled to vote at the Annual Meeting but will not be counted as votes cast. Accordingly, abstentions will have no effect on the vote. Similarly, where brokers submit proxies but are prohibited from, and thus refrain from exercising discretionary authority in voting shares on certain matters for beneficial owners who have not provided voting instructions with respect to such matters (commonly referred to as "broker non-votes"), those shares will be considered present and entitled to vote at the Annual Meeting but will not be counted as votes cast as to such matters and thus will have no effect on the vote.

If a signed proxy card is returned and the stockholder has given no direction regarding a voting matter, the shares will be voted with respect to that matter by the proxy agents as recommended by the Board. Execution and return of the enclosed proxy card will not affect a stockholder's right to attend the Annual Meeting and vote in person. Any stockholder that executes and returns a proxy card has the right to revoke it by giving notice of revocation to our Secretary at any time before the proxy is voted.

## ELECTION OF DIRECTORS

Our amended and restated certificate of incorporation provides for a Board consisting of nine members divided into three classes, with each class serving for a staggered three-year term. Our Board currently consists of nine directors and is classified with respect to terms of office into three classes. Our Class I directors are Charles F. Jacey, Jr., Edward L. Erickson and Nicholas J. Simon III. Our Class II directors are Carl W. Ehmann, M.D., Peter Ernster and Carol Raphael. Our Class III directors are Geert Cauwenbergh, Ph.D., Srinivas Akkaraju, M.D., Ph.D. and Robert E. Campbell.

Each Class II director elected at the Annual Meeting will serve until the 2009 annual meeting of stockholders and until such director's successor has been elected and qualified, except in the event of such director's earlier death, resignation or removal. The term of office of the Class I directors will expire at the annual meeting of stockholders to be held in 2008 upon the election and qualification of their successors, and the term of office of the Class III directors will expire at the annual meeting of stockholders to be held in 2007 upon the election and qualification of their successors.

Our Board has nominated Carl W. Ehmann, M.D., Peter Ernster and Carol Raphael for election as the Class II directors, all of whom currently are our directors. The persons named as proxy agents in the enclosed proxy card intend (unless instructed otherwise by a stockholder) to vote for the election of Carl W. Ehmann, M.D., Peter Ernster and Carol Raphael as the Class II directors. In the event that a nominee should become unable to accept nomination or election (a circumstance that the Board does not expect), the proxy agents intend to vote for any alternate nominee designated by the Board or, in the discretion of the Board, the position may be left vacant.

**THE BOARD UNANIMOUSLY RECOMMENDS A VOTE "FOR" EACH CLASS II NOMINEE.**

## Vote Required for the Election of Directors

The affirmative vote of the holders of a plurality of the shares of Common Stock present and voting at the Annual Meeting is required to elect each of the nominees for director. Each share of Common Stock which is represented, in person or by proxy, at the Annual Meeting will be accorded one vote on each nominee for director. For purposes of this vote, abstentions and broker non-votes will, in effect, not be counted. The Board recommends that stockholders vote FOR the election of each of the nominees named above.

Set forth below is certain information with respect to each nominee for director and each other person currently serving as our director whose term of office will continue after the Annual Meeting, including the class and term of office of each such person. This information has been provided by each director at our request. None of our directors are related to each other or any of our executive officers.

| Name | Age | Position |
|---|---|---|
| Geert Cauwenbergh, Ph.D. | 52 | Chairman of the Board, Chief Executive Officer and Director |
| Robert E. Campbell (1) | 72 | Lead Director |
| Srinivas Akkaraju, M.D., Ph.D. (2) | 38 | Director |
| Carl W. Ehmann, M.D. (2) | 63 | Director |
| Edward L. Erickson (2) | 59 | Director |
| Peter Ernster (1)(3) | 63 | Director |
| Charles F. Jacey, Jr. (3) | 70 | Director |
| Carol Raphael (3) | 64 | Director |
| Nicholas J. Simon III (1) | 52 | Director |

(1) Member of the Compensation Committee.
(2) Member of the Corporate Governance and Nominating Committee.
(3) Member of the Audit Committee.

## Class II—Director Nominees for Term Continuing until 2009

*Carl W. Ehmann, M.D.* has been our director since September 2004. Dr. Ehmann is a private pharmaceutical industrial consultant, and is a member of our Scientific Advisory Board. He previously worked at Hoffman-LaRoche, Inc., Bristol-Myers and Johnson & Johnson where he respectively served as Director of Clinical Research/Dermatology, Department of Medical Research at Hoffman-LaRoche, Inc.; Vice President, Pharmaceutical Research & Development/ Dermatology at Bristol-Myers; and, as Executive Vice President and Head of Global Research & Development for Consumer Products, Inc. at Johnson & Johnson. Dr. Ehmann serves as Chairman of the Board for the Medical University of South Carolina Foundation for Research Development. Dr. Ehmann received his M.D. and B.A. in Biology from the State University of New York at Buffalo and is a Fellow of the American Academy of Dermatology.

*Peter Ernster* has been our director since September 2003. In December 2000, Mr. Ernster retired from Merck & Co., Inc. as Senior Vice President, Business Management of the U.S. Pharmaceutical Division, after a 27 year career in which he held a wide range of management positions in Merck's domestic and international businesses. Prior to joining Merck in 1974 as European Counsel, Mr. Ernster practiced international commercial law for six years in New York City. Mr. Ernster has served as Chairman of the Board of Optio Research, Inc., a company that develops syndicated, predictive, therapeutic models for the pharmaceutical industry, since he co-founded it in July 2003. He also is Chairman of the Board for Sopherion Therapeutics, Inc., serves on the Business Advisory Boards of Medem, Inc. and Mediphase Venture Partners and is Vice Chairman of the Philadelphia Orchestra Association. Mr. Ernster completed his undergraduate studies at New York University, receiving a bachelor's degree in Economics and European History. A graduate of Rutgers University School of Law, Mr. Ernster completed advanced studies at Columbia University's Parker School of Foreign and Comparative Law.

*Carol Raphael* has been our director since August 2005. Ms. Raphael currently serves as the President and Chief Executive Officer of the Visiting Nurse Service of New York, the largest nonprofit home health care organization in the U.S. Prior to joining the Visiting Nurse Service, Ms. Raphael was Director of Operations Management at Mount Sinai Medical Center in New York City. Before that, she worked at the New York City Human Resources Administration for 10 years, ending in the position of Executive Deputy Commissioner of the Income and Medical Assistance Administration. Ms. Raphael was a member of the Medicare Payment Advisory Commission (MedPAC), the commission that advises Congress on Medicare payment and policies from 1999 to 2005. She has served on several Robert Wood Johnson national advisory committees and currently chairs its Better Jobs, Better Care Initiative. Ms. Raphael also currently serves on the Boards of Excellus/Lifetime Healthcare Company, the American Foundation for the Blind and Pace University. She has an M.P.A. from Harvard University's Kennedy School of Government and has completed its senior executive program.

## Class I—Directors with Term Continuing until 2008

*Edward L. Erickson* has been our director since January 2006. Mr. Erickson is the Chairman of the board of directors of Immunicon Corporation, a public medical products company, which position he has held since April 1998. Mr. Erickson served as Immunicon's Chief Executive Officer from March 1999 to December 31, 2005 and as its President from January 2000 to April 2005. From 1993 to 1998, Mr. Erickson served as President, Chief Executive Officer and as a director of DepoTech Corporation, at that time a publicly-traded pharmaceutical company in the drug delivery field. From 1991 to 1993, he served as President, Chief Executive Officer and as a director of Cholestech Corporation, a publicly-traded diagnostics company in the field of point-of-care testing and screening. Earlier in his career, Mr.

Erickson held general and executive management positions with The Ares-Serono Group, now Serono, a publicly-traded biotechnology company headquartered in Switzerland and Amersham International plc, a British medical and research products company now a unit of General Electric. Mr. Erickson holds a B.S. in Mathematics with a minor in Physics and an M.S. in Mathematics from the Illinois Institute of Technology, and an M.B.A. with high distinction from Harvard University.

*Charles F. Jacey, Jr.* has been our director since September 2004. Mr. Jacey is a retired Senior Partner of Coopers & Lybrand, L.L.P. where he was with the firm for 40 years. Mr. Jacey previously served as National Vice Chairman at Coopers & Lybrand, L.L.P. for over 10 years during which time he had responsibility for various United States geographic regions and several staff organizations. He was also in charge of International Operations for five years. He was elected to the firm's Executive Committee five times serving three Chairmen over 15 years. While at Coopers & Lybrand, Mr. Jacey provided professional services to major multinational companies. Mr. Jacey received his B.B.A. from Pace University and is a Certified Public Accountant. Mr. Jacey currently serves on the Board of Directors for The Greater New York Insurance Company, The Cancer Institute of New Jersey and the Police Athletic League of New York and is also a member of the Board of Trustees for Pace University.

*Nicholas J. Simon III* has been our director since December 2003. Mr. Simon has been a general partner at MPM BioVentures III since October 2001. He is co-founder and managing director of Clarus Ventures, LLC, a venture capital firm focused on investments in the life sciences industry. Prior to joining MPM BioVentures III, from April 2000 to July 2001, Mr. Simon was Chief Executive Officer and the founder of Collabra Pharma, Inc., a pharmaceutical development company. From 1989 to March 2000, Mr. Simon held several business development positions at Genentech, Inc., including, most recently, Vice President, Business & Corporate Development. He also currently serves as a director of CoTherix, Inc., Rigel Pharmaceuticals, Inc. and several private companies. Mr. Simon received a bachelor's degree in Microbiology from the University of Maryland and an M.B.A. in Marketing from Loyola College.

## Class III—Directors with Term Continuing until 2007

*Srinivas Akkaraju, M.D., Ph.D.* has been our director since May 2002. Dr. Akkaraju is a Partner of JPMorgan Partners, LLC, on the Life Sciences team of the Healthcare Group, and a Managing Director of Panorama Capital. Dr. Akkaraju joined JPMorgan Partners, LLC, in April, 2001. From October 1998 to April 2001, Dr. Akkaraju was in the Business and Corporate Development group at Genentech, Inc. where he served in various capacities, most recently as Senior Manager and project team leader for one of Genentech's clinical development products. Dr. Akkaraju also currently serves as a director of Seattle Genetics, Inc.; he is also a director for several private biotech companies. Dr. Akkaraju received his undergraduate degrees in Biochemistry and Computer Science from Rice University and his M.D. and Ph.D. in Immunology from Stanford University.

*Robert E. Campbell* has been our director since September 2004 and has been Lead Director of the Board since December 2004. Mr. Campbell is a retired executive from Johnson & Johnson after having served as Vice Chairman of the Board of Directors from April 1989 to January 1995 and in various other positions including Vice Chairman of the Executive Committee, Chairman of the Professional Sector and Chief Financial Officer. Mr. Campbell received a B.S. degree from Fordham University and an M.B.A. from Rutgers University. He is also the recipient of honorary doctorate degrees from Fordham University and the University of Medicine and Dentistry of New Jersey. Mr. Campbell is presently the Chairman of the Board of The Cancer Institute of New Jersey and past Chairman and present board member of The Robert Wood Johnson Foundation and Fordham University.

*Geert Cauwenbergh, Ph.D.* is our founder and has been our Chairman of the Board and Chief Executive Officer since our inception in September 2001. Prior to joining us, Dr. Cauwenbergh was at Johnson & Johnson Consumer and Personal Care Products Companies from 2000 to 2002 where he served in various capacities, most recently as Vice President of Technology. From 1994 to 2000, Dr. Cauwenbergh was at Johnson & Johnson Consumer Companies Worldwide where he served in various capacities, most recently as Vice President of Research & Development. He received his Ph.D. in Medical Sciences from the Catholic University of Leuven, Faculty of Medicine, Belgium where he also completed his Masters and undergraduate work.

## RATIFICATION OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors has appointed Ernst &Young LLP, as our independent registered public accounting firm to perform the audit of our financial statements for the fiscal year ending December 31, 2006, and the stockholders are being asked to ratify that appointment. Ernst & Young LLP, an independent registered public accounting firm, has audited our consolidated balance sheets as of December 31, 2002, 2003, 2004 and 2005, and the related consolidated statements of operations, stockholders' equity (deficiency) and cash flows for the period ended September 17, 2001 (inception) to December 31, 2001, the years ended December 31, 2002, 2003, 2004 and 2005 and the period from September 17, 2001 (inception) through December 31, 2005, as set forth in their report. We have included our financial statements in our Annual Report on Form 10-K in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

Representatives from Ernst & Young LLP are expected to be present at the Annual Meeting. These representatives will have the opportunity to make a statement if they desire to do so, and they are expected to be available to respond to appropriate questions from stockholders.

We are asking our stockholders to ratify the appointment of Ernst & Young LLP as our independent registered public accounting firm. Although ratification is not required by our bylaws or otherwise, the Board is submitting the appointment of Ernst & Young LLP for ratification as a matter of good corporate practice. If the stockholders do not ratify the appointment of Ernst & Young LLP, the Audit Committee will consider whether to appoint another independent registered public accounting firm before the end of 2006. Even if the appointment is ratified, our Audit Committee may in its discretion appoint a different independent registered public accounting firm at any time during the year if the Committee determines that such a change would be in the best interests of us and our stockholders.

### Vote Required for Ratification of Independent Registered Public Accounting Firm

The affirmative vote of the holders of a majority of the shares of Common Stock present and voting at the Annual Meeting is required to ratify the appointment of Ernst & Young LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2006. Each share of Common Stock which is represented, in person or by proxy, at the Annual Meeting will be accorded one vote on this proposal. For purposes of this vote, abstentions and broker non-votes will in effect not be counted.

**THE BOARD OF DIRECTORS RECOMMENDS A VOTE "FOR" THE RATIFICATION OF THE APPOINTMENT OF ERNST & YOUNG LLP.**

## EXECUTIVE OFFICERS

The following table identifies our current executive officers:

| Name | Age | Position |
|---|---|---|
| Geert Cauwenbergh, Ph.D | 52 | Chairman of the Board, Chief Executive Officer and Director |
| Alfred Altomari (1) | 47 | Chief Operating Officer |
| Albert C. Bristow (2) | 36 | General Counsel and Secretary |
| Charles T. Nomides (3) | 49 | Chief Research and Development Officer |
| Anne M. VanLent (4) | 58 | Executive Vice President, Chief Financial Officer and Treasurer |

(1) Alfred Altomari was appointed our Chief Operating Officer in February 2006. From August 2003 until February 2006, Mr. Altomari served as our Chief Commercial Officer. Prior to joining us, Mr. Altomari was at affiliates of Johnson & Johnson from 1982 to 2003 where he most recently served as General Manager of the Ortho Neutrogena prescription drug development group. Mr. Altomari also serves as a director of Auxilium Pharmaceuticals, Inc. and Agile Therapeutics, Inc. Mr. Altomari received a bachelor's degree in Science with a dual major in finance and accounting from Drexel University and received his M.B.A. from Rider University.

(2) Albert C. Bristow has been our General Counsel since October 2003. Mr. Bristow was an attorney with Morgan, Lewis & Bockius LLP, Princeton, New Jersey, from January 2000 until joining us, and an attorney with Archer & Greiner, P.C., Haddonfield, New Jersey, from September 1995 until January 2000. Mr. Bristow received a bachelor's degree in the Arts from Lafayette College and a J.D. from the University of Pennsylvania.

(3) Charles T. Nomides was appointed our Chief Research and Development Officer in February 2006. From July 2002 until February 2006, Mr. Nomides served as our Chief Operating Officer. Prior to joining us, Mr. Nomides was at Johnson & Johnson Consumer Products Worldwide from 1997 to 2002 where he most recently served as Director of Research and Development in charge of the Ortho Neutrogena prescription drug development group. Mr. Nomides received a bachelor's degree in Biology from Clarion State University and received graduate training from Temple University and The Milton S. Hershey Medical Center.

(4) Anne M. VanLent has been our Executive Vice President, Chief Financial Officer and Treasurer since May 2002. Prior to joining us, Ms. VanLent served as a principal of the Technology Compass Group, LLC, a healthcare/technology consulting firm, since she founded it in October 2001. From July 1997 to October 2001, she was the Executive Vice President - Portfolio Management for Sarnoff Corporation, a multidisciplinary research and development firm. Ms. VanLent also currently serves as a director of Penwest Pharmaceuticals Co. and Integra Lifesciences Holdings Corp. She received a bachelor's degree in Physics from Mount Holyoke College and did graduate work in biophysics.

## SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information regarding the beneficial ownership of our Common Stock as of April 7, 2006 for:

- each of our named executive officers;
- each of our directors;
- all of our directors and executive officers as a group; and
- all persons known by us to beneficially own more than 5% of our Common Stock.

The number of shares beneficially owned by each stockholder is determined under rules issued by the Securities and Exchange Commission. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power and includes any shares that an individual or entity has the right to acquire beneficial ownership of within 60 days of April 7, 2006 through the exercise of any warrant, stock option or other right. Each of the stockholders listed has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

| Name and Address of Beneficial Owner (1) | Number of Shares Beneficially Owned | Percentage of Shares Beneficially Owned (1) |
|---|---|---|
| **Executive Officers and Directors:** | | |
| Geert Cauwenbergh, Ph.D.(2) | 606,112 | 2.5% |
| Alfred Altomari (3) | 87,898 | * |
| Albert C. Bristow (4) | 42,093 | * |
| Charles T. Nomides (5) | 117,819 | * |
| Anne M. VanLent (6) | 139,879 | * |
| Srinivas Akkaraju, M.D., Ph.D. (7) | 2,656,840 | 11.0% |
| Robert E. Campbell (8) | 37,000 | * |
| Carl W. Ehmann, M.D. (9) | 47,250 | * |
| Edward L. Erickson (10) | 24,000 | * |
| Peter Ernster (11) | 34,000 | * |
| Charles F. Jacey, Jr. (12) | 34,300 | * |
| Carol Raphael (13) | 24,000 | * |
| Nicholas J. Simon III (14) | 1,946,788 | 8.1% |
| All current directors and executive officers as a group (13 persons) (15) | 5,797,979 | 24.0% |
| **5% Stockholders:** | | |
| Johnson & Johnson (16) | 3,753,749 | 15.6% |
| JPMP Capital Corp. (17) | 2,656,840 | 11.0% |
| Perseus-Soros BioPharmaceutical Fund, LP (18) | 2,324,734 | 9.6% |
| MPM BioVentures III-QP, L.P. (14) | 1,946,788 | 8.1% |
| TL Ventures V L.P. (19) | 1,967,671 | 8.2% |

* Less than 1%.

(1) Unless otherwise indicated, the address of each beneficial owner is c/o Barrier Therapeutics, Inc., 600 College Road East, Suite 3200, Princeton, New Jersey 08540. Our calculation of the percentage of shares beneficially owned is based on 24,133,804 shares of our Common Stock outstanding as of April 7, 2006.

(2) Includes 84,552 shares of Common Stock issuable upon exercise of stock options exercisable within 60 days of April 7, 2006. Also includes 7,813 shares of restricted Common Stock held by him that we have the right to repurchase in specific situations which shares shall be fully vested as of May 7, 2006, and includes 4,000 shares owned by Dr. Cauwenbergh's wife, 1,000 shares owned by his daughter and 1,000 shares owned by his son.

(3) Includes 86,206 shares of Common Stock issuable upon exercise of stock options exercisable within 60 days of April 7, 2006.

(4) Includes 41,102 shares of Common Stock issuable upon exercise of stock options exercisable within 60 days of April 7, 2006.

(5) Includes 42,819 shares of Common Stock issuable upon exercise of stock options exercisable within 60 days of April 7, 2006. Also includes 3,516 shares of restricted Common Stock that within 60 days of April 7, 2006 we have the right to repurchase in specific situations, of which 1,172 shares are released from restriction each month.

(6) Includes 26,278 shares of Common Stock issuable upon exercise of stock options exercisable within 60 days of April 7, 2006. Also includes 1,825 shares of restricted Common Stock that we have the right to repurchase in specific situations which shares shall be fully vested as of May 1, 2006, and includes 1,000 shares of Common Stock owned by Ms. VanLent's mother's irrevocable living trust.

(7) Srinivas Akkaraju, M.D., Ph.D. is an executive officer of JPMP Capital Corp., the general partner of (i) MFM, the general partner of BHCA and (ii) JPMP Global Investors, L.P., the general partner of each of Global Domestic, Global Cayman, Global Domestic A, Global Cayman II and Selldown. Dr. Akkaraju may, therefore, be deemed to be a beneficial owner of the shares held by BHCA, Global Domestic, Global Domestic A, Global Cayman, Global Cayman II and Selldown, as described in footnote (17) below. However he disclaims beneficial ownership of such shares, except to the extent of his pecuniary interest therein, if any.

(8) Includes 34,000 shares of Common Stock issuable upon exercise of stock options exercisable within 60 days of April 7, 2006 that we have the right to repurchase in specific situations, which consists of a grant for 24,000 of which 6,000 shares are released from restriction annually beginning in September 2005 and a grant for 10,000 which becomes fully vested as of June 20, 2006.

(9) Includes 45,250 shares of Common Stock issuable upon exercise of stock options exercisable within 60 days of April 7, 2006, of which we have the right to repurchase in specific situations, which consists of a grant for 24,000 of which 6,000 shares are released from restriction annually beginning in September 2005, a grant for 10,000 which becomes fully vested as of June 20, 2006.

(10) Represents 24,000 shares of Common Stock issuable upon exercise of stock options exercisable within 60 days of April 7, 2006, of which we have the right to repurchase in specific situations. 6,000 shares will be released from restriction annually beginning in January 2007.

(11) Represents 34,000 shares of Common Stock issuable upon exercise of stock options exercisable within 60 days of April 7, 2006, of which we have the right to repurchase in specific situations which consists of a grant for 14,000 of which 3,500 shares are released from restriction annually beginning in June 2005 and a grant for 10,000 which becomes fully vested as of June 20, 2006.

(12) Includes 34,000 shares of Common Stock issuable upon exercise of stock options exercisable within 60 days of April 7, 2006 that we have the right to repurchase in specific situations, which consists of a grant for 24,000 of which 6,000 shares are released from restriction annually beginning in September 2005 and a grant for 10,000 which becomes fully vested as of June 20, 2006.

(13) Represents 24,000 shares of Common Stock issuable upon exercise of stock options exercisable within 60 days of April 7, 2006 that we have the right to repurchase in specific situations. 6,000 shares will be released from restriction annually beginning in August 2006.

(14) As reported on an Amended Schedule 13G filed on February 13, 2006, the ownership consists of 1,620,553 shares held by MPM BioVentures III-QP, L.P., 136,957 shares held by MPM BioVentures III GmbH & Co. Beteiligungs KG, 108,961 shares held by MPM BioVentures III, L.P., 48,942 shares held by MPM BioVentures III Parallel Fund, L.P. and 31,375 shares held by MPM Asset Management Investors 2003 BVIII LLC. MPM Capital LP and Medical Portfolio Management LLC, its general partner, are direct or indirect parents and/or control persons of MPM BioVentures III LLC, funds managed or advised by them, including the funds listed in this footnote above, and the general partners of such funds, and may be deemed to beneficially hold the securities owned by such entities. Mr. Simon is the general partner of MPM BioVentures III. Although Mr. Simon may be deemed a beneficial owner of the shares held by the MPM BioVentures entities, he disclaims beneficial ownership of such shares, except to the extent of his pecuniary interest therein. The principal business address of MPM BioVentures III-QP, L.P. is 200 Clarendon Street, 54th Floor, Boston, MA 02116. Mr. Simon's address is c/o MPM BioVentures III-QP, L.P., 200 Clarendon Street, 54th Floor, Boston, MA 02116.

(15) Includes 476,207 shares of Common Stock issuable upon exercise of stock options exercisable within 60 days of April 7, 2006.

(16) As reported on an Amended Schedule 13G filed on February 9, 2006, the ownership consists of 2,641,311 shares held by Janssen Pharmaceutica Products, L.P., 856,028 shares held by Johnson & Johnson Consumer Companies, Inc. and 256,410 shares held by Johnson & Johnson Development Corporation. Johnson & Johnson is the ultimate parent of Janssen Pharmaceutica Products, L.P., Johnson & Johnson Consumer Companies, Inc. and Johnson & Johnson Development Corporation. The principal business address of Johnson & Johnson is 1 Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

(17) As reported on an Amended Schedule 13G filed on February 14, 2006, the ownership consists of 1,943,169 shares held by J.P. Morgan Partners (BHCA), L.P. ("BHCA"), 332,807 shares held by J.P. Morgan Partners Global Investors, L.P. ("Global Domestic"), 168,617 shares held by J.P. Morgan Partners Global Investors (Cayman), L.P. ("Global Cayman"), 46,312 shares held by J.P. Morgan Partners Global Investors A, L.P. ("Global Domestic A"), 18,801 shares held by J.P. Morgan Partners Global Investors (Cayman) II, L.P. ("Global Cayman II"), 147,134 shares held by J.P. Morgan Partners Global Investors (Selldown), L.P. ("Selldown"), and 1,093,786 shares held by The Bank of New York, as voting trustee for BHCA and Selldown under that certain Voting Trust Agreement dated as of June 22, 2004. The general partner of BHCA is JPMP Master Fund

Manager, L.P. ("MFM"). The general partner of each of Global Domestic, Global Cayman, Global Domestic A, Global Cayman II and Selldown is JPMP Global Investors, L.P. JPMP Capital Corp., a wholly owned subsidiary of J.P. Morgan Chase & Co., a publicly traded company, is the general partner of each of MFM and JPMP Global Investors, L.P. Each of MFM, JPMP Global Investors, L.P. and JPMP Capital Corp., may be deemed beneficial owners of the shares held by BHCA, Global Domestic, Global Domestic A, Global Cayman, Global Cayman II and Selldown, however, the foregoing shall not be constructed as an admission that such entities are the beneficial owners of the shares held by BHCA, Global Domestic, Global Domestic A, Global Cayman, Global Cayman II and Selldown. The principal business address of JPMP Capital Corp. is 1221 Avenue of the Americas, New York, New York 10020.

(18) As reported on an Amended Schedule 13G filed on February 14, 2006. The principal business address of Perseus-Soros BioPharmaceutical Fund, LP is 888 Seventh Avenue, 29th Floor, New York, New York 10106.

(19) Includes 1,934,217 shares held by TL Ventures V L.P. and 33,454 shares held by TL Ventures V Interfund L.P. TL Ventures V LLC is the general partner of TL Ventures V Management L.P., the general partner of TL Ventures V L.P. and the general partner of TL Ventures V Interfund L.P. TL Ventures V LLC's members are Robert E. Keith, Jr., Gary J. Anderson, Mark J. DeNino and Christopher Moller, each of which may be deemed to have shared voting and dispositive power over the shares held by both TL Ventures V L.P. and TL Ventures V Interfund L.P. TL Ventures V LLC disclaims beneficial ownership of all shares, except to the extent of any indirect pecuniary interest therein. The principal business address of TL Ventures V L.P. is 700 Building, 435 Devon Park Drive, Wayne, Pennsylvania 19087.

## BOARD STRUCTURE AND COMPENSATION

### Board of Directors' Meetings and Committees

Our Board has an Audit Committee, Compensation Committee and Corporate Governance and Nominating Committee, each of which operates under a charter that has been approved by the Board. Each of our respective committee charters are posted under Investor Relations, Corporate Governance on our website at ***www.barriertherapeutics.com***. During fiscal year 2005, the Board held eight (8) meetings and acted by unanimous written consent four (4) times, the Audit Committee held eleven (11) meetings, the Compensation Committee held three (3) meetings and acted by unanimous written consent five (5) times, and the Corporate Governance and Nominating Committee held two (2) meeting and acted by unanimous written consent three (3) times. During 2005, each director attended at least 75% of the aggregate number of meetings of the Board and of the Board committee or committees on which they served during the year.

***Audit Committee.*** The members of our Audit Committee are Peter Ernster, Charles F. Jacey, Jr., and Carol Raphael. Mr. Jacey chairs the committee. Our Audit Committee assists our Board in its oversight of our financial reporting and accounting processes. Management has the primary responsibility for the preparation of financial statements and the reporting processes, including the system of internal controls. Our independent registered public accountants are responsible for auditing our annual financial statements and issuing a report on the financial statements. In this context, the oversight function of our Audit Committee includes:

- a review of the audits of our financial statements, including the integrity of our financial statements and internal controls over financial reporting;
- a review of our compliance with legal and regulatory requirements;
- a review of the performance of our independent registered public accounting firm, including the engagement of the independent registered public accounting firm and the monitoring of the independent registered public accounting firm's qualifications and independence;
- the preparation of the report required to be included in our annual proxy statement in accordance with Securities and Exchange Commission rules and regulations; and
- a review of the quarterly and annual reports filed with the Securities and Exchange Commission.

***Compensation Committee.*** The members of our Compensation Committee are Robert E. Campbell, Peter Ernster and Nicholas J. Simon III. Mr. Ernster chairs the committee. The purpose of our Compensation Committee is to discharge the responsibilities of our Board relating to compensation of our executive officers. Specific responsibilities of our Compensation Committee include:

- establishing and periodically reviewing our compensation philosophy and the adequacy of compensation plans and programs for our executive officers and other employees;
- establishing compensation arrangements and incentive goals for our executive officers and administering compensation plans;
- reviewing the performance of our executive officers and awarding incentive compensation and adjusting compensation arrangements as appropriate based upon performance;
- reviewing and monitoring our management development and succession plans and activities; and
- preparing our report on executive compensation for inclusion in our annual proxy statement in accordance with Securities and Exchange Commission rules and regulations.

***Corporate Governance and Nominating Committee.*** The members of our Corporate Governance and Nominating Committee are Srinivas Akkaraju, M.D., Ph.D., Carl W. Ehmann, M.D. and Edward L. Erickson. Dr. Ehmann chairs the committee. The purpose of our Corporate Governance and Nominating Committee is to advise our Board regarding its operations. In particular, our Corporate Governance and Nominating Committee assists our Board in its operations by:

- identifying individuals qualified to serve as directors, recommending to our Board the director nominees for the next annual meeting of stockholders and recommending to our Board individuals to fill vacancies on the Board;
- recommending to our Board the responsibilities of each Board committee, the structure and operation of each Board committee, and the director nominees for assignment to each Board committee;

- overseeing our Board's annual evaluation of its performance and the performance of other Board committees; and
- periodically reviewing corporate governance guidelines applicable to us.

## Compensation Committee Interlocks and Insider Participation

None of our executive officers serves as a member of the board or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our Board or Compensation Committee. None of the members of our Compensation Committee has ever been our employee.

## Affirmative Determination Regarding Director Independence and Other Corporate Governance Matters

We operate within a comprehensive plan of corporate governance for the purpose of defining director independence, assigning Board responsibilities, setting high standards of professional and personal conduct for directors, officers and employees and assuring compliance with such responsibilities and standards. We regularly monitor developments in the area of corporate governance. In July 2002, Congress passed the Sarbanes-Oxley Act of 2002 which, among other things, established or provided the basis for a number of new corporate governance standards and disclosure requirements. In addition, NASDAQ adopted changes to its corporate governance and listing requirements. The Board has also adopted corporate governance guidelines, which are posted under Investor Relations, Corporate Governance on our website at www.barriertherapeutics.com.

Our Board has determined that the following directors, constituting eight of our nine directors and thus a majority of the Board, are each an "independent director" under applicable National Association of Securities Dealers, or NASD, and SEC rules: Srinivas Akkaraju, M.D., Ph.D., Nicholas J. Simon III, Carol Raphael, Edward L. Erickson, Charles F. Jacey, Jr., Carl W. Ehmann, M.D., Peter Ernster, and Robert E. Campbell. Our Board also has determined that each member of the Audit Committee, the Compensation Committee and the Corporate Governance and Nominating Committee meets the independence requirements applicable to those committees as prescribed by the NASD, the Securities and Exchange Commission, the Internal Revenue Service and the applicable committee charters. Our Board has further determined that Charles F. Jacey, Jr., who chairs the Audit Committee, is an "audit committee financial expert" as such term is defined in Item 401(h) of Regulation S-K promulgated by the Securities and Exchange Commission.

## Director Compensation

Each non-employee, non-investor member of our Board receives certain directors' fees as follows: $12,000 annual retainer for the lead director, $8,000 annual retainer for each director other than the lead director, $8,000 annual retainer for each committee chair, $2,000 annual retainer for each committee member other than the chair, and $1,500 per meeting of the Board. For fiscal 2005, each of Carol Raphael, Charles F. Jacey, Jr., Carl W. Ehmann, M.D., Peter Ernster, and Robert E. Campbell were deemed to be non-employee, non-investor members of our Board.

In addition, each non-employee, non-investor director is granted options to purchase 24,000 shares of Common Stock upon such director's election to the Board, which are immediately exercisable and vest in four equal annual installments upon completion of each year of service as a Board member over the four year period measured from the date of such grant, and options to purchase 10,000 shares of Common Stock on an annual basis which are immediately exercisable and shall vest in one installment measured from the anniversary of the date of such grant. All such options are granted at the fair market value on the date of the grant. Any unvested shares purchased under such options are subject to repurchase by us upon such director's cessation of Board service at the lower of the exercise price paid per share and the fair market value per share of Common Stock at the time of repurchase. We are obligated to reimburse the members of the Board who are not employees for all reasonable expenses incurred in connection with their attendance at directors' meetings. Directors who are also our officers or employees will not receive compensation for their services as directors.

## INFORMATION ABOUT EXECUTIVE COMPENSATION

### Compensation

The following summary compensation table sets forth information concerning compensation for services rendered in all capacities during the years ended December 31, 2003, 2004 and 2005 awarded to, earned by or paid to our Chief Executive Officer and our other most highly compensated executive officers for the year ended December 31, 2005. We refer to these persons as our named executive officers.

**Summary Compensation Table**

| Name and Principal Position | Fiscal Year | Annual Compensation Salary($) | Annual Compensation Bonus($) | Long-Term Compensation Shares Underlying Options(#) | All Other Compensation ($)(1) |
|---|---|---|---|---|---|
| Geert Cauwenbergh, Ph.D. | 2005 | $315,000 | $100,000 | 25,000 (2) | 2,151 |
| Chairman of the Board and | 2004 | $289,583 | $108,000 | 141,000 (3) | 448 |
| Chief Executive Officer | 2003 | $241,298 | — | 9,000 (4) | 270 |
| Alfred Altomari (5) | 2005 | $243,000 | $60,000 | 20,000 (2) | 2,117 |
| Chief Operating Officer | 2004 | $228,250 | $67,250 | 48,500 (3) | 205 |
| | 2003 | $82,500 | — | 79,000 (4) | 60 |
| Albert C. Bristow (5) | 2005 | $200,000 | $50,000 | 15,000 (2) | 2,096 |
| General Counsel and Secretary | 2004 | $160,000 | $56,000 | 30,000 (3) | 160 |
| | 2003 | $30,192 | $30,000 (6) | 36,500 (4) | 24 |
| Charles T. Nomides | 2005 | $236,000 | $50,000 | 10,000 (2) | 114 |
| Chief Research and Development | 2004 | $219,792 | $60,500 | 50,375 (3) | 308 |
| Officer | 2003 | $190,000 | — | 8,000 (4) | 252 |
| Anne M. VanLent | 2005 | $257,500 | $58,000 | 15,000 (2) | 2,124 |
| Executive Vice President and | 2004 | $242,000 | $84,750 | 20,875 (3) | 882 |
| Chief Financial Officer | 2003 | $221,500 | — | 9,000 (4) | 714 |

1) Consists of the payment of premiums for group term life insurance and 401(k) matching contribution.

2) All such options were earned as a bonus for performance in 2005, but were granted on March 31, 2006 with an exercise price of $9.68 per share and all of which expire on March 31, 2016.

3) Includes options to purchase 25,000 shares with respect to Dr. Cauwenbergh, options to purchase 15,000 shares with respect to Mr. Altomari, options to purchase 15,000 shares with respect to Mr. Bristow, options to purchase 15,000 shares with respect to Mr. Nomides, and options to purchase 15,000 shares with respect to Ms. VanLent, all of such options were earned as a bonus for performance in 2004, but which were granted on April 1, 2005 with an exercise price of $15.52 per share and all of which expire on April 1, 2015.

4) Includes options to purchase 9,000 shares with respect to Dr. Cauwenbergh, options to purchase 8,000 shares with respect to Mr. Nomides, options to purchase 9,000 shares with respect to Ms. VanLent, options to purchase 4,000 shares with respect to Mr. Altomari and options to purchase 1,500 shares with respect to Mr. Bristow that were earned as a bonus for performance in 2003 but granted in January 2004. These options have an exercise price of $3.50 per share and expire on January 19, 2014.

5) Mr. Altomari joined us as our Chief Commercial Officer in August 2003, and Mr. Bristow joined us as our General Counsel and Secretary in October 2003.

6) Represents the payment of a signing bonus.

## Stock Options

The following table contains information regarding grants of options to purchase shares of our Common Stock to our named executive officers during the year ended December 31, 2005.

Amounts in the following table represent potential realizable gains that could be achieved for the options if exercised at the end of the option term. The 5% and 10% assumed annual rates of compounded stock price appreciation are calculated based on the requirements of the Securities and Exchange Commission and do not represent an estimate or projection of our future Common Stock prices. These amounts represent certain assumed rates of appreciation in the value of our Common Stock from the fair market value on the date of grant. Actual gains, if any, on stock option exercises depend on the future performance of the Common Stock and overall stock market conditions. The amounts reflected in the following table may not necessarily be achieved.

## Option Grants in Last Fiscal Year

| Name | Number of Securities Underlying Options Granted | Percentage of Total Options Granted to Employees in Fiscal Year | Exercise Price ($/Share) | Expiration Date | Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term(1) 5%($) | 10%($) |
|---|---|---|---|---|---|---|
| Geert Cauwenbergh, Ph.D.... | 25,000 | 4.07 | 15.52 | 04/1/2015(2) | (54,077) | 143,717 |
| Alfred Altomari ..... | 15,000 | 2.44 | 15.52 | 04/1/2015(2) | (32,446) | 86,230 |
| Albert C. Bristow..... | 15,000 | 2.44 | 15.52 | 04/1/2015(2) | (32,446) | 86,230 |
| Charles T. Nomides ..... | 15,000 | 2.44 | 15.52 | 04/1/2015(2) | (32,446) | 86,230 |
| Anne M. VanLent..... | 15,000 | 2.44 | 15.52 | 04/1/2015(2) | (32,446) | 86,230 |

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(1) The dollar amounts under these columns are the result of calculations at rates set by the Securities and Exchange Commission and, therefore, are not intended to forecast possible future appreciation, if any, in the price of the underlying Common Stock. The potential realizable values are calculated using the closing price of $8.20 per share of our Common Stock as quoted on the NASDAQ National Market on the last day of the fiscal year, or December 31, 2005, and assuming that the market price appreciates from this price at the indicated rate for the entire term of each option and that each option is exercised and sold on the last day of its term at the assumed appreciated price.

(2) Options vest 25% on the date of grant, with the balance vesting in three (3) equal annual installments commencing measured from the date of grant.

## Option Exercises and Year-End Option Values

The following table provides information regarding the exercise of stock options during the fiscal year ended December 31, 2005 and the number and value of unexercised options to purchase our Common Stock held as of December 31, 2005 by our named executive officers. As permitted by the rules of the Securities and Exchange Commission, we have calculated the value of the unexercised in-the-money options at fiscal year end on the basis of the closing price of $8.20 per share of our Common Stock as quoted on the NASDAQ National Market on the last day of the fiscal year, or December 30, 2005, less the applicable exercise price multiplied by the number of shares which may be acquired on exercise. We have calculated the value realized of exercised options based on the difference between the per share option exercise price and the fair market value per share of our Common Stock on the date of exercise, multiplied by the number of shares for which the option was exercised.

## Aggregated Fiscal Year-End Option Values

| Name | Shares Acquired on Exercise (#) | Value Realized ($) | Number of Securities Underlying Unexercised Options at December 31, 2005(#) Exercisable | Number of Securities Underlying Unexercised Options at December 31, 2005(#) Unexercisable | Value of Unexercised In-the-Money Options at December 31, 2005($) Exercisable | Value of Unexercised In-the-Money Options at December 31, 2005($) Unexercisable |
|---|---|---|---|---|---|---|
| Geert Cauwenbergh, Ph.D.. | 2,970 | 33,056 | 56,999 | 86,971 | 10,150 | 27,009 |
| Alfred Altomari ..... | — | — | 64,835 | 62,665 | 330,520 | 234,980 |
| Albert C. Bristow..... | — | — | 27,900 | 35,600 | 145,421 | 146,529 |
| Charles T. Nomides ..... | — | — | 29,416 | 35,584 | 64,029 | 29,671 |
| Anne M. VanLent..... | — | — | 13,930 | 20,268 | 48,809 | 34,918 |

## Equity Compensation Plan Information

The following table sets forth certain information as of the end of our fiscal year ended December 31, 2005 with respect to our compensation plans under which equity securities are authorized for issuance.

| Plan Category | Number of securities to be issued upon exercise of outstanding options, warrants and rights (a) | Weighted-average exercise price of outstanding options, warrants and rights (b) | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c) |
|---|---|---|---|
| Equity compensation plans approved by security holders | 1,819,587 | $8.32 | 2,117,913 * |
| Equity compensation plans not approved by security holders | -0- | -0- | -0- |
| Total | 1,819,587 | $8.32 | 2,117,913 |

* Effective as of January 2, 2006, this number reflects an increase of 1,000,000 shares of Common Stock reserved for issuance under our 2004 Stock Incentive Plan (the "Plan"). The Plan contains an evergreen provision which provides for an automatic increase of reserved shares under the Plan each year on the first trading day in January of each calendar year by an amount equal to 5% of the total number of shares of Common Stock outstanding on the last trading day in December, not in excess of 1,000,000 shares.

## Employment Agreements

Each of the following executive officers has entered into an employment agreement with us, each dated as of April 1, 2004 and amended from time to time: Geert Cauwenbergh, Ph.D., as our Chief Executive Officer; Alfred Altomari, as our Chief Operating Officer; Albert C. Bristow, as our General Counsel and Secretary; Charles T. Nomides, as our Chief Research and Development Officer; and Anne M. VanLent, as our Executive Vice President, Chief Financial Officer and Treasurer. Each of the employment agreements provides that the executive's annual salary is subject to any increases determined by the compensation committee of our Board from time to time. Accordingly, effective April 1, 2006, our compensation committee increased the annual salaries for our executive officers for fiscal 2006 as follows: $325,000 for Dr. Cauwenbergh; $253,000 for Mr. Altomari; $212,000 for Mr. Bristow; $244,000 for Mr. Nomides; and $266,000 for Ms. VanLent. Subsequently on April 13, 2006, our compensation committee increased the annual salary of Mr. Altomari to $275,000, effective May 1, 2006, to reflect the increased responsibilities of Mr. Altomari as a result of his having been appointed as our Chief Operating Officer on February 15, 2006.

Each of our executive officers also has agreed to certain confidentiality and non-competition provisions in his or her employment agreement. Each of these executives is entitled to participate in all bonus and incentive programs, including our equity compensation programs, with the amount of any such bonus or incentive being determined by the compensation committee. Each of the agreements may be terminated by either us or the executive with or without cause at any time. If the executive terminates his or her agreement for good reason or if we terminate the agreement without cause, the executive is entitled to continuation of his or her base salary for a severance period and immediate vesting, or release of repurchase right, of any restricted stock, option or other equity award to the extent of the vesting that would otherwise have occurred during the severance period. The severance period for Dr. Cauwenbergh is 12 months, for each of Mr. Altomari, Mr. Nomides and Ms. VanLent is 9 months and for Mr. Bristow is 6 months. In addition, if we complete certain specified corporate transactions, such as a merger or a sale of substantially all of our assets, or if more than 50% of our outstanding voting shares are acquired by any person or group, or if the executive dies or becomes disabled, then all shares of restricted stock, options or other equity awards will immediately vest, or be released from our repurchase right.

In addition, we entered into restricted stock purchase agreements with Dr. Cauwenbergh, Mr. Nomides and Ms. VanLent at the time each first became employed by us. Under the terms of these agreements, we sold 500,000 shares of our Common Stock to Dr. Cauwenbergh, 75,000 shares of our Common Stock to Mr. Nomides and 100,000 shares of our Common Stock to Ms. VanLent. The restricted stock purchase agreements provide that upon the termination of the employment of any of Dr. Cauwenbergh, Mr. Nomides or Ms. VanLent, we have an option to purchase all or any portion of his or her then unvested shares for a per share price of $0.002 from Dr. Cauwenbergh and Mr. Nomides and $0.60 from Ms. VanLent.

As of April 7, 2006, 7,813 shares of Dr. Cauwenbergh's 500,000 shares remain subject to our repurchase option with such shares being fully vested as of May 7, 2006, 4,688 shares of Mr. Nomides' 75,000 shares remain subject to our repurchase option, with 1,172 shares being released each month thereafter, and 1,825 shares of Ms. VanLent's 100,000 shares remain subject to our repurchase option with such shares being fully vested as of May 1, 2006. If we terminate the employment agreement of any of these three executive officers without cause or if the executive terminates his or her employment for good reason, then the number of shares that would otherwise have been released during the severance period if the executive remained employed by us during this period will be immediately released from our repurchase right under the restricted stock purchase agreement. If Dr. Cauwenbergh, Mr. Nomides or Ms. VanLent dies or becomes disabled, or in the event of a change of control, all shares that remain subject to his or her restricted stock purchase agreement will be released from our repurchase right.

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

***Purchases of Raw Materials, Clinical Supplies and Commercial Supplies***

In July 2004, we entered into an agreement with Janssen Pharmaceutica, NV under which we committed to purchase € 1,000,000 of inventory within the two-year period ending July 2008. We recorded approximately $57,000 in 2005 related to this agreement.

We expensed approximately $14,000, $21,000 and $1,607,000 for the purchase of raw materials and clinical supplies from a Janssen during 2005, 2004 and 2003, respectively.

***Director Compensation***

Please see "Director Compensation" for a discussion of options granted to our non-investor, non-employee directors.

***Executive Compensation and Employment Agreements***

Please see "Information about Executive Compensation" for a discussion of additional information on compensation of our executive officers. Information regarding employment and restricted stock agreements with several of our executive officers is set forth under "Information about Executive Compensation—Employment Agreements."

## CODE OF CONDUCT

Our Board has adopted a Code of Conduct applicable to all of our directors, officers and employees. Violations of the Code of Conduct, including those involving accounting, internal accounting controls or auditing matters may be reported to our General Counsel, who the Board has designated as the compliance officer for the implementation and administration of the Code of Conduct. A copy of the Code of Conduct can be obtained from our Internet web site at www.barriertherapeutics.com without charge.

## REPORT OF THE COMPENSATION COMMITTEE OF THE BOARD OF DIRECTORS

The following report of the Compensation Committee is required by the rules of the Securities and Exchange Commission to be included in this Proxy Statement. This report shall not be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act, by virtue of any general statement in such filing incorporating this Proxy Statement by reference, except to the extent that the Company specifically incorporates the information contained in this section by reference, and shall not otherwise be deemed filed under either the Securities Act or the Exchange Act.

The Compensation Committee is responsible for establishing compensation plans for the Company's executive officers and other employees and administers the Company's incentive and equity based plans and programs. The Compensation Committee operates pursuant to a Charter that the Board approved on February 27, 2004, a copy of which is available on the Company's website.

The Company maintains the philosophy that its compensation program for employees, including executive officers, should be directly and materially linked to the interests of the Company and its stockholders, and is designed to secure, retain and motivate high quality individuals possessing the skills necessary for the development and growth of the Company.

The compensation program consists of base salary, an annual incentive program conditioned on achievement of predetermined objectives payable in cash and incentive stock options, and an initial incentive stock option grant at the time of hire.

**Base Salary**. The Compensation Committee establishes annual base salary levels based on level of experience, position, responsibility, and competitive data. The Compensation Committee uses information from several sources, including consultants and data contained in third party surveys to identify competitive salary grades and ranges. The Compensation Committee analysis includes consideration of data from companies with similar size (based on market capitalization and revenue size), geography, market, and growth profile.

**Cash and Stock Option Based Annual Incentive Program**. This program is designed to enhance stockholder value by providing the Company's eligible employees, including its executive officers, with added incentive to achieve specific annual objectives. The program also provides the Company with a tool to attract, retain, and motivate qualified personnel, allowing the Company to compete with industry peers. The Compensation Committee believes strongly that a combination of targets requiring the achievement of short-term operating goals and longer-term strategic objectives translates directly into increasing the long-term value of the Company's stock. Under the plan, eligible participants can earn a cash bonus based on a percentage of their base salary, as well as an incentive stock option grant. Generally, these stock options vest partially on the date of grant with the remainder vesting over three (3) years from the date of grant. The incentive bonus opportunities vary by each employee's level of responsibility, and are dependent on the actual achievement level, as compared to predetermined corporate and individual objectives. For the executive officers, other than the Chief Executive Officer, the target cash bonus is equal to 35% of the officer's base salary and the target number of stock options is 15,000 shares. For the Chief Executive Officer, the target cash bonus is equal to 50% of base salary and the target number of stock options is 25,000 shares. Awards can exceed targets when quantitative and qualitative targets are exceeded. For 2005, incentive awards were paid based on the achievement of 65% of the Company's predetermined objectives which primarily related to advancing the Company's clinical product pipeline and the results of commercial operations.

Under the annual incentive program there is no provision for a mandatory minimum incentive award and the Committee and the Board retain full discretion as to the total amount of cash and options

distributed to all employees and the Committee reviewed and approved the annual incentive compensation amounts for the executive officers.

**Stock Options**. The Compensation Committee encourages all employees to build an ownership position, over time, in the Company's Common Stock. In addition to the stock options granted under the Company's annual incentive program described above, each employee is provided with an initial grant of stock options when the employee first joins the Company, with the amount of the grant dependent upon the employee's salary level. These initial grants are intended to supplement the employee's base salary and to bring the total compensation to a level that the Company believes is competitive with the amounts paid by the Company's competitors. These initial grants also have the potential to yield significant returns over time if the Company is successful, thereby serving as an additional motivator for the employee and a retention tool for the Company. The initial grants vest 25% on the first anniversary of the date of grant and thereafter in 36 equal monthly installments.

**Other Benefits**. The Company also makes available health and welfare benefits, a 401(k) plan and an employee stock purchase plan for executive officers on terms generally available to all Company employees. The Compensation Committee believes that such benefits are comparable to those offered by other companies of similar size, market, and growth profile.

**CEO Compensation**. As discussed above, the Company's compensation program includes base salary, and a cash and stock option based incentive program. Dr. Cauwenbergh participates in the same compensation program applicable to other named executive officers. The Compensation Committee's objective is to correlate Dr. Cauwenbergh's remuneration with the Company's performance and the achievement of predetermined goals. Dr. Cauwenbergh's base salary is reviewed annually in an effort to maintain market competitiveness, and based on such review increased 9.1% in 2004, 5.0% in 2005 and 3.2% in 2006. Dr. Cauwenbergh's cash incentive award was paid in April 2006 for fiscal 2005 performance goal results. If the Company had achieved 100% of its stated goals then Dr. Cauwenbergh would have received a cash bonus equal to 50% of his 2005 base salary. However, the Compensation Committee determined that the Company had achieved 65% of the target and, as a result, Dr. Cauwenbergh's cash bonus award was $100,000, or approximately 31.8% of his 2005 base salary. Dr. Cauwenbergh was also granted incentive stock options to purchase 25,000 shares of Common Stock.

**Compliance with Internal Revenue Code Section 162(m)**. Section 162(m) of the Internal Revenue Code of 1986, as amended, generally disallows a tax deduction to public companies for compensation over $1 million paid to its Chief Executive Officer and its four other most highly compensated executive officers. However, qualifying performance-based compensation will not be subject to the deduction limit if certain requirements are met. The Compensation Committee reviews the potential effect of Section 162(m) periodically and generally seeks to structure the long-term incentive compensation granted to the Company's executive officers in a manner that is intended to avoid disallowance of deductions under Section 162(m). Nevertheless, the Compensation Committee reserves the right to use its judgment to authorize compensation payments that may be subject to the limit when the Compensation Committee believes that such payments are appropriate, and in the best interests of the Company and its stockholders, after taking into consideration changing business conditions and the performance of its employees.

SUBMITTED BY THE COMPENSATION COMMITTEE
OF THE COMPANY'S BOARD OF DIRECTORS

*Peter Ernster, Chairman of the Committee*
*Robert E. Campbell*
*Nicholas J. Simon III*

## REPORT OF THE AUDIT COMMITTEE OF THE BOARD OF DIRECTORS

The following report of the Audit Committee is required by the rules of the Commission to be included in this Proxy Statement. This report shall not be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act, by virtue of any general statement in such filing incorporating this Proxy Statement by reference, except to the extent that the Company specifically incorporates the information contained in this section by reference, and shall not otherwise be deemed filed under either the Securities Act or the Exchange Act.

The purpose of the Audit Committee is to oversee the Company's accounting and financial reporting process and the audits of the Company's financial statements. The Audit Committee operates pursuant to a Charter that the Board approved on February 27, 2004.

As set forth in the Audit Committee Charter, management of the Company is responsible for the preparation, presentation and integrity of the Company's financial statements, the Company's financial reporting process, accounting policies, internal controls and disclosure controls and procedures. The independent registered public accounting firm is responsible for auditing the Company's financial statements and expressing an opinion as to their conformity with U.S. generally accepted accounting principles. The Audit Committee's responsibility is to monitor and oversee this process.

In the performance of its oversight function, the Audit Committee has reviewed and discussed with the Company's independent registered public accounting firm the overall scope and plans for, and results of, the 2005 audits. The Audit Committee meets with the independent registered public accounting firm, with and without management present, to discuss the results of their examinations and their evaluation of the Company's internal controls, and the overall quality of the Company's financial reporting. The Audit Committee has also discussed with the independent registered public accounting firm the matters required to be discussed by Statement on Auditing Standards No. 61, "*Communication with Audit Committees,*" as currently in effect. Finally, the Audit Committee has received the written disclosures and the letter from the independent registered public accounting firm required by Independence Standards Board Standard No. 1, "*Independence Discussions with Audit Committees,*" as currently in effect, has discussed with the independent registered public accounting firm their independence in relation to the Company and has considered the compatibility of non-audit services with such independence. Management has represented to the Audit Committee that the Company's consolidated financial statements were prepared in accordance with U.S. generally accepted accounting principles.

Based upon the review and discussions referred to above, the Audit Committee recommended to the Board of Directors that the audited financial statements of the Company for the fiscal year ended December 31, 2005, and the Attestation Reports of the Company's Independent Registered Public Accounting Firm, each be included in the Company's Annual Report on Form 10-K for such fiscal year, for filing with the Commission.

SUBMITTED BY THE AUDIT COMMITTEE
OF THE COMPANY'S BOARD OF DIRECTORS

*Charles F. Jacey, Jr., Chairman of the Committee*
*Peter Ernster*
*Carol Raphael*

## INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM AUDIT FEES AND ALL OTHER FEES

The following table sets forth the aggregate fees billed by Ernst & Young LLP, our independent registered public accounting firm, for audit services rendered in connection with the consolidated financial statements and reports for 2005, 2004 and 2003 and for other services rendered during 2005, 2004 and 2003 on our behalf, as well as all out-of-pocket costs incurred in connection with these services, which have been billed to us (in thousands):

| Fee Category | 2005 | % of 2005 Total | 2004 | % of 2004 Total |
|---|---|---|---|---|
| Audit Fees | $ 535 | 93% | $ 572 | 95% |
| Audit Related Fees | -0- | -0- | -0- | -0- |
| Total Audit Fees | $ 535 | 93% | $572 | 95% |
| Tax Fees: | | | | |
| Tax Compliance/Preparation | $ 38 | 7% | $ 31 | 5% |
| Total Fees | $ 573 | 100% | $ 603 | 100% |

Audit Fees: Consists of fees billed for professional services rendered for the audit of our consolidated financial statements and review of the interim condensed consolidated financial statements, and other professional services rendered in connection with our initial public offering included in our registration statements on Form S-1 filed in April 2004, our follow-on offering included in our registration statements on Form S-1 filed in February 2005 and services that are normally provided by Ernst & Young LLP in connection with statutory and regulatory filings or engagements, except those not required by statute or regulation.

Audit-Related Fees: Consists of fees billed for assurance and related services that are reasonably related to the performance of the audit or review of our consolidated financial statements and are not reported under "Audit Fees".

Tax Fees: Consists of tax compliance/preparation and other tax services. Tax compliance and preparation consists of fees billed for professional services related to federal, state and international tax compliance.

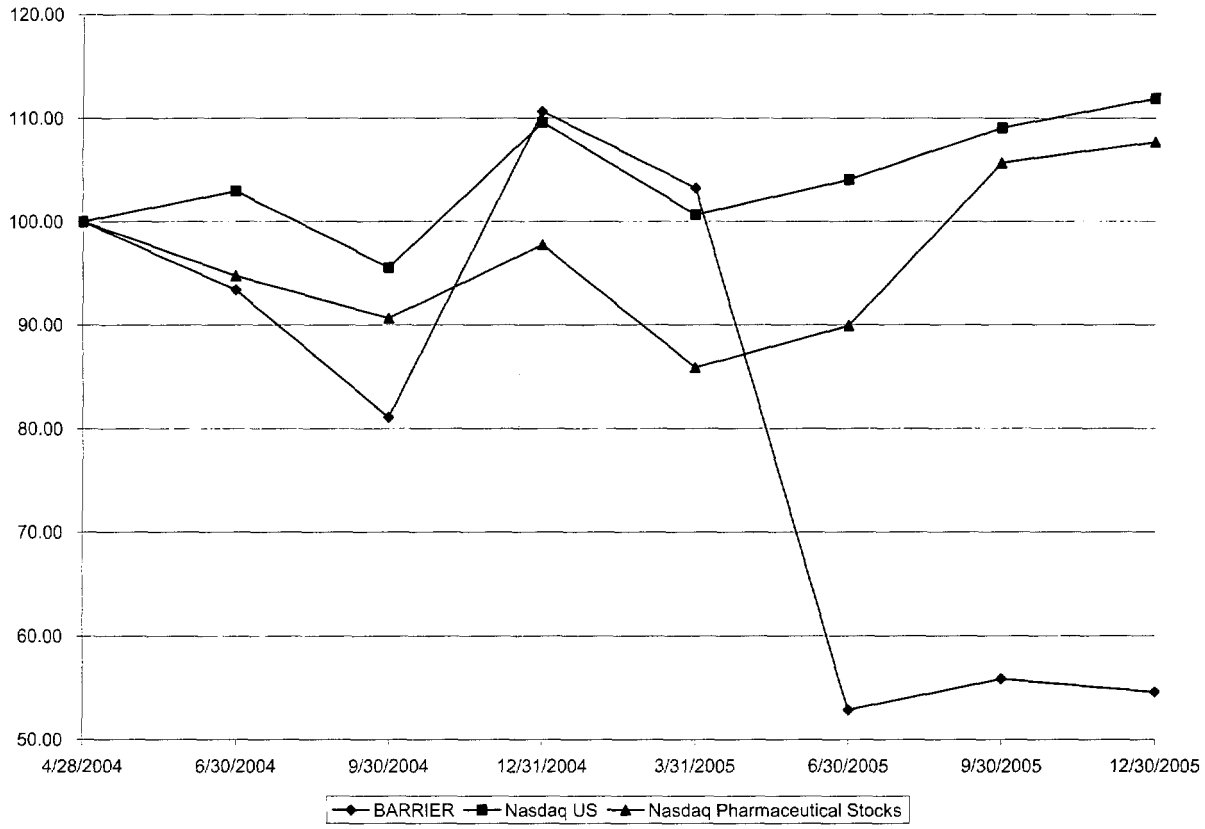
In making its recommendation to ratify the appointment of Ernst & Young LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2006, the Audit Committee has determined that the services other than audit and audit-related provided by Ernst & Young LLP are compatible with maintaining the independence of Ernst & Young LLP.

## AUDIT COMMITTEE PRE-APPROVAL OF AUDIT AND PERMISSIBLE NON-AUDIT SERVICES OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Audit Committee pre-approves all audit and permissible non-audit services provided by the independent registered public accounting firm. These services may include audit services, audit-related services, tax services and other services.

## COMPARATIVE STOCK PERFORMANCE GRAPH

The following line graph compares the quarterly change in the cumulative total stockholder return on our Common Stock since our initial public offering with the cumulative total return of the Nasdaq Composite Index and the Nasdaq Pharmaceutical Index for the same period. The graph assumes that $100 was invested in our Common Stock at our initial public offering price of $15 per share, the Nasdaq Composite Index (US) and the Nasdaq Pharmaceutical Index, and that all dividends were reinvested. We did not pay any dividends during the period indicated. Historical stock price performance is not necessarily indicative of future stock price performance.




ASSUMES $100 INVESTED ON APRIL 28, 2004
ASSUMES DIVIDENDS REINVESTED
THROUGH FISCAL YEAR ENDING DECEMBER 31, 2005

| | 4/28/04 | 6/30/04 | 9/30/04 | 12/31/04 | 3/31/05 | 6/30/05 | 9/30/05 | 12/30/05 |
|---|---|---|---|---|---|---|---|---|
| Barrier Therapeutics, Inc. | $100 | $93.40 | $81.07 | $110.67 | $103.27 | $52.87 | $55.93 | $54.67 |
| Nasdaq Composite Index (US) | $100 | $102.98 | $95.56 | $109.60 | $100.68 | $104.10 | $109.07 | $111.93 |
| Nasdaq Pharmaceutical Index | $100 | $94.77 | $90.64 | $97.77 | $85.86 | $89.92 | $105.70 | $107.67 |

## OTHER MATTERS

### Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires that our directors, certain of our officers and persons who own more than ten percent of our Common Stock, file reports of ownership of our securities and changes in ownership of our securities with the Securities and Exchange Commission. To our knowledge, based solely on a review of the copies of such reports furnished to us and written representations that no other reports were required, all filings required to be made by our Section 16(a) reporting persons during fiscal year 2005 were made on a timely basis.

### Directors' Attendance at Annual Meeting of Stockholders

It is the policy of the Board that all directors attend the annual meeting of stockholders except where the failure to attend is due to unavoidable circumstances or conflicts discussed in advance by such director with the Chairman of the Board. All members of the Board attended the 2005 annual meeting of stockholders, and all members of the Board are expected to attend the 2006 annual meeting of stockholders.

### Director Candidates

The process followed by our Nominating and Corporate Governance Committee to identify and evaluate director candidates includes requests to Board members and others for recommendations, meetings from time to time to evaluate biographical information and background material relating to potential candidates and interviews of selected candidates by members of the committee and the Board.

In considering whether to recommend any particular candidate for inclusion in the Board's slate of recommended director nominees, our Nominating and Corporate Governance Committee will apply the criteria contained in the committee's charter. These criteria include the candidate's understanding of and experience in the pharmaceutical industry, understanding of and experience in accounting oversight and governance, finance and marketing and leadership experience with public companies or other significant organizations. We believe that the backgrounds and qualifications of our directors as a whole should collectively possess a broad range of skills, expertise, industry and other knowledge, and business and other experience useful to the effective oversight of our business.

Stockholders may recommend individuals to our Nominating and Corporate Governance Committee for consideration as potential director candidates by submitting their names, together with appropriate information about the candidate that would be required to be included in a proxy statement under the rules of the Securities and Exchange Commission, information about the relationship between the candidate and the recommending stockholder, the consent of the candidate to serve as a director and proof of the number of shares of our Common Stock that the recommending stockholder owns and the length of time the shares have been owned to: Nominating and Corporate Governance Committee, c/o Barrier Therapeutics, Inc., 600 College Road East, Suite 3200, Princeton, New Jersey 08540, Attention: Secretary, at least 120 days before the one-year anniversary of the date of mailing of our proxy materials for the prior year's annual meeting of stockholders. Assuming that appropriate material has been provided on a timely basis, the committee will evaluate stockholder-recommended candidates by following substantially the same process, and applying substantially the same criteria, as it follows for candidates submitted by others. In addition, our bylaws provide certain requirements for advance notification of director nominations by stockholders. In order to be timely, a stockholder notice must be received in writing by our Secretary at our principal executive offices not less than 120 days nor more than 150 days prior to the first anniversary of the preceding year's annual meeting. These requirements

are separate from and in addition to requirements that a stockholder must meet in order to have a stockholder proposal included in our proxy statement.

## Stockholder Communications with the Board of Directors

Our Board will give appropriate attention to written communications that are submitted by stockholders, and will respond if and as appropriate. Our Chairman of the Board is primarily responsible for monitoring communications from our stockholders and for providing copies or summaries to the other directors as he considers appropriate.

Stockholders who wish to send communications on any topic to our Board as a whole should send such communication to the attention of the Chairman of the Board via U.S. Mail (including courier or expedited delivery service) to Barrier Therapeutics, Inc., 600 College Road East, Suite 3200, Princeton, New Jersey 08540 or by facsimile at 609-945-1212.

Stockholders who wish to send communications on any topic to an individual director in his capacity as a member of the Board, may send such communications to the attention of the individual director via U.S. Mail (including courier or expedited delivery service) to Barrier Therapeutics, Inc., 600 College Road East, Suite 3200, Princeton, New Jersey 08540 or by facsimile at 609-945-1212.

## Stockholder Proposals to be Presented at the 2007 Annual Meeting

Stockholders may submit proposals on matters appropriate for stockholder action at annual meetings in accordance with the rules and regulations adopted by the Securities and Exchange Commission. Any proposal which an eligible stockholder desires to have included in our proxy statement and presented at the 2007 annual meeting of stockholders (which is expected to be held on or about June 6, 2007) will be included in our proxy statement and related proxy card if it is received by us no later than December 27, 2006 (120 calendar days prior to the anniversary of the mailing date of this Proxy Statement) and if it complies with Securities and Exchange Commission rules regarding inclusion of proposals in proxy statements.

Other deadlines apply to the submission of stockholder proposals for the 2007 annual meeting that are not required to be included in our proxy statement under Securities and Exchange Commission rules. With respect to stockholder proposals relating to director nominations, see page 25 of this Proxy Statement. With respect to other stockholder proposals for the 2007 annual meeting, our bylaws provide certain requirements for advance notification by stockholders of business to be conducted at annual meetings but not necessarily included in our proxy statement. In order to be timely, a stockholder notice must be received in writing by our Secretary at our principal executive offices not less than 120 days nor more than 150 days prior to the first anniversary of the preceding year's annual meeting. These requirements are separate from and in addition to requirements that a stockholder must meet in order to have a stockholder proposal included in our proxy statement. If a stockholder does not provide timely notice of a proposal, our proxy agents will be allowed to use their discretionary voting authority to vote against the stockholder proposal when and if the proposal is raised at the 2007 annual meeting.

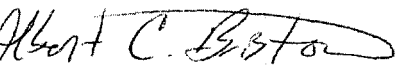
## Other Matters to be Considered at the Annual Meeting

The Board does not intend to bring any other matters before the Annual Meeting and has no reason to believe any other matters will be presented. If, however, other matters properly do come before the meeting, it is the intention of the persons named as proxy agents in the enclosed proxy card to vote upon such matters in accordance with the recommendation of the Board.

## Householding of Annual Meeting Materials

Some banks, brokers and other nominee record holders may be participating in the practice of "householding" proxy statements and annual reports. This means that only one copy of this Proxy Statement or annual report may have been sent to multiple stockholders in your household. We will promptly deliver a separate copy of either document to you if you call or write us at the following address or phone number: Barrier Therapeutics, Inc., 600 College Road East, Suite 3200, Princeton, New Jersey 08540, or by telephone at 609-945-1200. If you want to receive separate copies of our annual report and proxy statement in the future or if you are receiving multiple copies and would like to receive only one copy for your household, you should contact your bank, broker, or other nominee record holders, or you may contact us at the above address and phone number.

By Order of the Board of Directors,



ALBERT C. BRISTOW
*Secretary*

Princeton, New Jersey
April 28, 2006

**Barrier** *Therapeutics, Inc.*

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**
**WASHINGTON, DC 20549**

# FORM 10-K

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

**For the fiscal year ended December 31, 2005**

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____.

**Commission file number 0-50680**

# BARRIER THERAPEUTICS, INC.

*(Exact Name of Registrant as Specified in Its Charter)*

| **Delaware** | **22-3828030** |
|---|---|
| *(State of Incorporation)* | *(I.R.S. Employer Identification No.)* |

**600 College Road East, Suite 3200**
**Princeton, New Jersey 08540**
*(Address of Principal Executive Offices) (Zip Code)*

**(609) 945-1200**
*(Registrant's telephone number, including area code)*

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:
**Common Stock, par value $.0001 per share**
(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. ☐ Yes ☒No

Indicate by check mark whether the registrant (1) has filed all reports to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 2 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. 'es ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of :gistrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large :celerated filer" in Rule 12b-2 of the Exchange Act. (Check one): ☐ Large accelerated filer ☒ Accelerated filer ☐Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). ☐ Yes ☒No

The aggregate market value of the voting Common Stock held by non-affiliates of the registrant as of June 30, 2005 was approximately $99.8 million. Such aggregate ıarket value was computed by reference to the closing price of the Common Stock as reported on the NASDAQ National Market on June 30, 2005. For purposes of ıaking this calculation only, the registrant has defined affiliates as including all directors and executive officers.

The number of shares of the registrant's Common Stock outstanding as of March 10, 2006 was 24,130,383.

## DOCUMENTS INCORPORATED BY REFERENCE.

Portions of the registrant's definitive proxy statement for its 2006 annual meeting of stockholders of the registrant to be held on June 21, 2006 are incorporated by ference into Part III of this Annual Report on Form 10-K.

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## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

In addition to historical facts or statements of current condition, this report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements contained in this report constitute our expectations or forecasts of future events as of the date this report was filed with the SEC and are not statements of historical fact. You can identify these statements by the fact that they do not relate strictly to historical or current facts. Such statements may include words such as "anticipate," "will," "estimate," "expect," "project," "intend," "should," "plan," "believe," "hope," and other words and terms of similar meaning. In particular, these forward-looking statements include, among others, statements about:

- the increasing trend of operating losses and the reasons for those losses;
- our spending on the clinical development of our product candidates;
- our plans regarding the development or regulatory path for any of our product candidates, particularly with respect to our Liarozole and Hyphanox™ product candidates;
- the timing of the initiation or completion of any clinical trials, particularly with respect to our Liarozole, Hyphanox, Rambazole™ and Azoline product candidates;
- the timing of filing for regulatory approvals with governmental agencies;
- the commercialization of our products, particularly our Vusion™ and Solagé® products;
- the timing of the commercial launch of any of our product candidates, if approved;
- the commercialization of any of our product candidates, if approved; and
- other statements regarding matters that are not historical facts or statements of current condition.

Any or all of our forward-looking statements in this report may turn out to be wrong. These statements involve known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, level of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Therefore, you should not place undue reliance on any such forward-looking statements. T factors that could cause actual results to differ from those expressed or implied by our forward-looking statements include, in addition to those set forth in Part I, Item 1A under the heading "Risk Factors," our ability to:

- obtain substantial additional funds;
- obtain and maintain all necessary patents or licenses;
- market our Vusion and Solagé products and product candidates, if approved, and generate revenues;
- demonstrate the safety and efficacy of product candidates at each stage of development;
- meet applicable regulatory standards in the United States to commence or continue clinical trials, particul with respect to our Liarozole, Hyphanox, Azoline and Rambazole product candidates;
- meet applicable regulatory standards and file for or receive required regulatory approvals, particularly wit respect to our Sebazole™ product candidate;
- produce our drug products in commercial quantities at reasonable costs and compete successfully against other products and companies; and
- meet our obligations and required milestones under our license and other agreements, including our agreements with the Johnson & Johnson family of companies.

# PART I

## ITEM 1. BUSINESS

### Overview

We are a pharmaceutical company focused on the discovery, development and commercialization of pharmaceutical products in the field of dermatology. We currently market two pharmaceutical products in the United States, Vusion™ (0.25% miconazole nitrate, 15% zinc oxide, and 81.35% white petrolatum) Ointment and Solagé® (mequinol 2.0% and tretinoin 0.01%) Topical Solution. We also market our Solagé product in Canada, along with VANIQA® (elflornithine HCl) Cream 13.9%, for which we are the exclusive distributor in Canada. We promote our marketed products through a sales force consisting of our own sales representatives and those of a contract sales organization. We have one New Drug Application, or NDA, under review by the United States Food and Drug Administration, or FDA, for our Sebazole™ product candidate. Our product pipeline includes six other product candidates in Phases 2 and 3 of clinical development.

*Recent Developments*

On February 16, 2006, the FDA issued an approval letter for Vusion for the treatment of infants and children with diaper dermatitis complicated by candidiasis. Our existing sales force has begun to actively promote the product to pediatricians and dermatologists. We have also begun implementing our plan to hire an additional 39 sales representatives, which would bring our total number of sales representatives to 60. We expect to begin shipping the product to wholesalers in the United States early in the second quarter of 2006.

*Our Marketed Products*

Our marketed products are:

- *Vusion*: a topical ointment indicated for the treatment of infants and children with diaper dermatitis complicated by candidiasis, an inflammatory disease characterized by diaper rash infected by a yeast called *Candida*.

- *Solagé*: a topical solution indicated for the treatment of solar lentigines, commonly known as "age spots". We currently market this product in the United States and Canada.

- *VANIQA*: a topical cream indicated for slowing the growth of unwanted facial hair in women. We are the exclusive distributor of this product in Canada under an agreement with Shire Pharmaceutical Contracts Limited.

*Our Product Pipeline*

Our most advanced product candidate is Sebazole, a gel for the treatment of seborrheic dermatitis. Seborrheic dermatitis is a type of eczema characterized by inflammation and scaling of the skin, principally of the scalp, face and chest. In September 2005, we submitted an NDA for Sebazole in the United States. In December 2005, the FDA accepted the NDA for filing. The NDA is currently being reviewed at the FDA, and we expect an action letter at the end of July of 2006.

We have six other product candidates in Phases 2 and 3 clinical development for the treatment of a range of dermatological conditions, including acne, psoriasis, congenital ichthyosis, onychomycosis and other fungal infections. In addition, we have access to the classes of compounds claimed in the patents licensed to us under our license agreements with affiliates of Johnson & Johnson. We are currently conducting a screening program of those compounds to search for new product candidates in the field of dermatology.

*Our History*

Our management team consists of a number of experienced pharmaceutical industry executives and recognized experts in dermatological drug discovery, development and commercialization. We were founded by Geert Cauwenbergh, Ph.D., our Chief Executive Officer, who identified a portfolio of dermatological product candidates and intellectual property within the Johnson & Johnson family of companies that he believed could form the basis for an independent pharmaceutical company focused on dermatology. In May 2002, we acquired these assets through licenses from Janssen Pharmaceutica Products, L.P., Johnson & Johnson Consumer Companies, Inc. and Ortho-McNeil Pharmaceutical, Inc., each a Johnson & Johnson company, in exchange for an equity interest in us. In this document, we sometimes refer to Janssen Pharmaceutica Products, L.P. and its affiliates as Janssen. We were incorporated in Delaware in September 2001 and commenced active operations in May 2002. Our principal offices are located at 600 College Road East, Suite 3200, Princeton, New Jersey 08540.

**Dermatology Overview**

Dermatology is the field of medicine concerned with the study and treatment of disorders and diseases of the skin. Ski is a vital organ of the human body. Skin functions as a barrier, protecting organs and tissues in the body from injury and invasion by foreign organisms that may cause infections or other damage. It helps regulate body temperature and sense external stimuli. The condition of one's skin also has a significant impact on an individual's overall health and appearance.

Skin is a complex system composed of three major layers:

- the epidermis is a protective layer and contains melanin, which is the pigment that gives skin its color and protects it against the harmful effects of the sun;
- the dermis contains nerves, blood vessels, hair follicles and many of the functional glands of the skin, including sweat glands and oil producing glands, known as sebaceous glands; and
- the subcutaneous tissue is a layer of fat that helps insulate the body from heat and cold.

Dermatological diseases and disorders may result from a number of factors, including aging, sun damage, immunological diseases, genetic background, viral, fungal or bacterial infections, allergic reactions and emotional or seasonal factors. These diseases and disorders can have a significant impact on an individual's physical and mental healtl and his or her social acceptance.

Despite the significant sales of prescription products for treatment of diseases of the skin, we believe that many limitations remain in the treatment of these diseases. Existing treatments are often inadequate for reasons of efficacy, toxicity or patient noncompliance. Many of the drugs currently used to treat dermatological diseases originally were developed to treat diseases of other parts of the body. For example, many of the oral antifungal drugs used today to treat dermatological infections first were developed as treatments for fungal infections of other parts of the anatomy. We believe that our focus on understanding the molecular basis for diseases of the skin may yield more convenient and effective drugs with fewer undesirable side effects.

**Business Strategy**

Our goal is to develop a portfolio of innovative products that address major medical needs in the treatment of dermatological diseases and disorders and become a global leader in the discovery, development and commercialization of prescription pharmaceutical products to treat these diseases and disorders. To achieve our goal, we intend to:

*Commercialize our products directly through our own sales organization in the United States and Canada and throu collaborations with third parties outside the United States and Canada.* We are building our own sales force to market our products directly to dermatologists and other target physicians in the United States and Canada. To pursue global market penetration of our products, we have entered into, and will continue to seek, collaborations with third parties outside the United States and Canada.

*Aggressively pursue the development and regulatory approval of our product candidates.* We are committing substantial resources towards completing development of, and obtaining regulatory approvals for, our product candidates in the United States and in other markets outside the United States.

*Maintain a diverse portfolio of product candidates.* We are developing a product portfolio that includes product candidates at various stages of preclinical and clinical development. We believe that the diversity in our product development pipeline increases the probability of our long-term commercial success.

*Expand our product portfolio through a combination of internal development efforts and, if appropriate, selective acquisitions of compounds, marketed products and businesses.* We intend to continue expanding our product development pipeline by screening compounds to which we have access under our principal license agreements. We plan to supplement these efforts by licensing or otherwise acquiring additional compounds that we believe to be potentially superior to currently marketed products and by seeking to selectively acquire marketed dermatological products or businesses that complement our development and commercialization strategy.

**Marketed Products and Development Pipeline**

The following tables summarize our marketed products and product candidates in clinical development, all of which we plan to develop as prescription drugs. The names listed below for our product candidates in clinical development are our current designations for these programs and may not be the final approved trade name.

**Marketed Products**

| Product | Active Ingredients | Method of Administration | Indications | Countries |
|---|---|---|---|---|
| Fusion™ | miconazole nitrate<br>zinc oxide<br>white petrolatum | Topical | diaper dermatitis complicated by candidiasis | United States<br>Belgium<br>The Netherlands |
| Solagé® | mequinol<br>tretinoin | Topical | solar lentigines | United States<br>Canada |
| VANIQA® | eflornithine HCl | Topical | slowing the growth of unwanted facial hair in women | Canada |

**Development Pipeline**

| Product | Active Ingredients or Class of Molecule | Method of Administration | Indications | Stage of Development |
|---|---|---|---|---|
| Sebazole™ | ketoconazole | Topical | seborrheic dermatitis | NDA filed |
| Cyphanox™ | itraconazole | Oral | onychomycosis | Phase 3 |
| Azoline | pramiconazole | Oral | tinea versicolor | Phase 2b |
| Liarozole | RAMBA class | Oral | congenital ichthyosis (lamellar) | Phase 2/3 |
| Tambazole™ | RAMBA class | Oral | psoriasis (moderate to severe)<br>nodular acne | Phase 2b<br>Phase 2a |
| Tambazole™ | RAMBA class | Topical | acne (mild to moderate) | Phase 2a |
| Vivenyl™ | vapitadine hydrochloride | Oral | skin allergies | Phase 2a |

*Our Marketed Products*

**Vusion.** Vusion is a topical ointment containing 0.25% miconazole nitrate, an antifungal agent, 15% zinc oxide and 81.35% white petrolatum. Vusion is indicated for use in the treatment of diaper dermatitis complicated by candidiasis in infants and children four weeks and older. This inflammatory condition occurs when diaper dermatitis, also known as diaper rash, is complicated with a fungal infection caused by a yeast called *Candida*. The existence of *Candida*, which thrive in the warm, moist conditions typically found in an infant's diaper, is determined by microscopic evaluation for presence of pseudohyphae or budding yeast. Vusion is the only prescription product approved for the treatment of this condition in the United States. Miconazole nitrate is an antifungal agent that treats the *Candida* infection. The ointment base in Vusion is comprised of zinc oxide and white petrolatum, which are the main components in most common diaper rash products.

Based on data from the Centers for Disease Control and Prevention, we estimate that there are 8 million infants under the age of two in the United States. Based on published reports, we estimate that diaper dermatitis is observed in approximately one million pediatric outpatient visits each year, and that of all diaper dermatitis cases treated by physicians, more than 40% are complicated by the fungus *Candida*.

We received FDA marketing approval for Vusion in February 2006. Our existing sales force has begun actively promoting the product to pediatricians and dermatologists. We have also begun implementing our plan to hire an additional 39 sales representatives, which would bring our total number of sales representatives to 60. We expect to begin shipping product to the trade early in the second quarter of 2006.

In connection with the FDA's approval of Vusion, we agreed to conduct two Phase 4 clinical studies: a percutaneous absorption study to determine the amount, if any, of miconazole nitrate which is absorbed into the bloodstream through the skin and its potential effect on liver function; and a microbial resistance study to evaluate the extent, if any, to which the *Candida* yeast may develop resistance to repeated treatment courses with Vusion. We expect to be able to commence and complete both studies in a timely manner, consistent with the FDA's requirements.

Vusion, which we intend to market under the name "Zimycan®" in Europe, has received marketing approval from the Belgian and German health authorities and is the subject of a mutual recognition procedure in Europe. The mutual recognition procedure, or MRP, has been completed in the following eight countries: Austria, Denmark, Finland, Greece, Luxemburg, the Netherlands, Portugal and Sweden, meaning that these countries have indicated they are prepared to gran marketing authorization. In the remaining European countries which we had included in our initial MRP filing, including the United Kingdom and Spain, we expect to make an additional MRP filing containing additional clinical data to address questions raised by the regulatory authorities in those countries. In January 2006, we began marketing this product on a limited basis in Belgium and, through Pharmadeal, B.V., a third party distributor, in the Netherlands. We expect our primary European distributor, Grupo Ferrer, to begin marketing this product in Portugal and Germany during 2006. We do not anticipate sales of Vusion outside of the United States to have a material impact on our revenues. We believe that the primary benefit of these activities is to begin to develop our commercial partnerships outside of the United States and Canada.

We have an exclusive, royalty-free license in the field of dermatology to an issued United States patent covering the formulation of the combination of miconazole nitrate and zinc oxide contained in Vusion and methods of treating diaper dermatitis. The United States patent expires in March 2007. Each of the active ingredients in Vusion, miconazole nitrate, zinc oxide and petrolatum, are off patent. Under the United States Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, we believe Vusion is entitled to three years of marketing exclusivity which will expire in February of 2009.

**Solagé.** Solagé is a topical solution containing 2.0% mequinol and 0.01% tretinoin. In the United States, the product s indicated for use in the treatment of solar lentigines or "age spots". In Canada, the indication is somewhat broader and ncludes use for related hyperpigmented lesions. Solagé is packaged in a bottle with a convenient, contoured felt tip lelivery system that allows for targeted application for twice daily use. According to published reports, solar lentigines or 'age spots" are very common in light skinned individuals and appear in as many as 90% of those over the age of 60 and '0% of those under the age of 35. We estimate that more than 20 million people in the United States have this condition.

We acquired the United States and Canadian rights to Solagé in February 2005 from Moreland Enterprises Limited. Jnder the terms of the acquisition, we made an initial cash payment of $3 million and will make future payments, rimarily as royalties on our net sales, totaling an additional $2 million. In July 2005, we re-launched the product and egan promoting it to dermatologists with 21 sales representatives in the United States and 4 sales representatives in anada. As we expand our United States sales force to 60 representatives, we plan to continue to actively market Solagé o dermatologists.

As part of the Solagé acquisition, we were assigned all United States and Canadian marketing authorizations, patents nd trademarks for the product and we purchased all of the then existing inventory. The patent rights include United tates and Canadian patents covering the product's pharmaceutical formulation and methods of use. The earliest of the Jnited States patents expires in 2013 while a United States patent encompassing a version of Solagé with extended shelf ife expires in 2020. The Canadian patent expires in 2010 while any patents to issue from a Canadian patent application ncompassing a version of Solagé with extended shelf life would expire in 2021. Each of the active ingredients in Solagé, nequinol and tretinoin, is off patent.

**VANIQA.** In June 2005, we obtained the right to distribute VANIQA (elflornithine HCI) Cream 13.9% in Canada rom Shire Pharmaceutical Contracts Limited. VANIQA is currently the only prescription product approved by Health anada for slowing the growth of unwanted facial hair in women. Under the terms of our agreement with Shire, we are ie exclusive distributor for VANIQA in Canada and are responsible for all sales, marketing, regulatory and distribution ctivities. Shire Pharmaceuticals is responsible for supplying us with drug product. Although approved, this product had ever been launched in Canada. We launched and began marketing VANIQA in Canada with four sales representatives in lovember 2005.

***ur Development Pipeline***

Our product development pipeline includes product candidates that are in various stages of clinical development. All f these product candidates are based on intellectual property licensed to us under our principal license agreements. We e developing these product candidates as treatments for a wide range of dermatological diseases and disorders, including ne, psoriasis, congenital ichthyosis, onychomycosis and other fungal infections.

We plan to advance the clinical development of these product candidates based on our assessment of their market otential, the results of pilot studies and clinical trials, the requirements of regulatory agencies and our available sources. The preliminary observations of efficacy and safety from any of our preclinical or clinical trials for our product ndidates are not necessarily indicative of the results that may be demonstrated in future clinical trials. No assessment of e safety or efficacy of any product candidate can be considered definitive until all clinical trials needed to support a bmission for marketing approval are complete. Except with respect to Sebazole for which we have submitted an NDA the FDA, we will need to conduct significant additional preclinical studies or clinical trials prior to seeking marketing proval for the product candidates in our development pipeline.

**Sebazole.** Sebazole is a topical formulation of 2.0% ketoconazole, an antifungal agent, in a waterless gel that we are veloping as a once daily treatment for seborrheic dermatitis. Seborrheic dermatitis is a type of eczema that is aracterized by a red, scaly, itchy rash primarily occurring on the face, scalp, behind the ears and in the middle of the est. The condition often recurs, thereby requiring retreatment over time. Ketoconazole has potent pharmacological fects against the fungus known as *P. ovale*, which, when overcolonizing the skin, is considered to be one of the main uses of seborrheic dermatitis. Ketoconazole quickly suppresses this type of fungus and also exhibits anti-inflammatory

effects that help to reduce redness in affected areas. We have designed Sebazole to deliver the benefits of ketoconazole with the advantages of our waterless gel.

*Product Background.* In November 2003, we completed two Phase 3 clinical trials which enrolled more than 900 patients in approximately 50 locations in the United States and Europe. Each trial had four arms and compared the safety and efficacy of Sebazole, a placebo consisting of our gel with no active ingredients, the gel containing the combination of 2.0% ketoconazole and 0.05% desonide, and the gel containing 0.05% of the steroid desonide. Patients were treated once daily for a period of two weeks. The primary efficacy endpoint in these trials was the proportion of patients that were effectively treated at day 28, which was 14 days following the end of treatment. Effectively treated for the purpose of these Phase 3 clinical trials means a patient was cleared or almost cleared of seborrheic dermatitis. We initially designed the trials primarily for the product containing both ketoconazole and the steroid and, as a result, we conducted the trials following FDA regulations for combination product development. However, based on the results of these clinical trials, we determined that Sebazole was the stronger product candidate. In both trials, Sebazole achieved the primary efficacy endpoint versus the vehicle gel with statistical significance. In these trials, Sebazole was well tolerated, with no serious drug-related adverse events reported.

*Clinical Development.* Upon review of the results from these trials, the FDA requested that we perform one additional Phase 3 pivotal clinical trial of Sebazole. We completed this trial in December 2004. In this trial, we enrolled 459 patients in 24 locations in the United States. The trial compared the safety and efficacy of Sebazole to a placebo consisting of our gel with no active ingredient. Patients were treated once daily for a period of two weeks. The primary efficacy endpoint was the same as in our two earlier Phase 3 trials — the proportion of patients that were effectively treated at day 28, which was 14 days following the end of treatment. In this trial, Sebazole was well tolerated, with no serious drug-related adverse events reported.

The results of the primary efficacy endpoint from all three Phase 3 trials of Sebazole are summarized in the table below:

| | Percentage of Patients Effectively Treated at Day 28 (14 Days after the End of Treatment) | | |
|---|---|---|---|
| Study (location) | Sebazole | Vehicle | p-value |
| Pivotal (United States) | 25% | 14% | 0.001 |
| Supportive (United States) | 28% | 7% | <0.001 |
| Supportive (Europe) | 37% | 22% | 0.021 |

As indicated in the table, the results of each trial were statistically significant. In addition, in our pivotal trial, the secondary efficacy endpoint for mean change from baseline for scaling was statistically significant. The results with respect to the secondary efficacy endpoints for redness and itching were better as compared to vehicle alone but were not statistically significant. We also performed a cumulative irritation patch study in volunteers in which we observed that Sebazole was approximately five times less irritating than a ketoconazole cream.

*Regulatory Strategy.* In September, 2005, we submitted an NDA for Sebazole with the FDA. In December 2005, the FDA accepted the NDA for filing. The filing of an NDA with the FDA is an important step in the approval process in the United States. Acceptance for filing by the FDA does not mean that the NDA has been or will be approved, nor does it represent an evaluation of adequacy of the data submitted. The NDA is currently being reviewed at the FDA, and we expect an action letter at the end of July of 2006.

At the request of the FDA, we also conducted a long-term safety study to assess the long-term safety of Sebazole for up to one year of intermittent use. Consistent with applicable regulatory guidelines, we included six-month safety data from our long term safety study in our NDA submission and provided the one year safety data at the four month safety update. If the FDA determines that the one year data is a substantial addition to the NDA during its review, the FDA could extend its review time.

*Proprietary Rights.* We have an exclusive, royalty-free license in the field of dermatology to a United States patent application claiming specific formulations of ketoconazole in a waterless gel. Any patent issued in the United States from this application would expire in 2018. The active ingredient of Sebazole, ketoconazole, is off patent.

**Oral Antifungals: Hyphanox.**

Hyphanox is an oral formulation of itraconazole, an antifungal agent that we are developing for the treatment of onychomycosis, commonly known as nail fungus. Itraconazole is effective in treating this type of fungal infection. Janssen currently markets different formulations of itraconazole under Sporanox and other brand names in various countries. Sporanox is approved in the United States for the treatment of various disorders, including onychomycosis. A generic form of itraconazole has also been approved in the United States. A 100 mg capsule is the maximum strength in which oral Sporanox is currently available. We are developing Hyphanox as a 200 mg tablet. We believe this 200 mg formulation may provide a more convenient form of dosing and potentially less inter-patient variability.

*Product Background.* In an effort to produce a more convenient dosing form of Sporanox, Janssen conducted a program to reformulate itraconazole into 200 mg tablets using a proprietary formulation of itraconazole requiring a manufacturing process known as melt extrusion. Melt extrusion is a manufacturing process that makes it possible to formulate itraconazole into tablets. We obtained the rights to Janssen's tablet formulation under our license agreements.

In the first quarter of 2004, we commenced a Phase 3 pivotal clinical trial in the United States for the use of a single day, single dose treatment of two 200 mg tablets of Hyphanox in the treatment of vaginal candidiasis, commonly known as a yeast infection. The trial was designed to demonstrate that a single dose of Hyphanox is not clinically inferior to a single dose of fluconazole. In June, 2005, we announced that Hyphanox failed to reach the primary regulatory endpoint of therapeutic cure in that trial. In the study Hyphanox did achieve statistical significance for the secondary endpoint of clinical efficacy and based on this, we triggered the 90 day assessment period for Janssen Pharmaceutica to exercise their pre-negotiated option for this product. In September 2005, we announced that Janssen had notified us that it would not exercise its option and, as a result, we retain worldwide rights for all indications for this product candidate. Although we have no plans to continue to internally develop Hyphanox for the vaginal candidiasis indication, we are seeking a commercial partner to continue such development.

*Clinical Development.* During 2005, we had planned to conduct two Phase 3 pivotal clinical trials designed to test a once daily dosage of two 200 mg tablets of Hyphanox for the treatment of fingernail onychomycosis. We did not initiate those studies due to the timeline delay we expected would result from the FDA's request that we conduct an additional pharmacokinetic, or PK, study prior to finalizing the design for, and subsequently initiating, those trials.

*Regulatory Strategy.* We are currently developing a protocol for a Phase 3 clinical trial to test once daily dosing of one 200 mg tablet in the treatment of toenail onychomycosis. We do not expect the FDA will require us to perform an additional PK study prior to initiating this trial since Sporanox and generic itraconazole are currently approved for once daily dosing of 200 mg, albeit in two 100 mg capsules. If the FDA does require us to perform an additional PK study prior to commencing with this trial, the development of Hyphanox for onychomycosis would be further delayed.

*Proprietary Rights.* We have an exclusive license in the field of dermatology to a United States patent claiming the Hyphanox formulation and methods of using this formulation for treatment of fungal infections. The United States patent claiming the formulation and methods of treatment expires in 2017. We also have an exclusive license to corresponding patents and patent applications in Europe, Japan and other foreign countries. The issued patent and any additional patents issuing from the patent applications in Europe, Japan and other foreign countries will expire in 2016 through 2017. The active ingredient of Hyphanox, itraconazole, is off patent.

**Oral Antifungals: Azoline.**

Azoline is an oral formulation of pramiconazole, a novel antifungal agent that we are developing as an oral treatment for skin and mucosal fungal infections. Preclinical testing has shown Azoline to be more potent than itraconazole against dermatological fungal infections and less interactive than itraconazole with the metabolism of other drugs.

*Clinical Development.* We have completed a one week Phase 1 clinical trial for Azoline in two different dose strengths. The results of this trial indicate that at the doses tested, Azoline has a half-life in the body of approximately 81 hours, which is nearly three times longer than that of itraconazole. As a result, we believe that Azoline may be an effective short course oral treatment for fungal infections. In this trial, Azoline was well tolerated, with no serious drug-related adverse events reported.

In 2005, we announced positive results from Phase 2a clinical trials involving 67 patients with various fungal infections of the skin. These patients were treated with 200 mg of Azoline once daily for one, three or five days. The product candidate was studied in tinea pedis, commonly known as athlete's foot, tinea corporis, commonly known as ring worm, tinea cruris, commonly known as jock itch, tinea versicolor and seborrheic dermatitis. In these trials, at day 28, more than three weeks after treatment, patients treated for one day demonstrated response rates of 60% and patients treated for three or five days demonstrated clinical response rates (percent reduction in overall signs and symptoms) of between 78% and 100%, depending on the skin condition treated. There were no serious treatment-related adverse effects reported.

*Regulatory Strategy.* Based on this data, we submitted an IND with the FDA and the European equivalent, a Clinical Trial Application, or CTA. During 2006, we plan to conduct three Phase 2 clinical trials for Azoline in Europe. The first of these is a Phase 2b dose finding clinical trial in pityriasis versicolor. The other two are Phase 2a clinical trials in vaginal candidiasis and onychomycosis, respectively.

*Proprietary Rights.* We have an exclusive license in the field of dermatology to a United States patent claiming the chemical compound pramiconazole, pharmaceutical formulations containing pramiconazole and methods of treatment with pramiconazole. The United States patent expires in 2018. We also have an exclusive license to corresponding patents and patent applications in Europe, Japan and other foreign countries. The issued patent and any additional patents issuing from the patent applications in Europe, Japan and other foreign countries will expire in 2017 through 2018.

**RAMBAs: Liarozole.**

Liarozole is our first product candidate based on a class of molecules known as retinoic acid metabolism blocking agents, or RAMBAs. We are developing Liarozole as an oral treatment for congenital ichthyosis. Congenital ichthyosis is a rare genetic disease, affecting one in 6,000 people in the United States. The disease is characterized by severe dryness and scaling of the skin, with the scaling often occurring over large areas of the body. There is no prescription drug currently approved in the United States that is indicated for the treatment of congenital ichthyosis.

RAMBAs work by blocking the intracellular metabolism of natural retinoic acid in cells. This blocking results in an increased accumulation of the body's own retinoic acid in the body's cells, which we believe may provide the same therapeutic benefits as synthetic retinoid therapy but potentially with less risk of adverse side effects related to the accumulation of synthetic retinoids in the body's tissues. We believe that one of the potential advantages of Liarozole and other RAMBAs over synthetic retinoids may be the reduction or absence of long-term risk for birth defects. Because of the risk of birth defects arising from the tissue retention of synthetic retinoids, long-term contraception is strongly recommended in women after the use of these agents. Preclinical studies conducted in rats dosed with Liarozole showed no birth defects in pups conceived one week after completion of a one week treatment with Liarozole. In contrast, after treatment is completed with acitretin, the active ingredient in Soriatane, which is marketed by Hoffmann-La Roche Inc. and Connetics, there is a risk of birth defects for several months.

*Product Background.* Liarozole was originally developed for the treatment of prostate cancer and was tested in clinical trials at various doses of up to 600 mg per day. In these clinical trials, subjects treated with higher levels of Liarozole experienced serious toxic side effects as is often the situation with anti-cancer therapies. However, because subjects in these trials exhibited retinoid-like effects in the skin, a development program was started to explore the therapeutic potential of Liarozole at lower doses in a variety of retinoid-responsive diseases, including congenital ichthyosis.

In a Phase 2 clinical trial of Liarozole for the treatment of congenital ichthyosis, that was conducted prior to our acquisition of rights to Liarozole, 11 of 12 subjects that were treated with a twice daily 150 mg dosage of oral Liarozole showed marked improvement. The other subject showed moderate improvement. In addition, in a Phase 3 clinical trial of Liarozole and acitretin, 15 of the 32 subjects with severe ichthyosis were treated with a twice daily 75 mg dosage of Liarozole. In this trial, Liarozole demonstrated similar efficacy as acitretin and was well tolerated.

The FDA and the Commission for the European Community have granted Liarozole orphan drug status for the treatment of congenital ichthyosis. Because of its orphan drug status, if Liarozole is the first product candidate to receive FDA approval for congenital ichthyosis, it will be entitled to orphan drug exclusivity. This means that the FDA may not

pprove any other application to market the same drug for the same indication for a period of seven years in the United tates and 10 years in Europe, except in limited circumstances, such as a showing of clinical superiority or improved afety to the product with orphan exclusivity. The marketing exclusivity of an orphan drug would not prevent other drugs rom being approved for the same indication. The granting of orphan drug status does not mean that the FDA or uropean Community has, or will, grant marketing approval for the drug.

*Clinical Development.* We performed a retrospective review of the side effects observed in people treated with iarozole at doses of up to 600 mg per day. The results of this review suggest that the serious side effects seen at higher oses are less likely to be encountered at our proposed 75 mg or 150 mg per day dose for dermatological use.

In 2005, we filed an IND with the FDA to conduct a Phase 2/3 clinical trial in the treatment of the lamellar form of ongenital ichthyosis. The FDA has placed this trial on clinical hold, meaning that we may not initiate our planned Phase /3 clinical trial in the United States, or any other clinical studies in humans in the United States, until we address the DA's concerns. In January 2006, we began enrolling patients in a Phase 2/3 clinical study for the treatment of the mellar form of congenital ichthyosis in Europe and other countries outside of the United States.

*Regulatory Strategy.* We are in discussions with the FDA concerning the requirements to remove the clinical hold. he further development of Liarozole is dependent upon the outcome of those discussions.

*Proprietary Rights.* We have an exclusive, royalty-free license in the field of dermatology to United States patents laiming the chemical compound Liarozole, pharmaceutical formulations containing Liarozole and methods of treatment vith Liarozole. The United States patents claiming the chemical compound Liarozole and pharmaceutical formulations ontaining Liarozole expire in 2006. The United States patent claiming methods of treatment for congenital ichthyosis sing Liarozole as a RAMBA expires in 2009. We also have an exclusive, royalty-free license to corresponding patents nd patent applications in Europe, Japan and other foreign countries. The issued patent and any additional patents issuing om the patent applications in Europe, Japan and other foreign countries will expire in 2007 through 2009.

**RAMBAs: Oral Rambazole.**

Rambazole is our second product candidate based on the RAMBA class of molecules. We are developing an oral rmulation of Rambazole for the treatment of psoriasis and severe acne. We believe that Rambazole may address some of ie limitations of existing therapies, such as toxicity, or the degree to which existing therapies are harmful at certain levels f treatment, and immune suppression, or the tendency of some existing therapies to compromise a patient's immune stem.

*Product Background.* Various preclinical and clinical studies were conducted on Rambazole prior to our acquisition of ghts to this product candidate. In preclinical *in vitro* and animal studies, oral Rambazole demonstrated potential fectiveness in the treatment of psoriasis and acne. These studies also suggested that Rambazole is more selective and ore active than first generation RAMBA-based product candidates, such as Liarozole. An oral formulation of mbazole was tested in two Phase 1 clinical trials. One of these clinical trials was a single dose escalation study, and the her was a multiple dose escalation study. In the multiple dose escalation study, increased doses of Rambazole resulted in creased manifestation of skin effects typical for retinoid therapy, including dry lips and skin.

*Clinical Development.* In 2005, we announced positive results from two Phase 2a clinical trials in Europe using oral mbazole, one in moderate to severe psoriasis, and the other in moderate to severe nodular acne. In the Phase 2a trial in oriasis, 17 patients with moderate to severe psoriasis who were treated with 1mg of Rambazole once daily for eight nsecutive weeks demonstrated a reduction in the psoriasis area severity index, commonly known as PASI score, by an erage of approximately 50%. These PASI scores were measured at week 10, two weeks after stopping the treatment. iere were no serious treatment-related adverse effects reported, while non-serious side effects experienced by this tient group included dryness of skin and lips.

In the Phase 2a trial in acne, 17 patients with moderate to severe nodular acne were treated with 1 mg of oral mbazole once daily for 12 consecutive weeks. The results of this study indicate that 16 of 17 patients experienced a duction in total acne lesion count of more that 50% and 6 of 17 subjects were considered "cleared or almost cleared". ) be considered "cleared or almost cleared" a patient must have had more than 90% reduction in total lesion count. In : study inflammatory and non-inflammatory lesions responded equally to the treatment. There were no serious

treatment related adverse effects reported, while non-serious side effects experienced by this patient group included some dryness of skin and lips.

*Regulatory Strategy.* Based on these data, we have submitted an IND with the FDA and a CTA in Europe. We plan to commence a Phase 2b dose finding clinical trial in severe plaque psoriasis in Europe in the first half of 2006.

*Proprietary Rights.* We have an exclusive license in the field of dermatology to a United States patent claiming the chemical compound Rambazole, pharmaceutical formulations containing Rambazole and methods of treatment with Rambazole. The United States patent expires in 2017. We also have an exclusive license to corresponding patents and patent applications in Europe, Japan and other foreign countries. The issued patent and any additional patents issuing from the patent applications in Europe, Japan and other foreign countries will expire in 2016 through 2017.

***Earlier Stage Clinical Candidates***

**Topical Rambazole**. We are developing a topical formulation of Rambazole for dermatological indications, including common forms of acne and psoriasis. In preclinical *in vitro* and animal studies, topical Rambazole demonstrated potential effectiveness in the treatment of psoriasis, acne and photo-damage. In addition, animal studies conducted with RAMBAs indicate that topical RAMBA treatment may produce the same therapeutic results as retinoic acid treatments but potentially with less irritation. However, as with any study performed on animals, this data is not necessarily indicative of the results that may be demonstrated in future clinical trials. A Phase 2a clinical trial for acne compared 13 subjects treated with a topical formulation of Rambazole to 13 subjects treated with a placebo. Subjects were treated for 12 weeks. In this trial, subjects receiving topical Rambazole showed a greater percentage reduction of acne lesions than those receiving the placebo. In addition, topical Rambazole was well tolerated, with no serious drug-related adverse events reported.

In 2005 we announced data from a double blind, vehicle controlled biomarker study with a topical formulation of Rambazole. In this study, 15 healthy volunteers were treated for 9 days with both the drug at a 0.07% concentration or a 0.35% concentration and its vehicle. Skin biopsies were taken and analyzed for three key biological markers that are known signals for potential therapeutic effect when topical retinoids are applied. The results from the analysis of the Rambazole treated skin compared to the vehicle treated skin showed strong dose dependent activity with changes of 10 to 1000 fold for three key biological markers as compared to baseline. Virtually no changes were observed in the vehicle treated skin. The levels of biomarkers obtained with the 0.35% concentration of the topical Rambazole formulation are equivalent to those reported in the literature for currently marketed concentrations of topical retinoic acid. None of the volunteers reported signs of irritation after application of topical Rambazole or its vehicle. Based on these data, we have filed a CTA in Europe. We plan to commence a Phase 2a clinical trial in Europe to evaluate the effectiveness of topical Rambazole in mild to moderate acne in the first half of 2006.

**Hivenyl.** Hivenyl is an antihistamine that we are developing as an oral treatment for allergic reactions of the skin, such as the types of reactions associated with hives, which may not cause sedation typically associated with antihistamines. Patients experience sedation when an antihistamine crosses the blood-brain barrier. In preclinical studies in animal models, Hivenyl did not cross the blood-brain barrier. In addition, the results of two dose escalation Phase 1 clinical trials of Hivenyl suggest that Hivenyl inhibits allergic reactions, has a fast onset of action and does not cause sedation. In these trials, no cardiovascular side effects or sedation was experienced at doses of five to 15 times those that elicited an antihistamine response. We are currently conducting two Phase 2a clinical trials in Europe for Hivenyl, in the treatment of chronic idiopathic urticaria and the itch associated with atopic dermatitis, respectively.

***Other Product Candidates and Preclinical Development***

One of our clinical product candidates, Atopik, is currently undergoing reformulation and will require additional preclinical evaluation. In addition, we have rights to two other products, Ketanserin and Oxatomide, that are marketed by third parties in some countries outside the United States and Europe. We would need to reformulate those product candidates prior to initiating clinical trials.

Under our principal license agreements we have access to the classes of compounds claimed in the patents licensed to us in the field of dermatology. We are screening these compounds to determine if they are suitable product development

candidates. We also work with academic institutions and third-party laboratories to perform the screening on selected compounds. We plan to supplement these efforts by licensing or otherwise acquiring additional compounds that we believe to be potentially superior to currently marketed products.

**Sales and Marketing**

We are building a sales and marketing organization with experienced, qualified employees. The dermatological medical communities in the United States and Canada are relatively small. We believe that we can best serve this discrete target physician market with a focused, specialty sales force. We believe that by developing our own sales force, we can control marketing efforts more effectively and obtain better access to the physicians that we target. In 2005, we launched a sales force in the United States and Canada to market our products directly to dermatologists and other target physicians. The United States sales force is comprised of our employees as well as those of a third party contract sales organization, Ventiv Health, Inc.

As a result of the recent approval of Vusion, we are in the process of expanding the sales force in the United States from approximately 21 sales representatives to approximately 60. We expect that approximately one-third of our sales representatives will be Barrier employees and two-thirds will be Ventiv employees. However, over time, we may decide to increase the percentage of our sales force who are Barrier employees. We have also hired three additional regional managers, for a total of six, all of whom are our employees. In Canada, our sales force is currently comprised of four sales representatives and we may hire an additional two representatives in 2006. Ventiv also provides us with supplemental sales and marketing services such as sales information services, fleet management, training and logistics and recruiting support.

We rely on the Specialty Pharmaceutical Services unit of Cardinal Health PTS, LLC, to perform a variety of functions related to the sale and distribution of Vusion and Solagé and any subsequently approved products in the United States. These services include distribution, logistics management, inventory storage and transportation, invoicing and collections. We rely on McKesson Logistics Solutions for similar functions related to the import, quality testing, sale and distribution of Solagé and VANIQA and any subsequently approved products in Canada.

We intend to market our products globally. We have entered into third-party distribution arrangements and marketing alliances for Vusion and some of our later stage product candidates with potential collaborators and distributors for the major European countries and some less significant markets. Our primary European distributor is Grupo Ferrer nternacional, S.A. Our agreement provides for Grupo Ferrer to be our exclusive marketer and distributor of our Vusion, ebazole, Liarozole and Ketanserin product candidates in several countries throughout Europe, Latin America and Africa. n addition, we have distribution agreements for Vusion for the United Kingdom, Ireland, the Netherlands, Israel, and the erritories administered by the Palestinian Authority. We plan to enter into similar third-party distribution arrangements nd marketing alliances for our other products when and if we determine that these products have progressed to later tages of development. To date, none of our products have been launched under these distribution agreements.

In January 2006, we began marketing Zimycan on a limited basis in Belgium and, through Pharmadeal, B.V., a third arty distributor, in the Netherlands. We expect our primary European distributor, Grupo Ferrer, to begin marketing imycan in Portugal and Germany during 2006.

In general, should we decide to enter into third-party distribution arrangements and marketing alliances for the arketing and sale of any of our later stage product candidates in the United States, we would first need to trigger the ight of first negotiation with respect to any such product as further described under the caption "—Johnson & Johnson icense Agreements."

**ohnson & Johnson License Agreements**

In May 2002, we licensed our initial portfolio of product candidates and the patents and other intellectual property and now-how, test data, marketing data and other tangible property associated with those product candidates, from Janssen harmaceutica Products, L.P., Johnson & Johnson Consumer Companies, Inc. and Ortho-McNeil Pharmaceutical, Inc., nder two similar but separate intellectual property transfer and license agreements. In September 2004, we amended ese two intellectual property transfer and license agreements to provide for revised territories and exclusivity terms.

Under these license agreements, we obtained exclusive licenses to a portfolio of patents and non-exclusive licenses to related know-how to make, use and sell our initial product candidates in the field of dermatology. For purposes of the agreements, the field of dermatology includes applications for the treatment or prevention of diseases of human skin, hair, nails and oral and genital mucosa, but excludes treatments for skin cancer. We also have access to classes of compounds claimed in the patents licensed to us under the agreements, which we can screen in our search for new product candidates in the field of dermatology. If we or an affiliate of Johnson & Johnson advance one of these compounds to Phase 1 clinical development, the developing party must give notice to the other party when the developing party has initiated a Phase 1 clinical trial for the particular compound. At that point, the other party must discontinue any activity towards the development or commercialization of that compound for any indication in any field for so long as the compound continues to be in active clinical development or commercialization by the developing party. In addition, neither Johnson & Johnson nor its affiliates may develop Liarozole, Rambazole, Azoline Hivenyl, Atopik and several specified preclinical candidates in any formulation for any indication in any field. In exchange for these licenses, we issued an aggregate of 8,333,333 shares of our series A convertible preferred stock to Johnson & Johnson Consumer Companies, Inc. and Janssen Pharmaceutica Products, L.P. All of these shares were converted into 4,166,666 shares of our common stock in connection with our initial public offering.

***License Terms for Our Product Candidates***

The following is a summary of the terms of the license agreements with respect to our existing product candidates and to any products that we may develop from the classes of compounds claimed in the patents licensed to us:

**Royalties.** The licenses are royalty free, except that, with respect to Hyphanox only, if we decide to use a third party to commercialize Hyphanox, we will owe a royalty based on our net sales of Hyphanox. This royalty would also apply to sales by a successor company in the event of a change of control.

**Territories and Exclusivity.** The licenses are exclusive throughout most of the world, except that our right to sell the following products in the following territories is semi-exclusive with the Johnson & Johnson companies:

- Vusion in Argentina, Australia, Belgium, Denmark, Germany, Indonesia, Luxembourg, Mexico, New Zealand, Peru and Venezuela; and

- Ketanserin in South America.

In addition, we have not been granted the right to sell Oxatomide in Japan, Italy, Mexico and much of Central America or Ketanserin in Mexico, Central America and the Caribbean.

**Commercialization and Manufacturing Rights.** We have the sole right to commercialize any product candidate covered by intellectual property licensed to us under the license agreements that we elect to commercialize ourselves or with the assistance of a contract sales organization. In other circumstances, however, Johnson & Johnson, through any of its affiliates, has a right of first negotiation for the commercialization of our product candidates based on such intellectual property. The rights of first negotiation for the commercialization of our product candidates can be exercised on a territory-by-territory basis. The material elements of these rights are as follows:

- If we intend to commercialize any product through a third party, other than a contract sales organization, in a particular territory, we must provide notice of this intention in accordance with the provisions of the license agreements. Johnson & Johnson has 90 days after the provision of this notice to advise us if it desires to enter into a commercialization agreement for that product in that territory.

- If, prior to the expiration of the 90-day offer period we do not receive that notice, we may enter into a commercialization agreement with a third party for that product without further restrictions or obligations under these rights of first negotiation.

- If, prior to the expiration of the 90-day offer period we do receive that notice, we must negotiate exclusively for 90 days to execute a commercialization agreement.

- If we do not agree on a definitive agreement within the 90-day negotiation period, we may, at any time within a specified period of time after the end of the 90-day negotiation period, enter into a commercialization agreement for that product with a third party so long as the terms are not, taken as a whole, materially less favorable to us than those proposed by the Johnson & Johnson affiliate with which we were negotiating.

- If within the specified negotiation period, we intend to enter into a commercialization agreement with a third party with terms materially less favorable to us than those proposed by the Johnson & Johnson affiliate or, if after the specified negotiation period, we intend to enter into a commercialization agreement with a third party on any terms, then Johnson & Johnson, through any of its affiliates, is entitled to an additional 45-day offer period to express an interest in commercializing that product. If, prior to the termination of the additional 45-day offer period, Johnson & Johnson notifies us of its interest in commercializing the product, we must negotiate exclusively for 60 days to execute a commercialization agreement.

- If we enter into a commercialization agreement with an affiliate of Johnson & Johnson, it will have the right to negotiate a manufacturing agreement with us relating to that particular product in the territory covered by the commercialization agreement. The terms of the right of first negotiation for a manufacturing agreement are the same as the terms of the right of first negotiation for a commercialization agreement.

We triggered this right of first negotiation with respect to Sebazole, Liarozole and Ketanserin by indicating our intention to commercialize these product candidates outside the United States through third-party arrangements. Since the 90-day offer period for these product candidates in this territory has expired, if we receive marketing approvals, we have the exclusive right to commercialize Sebazole, Liarozole and Ketanserin outside the United States, either by ourselves or with a third party, in the territories in which we hold these licenses under the license agreements. In addition, because we intend to commercialize these four product candidates in the United States ourselves, the rights of first negotiation do not apply to these product candidates in the United States. If we later decide to commercialize any of these product candidates in the United States through a third party, other than a contract sales organization, we will trigger the right of first negotiation with respect to that product candidate. In addition, we triggered this right of first negotiation with respect to Vusion by indicating our intention to commercialize this product candidate through third-party arrangements in all territories in which we hold commercialization rights, including the United States. Since the 90-day offer period for Vusion has expired, we have the exclusive right to commercialize Vusion, either by ourselves or with a third party, in all such territories. We expect that we would trigger the right of first negotiation with respect to Rambazole and Azoline following our receipt of data from our currently planned Phase 2b clinical studies for those product candidates.

**Term and Termination.** The license agreements expire on a country-by-country basis and product-by-product basis after the later of 10 years from the execution date or the expiration of the last patent included in the license agreement in the particular country. Following expiration of the license agreements with respect to a product, we receive a fully paid, royalty-free license applicable to that product in the particular country. These licenses may be terminated on a product-by-product basis, if, by dates specified in the license agreements, we are not conducting active clinical trials of the particular product or if we do not obtain regulatory approval for that product. Either of the license agreements may be terminated if we breach that agreement and do not cure the breach within 90 days or in the event of our bankruptcy or liquidation.

**Abbott Development and Supply Agreement**

In May 2002, we entered into a development and supply agreement with Abbott GmbH & Co. KG under which Abbott agreed to assist us in developing an itraconazole product using Abbott's proprietary melt extrusion manufacturing process. Pursuant to the agreement, we are required to pay agreed upon development costs and fees to Abbott. In addition, the agreement provides that as soon as reasonably possible after we submit an NDA for Hyphanox, we will enter into a supply agreement with Abbott under which Abbott will be our sole supplier and manufacturer of Hyphanox. Under the terms of the supply agreement, Abbott will be required to manufacture the itraconazole melt extrudate used in the manufacture of Hyphanox exclusively for us or our designee.

**Grupo Ferrer Distribution and License Agreement**

In November 2004, we entered into a distribution and license agreement with Grupo Ferrer Internacional, S.A. The agreement provides for Grupo Ferrer to be our exclusive marketer and distributor of our Vusion, Sebazole, Liarozole and Ketanserin product candidates in several countries throughout Europe, Latin America and Africa. In addition to marketing

and distributing the products, Grupo Ferrer will assist us in obtaining regulatory approvals for the products in the territories. Under the agreement, we will receive our primary revenues from the sale of finished products to Grupo Ferrer. The agreement also provided for an initial fee of €500,000, which we received in January 2005.

The distribution and license agreement expires on a country-by-country basis and product-by-product basis after the later of 10 years from the date of the first commercial sale with respect to a product or the expiration of the last patent covering the product in the particular country. Following the expiration of the agreement with respect to a product in a particular country, Grupo Ferrer's right to distribute and manufacture the product will become non-exclusive and royalty-free. If, following expiration, Grupo Ferrer desires to continue to utilize any of our trademarks; it could do so for a nominal royalty. To date none of our products have been launched by Grupo Ferrer under this Agreement. We expect Grupo Ferrer to launch Vusion in Portugal, under the name "Zimycan", and in Germany during 2006.

**Patent Protection and Intellectual Property; Orphan Drug; Hatch-Waxman Act; Pediatric Treatment Exclusivity**

We are pursuing a number of methods to establish and maintain market exclusivity for our product candidates, including seeking patent protection for our product candidates, the use of statutory market exclusivity provisions and otherwise protecting our intellectual property.

***Patents and Intellectual Property Protection***

Our success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing United States and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

Our patent portfolio includes patents and patent applications with claims directed to the active ingredients, pharmaceutical formulations, methods of use and methods of manufacturing of a number of our product candidates. We include a discussion of our proprietary rights related to each of our later stage products and the applicable limitations to our rights in the discussion of those products elsewhere in this "Business" section and in the "Risk Factors" section.

United States patents issuing from patent applications filed on or after June 8, 1995 have a term of twenty years from the earliest claimed priority date. For United States patents in force on or after December 8, 1994 that issued from applications filed before June 8, 1995, the term is the greater of twenty years from the earliest claimed priority date or seventeen years from the date of issue.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of our patent applications or those patent applications that we license will result in the issuance of any patents. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or the length of term of patent protection that we may have for our products. In addition, the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, scientific advisors and other contractors. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently

discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

***Orphan Drug Designation***

Some jurisdictions, including Europe and the United States, may designate drugs for relatively small patient populations as orphan drugs. The FDA and the Commission for the European Community have granted Liarozole orphan drug status for the treatment of congenital ichthyosis. The FDA grants orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. In the United States, orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Also, competitors may receive approval of different drugs or biologics for the indications for which the orphan product has exclusivity.

Under European Union medicines laws, criteria for designation as an "orphan medicine" are similar but somewhat different from those in the United States. Orphan medicines are entitled to ten years of market exclusivity, except under certain limited circumstances comparable to United States law. During this period of market exclusivity, no "similar" product, whether or not supported by full safety and efficacy data, will be approved unless a second applicant can establish that its product is safer, more effective or otherwise clinically superior. This period may be reduced to six years if the conditions that originally justified orphan designation change or the sponsor makes excessive profits.

***The Hatch-Waxman Act***

Under the United States Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, newly approved drugs and indications benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Act provides five year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, meaning that the FDA has not previously approved any other new drug containing the same active ingredient. Hatch-Waxman prohibits an abbreviated new drug application, an ANDA, or an NDA where the applicant does not own or have a legal right of reference to all the data required for approval, to be submitted by another company for another version of such drug during the five year exclusive period. Protection under Hatch-Waxman will not prevent the filing or approval of another full NDA, however, the applicant would be required to conduct its own adequate and well-controlled clinical trials to demonstrate safety and effectiveness.

The Hatch-Waxman Act also provides three years of marketing exclusivity for the approval of new NDAs with new clinical trials for previously approved drugs and supplemental NDAs, for example, for new indications, dosages, or strengths of an existing drug, if new clinical investigations are essential to the approval. This three year exclusivity covers only the new changes associated with the supplemental NDA and does not prohibit the FDA from approving ANDAs for drugs containing the original active ingredient. Our Vusion product has been granted three years of exclusivity under this Act.

The Hatch-Waxman Act also permits a patent extension term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent extension cannot extend the remaining term of a patent beyond a total of 14 years. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and it must be applied for prior to expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for patent term extension. We are considering applying for patent term extensions for some of our current patents, to add patent life beyond the expiration date, depending on the expected length of clinical trials and other factors involved in the filing of a new drug application.

*Pediatric Treatment Exclusivity*

The Best Pharmaceuticals for Children Act provides an additional six months of marketing exclusivity for new or marketed drugs for specific pediatric studies conducted at the written request of the FDA. The Pediatric Research Equity Act of 2003, or PREA, authorizes the FDA to require pediatric studies for drugs to ensure the drugs' safety and efficacy in children. PREA requires that new NDAs or supplements to NDAs contain data assessing the safety and effectiveness for the claimed indication in all relevant pediatric subpopulations. Dosing and administration must be supported for each pediatric subpopulation for which the drug is safe and effective. The FDA may also require this data for approved drugs that are used in pediatric patients for the labeled indication, or where there may be therapeutic benefits over existing products. The FDA may grant deferrals for submission of data, or full or partial waivers from PREA. Unless otherwise required by regulation, PREA does not apply to any drug for an indication with orphan designation.

*Manufacturing*

Our products and product candidates include both oral and topical formulations and are produced through a variety of manufacturing processes of varying degrees of difficulty. For example, Vusion, Solagé and Sebazole are produced through a fairly common manufacturing process, while Hyphanox is manufactured as a tablet using a proprietary melt extrusion process that is currently only available through our development agreement with a contract manufacturer. We have relied and will continue to rely on third-party contract manufacturers to produce sufficient quantities of our products for commercial supply and product candidates for use in our preclinical studies and clinical trials.

The following table summarizes our manufacturing relationships for our marketed products and for our most advanced product candidate, Sebazole.

| Product | Country Where Product is Sold | Manufacturer/Supplier | Country Where Product is Made | Contract Expiration |
|---|---|---|---|---|
| Vusion | United States<br>Europe | DSM Pharmaceuticals, Inc.<br>Janssen Pharmaceutica, NV | United States<br>Belgium | Dec. 31, 2009<br>June 30, 2008 |
| Solagé | United States and Canada | Contract Pharmaceuticals Limited Niagra | United States | Dec. 6, 2007 |
| VANIQA | Canada | Shire Pharmaceutical Limited | United States | June 20, 2010 |
| Sebazole | United States | DPT Laboratories, Ltd. | United States | 5 years from first commercial sale |

The active pharmaceutical ingredients of marketed products and our Sebazole and Hyphanox product candidates are generic and are currently available from a number of suppliers. However, we predominately rely on a single source of supply for those active ingredients. If any of the manufacturers of our products, product candidates or active ingredients, were to become unable or unwilling to continue to provide us with these products or ingredients, we may need to obtain an alternate supplier. The active pharmaceutical ingredient of Liarozole, Ramabazole, Azoline and Hivenyl are proprietary. We have relied and will continue to rely on third-party contract manufacturers to produce sufficient quantities these active ingredients for our product candidates for use in our preclinical studies and clinical trials.

Our contract manufacturers are subject to an extensive governmental regulation process. Regulatory authorities in our markets require that drugs be manufactured, packaged and labeled in conformity with current Good Manufacturing Processes, or cGMPs. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures.

*Government Regulation*

Government authorities in the United States, at the federal, state, and local level, and foreign countries extensively egulate, among other things, the following areas relating to our marketed products and product candidates:

- the research, development, and testing;
- manufacture and distribution;
- labeling, promotion, advertising, sampling, and marketing; and
- import and export.

All of our product candidates will require regulatory approval by government agencies prior to commercialization. In ›articular, human therapeutic products are subject to rigorous preclinical and clinical trials and other approval procedures ›f the FDA and similar regulatory authorities in foreign countries. Various federal, state, local, and foreign statutes and egulations also govern testing, manufacturing, safety, labeling, storage and record-keeping related to such products and heir marketing. The process of obtaining these approvals and the subsequent substantial compliance with appropriate ederal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial esources.

*United States Government Regulation*

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act and implementing egulations. If we fail to comply with the applicable requirements at any time during the product development process, ›pproval process, or after approval, we may become subject to administrative or judicial sanctions. These sanctions could nclude the FDA's refusal to approve pending applications, withdrawals of approvals, clinical holds, warning letters, ›roduct recalls, product seizures, total or partial suspension of our operations, injunctions, fines, civil penalties or criminal ›rosecution. Any agency enforcement action could have a material adverse effect on us.

The steps required before a drug may be marketed in the United States include:

- preclinical laboratory tests, animal studies and formulation studies under the FDA's good laboratory practices regulations;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin;
- execution of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each indication for which approval is sought;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practice, or cGMP; and
- FDA review and approval of the NDA.

Preclinical studies generally are conducted in laboratory animals to evaluate the potential safety and activity of a roduct. Violation of the FDA's good laboratory practices regulations can, in some cases, lead to invalidation of the udies, requiring these studies to be replicated. In the United States, drug developers submit the results of preclinical ials, together with manufacturing information and analytical and stability data, to the FDA as part of the IND, which ıust become effective before clinical trials can begin in the United States. An IND becomes effective 30 days after ceipt by the FDA unless before that time the FDA raises concerns or questions about issues such as the proposed clinical ials outlined in the IND. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or

questions before clinical trials can proceed. If these concerns or questions are unresolved, the FDA may not allow the clinical trials to commence.

Pilot studies generally are conducted in a limited patient population to determine whether the product candidate warrants further clinical trials based on preliminary indications of efficacy. These pilot studies may be performed in the United States after an IND has become effective or outside of the United States prior to the filing of an IND in the United States in accordance with government regulations and institutional procedures in the country in which the trials are conducted.

Clinical trials involve the administration of the investigational product candidate to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in assessing the safety and the effectiveness of the drug. Each protocol must be submitted to the FDA as part of the IND prior to beginning the trial.

Typically, clinical evaluation involves a time-consuming and costly three-phase sequential process, but the phases may overlap. Each trial must be reviewed, approved and conducted under the auspices of an independent institutional review board, and each trial must include the patient's informed consent.

Phase 1 — Refers typically to closely monitored clinical trials and includes the initial introduction of an investigational new drug into human patients or healthy volunteer subjects. Phase 1 clinical trials are designed to determine the safety, metabolism and pharmacologic actions of a drug in humans, the potential side effects associated with increasing doses of the product candidate and, if possible, to gain early evidence of the product candidate's effectiveness. Phase 1 trials also include the study of structure-activity relationships, drug metabolism and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes. During Phase 1 clinical trials, sufficient information about a drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid Phase 2 studies. The total number of subjects and patients included in Phase 1 clinical trials varies, but are generally in the range of 20 to 80 people.

Phase 2 — Refers to controlled clinical trials conducted to evaluate appropriate dosage and the effectiveness of a drug for a particular indication or indications in patients with a disease or condition under study and to determine the common short-term side effects and risks associated with the drug. These clinical trials are typically well controlled, closely monitored and conducted in a relatively small number of patients, usually involving no more than several hundred subjects. Although the FDA regulations do not do so, it is common practice in the pharmaceutical industry to sometimes distinguish Phase 2 clinical trials as Phase 2a and Phase 2b. In general, we believe that the common understanding in the industry of Phase 2a and Phase 2b is as follows:

- Phase 2a refers to a clinical trial in a targeted patient population to evaluate preliminary efficacy and/or further safety of a drug candidate. One or more of the following properties may be evaluated: dose response, duration of effect and kinetic/dynamic relationship.

- Phase 2b refers to a controlled dose ranging clinical trial to evaluate further the efficacy and safety of a candidate drug in a targeted patient population and to attempt to define an appropriate dosing regimen.

Phase 3 — Refers to expanded controlled and uncontrolled clinical trials. These clinical trials are performed after preliminary evidence suggesting effectiveness of a drug has been obtained. Phase 3 clinicals are intended to gather additional information about the effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 trials usually include from several hundred to several thousand subjects.

Phase 1, 2 and 3 testing may not be completed successfully within any specified time period, if at all. The FDA closely monitors the progress of each of the three phases of clinical trials that are conducted in the United States and may, at its discretion, reevaluate, alter, suspend or terminate the testing based upon the data accumulated to that point and the FDA's assessment of the risk/benefit ratio to the patient. A clinical program is designed after assessing the causes of the disease, the mechanism of action of the active pharmaceutical ingredient of the product candidate and all clinical and preclinical

data of previous trials performed. Typically, the trial design protocols and efficacy endpoints are established in consultation with the FDA. Upon request through a special protocol assessment, the FDA can also provide specific guidance on the acceptability of protocol design for clinical trials. The FDA, an institutional review board, or we may suspend or terminate clinical trials at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. The FDA can also request additional clinical trials be conducted as a condition to product approval. During all clinical trials, physicians monitor the patients to determine effectiveness and to observe and report any reactions or other safety risks that may result from use of the drug.

Assuming successful completion of the required clinical trials, drug developers submit the results of preclinical studies and clinical trials, together with other detailed information including information on the manufacture and composition of the product, to the FDA, in the form of an NDA, requesting approval to market the product for one or more indications. In most cases, the NDA must be accompanied by a substantial user fee. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use.

Before approving an application, the FDA will inspect the facility or facilities at which the product is manufactured. The FDA will not approve the application unless cGMP compliance is satisfactory. The FDA will issue an approval letter if it determines that the application, manufacturing process and manufacturing facilities are acceptable. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and will often request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval and refuse to approve the application by issuing a not approvable letter.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products. Furthermore, the FDA may prevent a drug developer from marketing a product under a label for its desired indications or place other conditions on distribution as a condition of any approvals, which may impair commercialization of the product. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Similar regulatory procedures must also be complied with in countries outside the United States.

If the FDA approves the new drug application, the drug becomes available for physicians to prescribe in the United States. After approval, the drug developer must comply with a number of post-approval requirements, including delivering periodic reports to the FDA, submitting descriptions of any adverse reactions reported, and complying with drug sampling and distribution requirements. The holder of an approved NDA is required to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling. Also, quality control and manufacturing procedures must continue to conform to cGMPs after approval. Drug manufacturers and their subcontractors are required to register their facilities and are subject to periodic unannounced inspections by the FDA to assess compliance with cGMPs which imposes certain procedural and documentation requirements relating to quality assurance and quality control. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance. The FDA may require post market testing and surveillance to monitor the product's safety or efficacy, including additional studies, known as Phase 4 trials, to evaluate long-term effects.

In addition to studies requested by the FDA after approval, a drug developer may conduct other trials and studies to explore use of the approved compound for treatment of new indications, which require FDA approval. The purpose of these trials and studies is to broaden the application and use of the drug and its acceptance in the medical community.

We use, and will continue to use, third-party manufacturers to produce our products in clinical and commercial quantities. Future FDA inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product or the failure to comply with requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary or FDA-initiated action that could delay further marketing. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and

contraindications. Also, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

Marketed products are subject to continued regulatory oversight by the Office of Medical Policy Division of Drug Marketing, Advertising and Communications, and the failure to comply with applicable regulations could result in marketing restrictions, financial penalties and other sanctions.

***Foreign Regulation***

Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement also vary greatly from country to country. Although governed by the applicable country, clinical trials conducted outside of the United States typically are administered with the three-phase sequential process that is discussed above under — "United States Governmental Regulation."

Under European Union regulatory systems, we may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure which is available for medicines produced by biotechnology or which are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. This authorization is a marketing authorization approval, or MAA. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval. This procedure is referred to as the mutual recognition procedure, or MRP.

In addition, regulatory approval of prices is required in most countries other than the United States. We face the risk that the resulting prices would be insufficient to generate an acceptable return to us or our collaborators.

**Competition**

The pharmaceutical industry and the dermatology segment in particular, are highly competitive and include a number of established, large and mid-sized pharmaceutical companies, as well as smaller emerging companies, whose activities are directly focused on our target markets and areas of expertise. Our products compete, and if approved, our product candidates will compete, with a large number of products that include over-the-counter treatments, prescription drugs specifically indicated for a dermatological condition and prescription drugs that are prescribed off-label. In addition, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical industry at a rapid pace. These developments may render our product candidates or technologies obsolete or noncompetitive.

Our Vusion product faces competition in the treatment of diaper dermatitis complicated by candidiasis, from ointments and creams containing nystatin, Mycolog II from Bristol-Myers Squibb Company, clotrimazole containing creams from Bayer AG and from generic manufacturers and topical miconazole creams. None of these products are indicated for the treatment of diaper dermatitis complicated by candidiasis.

Our Solagé product faces competition in the treatment of solar lentigenes from Triluma from Galderma S.A., Avage from Allergan, Inc., EpiQuin Micro from SkinMedica, Inc. and other prescription 4% hydroquinone formulations as well as over-the-counter 2% hydroquinone products, Retin-A from Neutrogena and other tretinoin containing topical formulations.

If approved, each of our product candidates will compete for a share of the existing market with numerous products that have become standard treatments recommended or prescribed by physicians. For example, we believe the primary competition for our product candidates are:

- For Sebazole, in the treatment of seborrheic dermatitis, Nizoral from Janssen, Desowen from Galderma S.A., Loprox from Medicis Pharmaceutical Corporation and the generic equivalents of each.

- For Hyphanox, in the treatment of onychomycosis, Sporanox from Janssen and generic manufactures, Lamisil from Novartis AG, and Penlac from Dermik Laboratories.

- For Liarozole, in the treatment of congenital ichthyosis, Soriatane from Hoffmann-La Roche Inc. and Connetics Corporation and over-the-counter topical moisturizers and emollients.

- For oral Rambazole, in the treatment of acne, Accutane from Hoffman-La Roche and generic manufacturers. For oral Rambazole, in the treatment of psoriasis, Soriatane from Hoffman-La Roche and Connetics, biologic agents such as Amevive from Biogen Idec Inc. and Raptiva from Genentech, Inc., methotrexate from generic manufacturers.

We also believe that many of the competitive products for our later stage product candidates may similarly compete with our earlier stage product candidates because of the indications for these product candidates.

We expect to compete on, among other things, the efficacy of our products, the reduction in adverse side effects experienced and more desirable treatment regimens, combined with the effectiveness of our experienced management team. Competing successfully will depend on our continued ability to attract and retain skilled and experienced personnel, to identify, secure the rights to and develop pharmaceutical products and compounds and to exploit these products and compounds commercially before others are able to develop competitive products. In addition, our ability to compete may be affected because insurers and other third-party payors in some cases seek to encourage the use of generic products making branded products less attractive, from a cost perspective, to buyers.

Although we believe that, if approved, our product candidates will have favorable features for the treatment of their intended indications, existing treatments or treatments currently under clinical development that also receive regulatory approval may possess advantages in competing for market share.

**Third-Party Reimbursement and Pricing Controls**

In the United States and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. It will be time-consuming and expensive for us to go through the process of seeking reimbursement from Medicare and private payors. Our products may not be considered cost effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis. The passage of the Medicare Prescription Drug and Modernization Act of 2003 imposes new requirements for the distribution and pricing of prescription drugs which may affect the marketing of our products.

In many foreign markets, including the countries in the European Union, pricing of pharmaceutical products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental pricing control. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

**Employees**

As of December 31, 2005, we had 89 full time employees. Of our full time employees, 32 were engaged in sales and marketing, 36 were engaged in research and development and 21 were engaged in general and administrative. None of our employees is represented by a collective bargaining arrangement, and we believe our relationship with our employees is good.

**Trademarks**

Solagé® is a registered trademark of Barrier Therapeutics, Inc. Zimycan® is a registered European Community Trademark of Barrier Therapeutics, Inc. We are seeking United States trademark registrations for our trademarks Barrier Therapeutics™, Vusion™, Sebazole™, Hyphanox™, Rambazole™ and Hivenyl™. Liarozole, Azoline and Atopik are temporary designations. We are developing commercial names for our Liarozole, Azoline and Atopik product candidates. Shire International Licensing, B.V., owns the Canadian registration of the VANIQA® trademark. All other trademarks or service marks appearing in this Report are the property of their respective companies.

**Available Information**

We maintain a website at *www.barriertherapeutics.com*. General information about us, including our Corporate Governance Guidelines and the charters for the committees of our Board of Directors, can be found on this website. Our Board of Directors has adopted a Code of Conduct, which applies to all employees, officers and directors. This Code of Conduct can also be found on our website. We make available free of charge through the Investor Relations section of our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission. We include our website address in this Annual Report on Form 10-K only as an inactive textural reference and do not intend it to be an active link to our website. The material on our website is not part of our Annual Report on Form 10-K. You may also obtain a free copy of these reports and amendments, as well as our Corporate Governance Guidelines, committee charters and Code of Conduct, by contacting our General Counsel at Barrier Therapeutics, Inc., 600 College Road East, Suite 3200, Princeton, NJ 08540.

## ITEM 1A. RISK FACTORS

### Risks Related to Our Business

#### Risks Related to Our Financial Results and Need for Additional Financing

***We have incurred losses since inception and anticipate that we will continue to incur losses for the foreseeable future.***

Since our inception in September 2001, we have incurred significant operating losses and, as of December 31, 2005, we had an accumulated deficit of $151.4 million. We currently market Vusion and Solagé in the United States and Solagé and VANIQA in Canada. Our product pipeline includes several product candidates in various stages of clinical development. Prior to our acquisition of Solagé in February 2005, we had generated no revenues from the sale of our products. We expect to continue to incur significant operating expenses and anticipate that our expenses may increase substantially in the foreseeable future as we:

- conduct additional clinical trials;
- conduct research and development on existing and new product candidates;
- seek regulatory approvals for our product candidates;
- commercialize our products and product candidates, if approved;
- hire additional clinical, scientific, sales and marketing and management personnel;
- add operational, financial and management information systems; and
- identify and in-license or acquire additional compounds, marketed products or businesses.

We need to generate significant revenue to achieve profitability. We may never generate sufficient sales revenue to achieve and then maintain profitability. We expect to incur operating losses for the foreseeable future.

***We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.***

As of December 31, 2005, we had cash, cash equivalents and marketable securities of $78.1 million. We believe that our existing cash resources and our interest on these funds will be sufficient to meet our projected operating requirements for at least the next twelve months. We currently have no additional commitments or arrangements for any additional financing to fund the commercialization of our marketed products and the research, development and commercial launch of our product candidates. We will require additional funding in order to continue our commercialization efforts and our research and development programs, including preclinical studies and clinical trials of our product candidates, pursue regulatory approvals for our product candidates, pursue the commercial launch of our product candidates, expand our sales and marketing capabilities and for general corporate purposes. Our future capital requirements will depend on many factors, including:

- the success of our commercialization of our marketed products;
- the costs of commercialization activities, including product marketing, sales and distribution and related working capital needs;
- the success of our development of our product candidates;
- the scope and results of our clinical trials;
- advancement of other product candidates into clinical development;
- the timing of, and the costs involved in, obtaining regulatory approvals;
- the costs of manufacturing activities;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property-related costs, including any possible litigation costs;
- our ability to establish and maintain collaborative and other strategic arrangements; and
- potential acquisition or in-licensing of other technologies, products or businesses.

Adequate financing may not be available on terms acceptable to us, if at all. We may continue to seek additional capital through public or private equity offerings, debt financings or collaborative arrangements and licensing agreements.

If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing that we raise or additional equity we may sell may contain terms that are not favorable to us or our common stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it will be necessary to relinquish some rights to our technologies or our product candidates or grant licenses on terms that may not be favorable to us. Lack of funding could adversely affect our ability to pursue our business. For example, if adequate funds are not available, we may be required to curtail significantly or eliminate one or more of our product development programs.

***Our revenues, operating results and cash flows may fluctuate in future periods and we may fail to meet investor expectations, which may cause the price of our common stock to decline.***

Variations in our quarterly operating results are difficult to predict and may fluctuate significantly from period to period. We are a relatively new company and our sales prospects are uncertain. We have only recently launched our Vusion product and we have only owned Solagé since the first quarter of 2005. We cannot predict with certainty the timing of level of sales on these products in the future. If our quarterly sales or operating results fall below expectations of investors or securities analysts, the price of our common stock could decline substantially.

**Risks Related to Development of Product Candidates**

***We will not be able to commercialize our product candidates if our preclinical studies do not produce successful results or if our clinical trials do not demonstrate safety and efficacy in humans.***

We intend to market our products in the United States and in various other countries. As a result, we will need to obtain separate regulatory approvals in most jurisdictions. Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive preclinical studies and clinical trials to demonstrate the safety and efficacy in humans of our product candidates. Preclinical studies and clinical trials are expensive, can take many years and have uncertain outcomes. In addition, the regulatory approval procedures vary among countries and additional testing may be required in some jurisdictions. For example, even if our ongoing European Phase 2/3 clinical trial for Liarozole in congenital ichtyosis is successful, the FDA may require additional clinical trials or other testing prior to accepting for filing, or approving, any application we may submit in the United States for this product candidate.

Our success will depend on the success of our currently ongoing clinical trials and subsequent clinical trials that have not yet begun. It may take several years to complete the clinical trials of a product, and a failure of one or more of our clinical trials can occur at any stage of testing. We believe that the development of each of our product candidates involves significant risks at each stage of testing. If clinical trial difficulties and failures arise, our product candidates may never be approved for sale or become commercially viable. We do not believe that any of our product candidates have alternative uses if our current development activities are unsuccessful.

There are a number of difficulties and risks associated with clinical trials. These difficulties and risks may result in the failure to receive regulatory approval to sell our product candidates or the inability to commercialize any of our product candidates. The possibility exists that:

- we may discover that a product candidate does not exhibit the expected therapeutic results in humans, may cause harmful side effects or have other unexpected characteristics that may delay or preclude regulatory approval or limit commercial use if approved;

- the results from early clinical trials may not be statistically significant or predictive of results that will be obtained from expanded, advanced clinical trials;

- institutional review boards or regulators, including the FDA, may hold, suspend or terminate our clinical research or the clinical trials of our product candidates for various reasons, including noncompliance with regulatory requirements or if, in their opinion, the participating subjects are being exposed to unacceptable health risks;

- subjects may drop out of our clinical trials;

- our preclinical studies or clinical trials may produce negative, inconsistent or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials; and

- the cost of our clinical trials may be greater than we currently anticipate.

For example, in June 2005, we announced that our Hyphanox product candidate failed to reach the primary endpoint in its Phase 3, non-inferiority trial for the treatment of vaginal candidiasis. Consequently, the results of trial were not sufficient to support a filing for regulatory approval for Hyphanox in that indication.

With respect to some of our product candidates, we expect to rely on the results of clinical trials that were performed by or on behalf of Janssen Pharmaceutica Products, L.P. and its affiliates prior to our acquisition of these product candidates. It is possible that these trial results may not be predictive of the results of the clinical trials that we conduct for our product candidates. In addition, the results of these prior clinical trials may not be acceptable to the FDA or similar foreign regulatory authorities because the data may be incomplete, outdated or not otherwise acceptable for inclusion in our submissions for regulatory approval. For example, although our product candidates Ketanserin and Oxatomide are marketed by other companies in some countries outside the United States and Europe, the data used to support the current regulatory approvals for these products do not meet current regulatory guidelines in the United States and Europe. As a

result, we would need to repeat most of the clinical work already completed prior to filing for marketing approval in the United States and Europe for these product candidates.

If we do not receive regulatory approval to sell our product candidates or cannot successfully commercialize our product candidates, we would not be able to grow revenues in future periods, which would result in significant harm to our financial position and adversely impact our stock price.

***If our clinical trials for our product candidates are delayed, we would be unable to commercialize our product candidates on a timely basis, which would materially harm our business.***

Planned clinical trials may not begin on time or may need to be restructured after they have begun. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining an effective investigational new drug application, or IND, or regulatory approval to commence a clinical trial;
- negotiating acceptable clinical trial agreement terms with prospective trial sites;
- obtaining institutional review board approval to conduct a clinical trial at a prospective site;
- recruiting qualified subjects to participate in clinical trials;
- competition in recruiting clinical investigators;
- shortage or lack of availability of supplies of drugs for clinical trials;
- the need to repeat clinical trials as a result of inconclusive results or poorly executed testing;
- the placement of a clinical hold on a study;
- the failure of third parties conducting and overseeing the operations of our clinical trials to perform their contractual or regulatory obligations in a timely fashion; and
- exposure of clinical trial subjects to unexpected and unacceptable health risks or noncompliance with regulatory requirements, which may result in suspension of the trial.

For example, our planned pivotal clinical trials for Hyphanox for the treatment of fingernail onychomycosis were delayed due to the FDA's request that we conduct an additional pharmacokinetic, or PK, study prior to finalizing the design for, and subsequently initiating, those trials. We are currently developing a protocol for a Phase 3 clinical trial to test Hyphanox in the treatment of toenail onychomycosis. If the FDA require us to perform an additional PK study prior to commencing with this trial, or if the trial is otherwise further delayed we may not be able to commercialize this product candidate on a timely basis.

We believe that our product candidates have significant milestones to reach, including the successful completion of clinical trials, before commercialization. If we have significant delays in or termination of clinical trials, our financial results and the commercial prospects for our product candidates or any other products that we may develop will be adversely impacted. In addition, our product development costs would increase and our ability to generate revenue could be impaired.

***If we are wrong in our assessment of the stages of clinical development of our initial product candidates, we may need to perform preclinical studies or clinical trials that we did not anticipate, which would result in additional product development costs for us and delays in filing for regulatory approval for our product candidates.***

We acquired the rights to our initial product candidates from Janssen Pharmaceutica Products, L.P., Johnson & Johnson Consumer Companies, Inc. and Ortho-McNeil Pharmaceutical, Inc., each a Johnson & Johnson company. Prior to this acquisition, they had conducted preclinical studies and clinical trials on several of our product candidates. For our

product candidates for which we are not currently conducting a clinical trial, we have made an assessment as to whether the next clinical trial that we will perform will be a Phase 1, Phase 2 or Phase 3 clinical trial based on the results of these preclinical studies and clinical trials. We may be wrong in our assessment of the stages of clinical development of our initial product candidates for several reasons, including that the data we obtained from the previous trials may be outdated or otherwise no longer acceptable for our purposes or to the FDA or similar regulatory authorities in connection with applications that we may file for regulatory approval. If our current assessments prove to be inaccurate, we will likely have to perform additional preclinical studies or clinical trials, which will require us to expend additional resources and may delay filing for regulatory approval for that product.

## Risks Related to Regulatory Approval of Our Product Candidates

***We may not receive regulatory approvals for our product candidates or approvals may be delayed, either of which could materially harm our business.***

Government authorities in the United States and foreign countries extensively regulate the development, testing, manufacture, distribution, marketing and sale of our product candidates and our ongoing research and development activities. We believe that our product candidates have significant milestones to reach, including the receipt of regulatory approvals, before commercialization.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. According to the FDA, a Phase 1 clinical trial typically takes several months to complete, a Phase 2 clinical trial typically takes several months to two years to complete and a Phase 3 clinical trial typically takes one to four years to complete. Industry sources report that the preparation and submission of new drug applications, or NDAs, which are required for regulatory approval, generally take six months to one year to complete after completion of a pivotal clinical trial. Industry sources also report that approximately 10 to 15% of all NDAs accepted for filing by the FDA are rejected and that FDA approval, if granted, usually takes approximately one year after submission, although it may take longer if additional information is required by the FDA. Accordingly, we cannot assure you that the FDA will approve any NDA that we may file. In addition, the Pharmaceutical Research and Manufacturers of America reports that only one out of five product candidates that enter clinical trials will ultimately be approved by the FDA for commercial sale.

In particular, human therapeutic products are subject to rigorous preclinical studies, clinical trials and other approval procedures of the FDA and similar regulatory authorities in foreign countries. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record keeping, labeling, storage, approval, advertising, promotion, sale and distribution of pharmaceutical products. Securing FDA approval requires the submission of extensive preclinical and clinical data, information about product manufacturing processes and inspection of facilities and supporting information to the FDA for each therapeutic indication to establish the product candidate's safety and efficacy. Varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. For example in May 2005, the FDA issued a not approvable letter for Vusion. Although the FDA ultimately approved our Vusion product in February 2006, the FDA's initial interpretation of our data and resulting not-approvable letter resulted in delay of approximately nine months.

Changes in the FDA approval process during the development period or changes in regulatory review for each submitted product application may also cause delays in the approval or result in rejection of an application. In addition, recent withdrawals of approved products by major pharmaceutical companies may result in a renewed focus on safety at the FDA, which may result in delays in the approval process.

The FDA has substantial discretion in the approval process and may reject our data or disagree with our interpretations of regulations or our clinical trial data or ask for additional information at any time during their review, which could result in one or more of the following:

- delays in our ability to submit an NDA;
- the refusal by the FDA to file any NDA we may submit;

- delays of an approval; or
- the rejection of an application.

For example, the submission of our NDA for Sebazole was delayed until September of 2005 due the time it took us to respond to requests from the FDA for us to obtain six-month data from our long-term safety study. The FDA is now reviewing our NDA submission to determine if the product can be approved. It is possible that the FDA could request additional information prior to issuing an action letter which would result in delays in the approval process. In addition, consistent with applicable regulatory guidelines, we included six-month safety data from our long term safety study in our NDA submission and provided the one year safety data at the four month safety update submitted to the FDA in January 2006. If the FDA determines that the one year data is a substantial addition to the NDA during its review, the FDA could extend its review time.

The FDA may also determine that there is no substantial benefit over the products currently marketed to justify approval. The approval process may take many years to complete and may involve ongoing requirements for post-marketing studies.

Any FDA or other regulatory approval of our product candidates, once obtained, may be withdrawn, including for failure to comply with regulatory requirements or if clinical or manufacturing problems follow initial marketing. If our product candidates are marketed abroad, they will also be subject to extensive regulation by foreign governments.

In addition, any proposed brand name that we intend to use for our product candidates will require approval from the FDA. The FDA typically conducts a rigorous review of proposed product names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims. For example, we changed the brand name of our ointment for the treatment of infants with diaper dermatitis complicated by candidiasis to "Vusion" because the FDA did not approve the name "Zimycan" for use with that product.

Any failure to receive the regulatory approvals necessary to commercialize our product candidates would severely harm our business. The process of obtaining these approvals and the subsequent compliance with appropriate domestic and foreign statutes and regulations require spending substantial time and financial resources. If we fail to obtain or maintain, or encounter delays in obtaining or maintaining, regulatory approvals, it could adversely affect the marketing of any product candidate we develop, our ability to receive product or royalty revenues, and our liquidity and capital resources.

***If we fail to comply with regulatory requirements, regulatory agencies may take action against us, which could significantly harm our business.***

Our marketed products, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for these products, are subject to continual requirements and review by the FDA and other regulatory bodies. With respect to our product candidates being developed, even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

In addition, regulatory authorities subject a marketed product, its manufacturer and the manufacturing facilities to continual review and periodic inspections. We will be subject to ongoing FDA requirements, including required submissions of safety and other post-market information and reports, registration requirements, cGMP regulations, requirements regarding the distribution of samples to physicians and recordkeeping requirements. The cGMP regulations include requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. We rely on the compliance by our contract manufacturers with cGMP regulations and other regulatory requirements relating to the manufacture of products. We are also subject to state laws and registration requirements covering the distribution of our products. Regulatory agencies may change existing requirements or adopt new requirements or policies. We may be slow to adapt or may not be able to adapt to these changes or new requirements. Because many of our products contain ingredients that also are marketed in over-the-counter drug products, there is a risk that the FDA or an outside third party at some point would propose that our products be distributed over-the-counter

rather than by prescription potentially affecting third-party and government reimbursement for our products.

Later discovery of previously unknown problems with our products, manufacturing processes or failure to comply with regulatory requirements, may result in any of the following:

- restrictions on our products or manufacturing processes;
- warning letters;
- withdrawal of the products from the market;
- voluntary or mandatory recall;
- fines;
- suspension or withdrawal of regulatory approvals;
- suspension or termination of any of our ongoing clinical trials;
- refusal to permit the import or export of our products;
- refusal to approve pending applications or supplements to approved applications that we submit;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

***Some of our product candidates are based on new technologies that have not been extensively tested in humans, which may affect our ability or the time we require to obtain necessary regulatory approvals.***

Some of our product candidates are based on new technologies that have not been extensively tested in humans. The regulatory requirements governing these types of products may be less well defined or more rigorous than for conventional products. As a result, we may experience a longer and more expensive regulatory process in connection with obtaining regulatory approvals of these types of product candidates.

This risk is particularly applicable to our Liarozole and Rambazole product candidates, which are based on a novel class of molecules known as retinoic acid metabolism blocking agents, or RAMBAS. Both of these product candidates are currently on clinical hold in the United States. Since 2004, the FDA has become increasingly concerned about the safety profile of a class of drugs known as synthetic retiniods. Although Liarozole and Rambazole are not synthetic retinoids, as RAMBAS, they block the intracellular metabolism of natural retinoic acid in cells, resulting in an increased accumulation of the body's own retinoic acid. Since this accumulation is designed to provide the same therapeutic benefits of synthetic retinoid therapy, it is possible that the FDA may impose a more difficult, time consuming and expensive regulatory path in order to commence and complete the clinical testing of these product candidates as compared to others in our pipeline at the same stage of development.

***If we fail to obtain regulatory approval in foreign jurisdictions, we would not be able to market our products abroad, and the growth of our revenues, if any, would be limited.***

We intend to have our products marketed outside the United States. In order to market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and jurisdictions and can involve additional testing. The time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. The failure to obtain these approvals could materially adversely affect our business, financial condition and results of operations.

For example, our Vusion product candidate, which we intend to market under the name "Zimycan" in Europe, has received marketing approval from the Belgian Health Authorities and has been the subject of a mutual recognition procedure for approval in 14 other countries in Europe. Although, the product has received marketing approval from 8 of those countries, we still must obtain pricing approval prior to launching in those countries. In addition, we are considering amendments to those regulatory filings which, if required, may delay launch in those counties. In the remaining 6 countries, which consist of the larger market countries such as the United Kingdom and Spain, we must re-file our applications for approval in order to satisfy the requirements of those countries for additional clinical data. Although we believe we have the additional data, this request and the need to re-file, has delayed the launch of Vusion in these 6 countries. Also, we may not be able to obtain regulatory approval for our Sebazole product candidate in Europe if the European regulatory authorities require data that could only be obtained by conducting an additional clinical trial, which we currently do not plan to do.

**Risks Related to Commercialization**

***If our products and product candidates for which we receive regulatory approval do not achieve broad market acceptance, the revenues that we generate from their sales will be limited.***

The commercial success of our products and our product candidates for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon the acceptance of these products by physicians, patients and healthcare payors. Safety, efficacy, convenience and cost-effectiveness, particularly as compared to competitive products, are the primary factors that affect market acceptance. Even if a product displays a favorable efficacy and safety profile in clinical trials, market acceptance of the product will not be known until after it is launched. We only recently began actively marketing Solagé in July 2005 and Vusion in February 2006. Our efforts to educate the medical community and third-party healthcare payors on the benefits of Solagé, Vusion or any of our future products may require significant resources and may never be successful.

If our products fail to achieve and maintain market acceptance or if new products or technologies are introduced by others that are more favorably received than our products, or if we are otherwise unable to market and sell our products successfully, our business, financial condition, results of operations and future growth will suffer.

***If we are unable to expand our domestic sales and marketing infrastructure or enter into agreements with third parties to perform these functions in territories outside the United States and Canada, we will not be able to commercialize our product candidates.***

We currently have only limited internal sales, distribution and marketing capabilities. In order to commercialize our products, we must continue to develop and expand our sales, marketing and distribution capabilities.

In the United States and Canada, we are building our own sales force to market our products directly to dermatologists and other target physicians. In addition to hiring our own sales representatives and regional managers, we have entered into an agreement with a contract sales organization to provide us with additional sales representatives and a number of complementary services including sales information systems, fleet management, training and logistics and recruiting support. We may encounter difficulties hiring a sales force in a timely manner or one that is sufficient in size or adequate in expertise. We cannot control, other than by contract, the performance of our contract sales organization. The development and expansion of this sales force and establishing a distribution infrastructure for our domestic operations will require substantial resources.

***If we fail to comply with the laws governing the marketing and sale of our products regulatory agencies may take action against us, which could significantly harm our business.***

As a pharmaceutical company, we are subject to a large body of legal and regulatory requirements. In particular, there are many federal, state and local laws that we need to comply with now that we are engaged in the marketing, promoting, distribution and sale of pharmaceutical products. The FDA extensively regulates, among other things, promotions and advertising of prescription drugs. In addition, the marketing and sale of prescription drugs that are covered under Medicaid, such as Vusion, and Medicare, must comply with the Federal fraud and abuse laws, which are

enforced by the Office of the Inspector General of the Division, or OIG, of the Department of Health and Human Services. These laws make it illegal for anyone to give or receive anything of value in exchange for a referral for a product or service that is paid for, in whole or in part, by any federal health program. The OIG is also responsible for enforcing the Federal False Claims Act which makes it illegal to file, or induce or assist another person in filing, a fraudulent claim for payment to any governmental agency.

Since, as part of our commercialization efforts, we provide physicians with samples of both Vusion and Solagé, we must comply with the Prescription Drug Marketing Act, or PDMA, which governs the distribution of prescription drug samples to healthcare practitioners. Among other things, the PDMA prohibits the sale, purchase or trade of prescription drug samples. It also sets out record keeping and other requirements for distributing samples to licensed healthcare providers.

In addition, we must comply with the body of laws comprised of the Medicaid Rebate Program, the Veterans' Health Care Act of 1992 and the Deficit Reduction Act of 2005. This body of law governs product pricing for government reimbursement and sets forth detailed formulas for how we must calculate the pricing of our products so as to ensure that the federally funded programs will get the best price.

Moreover, many states have enacted laws dealing with fraud and abuse, false claims, the distribution of prescription drug samples and the calculation of best price. These laws typically mirror the federal laws but in some cases, the state laws are more stringent than the federal laws and often differ from state to state, making compliance more difficult. We expect more states to enact similar laws, thus increasing the number and complexity of laws with which we would need to comply.

Compliance with this body of laws is complicated, time consuming and expensive. We are a relatively small company that only recently began selling pharmaceutical products. As such, we have very limited experience in developing and managing, and training our employees regarding, a comprehensive healthcare compliance program. We cannot assure you that we are or will be in compliance with all potentially applicable laws and regulations. Failure to comply with all potentially applicable laws and regulations could lead to penalties such as the imposition of significant fines, debarment from participating in drug development and marketing and the exclusion from government-funded healthcare programs. The imposition of one or more of these penalties could adversely affect our revenues and our ability to conduct our business as planned.

***We rely on third parties to perform many necessary commercial services for our products, including services related to the distribution, storage, and transportation of our products.***

We rely on the Specialty Pharmaceutical Services unit of Cardinal Health PTS, LLC, to perform a variety of functions related to the sale and distribution of Vusion and Solagé and any subsequently approved products in the United States. These services include distribution, logistics management, inventory storage and transportation, invoicing and collections. We rely on McKesson Logistics Solutions for similar functions related to the import, quality testing, sale and distribution of Solagé, VANIQA and any subsequently approved products in Canada. If these third party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines or otherwise do not carry out their contractual duties, our ability to deliver products to meet commercial demand would be significantly impaired.

***We depend on three wholesalers for the vast majority of our product revenues in the United States, and the loss of any of these wholesalers would decrease our revenues.***

The prescription drug wholesaling industry in the United States is highly concentrated, with a vast majority of all sales made by three major full-line companies. Those companies are Cardinal Health, McKesson Corporation and AmerisourceBergen. We expect that a vast majority of our product revenues will be from these three companies. Although we have entered into agreements with each of these companies concerning the terms of their purchase of products from us, none of them is under an obligation to continue to purchase our products. The loss of any of these wholesalers, a material reduction in their purchases or the cancellation of product orders or unexpected returns of unsold products from any one of these wholesalers could decrease our revenues and impede our future growth prospects.

***We may acquire additional products, product candidates and businesses in the future and any difficulties from integrating such acquisitions could damage our ability to attain profitability.***

We have acquired our entire current product pipeline by licensing intellectual property from third parties, and we may acquire additional products or product candidates that complement or augment our existing product development pipeline.

However, because we acquired substantially all of our existing product candidates in the same transaction, we have limited experience integrating products or product candidates into our existing operations. Integrating any newly acquired product or product candidate could be expensive and time-consuming. We may not be able to integrate any acquired product or product candidate successfully. For example, in February 2005, we acquired the United States and Canadian rights to Solagé. Solagé is our first marketed product. As a result, we may have difficulty integrating it with our existing product candidates as we expand our resources dedicated to marketing. In addition, we have no experience with a commercial product and cannot assure you that our marketing efforts will be successful. Moreover, we may need to raise additional funds through public or private debt or equity financing to make these acquisitions, which may result in dilution for stockholders and the incurrence of indebtedness.

We plan to consider, as appropriate, acquisitions of businesses which may subject us to a number of risks that may affect our stock price, operating results and financial condition. If we were to acquire a business in the future, we would need to consolidate and integrate its operations with our business. Integration efforts often take a significant amount of time, place a significant strain on our managerial, operational and financial resources, and could prove to be more difficult and expensive than we predicted. If we fail to realize the expected benefits from acquisitions we may consummate in the future, our business, results of operations and financial condition could be adversely affected.

## Risks Related to Our Dependence on Third Parties for Manufacturing, Research and Development and Marketing and Distribution Activities

***Because we have no manufacturing capabilities, we will contract with third-party contract manufacturers whose performance may be substandard or not in compliance with regulatory requirements, which could increase the risk that we will not have adequate supplies of our product candidates and harm our ability to commercialize our product candidates.***

We do not have any manufacturing experience or facilities. We rely on third-party contract manufacturers to produce the products that we commercialize and use in our clinical trials. If we are unable to retain our current, or engage additional, contract manufacturers, we will not be able to conduct our clinical trials or sell any products for which we receive regulatory approval. The risks associated with our reliance on contract manufacturers include the following:

- Contract manufacturers may encounter difficulties in achieving volume production, quality control and quality assurance and also may experience shortages in qualified personnel. As a result, our contract manufacturers might not be able to meet our clinical development schedules or adequately manufacture our products in commercial quantities when required.

- Changing manufacturers may be difficult because the number of potential manufacturers for some of our product candidates may be limited and, in one case, there is only a single source of supply. Specifically, the intermediate for our product candidate Hyphanox is manufactured using a process that is proprietary to our contract manufacturer. We do not have a license to the technology used by our contract manufacturer to make the intermediate needed for the Hyphanox tablets. If this manufacturer cannot provide adequate supplies of the intermediate for Hyphanox, we cannot sublicense this technology to a third party to act as our supplier. As a result, it may be difficult or impossible for us to find a qualified replacement manufacturer quickly or on terms acceptable to us, the FDA and corresponding foreign regulatory agencies, or at all.

- Each or our marketed products and, with the exception of Hyphanox, each of our later stage product candidates, could be produced by multiple manufacturers. However, if we need to change manufacturers, the FDA and corresponding foreign regulatory agencies must approve these manufacturers in advance. This would involve testing and pre-approval inspections to ensure compliance with FDA and foreign regulations and standards.

- Our contract manufacturers are subject to ongoing periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with current Good Manufacturing Practices, or cGMPs, and other governmental regulations and corresponding foreign standards. Other than through contract, we do not have control over compliance by our contract manufacturers with these regulations and standards. Our present or future contract manufacturers may not be able to comply with cGMPs and other FDA requirements or similar regulatory requirements outside the United States. Failure of our contract manufacturers or

us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

- Our contract manufacturers may breach our manufacturing agreements because of factors beyond our control or may terminate or fail to renew a manufacturing agreement based on their own business priorities at a time that is costly or inconvenient for us.

We may compete with other drug developers for access to manufacturing facilities for our products and product candidates. If we are not able to obtain adequate supplies of our products we may not be able to distribute our products as planned which could adversely affect our revenues. If we are not able to obtain adequate supplies of our product candidates, it will be more difficult for us to develop our product candidates. Dependence upon third parties for the manufacture of our product candidates may reduce our profit margins, if any, and may limit our ability to develop and deliver products on a timely and competitive basis.

***We rely on a single source supplier for the manufacture of our marketed products and the active ingredients contained in those products and the loss of these suppliers could disrupt our business.***

Although each of our marketed products and the active ingredients in those products can be produced by multiple manufacturers, we predominately rely on a single source of supply for those products and active ingredients. If any of these manufacturers, or any manufacturer of any other ingredient or component contained in our marketed products or their packaging, were to become unable or unwilling to continue to provide us with these products or ingredients, we may need to obtain an alternate supplier. The process of changing or adding a manufacturer includes qualification activities and may require approval from the FDA and corresponding foreign regulatory agencies, and can be time consuming and expensive. If we are not able to manage this process efficiently or if an unforeseen event occurs, we could face supply disruptions that would result in significant costs and delays, undermine goodwill established with physicians and patients, damage the commercial prospects for our products and adversely affect our operating results.

***If third parties on whom we rely do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize our products and product candidates.***

We depend on independent clinical investigators and contract research organizations to conduct our clinical trials. Contract research organizations also assist us in the collection and analysis of trial data. We also depend on third parties to perform services related to our sales force and adverse event reporting requirements. The investigators, contract research organizations, and other contractors are not our employees, and we cannot control, other than by contract, the amount of resources, including time, that they devote to our product candidates. However, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial that have been approved by regulatory agencies and for ensuring that we report product-related adverse events in accordance with applicable regulations. Furthermore, the FDA and European regulatory authorities require us to comply with standards, commonly referred to as good clinical practice, for conducting, recording and reporting clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected.

In connection with our reliance on our independent clinical investigators and contract research organizations, our clinical trials may be extended, delayed, suspended or terminated, including as a result of:

- the failure of these investigators and research organizations to comply with good clinical practice or to meet their contractual duties;

- the failure of our independent investigators to devote sufficient resources to the development of our product candidates or to perform their responsibilities at a sufficiently high level;

- our need to replace these third parties for any reason, including for performance reasons or if these third parties go out of business; or

- the existence of problems in the quality or accuracy of the data they obtain due to the failure to adhere to clinical

protocols or regulatory requirements or for other reasons.

Extensions, delays, suspensions or terminations of our clinical trials as a result of the performance of our independent clinical investigators and contract research organizations will delay, and make more costly, regulatory approval for any product candidates that we may develop.

In addition, although we have used a number of contract research organizations to conduct our clinical trials, there are many other qualified contract research organizations available. Any change in a contract research organization during an ongoing clinical trial could seriously delay that trial and potentially compromise the results of the trial.

***We are dependent upon distribution arrangements and marketing alliances to commercialize our product candidates outside the United States and Canada. These distribution arrangements and marketing alliances place the marketing and sale of our product candidates in these regions outside our control.***

We have entered into distribution arrangements and marketing alliances relating to the commercialization of some of our product candidates. Dependence on these arrangements and alliances subjects us to a number of risks, including:

- we may not be able to control the amount and timing of resources that our distributors may devote to the commercialization of our product candidates;
- our distributors may experience financial difficulties;
- our distributors may determine not to launch our product candidates in countries where the distributor determines that commercialization of a particular product candidate is not feasible or is economically unreasonable due to government pricing controls or other market conditions existing in a particular country;
- business combinations or significant changes in a distributor's business strategy may also adversely affect a distributor's willingness or ability to complete its obligations under any arrangement; and
- these arrangements are often terminated or allowed to expire, which could interrupt the marketing and sales of a product and decrease our revenue.

We may not be successful in entering into additional distribution arrangements and marketing alliances with third parties for our earlier stage products. Our failure to enter into these arrangements on favorable terms could delay or impair our ability to commercialize our product candidates outside the United States and Canada and could increase our costs of commercialization. In addition, we may be at a competitive disadvantage in negotiating these agreements with third parties because under our license agreements, Johnson & Johnson, through any of its affiliates, has a right of first negotiation for the commercialization of our product candidates that are based on the licensed intellectual property. Because this first right of negotiation may only be triggered after Phase 2 clinical trials and could extend for up to 180 days, it may hinder our ability to enter into distribution agreements and marketing alliances. It may also delay our receipt of any milestone payments or reimbursement of development costs.

## Risks Related to Intellectual Property

***There are limitations on our patent rights relating to our products and product candidates that may affect our ability to exclude third parties from competing against us.***

The patent rights that we own or have licensed relating to our products and product candidates are limited in ways that may affect our ability to exclude third parties from competing against us. In particular:

- We do not hold composition of matter patents covering the active pharmaceutical ingredients of Vusion, Solagé, or our Sebazole and Hyphonox product candidates. Composition of matter patents on active pharmaceutical ingredients are the strongest form of intellectual property protection for pharmaceutical products as they apply without regard to any method of use or other type of limitation. The active ingredients for Solagé, Vusion, Sebazole and Hyphanox are off patent. As a result, competitors who obtain the requisite regulatory approval can offer products with the same active ingredients as our products so long as the competitors do not infringe any method of

use or formulation patents that we may hold. The United States patent covering the active ingredient in Liarozole expires in 2006.

- We do not hold composition of matter patents covering the formulations of some of our later stage product candidates. Composition of matter patents on formulations can provide protection for pharmaceutical products to the extent that the specifically covered formulations are important. For our product candidates for which we do not hold composition of matter patents covering the formulation, competitors who obtain the requisite regulatory approval can offer products with the same formulations as our products so long as the competitors do not infringe any active pharmaceutical ingredient or method of use patents that we may hold. The United States patent covering the formulation of miconazole nitrate and zinc oxide in Vusion expires in 2007. The United States patent covering the composition of Solagé expires in 2013.

- For some of our product candidates, the principal patent protection that covers, or that we expect will cover, our product candidate is a method of use patent. This type of patent only protects the product when used or sold for the specified method. However, this type of patent does not limit a competitor from making and marketing a product that is identical to our product for an indication that is outside of the patented method. Moreover, physicians may prescribe such a competitive identical product for off-label indications that are covered by the applicable patents. Although such off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

- Our patent licenses from Janssen Pharmaceutica Products, L.P., Johnson & Johnson Consumer Companies, Inc. and Ortho-McNeil Pharmaceutical, Inc. are limited to the field of dermatology. As a result, with some exceptions, Johnson & Johnson, its affiliates or its licensees could manufacture and market products similar to our products outside of this field. This also could result in off-label use of these competitive products for dermatological indications.

These limitations on our patent rights may result in competitors taking product sales away from us, which would reduce our revenues and harm our business.

***If we fail to comply with our obligations in the agreements under which we license development or commercialization rights to products or technology from third parties, we could lose license rights that are important to our business.***

All of our current product candidates in clinical development are based on intellectual property that we have licensed from Janssen Pharmaceutica Products, L.P., Johnson & Johnson Consumer Companies, Inc. and Ortho-McNeil Pharmaceutical, Inc. We depend, and will continue to depend, on these license agreements. The terms of these licenses are set out in two license agreements. These license agreements may be terminated on a product-by-product basis, if, by dates specified in the license agreements, we are not conducting active clinical development of the particular product or if we do not obtain regulatory approval for that product. Either of the license agreements may also be terminated if we breach that license agreement and do not cure the breach within 90 days or in the event of our bankruptcy or liquidation.

Disputes may arise with respect to our licensing agreements regarding manufacturing, development and commercialization of any products relating to this intellectual property. These disputes could lead to delays in or termination of the development, manufacture and commercialization of our product candidates or to litigation.

***Various aspects of our Johnson & Johnson license agreements may adversely affect our business.***

Under our principal license agreements, neither Johnson & Johnson nor any of its affiliates is restricted from developing or acquiring products that may address similar indications as our products or otherwise compete with our products. We have the sole right to commercialize any product candidate based on intellectual property licensed to us under these agreements that we elect to commercialize ourselves or with the assistance of a contract sales organization. In other circumstances, however, Johnson & Johnson and any of its affiliates has a right of first negotiation for the commercialization of our product candidates based on such intellectual property. The rights of first negotiation for the commercialization of our product candidates can be exercised on a territory-by-territory basis. This negotiation may extend for up to 180 days, which may delay our commercialization efforts or hinder our ability to enter into distribution agreements.

The license agreements also permit each of Janssen Pharmaceutica Products, L.P., Johnson & Johnson Consumer Companies, Inc. and Ortho-McNeil Pharmaceutical, Inc., to abandon its maintenance of any patents or the prosecution of any patent applications included in the licensed intellectual property for any reason. If any of these companies abandon these activities, we have the option to undertake their maintenance and prosecution if we decide to prevent their abandonment. To date, we have assumed the maintenance and prosecution for all of the patents and patent applications relating to our Sebazole and Vusion product candidates. If we are required to undertake these activities for any additional product candidates, our operating costs will increase.

In addition, our license agreements limit our use of our product candidates to the specific field of dermatology as defined in the license agreements. As so defined, dermatology consists of applications for the treatment or prevention of diseases of human skin, hair, nails and oral and genital mucosa, but excludes treatments for skin cancer. We have not been granted the right to sell Oxatomide in Japan, Italy, Mexico and much of Central America or to sell Ketanserin in Mexico, Central America and the Caribbean. Our right to sell the following products in the following countries is semi-exclusive with the Johnson & Johnson companies:

- Vusion in Argentina, Australia, Belgium, Denmark, Germany, Indonesia, Luxembourg, Mexico, New Zealand, Peru and Venezuela; and

- Ketanserin in South America.

This field of use and geographic restrictions limit our ability to market our products worldwide and, therefore, limit the potential market size for our products.

***If we are unable to obtain and maintain patent protection for our intellectual property, our competitors could develop and market products similar or identical to ours, which may reduce demand for our product candidates.***

Our success will depend in part on our ability to obtain and maintain patent protection for our proprietary technologies and product candidates and our ability to prevent third parties from infringing our proprietary rights. The patent situation in the field of biotechnology and pharmaceuticals generally is highly uncertain and involves complex legal and scientific questions. We may not be able to obtain additional issued patents relating to our technology or products. Even if issued, patents may be challenged, narrowed, invalidated, or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection we may have for our products. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

Because of the substantial length of time and expense associated with bringing new products through the development and regulatory approval processes in order to reach the marketplace, the pharmaceutical industry places considerable importance on patent protection for new technologies, products and processes. Accordingly, we expect to seek patent protection for our new proprietary technologies and some of our product candidates. The risk exists, however, that new patents may be unobtainable and that the breadth of the claims in a patent, if obtained, may not provide adequate protection for our proprietary technologies or product candidates.

Although we own or otherwise have rights to a number of patents, these patents may not effectively exclude competitors, the issuance of a patent is not conclusive as to its validity or enforceability and third parties may challenge the validity or enforceability of our patents. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our issued United States patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in the foreign patents or patent applications. It is possible that a competitor may successfully challenge our patents or that challenges will result in the elimination or narrowing of patent claims and, therefore, reduce our patent protection.

Moreover, competitors may infringe our patents or successfully avoid them through design innovation. To prevent infringement or unauthorized use, we may need to file infringement lawsuits, which are expensive and time-consuming. In particular, if a competitor were to file a paragraph IV certification under the United States Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, in connection with that competitor's submission

to the FDA of an abbreviated new drug application, or ANDA, for approval of a generic version of any of our products for which we believed we held a valid patent, then we would have 45 days in which to initiate a patent infringement lawsuit against such competitor. In any infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, may narrow our patent claims or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. If a court so found that one of our patents was invalid or not infringed in an infringement suit under paragraph IV of the Hatch-Waxman Act, then the FDA would be permitted to approve the competitor's ANDA resulting in a competitive generic product.

In addition, because of the size of our patent portfolio, we may not be able to prevent infringement or unauthorized use of all of our patents due to the associated expense and time commitment of monitoring these activities. Interference proceedings brought in the United States Patent and Trademark Office may be necessary to determine whether our patent applications or those of our collaborators are entitled to priority of invention relative to third parties. Litigation, interference or opposition proceedings may result in adverse rulings and, even if successful, may result in substantial costs and be a distraction to our management. We may not be able to prevent misappropriation of our respective proprietary rights, particularly in countries where the laws may not protect our rights as fully as in the United States.

***If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology may be adversely affected.***

In addition to patent protection, we rely upon trade secrets relating to unpatented know-how and technological innovations to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees, consultants and other third parties. We also have confidentiality and invention or patent assignment agreements with our employees and our consultants. If our employees, consultants or other third parties breach these agreements, we may not have adequate remedies for any of these breaches. In addition, our trade secrets may otherwise become known to or be independently developed by our competitors.

***If the development of our product candidates infringes the intellectual property of our competitors or other third parties, we may be required to pay license fees or cease our development activities and pay damages, which could significantly harm our business.***

Even if we have our own patents which protect our products and our product candidates they may nonetheless infringe the patents or violate the proprietary rights of third parties. In these cases, we may be required to obtain licenses to patents or proprietary rights of others in order to continue to develop and commercialize our product candidates. We may not, however, be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all. Even if we were able to obtain rights to a third party's intellectual property, these rights may be non-exclusive, thereby giving our competitors potential access to the same intellectual property.

Third parties may assert patent or other intellectual property infringement claims against us, or our collaborators, with respect to technologies used in potential product candidates. Any claims that might be brought against us relating to infringement of patents may cause us to incur significant expenses and, if successfully asserted against us, may cause us to pay substantial damages. Even if we were to prevail, any litigation could be costly and time-consuming and could divert the attention of our management and key personnel from our business operations. In addition, any patent claims brought against our collaborators could affect their ability to carry out their obligations to us.

Furthermore, as a result of a patent infringement suit brought against us, or our collaborators, the development, manufacture or potential sale of product candidates claimed to infringe a third party's intellectual property may have to be stopped or be delayed. Ultimately, we may be unable to commercialize some of our product candidates or may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business.

## Risks Related to Employees and Growth

***If we are not able to retain our current senior management team or attract and retain qualified scientific, technical and business personnel, our business will suffer.***

We are dependent on the members of our senior management team, in particular, our Chief Executive Officer, Dr. Geert Cauwenbergh, our Chief Research and Development Officer, Charles Nomides and our Chief Operating Officer, Alfred Altomari, for our business success. Dr. Cauwenbergh and Mr. Nomides have a long history and association with our current product candidates and intellectual property. Our employment agreements with these and our other executive officers are terminable on short notice or no notice. The loss of any one of these individuals would result in a significant loss in the knowledge and experience that we, as an organization, possess and could cause significant delays, or outright failure, in the development and approval of our product candidates. We do not carry key man life insurance on the lives of any of our personnel.

In addition, competition for qualified scientific, technical, and business personnel is intense in the pharmaceutical industry. If we are unable to hire and retain qualified personnel, our business will suffer.

***We will need to hire additional employees as we grow. Any inability to manage future growth could harm our ability to commercialize our product candidates, increase our costs and adversely impact our ability to compete effectively.***

Our growth will require us to hire a significant number of qualified scientific, commercial and administrative personnel. There is intense competition for human resources, including management in the technical fields in which we operate, and we may not be able to attract and retain qualified personnel necessary for the successful development and commercialization of our product candidates. The inability to attract new employees when needed and retain existing employees as we grow could severely harm our business.

Future growth will impose significant added responsibilities on members of our management, including the need to identify, recruit, retain and integrate additional employees. Our future financial performance and our ability to commercialize our product candidates and compete effectively will depend, in part, on our ability to manage any future growth effectively.

## Risk Related to Our Industry

***If third-party payors do not reimburse customers for any of our products candidates, they might not be used or purchased, and our revenues and profits will not develop or grow.***

Our revenues and profits depend heavily upon the availability of reimbursement for the use of our products from third-party health care and government payors, both in the United States and in foreign markets. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Since reimbursement approval for a product is required from each third-party and government payor individually, seeking this approval is a time-consuming and costly process. Third-party payors may require cost-benefit analysis data from us in order to demonstrate the cost-effectiveness of any product we might bring to market. We may not be able to provide data sufficient to gain acceptance with respect to reimbursement. There also exists substantial uncertainty concerning third-party reimbursement for the use of any drug product incorporating new technology. In addition, as a result of actions by these third-party payors, the health care industry is experiencing a trend toward containing or reducing costs through various means, including lowering reimbursement rates, limiting therapeutic class coverage and negotiating reduced payment schedules with service providers for drug products.

***New federal legislation will increase the pressure to reduce the price of pharmaceutical products paid for by Medicare, which will adversely affect our revenues.***

The Medicare Prescription Drug Improvement and Modernization Act of 2003 reforms the way Medicare will cover and reimburse for pharmaceutical products. The legislation expands Medicare coverage for drug purchases by the elderly and eventually will introduce a new reimbursement methodology based on average sales prices for drugs. In addition, the new legislation provides authority for limiting the number of drugs that will be covered in any therapeutic class. As a result of the new legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These costs initiatives and other provisions of this legislation could decrease the coverage and price that we receive for our products and could seriously harm our business.

***Foreign governments tend to impose strict price controls, which may adversely affect our revenues.***

In some foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to twelve months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels our business could be materially harmed. The risk of being unable to obtain pricing at a satisfactory level is greater for products for which the active ingredient is generically available such as our Vusion, Sebazole and Hyphanox product candidates.

For example, although our Vusion product candidate, which we intend to market under the name "Zimycan" in Europe, has received marketing approval from the Belgian Health Authorities and 8 other countries in Europe, our distributor has not launched that product in any of those countries, primarily due to the need to obtain pricing approval. This product might not be launched in any country in which we are not able to obtain pricing approval at a satisfactory level.

***We face potential product liability exposure, and, if successful claims are brought against us, we may incur substantial liability for a product and may have to limit its commercialization.***

The use of our product candidates in clinical trials and the sale of products may expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling our products. If we cannot successfully defend ourselves against these claims, we may incur substantial losses or expenses, be required to limit the commercialization of our product candidates and face adverse publicity. We have product liability insurance coverage with a $15 million annual aggregate coverage limit, and our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash.

***If our competitors develop and market products faster than we do or if the products of our competitors are considered more desirable than ours, revenues for any of our products and product candidates that are approved for marketing will not develop or grow.***

The pharmaceutical industry, and the dermatology segment in particular, is highly competitive and includes a number of established, large and mid-sized pharmaceutical companies, as well as smaller emerging companies, whose activities are directly focused on our target markets and areas of expertise. We face and will continue to face competition in the discovery, in-licensing, development and commercialization of our product candidates, which could severely impact our ability to generate revenue or achieve significant market acceptance of our product candidates. Furthermore, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical industry at a rapid pace. These developments may render our product candidates or technologies obsolete or noncompetitive.

Compared to us, many of our competitors and potential competitors have substantially greater:

- capital resources;
- research and development resources, including personnel and technology;
- regulatory experience;
- preclinical study and clinical trial experience; and
- manufacturing, distribution and sales and marketing experience.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than us. Our competitors may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates or technologies. Our competitors may also develop drugs that are more effective, useful and less costly than ours and may also be more successful than us in manufacturing and marketing their products.

Our Vusion product faces competition in the treatment of diaper dermatitis complicated by candidiasis, from ointments and creams containing nystatin, Mycolog II from Bristol-Myers Squibb Company, clotrimazole containing creams from Bayer AG and from generic manufacturers and topical miconazole creams.

Our Solagé product faces competition in the treatment of solar lentigenes from Triluma from Galderma S.A., Avage from Allergan, Inc., EpiQuin Micro from SkinMedica, Inc. and other prescription 4% hydroquinone formulations as well as over-the-counter 2% hydroquinone products, Retin-A from Neutrogena and other tretinoin containing topical formulations.

If approved, each of our product candidates will compete for a share of the existing market with numerous products that have become standard treatments recommended or prescribed by physicians. For example, we believe the primary competition for our product candidates are:

- For Sebazole, in the treatment of seborrheic dermatitis, Nizoral from Janssen, ketoconazole creams from generic manufacturers, Desowen from Galderma S.A. and Loprox from Medicis Pharmaceutical Corporation and the generic equivalents of each.
- For Hyphanox, in the treatment of onychomycosis, Sporanox from Janssen and generic manufacturers, Lamisil from Novartis AG and Penlac from Dermik Laboratories.
- For Liarozole, in the treatment of congenital ichthyosis, Soriatane from Hoffmann-La Roche Inc. and Connetics and over-the-counter topical moisturizers and emollients.
- For oral Rambazole, in the treatment of acne, Accutane from Hoffman-La Roche and generic manufacturers. For oral Rambazole, in the treatment of psoriasis, Soriatane from Hoffman-La Roche and Connetics, biologic agents such as Amevive from Biogen Idec Inc. and Raptiva from Genentech, Inc. and methotrexate from generic manufacturers.

We also believe that many of the competitive products for other product candidates will similarly compete with our earlier stage product candidates because of the indications for which we are developing these product candidates.

## Risks Related to Our Common Stock

***Our stock price is volatile, and the market price of our common stock may drop below the price you pay.***

Market prices for securities of biopharmaceutical and specialty pharmaceutical companies have been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- results of our clinical trials or those of our competitors;
- the regulatory status of our product candidates;
- failure of any of our product to achieve commercial success;
- developments concerning our competitors and their products;
- success of competitive products and technologies;
- regulatory developments in the United States and foreign countries;
- developments or disputes concerning our patents or other proprietary rights;
- our ability to manufacture any products to commercial standards;
- public concern over our drugs;
- litigation involving our company or our general industry or both;
- future sales of our common stock;
- changes in the structure of health care payment systems, including developments in price control legislation;
- departure of key personnel;
- period-to-period fluctuations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates of our financial results or recommendations by securities analysts;
- investors' general perception of us; and
- general economic, industry and market conditions.

If any of these risks occurs, it could cause our stock price to fall and may expose us to class action lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management. For example, in October 2005, a purported class action lawsuit was filed in the United States District Court for the District of New Jersey against the Company and certain of its officers on behalf of all persons who purchased or acquired securities of Barrier Therapeutics, Inc. between April 29, 2004 and June 29, 2005. At least four additional purported class action lawsuits have also been filed against the Company and certain of its officers, all pleading essentially the same allegations. The complaints filed allege violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, and under Sections 11, 12 and 15 of the Securities Exchange Act of 1933.

***Provisions in our certificate of incorporation and bylaws and under Delaware law may prevent or frustrate a change in control or a change in management that stockholders believe is desirable.***

Provisions of our certificate of incorporation and bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. These provisions include:

- a classified board of directors;
- limitations on the removal of directors;

- advance notice requirements for stockholder proposals and nominations;
- the inability of stockholders to act by written consent or to call special meetings; and
- the ability of our board of directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could be used to institute a rights plan, or a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors.

The affirmative vote of the holders of at least two-thirds of our shares of capital stock entitled to vote is necessary to amend or repeal the above provisions of our certificate of incorporation. In addition, absent approval of our board of directors, our bylaws may only be amended or repealed by the affirmative vote of the holders of at least two-thirds of our shares of capital stock entitled to vote.

In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns or within the last three years has owned 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Section 203 may discourage, delay or prevent a change in control of our company.

## ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

## ITEM 2. PROPERTIES

We lease approximately 20,300 square feet of administrative offices at our corporate headquarters, which is located in Princeton, New Jersey. We also lease approximately 10,600 square feet of administrative offices in Geel, Belgium. Our Princeton, New Jersey lease expires in 2010 if not renewed by September 30, 2010, and our lease in Belgium is short-term and renewable. We believe that our current facilities are adequate for our present purposes.

## ITEM 3. LEGAL PROCEEDINGS

In October 2005, a purported class action lawsuit was filed in the United States District Court for the District of New Jersey against the Company and certain of its officers on behalf of all persons who purchased or acquired securities of Barrier Therapeutics, Inc. between April 29, 2004 and June 29, 2005. At least four additional putative class action lawsuits have also been filed against the Company and certain of its officers, all pleading essentially the same allegations. In an Order entered on December 19, 2005, the Court consolidated these cases. By Order dated March 2, 2006, the Court appointed lead plaintiffs and approved co-lead counsel. The complaints filed allege violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, and under Sections 11, 12 and 15 of the Securities Exchange Act of 1933. Based on a preliminary review and analysis of the complaints, the Company believes that each of the lawsuits is without merit and intends to defend each of these lawsuits vigorously. The Company is not presently able to estimate the potential losses, if any, related to these lawsuits.

## ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

We did not submit any matters to the vote of security holders during the fourth quarter of fiscal 2005.

## OUR EXECUTIVE OFFICERS

The following table identifies our current executive officers:

| Name | Age | Position |
|---|---|---|
| Geert Cauwenbergh, Ph.D | 52 | Chairman of the Board, Chief Executive Officer and Director |
| Alfred Altomari | 47 | Chief Operating Officer |
| Albert C. Bristow | 36 | General Counsel and Secretary |
| Charles T. Nomides | 49 | Chief Research and Development Officer |
| Anne M. VanLent | 57 | Executive Vice President, Chief Financial Officer and Treasurer |

*Geert Cauwenbergh, Ph.D.* is the founder of our company and has been our Chairman of the Board and Chief Executive Officer since our inception in September 2001. Prior to joining us, Dr. Cauwenbergh was at Johnson & Johnson Consumer and Personal Care Products Companies from 2000 to 2002 where he served in various capacities, most recently as Vice President of Technology. From 1994 to 2000, Dr. Cauwenbergh was at Johnson & Johnson Consumer Companies Worldwide where he served in various capacities, most recently as Vice President of Research & Development. He received his Ph.D. in Medical Sciences from the Catholic University of Leuven, Faculty of Medicine, Belgium where he also completed his Masters and undergraduate work.

*Alfred Altomari* was appointed Chief Operating Officer in February 2006. From August 2003 until February 2006, Mr. Altomari served as our Chief Commercial Officer. Prior to joining us, Mr. Altomari was at affiliates of Johnson & Johnson from 1982 to 2003 where he most recently served as General Manager of the Ortho Neutrogena prescription drug development group. Mr. Altomari also serves as a director of Auxilium Pharmaceuticals, Inc. and Agile Therapeutics, Inc. Mr. Altomari received a bachelor's degree in Science with a dual major in finance and accounting from Drexel University and received his M.B.A. from Rider University.

*Albert C. Bristow* has been our General Counsel since October 2003. Mr. Bristow was an attorney with Morgan, Lewis & Bockius LLP, Princeton, New Jersey, from January 2000 until joining us, and an attorney with Archer & Greiner, P.C., Haddonfield, New Jersey, from September 1995 until January 2000. Mr. Bristow received a bachelor's degree in the Arts from Lafayette College and a J.D. from the University of Pennsylvania.

*Charles T. Nomides* was appointed Chief Research and Development Officer in February 2006. From July 2002 until February 2006, Mr. Nomides served as our Chief Operating Officer. Prior to joining us, Mr. Nomides was at Johnson & Johnson Consumer Products Worldwide from 1997 to 2002 where he most recently served as Director of Research and Development in charge of the Ortho Neutrogena prescription drug development group. Mr. Nomides received a bachelor's degree in Biology from Clarion State University and received graduate training from Temple University and The Milton S. Hershey Medical Center.

*Anne M. VanLent* has been our Executive Vice President, Chief Financial Officer and Treasurer since May 2002. Prior to joining us, Ms. VanLent served as a principal of the Technology Compass Group, LLC, a healthcare/technology consulting firm, since she founded it in October 2001. From July 1997 to October 2001, she was the Executive Vice President—Portfolio Management for Sarnoff Corporation, a multidisciplinary research and development firm. Ms. VanLent also currently serves as a director of Penwest Pharmaceuticals Co. and Integra Lifesciences Holdings Corp. She received a bachelor's degree in Physics from Mount Holyoke College and did graduate work in biophysics.

## PART II

## ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our Common Stock is quoted on the NASDAQ National Market under the symbol "BTRX." We began trading on the NASDAQ National Market on April 29, 2004. The following table sets forth the range of high and low sale prices for the common stock as reported on the NASDAQ National Market for the periods indicated below.

| | High | Low |
|---|---|---|
| **2005** | | |
| First Quarter | $22.40 | $13.45 |
| Second Quarter | $19.22 | $7.85 |
| Third Quarter | $10.12 | $7.50 |
| Fourth Quarter | $8.70 | $6.66 |
| **2004** | | |
| Second Quarter (commencing April 29, 2004) | $15.75 | $10.86 |
| Third Quarter | $15.00 | $8.50 |
| Fourth Quarter | $18.11 | $11.70 |

As of March 10, 2006, there were 29 holders of record of our Common Stock. On March 10, 2006, the last reported sale price of our common stock as reported on the NASDAQ National Market was $9.26 per share.

We have not paid any dividends on our common stock since our inception and do not anticipate paying any dividends on our Common Stock in the foreseeable future.

## ITEM 6. SELECTED FINANCIAL DATA

The selected consolidated financial data presented below for, and as of the end of, each of our last four fiscal years has been derived from and is qualified by reference to our consolidated financial statements. Our consolidated financial statements for the fiscal years ended December 31, 2005, 2004, 2003, 2002, and for the period beginning on our inception and ending on December 31, 2001, have been audited by Ernst & Young LLP, independent registered public accounting firm.

This information should be read in conjunction with our consolidated financial statements and the related notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" which is Item 7 of Part II of this annual report on Form 10-K.

We have not paid any cash dividends on our shares of Common Stock during the periods presented.

| | Year Ended December 31, | | | | Period From September 17, 2001 (inception) to December 31, |
|---|---|---|---|---|---|
| | 2005 | 2004 | 2003 | 2002 | 2001 |
| | (in thousands, except share and per share data) | | | | |
| **Consolidated Statement of Operations Data:** | | | | | |
| Revenues: | | | | | |
| Net product revenue | $ 792 | $ — | $ — | $ — | $ — |
| Other revenue | 1,748 | 897 | 367 | — | — |
| Total revenues | 2,540 | 897 | 367 | — | — |
| Operating expenses: | | | | | |
| Cost of product revenues | 544 | — | — | — | — |
| Research and development | 30,369 | 30,904 | 17,485 | 3,542 | — |
| Selling, general and administrative | 20,280 | 11,475 | 3,730 | 1,532 | 20 |
| In-process research and development | — | — | — | 25,000 | — |
| Total operating expenses | 51,193 | 42,379 | 21,215 | 30,074 | 20 |
| Loss from operations | (48,653) | (41,482) | (20,848) | (30,074) | (20) |
| Interest income | 2,929 | 1,408 | 419 | 275 | — |
| Interest expense | (53) | (36) | (3) | (5) | (1) |
| Loss before income tax benefit | (45,777) | (40,110) | (20,432) | (29,804) | (21) |
| Income tax benefit | 536 | 367 | 217 | — | — |
| Net loss | (45,241) | (39,743) | (20,215) | (29,804) | (21) |
| Preferred stock accretion | — | (4,592) | (8,432) | (3,392) | — |
| Net loss attributable to common stockholders | $ (45,241) | $ (44,335) | $ (28,647) | $ (33,196) | $ (21) |
| Basic and diluted net loss per share | $ (1.91) | $ (3.02) | $ (83.95) | $ (240.75) | — |
| Weighted average shares used in computing basic and diluted net loss per share | 23,656,306 | 14,677,710 | 341,256 | 137,889 | — |

| | December 31, | | | | |
|---|---|---|---|---|---|
| | 2005 | 2004 | 2003 | 2002 | 2001 |
| **Consolidated Balance Sheet Data:** | (in thousands) | | | | |
| Cash, cash equivalents and marketable securities | $ 78,120 | $ 89,081 | $ 53,776 | $ 18,144 | $ 89 |
| Working capital | 72,785 | 82,846 | 51,682 | 17,475 | 62 |
| Total assets | 84,961 | 92,784 | 56,971 | 19,296 | 107 |
| Long-term notes payable | 405 | 443 | 193 | — | — |
| Accumulated deficit | (151,441) | (106,200) | (61,865) | (33,217) | (21) |
| Total stockholders' equity (deficit) | 76,266 | 83,570 | (61,534) | (33,198) | (20) |

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes appearing at the end of this Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" in Item 1A of Part I of this Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

### Overview

We are a pharmaceutical company focused on the discovery, development and commercialization of pharmaceutical products in the field of dermatology. Our strategy is to develop a portfolio of innovative products that address major medical needs in the treatment of dermatological diseases and disorders.

We currently market two pharmaceutical products in the United States, Vusion (0.25% miconazole nitrate, 15% zinc oxide, and 81.35% white petrolatum) Ointment and Solagé (mequinol 2.0% and tretinoin 0.01%) Topical Solution. We also market our Solagé product in Canada, along with VANIQA (elflornithine HCI) Cream 13.9%, for which we are the exclusive distributor in Canada. In the United States, we promote our marketed products through a sales force consisting of our own sales representatives and those of a contract sales organization. In 2006, we plan on increasing our sales and marketing expenses significantly, including expenses related to a planned increase from 21 to 60 U.S. sales representatives and the launch of Vusion. We have one New Drug Application under review by the FDA for our Sebazole product candidate. We have six other product candidates in Phases 2 and 3 clinical development for the treatment of a range of dermatological conditions, including acne, psoriasis, congenital ichthyosis, onychomycosis and fungal infections. In addition, we have access to the classes of compounds claimed in the patents licensed to us under our license agreements with affiliates of Johnson & Johnson. We are currently conducting a screening program to search for new product candidates in the field of dermatology.

In 2005, we recognized product revenues of $792,000 for our sales of Solagé in the United States and Canada and sales of VANIQA in Canada. We expect product revenues to increase in 2006, primarily due to the launch of Vusion early in the second quarter and anticipated growth in sales of Solagé and VANIQA. In 2005, we transitioned from a company primarily focused on research and development to a company also with a significant commercial focus. As a result, we no longer consider ourselves a development stage enterprise.

We have financed our operations and internal growth almost entirely through proceeds from private placements of preferred stock, our initial public offering in the second quarter of 2004 and our follow-on public offering in the first quarter of 2005.

We were incorporated in September 2001 and commenced active operations in May 2002. Since our inception we have generated significant losses. As of December 31, 2005, we had an accumulated deficit of $151.4 million. We plan to continue to invest in research and clinical development studies to develop our product candidates and screen for new product candidates. We also plan to seek marketing approvals for our products in various countries throughout the world, particularly in the United States, Canada and Europe. We expect to continue to spend significant amounts on the commercial development of our products, including the sales and marketing of Vusion and Solagé. Additionally, we plan to continue to evaluate possible acquisitions of development-stage or approved products that would fit within our growth strategy. Accordingly, we will need to generate significantly greater revenues to achieve and then maintain profitability.

Research and clinical development expenses represent:

- cost incurred for the conduct of our clinical trials,
- cost incurred in screening and pre-clinical testing of our product candidates,
- manufacturing development costs related to our clinical product candidates,
- personnel and related costs related to our research and product development activities, and
- outside professional fees related to clinical development and regulatory matters.

We outsource the conduct of our clinical trials and all of our manufacturing development activities to third parties to maximize efficiency and minimize our internal overhead. We expense these research and development costs as they are incurred. We expect that our research and development expenses will be somewhat lower in 2006 compared to 2005.

Selling, general and administrative expenses consist primarily of salaries and other related personnel, marketing and promotion, general corporate activities, professional fees and facilities. We expect these costs to increase in 2006, as we continue to expand our sales organization and launch Vusion. In addition, if we were to acquire or in-license other products, or obtain regulatory approval for our product candidate Sebazole, we would then incur sales and marketing costs related to such products.

We expect to continue to incur net losses over the next several years as we continue our clinical development, apply for regulatory approvals, enter into arrangements with third parties for manufacturing and distribution services and market our products. We have a limited history of operations and anticipate that our quarterly results of operations will fluctuate for several reasons, including:

- the timing and extent of recognition of product and other revenue;
- the timing of any contract, license fee or royalty payments that we may receive or be required to make;
- the timing and outcome of our applications for regulatory approvals;
- the timing and extent of marketing and selling expenses;
- the timing and extent of our research and development efforts;
- the timing and extent of our adding new employees and infrastructure; and
- the timing and extent of employee stock grants and stock option grants.

**Recent Developments**

On February 16, 2006, the FDA issued an approval letter for Vusion for the treatment of diaper dermatitis complicated by candidiasis in infants. Our existing sales force has begun to actively promote the product to pediatricians and other targeted physicians. We have also begun implementing our plan to expand to 60 sales territories and expect to begin shipping product to the trade in the second quarter of 2006.

## Results of Operations

***Years ended December 31, 2005, 2004 and 2003***

*Net Revenue.* Net Revenues are summarized below:

| (in thousands) | Year ended December 31, 2005 | 2004 | 2003 |
|---|---|---|---|
| **Net product revenue** | | | |
| US | $ 684 | $ - | $ - |
| International | 108 | - | - |
| **Total net product revenue** | $ 792 | $ - | $ - |
| Grant revenue | 1,059 | 797 | 367 |
| Contract revenue | 689 | 100 | - |
| **Total net revenue** | $ 2,540 | $ 897 | $ 367 |

Total net revenue for 2005 increased $1.6 million over 2004, mostly related to the initial product revenue from sales of Solagé and increased grant revenue from the Belgium government. Total revenue for 2004 increased $530,000 over 2003, mostly related to an increase in grant revenue from the Belgium government and revenue from contract milestones recognized in 2004.

*Net Product Revenues.* In 2005, we recognized product revenues of $792,000 for our sales of Solagé in the United States and Canada and sales of VANIQA in Canada. We expect product revenues for these two products will increase and we expect a substantial increase in total product revenues due to the launch of Vusion. Prior to 2005, we had no product revenue.

*Other Revenues.* In 2005, we recorded grant revenue from a Belgian governmental agency promoting technology in the Flemish region of Belgium through a research grant of $1.1 million compared to $797,000 for the previous year. We recognized grant revenue of $367,000 for the year ended December 31, 2003. In addition, during 2005, we recognized revenue related to commercial contracts of $689,000 an increase from the $100,000 we recognized during 2004. The Belgium grant under which we receive revenue over the past three years has been completed. Additional future grants have been applied for, however, to date we have no new agreements in place.

*Cost of Product Revenues.* Cost of product revenue totaled $544,000 for the year ended December 31, 2005. This amount includes finished product costs, distribution expense related to product sales, including one-time start-up distribution expenses, and amortization of Solagé product rights. We did not report cost of product revenues during 2004 or 2003 because we did not have product sales. In the first quarter of 2005, we acquired the United States and Canadian rights to Solagé, and are amortizing the remaining intangible asset over the expected life. Amortization expense related to the product rights for the acquisition of Solagé was $320,000 for 2005. We expect that our gross margin will fluctuate as we increase our product sales of Solagé and VANIQA and begin to sell Vusion and other products, if and when they are approved.

*Research and Development Expenses.*

Total research and development expenses for 2005 compared to 2004 decreased by $535,000. Expenses related to our late stage candidates decreased $4.7 million from 2005 to 2004 as Phase 3 trials concluded for Sebazole in 2004 and Hyphanox during 2005. Research and development expenses increased $13.4 million from 2003 to 2004 primarily due to increases related to Hyphanox studies, other clinical stage products and internal costs.

Below is a summary of our research and development expenses:

| (in thousands) | Year ended December 31 2005 | % of Total | 2004 | % of Total | 2003 | % of Total |
|---|---|---|---|---|---|---|
| Sebazole | $ 3,888 | 13% | $ 5,750 | 18% | $ 5,016 | 29% |
| Hyphanox | 4,992 | 16% | 8,391 | 27% | 4,864 | 28% |
| Vusion | 2,268 | 7% | 1,778 | 6% | 1,774 | 10% |
| Liarozole | 1,275 | 4% | 1,249 | 4% | 334 | 2% |
| Other clinical stage products | 6,826 | 23% | 3,589 | 12% | 671 | 4% |
| Research and preclinical stage products costs | 1,388 | 5% | 1,896 | 6% | 713 | 4% |
| Internal costs | 9,732 | 32% | 8,251 | 27% | 4,113 | 23% |
| Total research and development expenses | $ 30,369 | 100% | $ 30,904 | 100% | $ 17,485 | 100% |

In the preceding table, research and development expenses are set forth in the following seven categories:

- Sebazole— Sebazole expenses for 2005 related primarily to the completion of our long-term safety study which commenced in the third quarter of 2004, as well as regulatory and manufacturing costs related to the development of this product. During 2004, our research and development costs related to Sebazole were up 734,000, or 15%, over 2003. We conducted two Phase 3 clinical trials in the United States and Europe in 2003, compared with a confirmatory Phase 3 clinical trial for Sebazole and a long-term safety study in 2004.

- Hyphanox— Our costs for Hyphanox for 2005 are related to the completion of a Phase 3 pivotal clinical trial for the treatment of vaginal candidiasis, supportive pharmacokinetics studies, and set-up costs for a Phase 3 clinical trial for the treatment of onychomycosis. The 2005 costs are $3.4 million, or 40%, lower than 2004, because the Phase 3 trial ran for only six months of 2005 compared to twelve months of 2004. Manufacturing development costs in 2005 were also lower for Hyphanox compared with 2004. Our costs for 2003 for Hyphanox were primarily for the purchase of raw materials and related manufacturing, as well as the costs of conducting pilot bioequivalence studies.

- Vusion— Our costs related to Vusion for 2005 increased $490,000 compared to 2004 primarily due to increased costs for manufacturing development and regulatory costs. In 2005, we incurred costs related to validation batches as well as a contract minimum payment made to our contract manufacturer. Costs for the year ended December 31, 2004 increased slightly due to the cost of our Phase 3 pivotal clinical trial, which began enrolling patients in the first half of 2003 and was completed during the third quarter of 2004, and the costs incurred in connection with the preparation of regulatory filings and filing fees in the United States and Europe.

- Liarozole— Our costs for Liarozole in 2005 were marginally higher than our costs in 2004. Our costs in 2005 are related to the set-up costs for our Phase 2/3 trial for the treatment of lamellar ichthyosis as well as costs for clinical supplies and manufacturing of the active ingredient. Our costs for Liarozole in 2004 related to the cost of the review of clinical data and the manufacturing of both active ingredient and clinical supplies. The 2003 Liarazole costs related primarily to the manufacturing of drug substance for clinical supplies.

- Other clinical stage product candidates— Other clinical stage product costs for 2005 increased $3.2 million compared to 2004 primarily due to higher direct program costs on Rambazole and Azoline. Increased spending on these product candidates was also the primary driver for the cost increase of $2.9 million from 2003 to 2004. Spending on Rambazole for 2005 was related to manufacturing development, pre-clinical studies, and preparation and set-up of our Phase 2b study. Spending on Azoline during 2005 was related to manufacturing development, pre-clinical studies, and preparation and set-up of our Phase 2b study.

- Research and preclinical stage product costs—direct expenses relating to the development of our research and preclinical product candidates and the screening of molecules to identify new product candidates.

- Internal costs— Internal costs for 2005 increased $1.5 million compared to 2004. Personnel and related costs totaled $6.7 million for 2005, an increase of $536,000 over the corresponding period in 2004. This increase is

primarily due to an increase in personnel, partially offset by a decrease in amortization of deferred compensation of $415,000. Other costs, which include consultants, overhead and other expenses, totaled $3.0 million, an increase of $946,000 compared to the corresponding period in 2004. Internal costs for 2004 increased $4.1 million compared to 2003. Personnel and related costs totaled $6.2 million for 2004, an increase of $3.1 million over the corresponding period in 2003. This increase is primarily due to an increase in headcount and includes amortization of deferred compensation of $730,000, which was $82,000 for 2003. Other costs, which include consultants, overhead and other expenses, totaled $2.1 million, an increase of $1.0 million compared to the corresponding period in 2003.

We anticipate that research and development expenses will remain at current levels in the near term and could increase as we further advance our late stage product candidates through clinical development. In addition, we will begin to incur additional expenses for our mid-stage pipeline as we move toward larger and more expensive Phase 2 and Phase 3 trials and devote additional resources to our earlier stage research and preclinical projects. We also expect our personnel and related expenses for research and development to increase.

*Selling general and administrative expense.* Selling, general and administrative expense for 2005 totaled $20.3 million, an increase of $8.8 million over 2004. This increase was largely the result of our establishment of commercial operations in 2005. Sales force costs for 2005 represented $2.7 million of this increase resulting from the creation of our 21 territory sales team in the United States and four person sales team in Canada. Marketing expenses increased $2.2 million, primarily related to the preparation for the launch of Vusion and launch and promotion of Solagé. We also increased spending on our commercial infrastructure by $2.6 million over 2004. This increase includes commercial management, supply chain expenses and support staff. Corporate administrative expenses also increased $1.3 million from 2004 and included higher personnel, consulting, overhead and other expenses to support our growing public company.

Selling, general and administrative expense for 2004 totaled $11.5 million, up $7.7 million over 2003. Marketing and commercial infrastructure expenses increased $4.3 million. This increase was primarily attributable to the build-up of our commercial infrastructure and the pre-launch marketing and market research expenses for Vusion. We recorded no sales and marketing expenses in 2003. Corporate administrative expenses totaled $7.2 million for 2004, an increase of $3.4 million over the corresponding period in 2003. This increase is primarily due to an increase in headcount and includes amortization of deferred compensation of $975,000 in 2004, which was $116,000 for 2003.

We expect sales force and marketing costs will continue to increase as we grow the sales force and support the launch of Vusion and potentially Sebazole, if approved. If we were to acquire additional products or in-license products these costs would also increase. We expect corporate administrative costs to continue to increase as required to support the growth of the Company.

*Interest income, net of interest expense.* Interest income, net of expense, totaled $2.9 million for 2005, an increase of $1.5 million as compared to the corresponding period in 2004. This increase was primarily due to our higher balances of cash, cash equivalents and marketable securities from our initial public offering and follow-on offering in 2005 compared to the 2004 period and higher average interest rates.

Interest income, net of expense totaled $1.4 million for 2004, an increase of $956,000 as compared to the corresponding period in 2003. These increases were primarily due to our higher balances of cash, cash equivalents and marketable securities obtained from our initial public offering in April 2004.

*Income taxes.* The income tax benefit of $536,000 in 2005 was up $169,000 from 2004. Income tax benefit in 2004 was $367,000, up $150,000 over 2003. Income tax benefits in all three years represent the net proceeds from the sale of a portion of unused prior years' New Jersey State net operating loss carry-forwards.

**Liquidity and Capital Resources**

*Sources of Liquidity.* Since our inception, we have funded our operations principally from issuances of our convertible preferred stock, the proceeds from our initial public offering of common stock and our follow-on public offering of common stock. We raised net proceeds of approximately $36.0 million from our follow-on public offering in February 2005, $67.9 million from our initial public offering in May 2004, and we have issued preferred stock, including

notes converted into preferred stock, for aggregate net cash proceeds of approximately $77.3 million. All of the preferred stock that we issued converted to common stock in connection with our initial public offering.

In September 2003, the Company entered into an equipment and furniture financing arrangement with a third party for up to $750,000, which was increased to $1,500,000 in 2004, with an interest rate of 6.15%, plus the three year Treasury Constant Maturities rate at the time of funding. Each time it receives funding, the Company will enter into a promissory note with a term of 3 years, secured by the related equipment and furniture.

At December 31, 2005, we had cash, cash equivalents and marketable securities totaling $78.1 million and net working capital of $72.8 million.

*Cash Flows.* At December 31, 2005, we had $16.9 million in cash and cash equivalents, as compared to $11.9 million at December 31, 2004. Our major uses of cash in 2005 include $44.2 million of cash used in operations, mostly related to research and development spending and the start-up of commercial operations. Cash used in operations for the years ended December 31, 2004 and 2003 was $32.2 million and $18.8 million, respectively. The increase was attributable to the increased operating loss and working capital requirements to fund our operations.

Cash provided by investing activities for year ended December 30, 2005 was $12.6 million. This is primarily attributable to $16.0 million of net proceeds from marketable securities offset by $3.1 million used for the acquisition of Solagé. Cash used in investing activities for the year ended December 30, 2004 and 2003 was $35.7 million and $31.0 million, respectively. Our investing activities reflect investments in marketable securities and purchases of fixed assets necessary for operations. We plan to continue utilizing third parties to manufacture our products and to conduct laboratory-based research. Therefore, we do not expect to make significant capital expenditures for the foreseeable future.

Net cash provided by financing activities was $36.7 million for the year ended December 31, 2005, which included our follow-on offering net proceeds of $36.0 million. Cash provided by financing activities during the year ended December 31, 2004 was $68.3 million, which included the net proceeds from our initial public offering of $67.9 million. Cash provided by financing activities for the year ended December 31, 2003 was $55.2 million primarily related from our receipt of $23.0 million in May 2003 upon the second closing of the series B convertible preferred stock financing and $31.9 million in October 2003 upon closing of the series C convertible preferred stock financing.

We expect that our existing cash at December 31, 2005 will be sufficient to fund our anticipated operating expenses, debt obligations and capital requirements for at least the next twelve months. We currently have no additional commitments or arrangements for any additional financing to fund the commercialization of our marketed products and the research, development and commercial launch of our product candidates. We will require additional funding in order to continue our commercialization efforts and our research and development programs, including preclinical studies and clinical trials of our product candidates, pursue regulatory approvals for our product candidates, pursue the commercial launch of our product candidates, expand our sales and marketing capabilities and for general corporate purposes. Our future capital requirements will depend on many factors, including:

- the success of our development and commercialization of our product candidates;
- the scope and results of our clinical trials;
- advancement of other product candidates into clinical development;
- potential acquisition or in-licensing of other products or technologies;
- the timing of, and the costs involved in, obtaining regulatory approvals;
- the costs of manufacturing activities; and
- the costs of commercialization activities, including product marketing, sales and distribution and related working capital needs.

The following table summarizes our material contractual commitments as of December 31, 2005:

| Contractual Obligation | Total | Less than one year | One to Three Years | Three to Five Years | After Five Years |
|---|---|---|---|---|---|
| Notes payable | $ 784,000 | $ 379,000 | $ 405,000 | $ — | $ — |
| Operating lease obligations | 3,026,000 | 666,000 | 1,887,000 | 473,000 | — |
| Other contractual obligations (a) | 20,573,000 | 8,799,000 | 8,024,000 | 3,750,000 | — |
| Total | $ 24,383,000 | $ 9,844,000 | $ 10,316,000 | $ 4,223,000 | $ — |

(a) The other contractual obligations reflected in the table include obligations to purchase product and product candidate materials contingent on the delivery of the materials and to fund various clinical trials contingent on the performance of services. These obligations also include long-term obligations, including milestone payments that may arise under agreements that we may terminate prior to the milestone payments being due. The table excludes contingent royalty payments that we may be obligated to pay in the future.

**Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and assumptions. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 1 to our consolidated financial statements appearing at the end of this annual report on Form 10-K, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results.

***Revenue Recognition***

We use revenue recognition criteria in Staff Accounting Bulletin No. 104, "Revenue Recognition in Financial Statements," Emerging Issues Task Force ("EITF") Issue 00-21 "Revenue Arrangements with Multiple Deliverables" ("EITF 00-21") and Statement of Financial Accounting Standards No 48 ("FAS 48") "Revenue Recognition When Right of Return Exists." Revenue arrangements that include multiple deliverables, are divided into separate units of accounting if the deliverables meet certain criteria, including whether the fair value of the delivered items can be determined and whether there is evidence of fair value of the undelivered items. In addition, the consideration is allocated among the separate units of accounting based on their fair values, and the applicable revenue recognition criteria are considered separately for each of the separate units of accounting.

***Net Product Revenue.*** In the United States and Canada, we sell our products primarily to wholesalers and distributors, who, in turn, sell to pharmacies. Although product revenue to date has been insignificant, the following are the Company's policies.

At the time of a new product launch, we utilize a pull-through sales method that recognizes revenue based on estimated prescription demand based on third party market research data and revenue for a normal level of wholesaler inventory based on our estimated current prescription demand. Estimating the amount of returns and discounts for new products is based in specific facts and circumstances including acceptance rates from established products with similar marketing characteristics. At the time of a new product launch, absent the ability to make reliable estimates we defer revenue on sales to wholesalers until we can make reliable estimates of these returns, discounts and related end user demand. We attempt to monitor our inventory levels at our wholesalers and pharmacies to ensure these levels remain within normal levels. We estimate inventory at wholesalers based on historical sales to wholesalers, inventory data

provided to us by these wholesalers and from third party market research data related to prescription trends and patient demand. Making these determinations involves estimating whether trends in past buying patterns will predict future product sales.

We record allowances for product returns, coupon rebates and other discounts at the time of sale, and report revenue net of such amounts. In determining allowances for product returns and rebates, we must make significant judgments and estimates. For example, in determining these amounts, we estimate prescription demand and the levels of inventory held by wholesalers. Making these determinations involves estimating whether trends in past buying patterns will predict future product sales.

The nature of our allowances requiring critical accounting estimates, and the specific considerations we use in estimating their amounts, are as follows:

- *Product returns.* Our customers have the right to return any unopened product during the 18-month period beginning six months prior to the labeled expiration date and ending 12 months after the labeled expiration date. As a result, in calculating the allowance for product returns, we must estimate the likelihood that product sold to wholesalers and pharmacies might remain in their inventory to within six months of expiration and analyze the likelihood that such product will be returned within 12 months after expiration.

  In estimating the likelihood of product remaining in our wholesalers' inventory, we rely on information from our wholesalers regarding their inventory levels, measured prescription demand as reported by third party sources and on internal sales data. We believe the information from our wholesalers and third party sources is directionally reliable, but we are unable to verify the accuracy of such data independently. We also consider our wholesalers' past buying patterns, estimated remaining shelf life of product previously shipped and the expiration dates of product currently being shipped. In estimating the likelihood of product return, we rely primarily on historic patterns of returns and estimated remaining shelf life of product previously shipped. At December 31, 2005, our allowance for returns was $5,000.

- *Discounts and rebates.* We sell Solagé primarily to wholesalers and distributors, who in turn sell to pharmacies. From time to time we offer patients a limited time coupon discount on their purchases of Solagé. We provide a mail-in rebate coupon to the patient with a proof of purchase of Solagé.

  As a result of these rebate offers, at the time of product shipment, we must estimate the likelihood that Solagé sold to wholesalers and pharmacies might be ultimately sold to a patient who redeems a coupon. We base our estimates on the historic coupon redemption rates for similar products we receive from third party administrators, which detail historic patterns. At December 31, 2005, our allowance for coupon redemptions was $4,000.

  We will adjust our allowances for product returns and coupon rebates based on our actual sales experience, and we will likely be required to make adjustments to these allowances in the future. We continually monitor our allowances and make adjustments when we believe actual experience may differ from our estimates.

- *International Distribution Partners.* Under our agreements with international distribution partners, we plan to sell our product to our distribution partners at a contractual price. These partners generally have no rights of return after they have accepted shipment of the product.

***Other Revenue.*** Contract revenues include license fees, royalties and other payments associated with collaborations with third parties. Revenue is generally recognized when there is persuasive evidence of an arrangement exists, delivery has occurred or services have been rendered, the price is fixed or determinable, and collectibility is reasonably assured.

Revenue from non-refundable, upfront license fees where we have a continuing involvement is recognized ratably over the performance period. Royalties from licensees are based on third-party sales of licensed products and are recorded in accordance with contract terms when third-party results are reliably measurable and collectibility is reasonably assured. We periodically re-evaluate our estimates of the performance period and revise our assumptions as appropriate. These changes in assumptions may affect the amount of revenue recorded in our financial statements in future periods.

Grant revenues are recognized as the Company provides the services stipulated in the underlying grant based on the time and materials incurred. Amounts received in advance of services provided are recorded as deferred revenue and amortized as revenue when the services are provided.

***Stock-based Compensation***

Stock-based compensation charges represent the difference between the exercise price of options granted to employees and the fair value of our common stock on the date of grant for financial statement purposes in accordance with Accounting Principles Board Opinion No. 25 and its related interpretations. We recognize this compensation charge over the vesting periods of the shares purchasable upon exercise of options. Should our assumptions of fair value change, the amount recorded as intrinsic value may increase or decrease in the future.

There was no deferred compensation related to options issued during 2005. We reversed prior year deferred compensation of approximately $89,000 related to employee terminations. We recorded amortization of $889,000 during the year ended December 31, 2005. In 2004 we recorded deferred stock compensation of $3.0 million and related amortization of $2.0 million during the year ended December 31, 2004. To date, we have recorded stock-based compensation of $3.7 million and related amortization expense of $3.1 million. We are applying a graded vesting amortization policy for our deferred compensation.

Stock-based compensation charges also include the periodic revaluation of stock options that we have granted to non-employees, in accordance with the provisions of Statement of Financial Accounting Standards No. 123 and Emerging Issues Task Force No. 96-18. Pursuant to this accounting literature, equity instruments, such as options, are required to be recorded at the fair value of the consideration received, or the fair value of the equity instrument issued, whichever may be more readily measured. For grants to our non-employees, the fair value of the equity instrument issued is more readily measured and we assign value to the options using a Black-Scholes methodology. As required, we revalue these options over the period when earned in accordance with their respective terms. Should our input assumptions change, for example, fair value of common stock at the measurement date, the fair value of our non-employee consultant compensation will change.

We recorded stock-based compensation expense totaling $378,000 for the year ended December 31, 2005, $756,000 for the year ended December 31, 2004, and $107,000 for the year ended December 31, 2003 in connection with the grant of stock options to our non-employees.

**Recent Accounting Pronouncements**

On December 16, 2004, the Financial Accounting Standards Board, referred to as FASB, issued Statement No. 123, revised 2004, *Share-Based Payment*, which is a revision of FASB Statement No. 123, *Accounting for Stock-Based Compensation*. Statement 123(R) supersedes Accounting Principal Board Opinion, referred to as APB, No. 25, *Accounting for Stock Issued to Employees*, and amends FASB No. 95, *Statement of Cash Flows*. Generally, the approach to accounting in Statement 123(R) is similar to the approach described in Statement 123. However, Statement 123(R) *requires* all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. On April 15, 2005, the Securities and Exchange Commission adopted a new rule that extended the compliance date for periods ending after January 1, 2006.

Currently, we account for these payments under the intrinsic value provisions of APB No. 25. Effective January 1, 2006 the Company will adopt Statement 123(R) using the modified prospective method. The Company will commence the new method of valuing stock-based compensation as prescribed by Statement 123(R) on all stock-based awards granted after the effective date. The Company estimates that the 2006 expense associated with recognition of additional non-cash compensation expense related to such awards will be approximately $6 million.

## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

Our exposure to market risk is limited to our cash, cash equivalents and marketable securities. We invest in high-quality financial instruments, primarily money market funds, federal agency notes, corporate debt securities and United States treasury notes, with the effective duration of the portfolio less than one year, which we believe are subject to limited credit risk. We currently do not hedge our interest rate exposure. Due to the short-term nature of our investments, we do not believe that we have any material exposure to interest rate risk arising from our investments.

Most of our transactions are conducted in United States dollars, although we do have some agreements with vendors located outside the United States. Transactions under some of these agreements are conducted in United States dollars, subject to adjustment based on significant fluctuations in currency exchange rates. Transactions under other of these agreements are conducted in the local foreign currency. We have a wholly-owned subsidiary, Barrier Therapeutics, N.V., which is located in Geel, Belgium and a wholly owned subsidiary, Barrier Therapeutics Canada Inc., which is located in Toronto, Canada. Except for funding being received under our grant from a Belgian governmental agency, which is denominated in Euros and locally earned interest income, all research costs incurred by Barrier Therapeutics, N.V. are funded under a service agreement with Barrier Therapeutics, Inc. from investments denominated in dollars. Our Canadian subsidiary, Barrier Therapeutics Canada, Inc. became operational in the third quarter of 2005. While we expect that there will be some income from sales of products during the next year which will be denominated in Canadian dollars, most of the funding for these operations will also come from investments denominated in dollars. Therefore, we are subject to currency fluctuations and exchange rate gains and losses on these transactions. If the exchange rate undergoes a change of 10%, we do not believe that it would have a material impact on our results of operations or cash flows.

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our financial statements are annexed to this Annual Report on Form 10-K beginning on page F-1.

## ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

## ITEM 9A. CONTROLS AND PROCEDURES

### Evaluation of Disclosure Controls and Procedures

Management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. A controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

### Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) promulgated under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of, our principal executive and principal financial officer and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2005. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework. Based on this assessment, management believes that, as of December 31, 2005, our internal control over financial reporting is effective based on those criteria.

Management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which appears below.

By: GEERT CAUWENBERGH
Geert Cauwenbergh, Ph.D.
Chairman And Chief Executive Officer

Dated March 9, 2006

By: ANNE M. VANLENT
Anne M. VanLent
Executive Vice President, Chief Financial Officer & Treasurer

Dated March 9, 2006

## Attestation Report of Independent Registered Public Accounting Firm

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

Barrier Therapeutics, Inc.

We have audited management's assessment, included in the accompanying Management's Report on Internal Control over Financial Reporting, that Barrier Therapeutics, Inc. (the "Company") maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that the Company maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on the COSO criteria.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of the Company as of December 31, 2005 and 2004, and the related consolidated statements of operations, common stockholders' equity and cash flows for each of the three years in the period ended December 31, 2005, and our report dated March 9, 2006, expressed an unqualified opinion thereon.

*/s/*ERNST & YOUNG LLP

MetroPark, New Jersey
March 9, 2006

### Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting during the quarter ended December 31, 2005, that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## ITEM 9B. OTHER INFORMATION

None.

## PART III

## ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

### Directors

The information concerning our directors required by Item 10 is incorporated by reference to the information contained under the heading "Election of Directors" in our definitive proxy statement for the 2006 annual meeting of stockholders.

### Our Executive Officers

The information concerning our executive officers required by Item 10 included herein at the end of Part 1 under the heading "Our Executive Officers".

### Audit Committee Financial Expert

The information concerning our audit committee financial expert required by Item 10 is incorporated by reference to the information contained under the heading "Meetings and Committees of the Board of Directors" in our definitive proxy statement for the 2006 annual meeting of stockholders.

### Identification of the Audit Committee

The information concerning our audit committee required by Item 10 is incorporated by reference to the information contained under the heading "Meetings and Committees of the Board of Directors" in our definitive proxy statement for the 2006 annual meeting of stockholders.

### Compliance with Section 16(a) of the Exchange Act

The information concerning our compliance with Section 16(a) of the Exchange Act by our directors and executive officers required by Item 10 is incorporated by reference to the information contained under the heading "Section 16(a) Beneficial Ownership Reporting Compliance" in our definitive proxy statement for the 2006 annual meeting of stockholders.

### Code of Ethics

The information concerning our code of ethics that applies to our principal executive officer and principal financial officer required by Item 10 is incorporated by reference to the information contained under the heading "Corporate Governance" in our definitive proxy statement for the 2006 annual meeting of stockholders.

## ITEM 11. EXECUTIVE COMPENSATION

The information required by Item 11 is incorporated by reference to the information contained under the headings "Executive Compensation" and "Director Compensation" in our definitive proxy statement for the 2006 annual meeting of stockholders.

## ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by Item 12 is incorporated by reference to the information contained under the headings "Ownership of Common Stock" and "Equity Compensation Plan Information" in our definitive proxy statement for the 2006 annual meeting of stockholders.

## ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by Item 13 is incorporated by reference to the information contained under the headings "Executive Compensation" in our definitive proxy statement for the 2006 annual meeting of stockholders.

## ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by Item 14 is incorporated by reference to the information contained under the heading "Independent Public Auditor" in our definitive proxy statement for the 2006 annual meeting of stockholders.

## PART IV

## ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

### Item 1B. DOCUMENTS FILED AS PART OF THIS REPORT

The following is a list of our consolidated financial statements and our subsidiaries and supplementary data included in this report under Item 8 of Part II hereof:

### 1. FINANCIAL STATEMENTS AND SUPPLEMENTAL DATA

Report of Independent Registered Public Accounting Firm.

Consolidated Balance Sheets as of December 31, 2005 and 2004.

Consolidated Statements of Operations for the years ended December 31, 2005, 2004 and 2003.

Consolidated Statements of Stockholders' Equity (Deficiency) for the years ended December 31, 2005, 2004 and 2003.

Consolidated Statements of Cash Flows for the years ended December 31, 2005, 2004 and 2003.

Notes to Consolidated Financial Statements.

### 2. FINANCIAL STATEMENT SCHEDULES

Schedules are omitted because they are not applicable or are not required, or because the required information is included in the consolidated financial statements or notes thereto.

### Exhibits

See the attached exhibit list filed as part of this annual report on Form 10-K. Where so indicated by footnote, exhibits that were previously filed are incorporated by reference. For exhibits incorporated by reference, the location of the exhibit in the previous filing is indicated.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

March 14, 2006

**BARRIER THERAPEUTICS, INC.**
(Registrant)

By: GEERT CAUWENBERGH
Geert Cauwenbergh, Ph.D.
Chairman And Chief Executive Officer
(Principal Executive Officer)

By: ANNE M. VANLENT
Anne M. VanLent
Executive Vice President, Chief Financial Officer & Treasurer
(Principal Financial and Accounting Officer)

## POWER OF ATTORNEY

Pursuant to the requirements of the Securities Act of 1934, as amended, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated. Each person whose signature appears below in so signing also makes, constitutes and appoints Geert Cauwenbergh, Ph.D. and Anne M. VanLent and each of them acting alone, his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to execute and cause to be filed with the Securities and Exchange Commission any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, and hereby ratifies and confirms all that said attorney-in-fact or his substitute or substitutes may do or cause to be done by virtue hereof.

| Signature | Title | Date |
|---|---|---|
| GEERT CAUWENBERGH<br>Geert Cauwenbergh, Ph.D. | Chairman and Chief Executive Officer<br>(Principal Executive Officer) | March 14, 2006 |
| ANNE M. VANLENT<br>Anne M. VanLent | Executive Vice President, Chief Financial Officer and Treasurer<br>(Principal Financial and Accounting Officer) | March 14, 2006 |
| SRINIVAS AKKARAJU<br>Srinivas Akkaraju, M.D., Ph.D. | Director | March 14, 2006 |
| ROBERT CAMPBELL<br>Robert Campbell | Director | March 14, 2006 |
| CARL EHMANN<br>Carl Ehmann, M.D. | Director | March 14, 2006 |
| EDWARD L. ERICKSON<br>Edward L. Erickson | Director | March 14, 2006 |
| PETER ERNSTER<br>Peter Ernster | Director | March 14, 2006 |
| CHARLES F. JACEY, JR.<br>Charles F. Jacey, Jr. | Director | March 14, 2006 |
| CAROL RAPHAEL<br>Carol Raphael | Director | March 14, 2006 |
| NICHOLAS SIMON<br>Nicholas Simon | Director | March 14, 2006 |

**BARRIER THERAPEUTICS, INC.**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders Barrier Therapeutics, Inc.

We have audited the accompanying consolidated balance sheets of Barrier Therapeutics, Inc. (the "Company") as of December 31, 2005 and 2004, and the related consolidated statements of operations, stockholders' equity (deficiency) and cash flows for each of the three years in the period ended December 31, 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2005 and 2004, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2005, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated March 9, 2006 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

MetroPark, New Jersey
March 9, 2006

## BARRIER THERAPEUTICS, INC.

## CONSOLIDATED BALANCE SHEETS

(In Thousands)

| | Year Ended December 31, | |
|---|---|---|
| | 2005 | 2004 |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 16,891 | $ 11,908 |
| Marketable securities | 61,229 | 77,173 |
| Interest receivable | 755 | 926 |
| Receivables, net of allowances of $14 | 593 | — |
| Inventories | 380 | — |
| Prepaid expenses and other current assets | 1,227 | 1,610 |
| Total current assets | 81,075 | 91,617 |
| Property and equipment, net | 1,055 | 1,125 |
| Product rights, net | 2,780 | — |
| Other assets | 51 | 42 |
| Total assets | $ 84,961 | $ 92,784 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Notes payable, current portion | $ 379 | $ 261 |
| Accounts payable | 3,110 | 3,148 |
| Accrued expenses | 4,146 | 4,687 |
| Deferred revenue | 637 | 650 |
| Other current liabilities | 18 | 25 |
| Total current liabilities | 8,290 | 8,771 |
| Notes payable, long-term portion | 405 | 443 |
| Stockholders' equity: | | |
| Common stock, $.0001 par value; 80,000,000 authorized, 24,095,875 issued and outstanding at December 31, 2005; and 21,894,830 issued and outstanding at December 31, 2004 | 2 | 2 |
| Additional paid-in capital | 228,490 | 191,568 |
| Accumulated deficit | (151,441) | (106,200) |
| Deferred compensation | (532) | (1,510) |
| Accumulated other comprehensive loss | (253) | (290) |
| Total stockholders' equity | 76,266 | 83,570 |
| Total liabilities and stockholders' equity | $ 84,961 | $ 92,784 |

*See accompanying Notes to Consolidated Financial Statements*

## BARRIER THERAPEUTICS, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS

**(In Thousands, except share and per-share amounts)**

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2005 | 2004 | 2003 |
| Revenues: | | | |
| Net product revenue | $ 792 | $ — | $ — |
| Other revenue | 1,748 | 897 | 367 |
| Total net revenue | 2,540 | 897 | 367 |
| Costs and Expenses: | | | |
| Cost of product revenues | 544 | — | — |
| Research and development | 30,369 | 30,904 | 17,485 |
| Selling, general and administrative | 20,280 | 11,475 | 3,730 |
| Total operating expenses | 51,193 | 42,379 | 21,215 |
| Loss from operations | (48,653) | (41,482) | (20,848) |
| Interest income | 2,929 | 1,408 | 419 |
| Interest expense | (53) | (36) | (3) |
| Loss before income tax benefit | (45,777) | (40,110) | (20,432) |
| Income tax benefit | 536 | 367 | 217 |
| Net loss | (45,241) | (39,743) | (20,215) |
| Preferred stock accretion | — | (4,592) | (8,432) |
| Net loss attributable to common stockholders | $ (45,241) | $ (44,335) | $ (28,647) |
| Basic and diluted net loss attributable to common stockholders per share | $ (1.91) | $ (3.02) | $ (83.95) |
| Weighted-average shares outstanding—basic and diluted | 23,656,306 | 14,677,710 | 341,256 |

*See accompanying Notes to Consolidated Financial Statements*

# BARRIER THERAPEUTICS, INC.

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIENCY)

**(In Thousands, except share amounts)**

| | Common Stock Shares | Common Stock Amount | Additional Paid-in Capital | Accumulated Deficit | Notes Receivable From Officer | Deferred Compensation | Accumulated Other Comprehensive Loss | Total Stockholders' Equity (Deficiency) |
|---|---|---|---|---|---|---|---|---|
| Balance at December 31, 2002 | 822,500 | $ — | $ 40 | $ (33,218) | $ (60) | $ — | $ 40 | $ (33,198) |
| Net loss | | | | (20,215) | | | | (20,215) |
| Unrealized loss on available for sale securities | | | | | | | (43) | (43) |
| Foreign currency translation loss | | | | | | | (26) | (26) |
| Total comprehensive loss | | | | | | | | (20,284) |
| Compensation expense related to options issued to non-employees | | | 107 | | | | | 107 |
| Restricted stock no longer subject to repurchase | | | 15 | | | | | 15 |
| Deferred compensation relating to stock options | | | 725 | | | (725) | | — |
| Amortization of deferred compensation | | | | | | 198 | | 198 |
| Repayment of notes receivable | | | | | 60 | | | 60 |
| Preferred stock accretion | | | | (8,432) | | | | (8,432) |
| Balance at December 31, 2003 | 822,500 | — | 887 | (61,865) | — | (527) | (29) | (61,534) |
| Net loss | | | | (39,743) | | | | (39,743) |
| Unrealized loss on available for sale securities | | | | | | | (179) | (179) |
| Foreign currency translation loss | | | | | | | (82) | (82) |
| Total comprehensive loss | | | | | | | | (40,004) |
| Conversion of preferred stock to common stock | 15,960,898 | 2 | 118,835 | | | | | 118,837 |
| Issuance of common stock | 5,000,000 | — | 67,941 | | | | | 67,941 |
| Stock issued upon exercise of stock options | 107,382 | — | 117 | | | | | 117 |
| Stock issued under employee stock purchase plan | 4,050 | — | 36 | | | | | 36 |
| Compensation expense related to options issued to non-employees | | | 756 | | | | | 756 |
| Restricted stock no longer subject to repurchase | | | 12 | | | | | 12 |
| Deferred compensation relating to stock options | | | 2,995 | | | (2,995) | | — |
| Amortization of deferred compensation | | | | | | 2,001 | | 2,001 |
| Reversal of deferred compensation due to employee terminations | | | (11) | | | 11 | | — |
| Preferred stock accretion | | | | (4,592) | | | | (4,592) |
| Balance at December 31, 2004 | 21,894,830 | 2 | 191,568 | (106,200) | — | (1,510) | (290) | 83,570 |
| Net loss | | | | (45,241) | | | | (45,241) |
| Unrealized gain on available for sale securities | | | | | | | 64 | 64 |
| Foreign currency translation loss | | | | | | | (27) | (27) |
| Total comprehensive loss | | | | | | | | (45,204) |
| Issuance of common stock | 2,000,000 | — | 36,043 | | | | | 36,043 |
| Stock issued upon exercise of stock options | 183,521 | — | 430 | | | | | 430 |
| Stock issued under employee stock purchase plan | 17,524 | — | 150 | | | | | 150 |
| Compensation expense related to options issued to non-employees | | | 378 | | | | | 378 |
| Restricted stock no longer subject to repurchase | | | 10 | | | | | 10 |
| Amortization of deferred compensation | | | | | | 889 | | 889 |
| Reversal of deferred compensation due to employee terminations | | | (89) | | | 89 | | — |
| Balance at December 31, 2005 | 24,095,875 | $ 2 | $ 228,490 | $ (151,441) | $ — | $ (532) | $ (253) | $ 76,266 |

*See accompanying Notes to Consolidated Financial Statements*

## BARRIER THERAPEUTICS, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

| | December 31, 2005 | 2004 | 2003 |
|---|---|---|---|
| **Operating activities** | | | |
| Net loss | $ (45,241) | $ (39,743) | $ (20,215) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation | 428 | 381 | 144 |
| Amortization of deferred compensation | 889 | 2,001 | 198 |
| Amortization of product rights | 320 | — | — |
| Non-cash compensation expense related to the issuance of options to non-employees | 378 | 756 | 107 |
| Changes in operating assets and liabilities: | | | |
| Prepaid expenses and other current assets | 383 | (371) | (384) |
| Accounts receivable | (593) | — | — |
| Inventory | (380) | — | — |
| Interest receivable | 171 | (209) | (472) |
| Accounts payable and accrued expenses | (579) | 4,879 | 1,420 |
| Deferred revenue | (13) | 197 | 453 |
| Other, net | (1) | (79) | (30) |
| Net cash used in operating activities | (44,238) | (32,188) | (18,779) |
| **Investing activities** | | | |
| Purchase of fixed assets | (358) | (660) | (751) |
| Purchase of product rights | (3,100) | — | — |
| Security deposits | — | (4) | (39) |
| Purchase of marketable securities | (94,057) | (104,324) | (52,593) |
| Maturities of marketable securities | 110,065 | 69,276 | 22,355 |
| Net cash provided by (used in) investing activities | 12,550 | (35,712) | (31,028) |
| **Financing activities** | | | |
| Repayment of loan by officer | — | — | 60 |
| Borrowings under notes payable | 341 | 555 | 268 |
| Repayment of notes payable | (261) | (298) | (7) |
| Proceeds from issuance of preferred stock | — | (16) | 54,919 |
| Proceeds from issuance of common stock, net | 36,043 | 67,941 | — |
| Proceeds from exercise of stock options and other benefit plans | 580 | 153 | — |
| Net cash provided by financing activities | 36,703 | 68,335 | 55,240 |
| Effect of exchange rate on cash and cash equivalents | (32) | 1 | 4 |
| Net increase in cash and cash equivalents | 4,983 | 436 | 5,437 |
| Cash and cash equivalents, beginning of period | 11,908 | 11,472 | 6,035 |
| Cash and cash equivalents, end of period | $ 16,891 | $ 11,908 | $ 11,472 |
| **Supplemental disclosures of cash flow information** | | | |
| Cash paid during the period for interest | $ 53 | $ 36 | $ 3 |
| **Non-cash investing and financing activities** | | | |
| Release of formerly restricted stock | $ 10 | $ 12 | $ 15 |
| Issuance of note payable in exchange for prepaid insurance | $ — | $ — | $ 186 |
| Conversion of preferred stock | $ — | $ 118,837 | $ — |
| Initial public offering expenses reclassified to Additional Paid-in Capital | $ — | $ 1,809 | $ — |

*See accompanying Notes to Consolidated Financial Statements*

BARRIER THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2005

## 1. Summary of Significant Accounting Policies

### *Organization, Description of Business and Basis of Presentation*

Barrier Therapeutics, Inc. (the "Company") was incorporated in Delaware on September 17, 2001 and commenced active operations in May 2002. The Company is a pharmaceutical company focused on the discovery, development and commercialization of pharmaceutical products in the field of dermatology. The Company's strategy is to develop a portfolio of innovative products that address major medical needs in the treatment of dermatological diseases and disorders. With the acquisition of Solagé in February 2005, the Company has commenced its planned principal operations of selling dermatology products and have transitioned from a company primarily focused on research and development to a company also with a significant commercial focus. As a result, the Company no longer considers itself a development stage enterprise. The Company has offices in Princeton, New Jersey, Toronto, Canada and Geel, Belgium.

Since inception, the Company has relied primarily upon the sale of equity securities to fund operations, most recently through the Company's initial public offering in April 2004 and follow-on public offering in February 2005. The Company believes that its existing resources should be sufficient to meet its capital and liquidity requirements for at least the next 12 months. However, the Company's capital requirements will depend on many factors, including the success of its development and commercialization of the Company's product candidates. Even if the Company succeeds in developing and commercializing one or more of its product candidates, it may never achieve sufficient sales revenue to achieve or maintain profitability. There can be no assurance that the Company will be able to obtain additional capital when needed on acceptable terms, if at all.

### *Public Offerings*

On May 4, 2004, the Company completed an initial public offering ("IPO") of 5,000,000 shares of the Company's common stock which resulted in net proceeds of approximately $67.9 million after payment of underwriting discounts and commissions and other expenses aggregating $7.1 million.

On February 15, 2005, the Company completed a follow-on offering of 2,000,000 shares of common stock, which resulted in net proceeds to the Company of $36.0 million. In connection with the stock sale, the Company paid $2.3 million in underwriting discounts and commissions to underwriters.

### *Consolidation*

The financial statements include the accounts of Barrier Therapeutics, Inc. and its wholly-owned subsidiaries, Barrier Therapeutics, NV and Barrier Therapeutics Canada Inc. All significant inter-company transactions and balances are eliminated in consolidation.

*Use of Estimates*

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

*Cash and Cash Equivalents*

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. At December 31, 2005, the Company has substantially all of its cash and cash equivalents deposited with one financial institution.

*Marketable Securities*

Investments classified as available-for-sale are carried at estimated fair value with unrealized gains and losses recorded as a component of accumulated other comprehensive income. EITF 03-01, *The Meaning of Other-Than-Temporary* requires disclosures addressing other-than-temporary impairments in a qualitative and quantitative manner. There were no other-than-temporary impairments through December 31, 2005.

*Fair Value of Financial Instruments*

The carrying amounts of the Company's financial instruments, which include cash and cash equivalents, marketable securities, accounts payable, accrued expenses, and notes payable approximate their fair values.

*Inventory*

The Company relies on third party manufacturers to supply all of its finished commercial product. All of the Company's current inventory is classified as finished goods. Inventory is recorded upon transfer of title from the vendors. Inventory is stated at the lower of cost or market value. The elements of inventory cost include third party acquisition cost. The cost of inventory is determined using the first-in, first-out (FIFO) method.

The Company reviews inventory for slow moving and obsolete amounts based on expected revenues. If actual revenues are less than expected, the Company may be required to make allowances for excess amounts of inventory in the future.

*Fixed Assets*

Fixed assets include furniture and fixtures, computer and office equipment, software and leasehold improvements. Fixed assets are stated at cost, less accumulated depreciation. Depreciation is provided over the estimated useful lives of the respective assets, generally three to five years, using the straight-line method. Leasehold improvements are amortized over the estimated useful lives of the assets or related initial lease terms, whichever is shorter.

*Impairment of Long-Lived Assets*

In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets,* the Company recognizes impairment losses on long-lived assets when indicators of impairment are

present and future undiscounted cash flows are insufficient to support the assets recovery. There were no impairments through December 31, 2005.

***Intangible Assets***

Product rights are being amortized on a straight-line basis over the life of the underlying patent, which expires in 2013. The Company continually evaluates the reasonableness of the carrying value of its intangible assets. An impairment may be recognized if the expected future undiscounted cash flows are less than their carrying amounts.

***Revenue Recognition***

The Company uses revenue recognition criteria in Staff Accounting Bulletin No. 104, *Revenue Recognition in Financial Statements,* Emerging Issues Task Force ("EITF") Issue 00-21 *Revenue Arrangements with Multiple Deliverables* ("EITF 00-21") and Statement of Financial Accounting Standards No 48 ("FAS 48") *Revenue Recognition When Right of Return Exists*. Revenue arrangements that include multiple deliverables, are divided into separate units of accounting if the deliverables meet certain criteria, including whether the fair value of the delivered items can be determined and whether there is evidence of fair value of the undelivered items. In addition, the consideration is allocated among the separate units of accounting based on their fair values, and the applicable revenue recognition criteria are considered separately for each of the separate units of accounting.

***Net Product Revenue.*** In the United States and Canada, the Company sells products primarily to wholesalers and distributors, who, in turn, sell to pharmacies. Although product revenue to date has been insignificant, the following are the Company's policies. The Company does not recognize revenue from product sales until there is persuasive evidence of an arrangement, delivery has occurred, the price is fixed and determinable, the buyer is obligated to pay, the obligation to pay is not contingent on resale of the product, the buyer has economic substance apart from the Company, the Company has no obligation to bring about the sale of the product, the amount of returns and other discounts can be reasonably estimated and collectibility is reasonably assured.

At the time of a new product launch, the Company utilizes a pull-through sales method, sometimes referred to as a consignment method, which recognizes revenue based on estimated prescription demand based on third party market research data and revenue for a normal level of wholesaler inventory based on estimated current prescription demand. Estimating the amount of returns and discounts for new products is based on specific facts and circumstances including acceptance rates from established products with similar marketing characteristics. At the time of a new product launch, absent the ability to make reliable estimates the Company defers revenue on sales to wholesalers until the Company can make reliable estimates of these returns, discounts and related end user demand. The Company attempts to monitor inventory levels at wholesalers and pharmacies to ensure these levels remain within normal levels. The Company estimates inventory at wholesalers based on historical sales to wholesalers, inventory data provided by these wholesalers and from third party market research data related to prescription trends and patient demand. Making these determinations involves estimating whether trends in past buying patterns will predict future product sales.

The Company records allowances for product returns and coupon rebates when revenue is recognized, and report revenue net of such amounts. In determining allowances for product returns and rebates, the Company must make significant judgments and estimates. For example, in determining these amounts, the Company estimates prescription demand and the levels of inventory held by wholesalers. Making these determinations involves estimating whether trends in past buying patterns will predict future product sales.

The nature of the Company's allowances requiring critical accounting estimates, and the specific considerations used in estimating their amounts, are as follows:

- *Product returns.* Customers have the right to return any unopened product during the 18-month period beginning six months prior to the labeled expiration date and ending 12 months after the labeled expiration date. As a result, in calculating the allowance for product returns, the Company must estimate the likelihood that product sold to wholesalers and pharmacies might remain in their inventory to within six months of expiration and analyze the likelihood that such product will be returned within 12 months after expiration.

  In estimating the likelihood of product remaining in wholesalers' inventory, the Company utilizes information from its wholesalers regarding their inventory levels, measured prescription demand as reported by third party sources and on internal sales data. The Company believes the information from its wholesalers and third party sources is directionally reliable, but the Company is unable to verify the accuracy of such data independently. The Company also considers our wholesalers' past buying patterns, estimated remaining shelf life of product previously shipped and the expiration dates of product currently being shipped. In estimating the likelihood of product return, the Company relies primarily on historic patterns of returns and estimated remaining shelf life of product previously shipped.

- *Discounts and rebates.* The Company sells Solagé primarily to wholesalers and distributors, who in turn sell to pharmacies. From time to time the Company offers patients a limited time coupon discount on their purchases of Solagé. A mail-in rebate coupon is provided to the patient with a proof of purchase of Solagé.

  As a result of these rebate offers, at the time of product shipment, the Company must estimate the likelihood that Solagé sold to wholesalers and pharmacies might be ultimately sold to a patient who redeems a coupon. The Company bases estimates on the historic coupon redemption rates for similar products received from third party administrators, which detail historic patterns.

  The Company will adjust its allowances for product returns and coupon rebates based on actual sales experience, and will likely be required to make adjustments to these allowances in the future. The Company continually monitors its allowances and makes adjustments when the Company believes actual experience may differ from its estimates.

- *International Distribution Partners.* Under agreements with international distribution partners, the Company plans to sell its product to its distribution partners at a contractual price. These partners generally have no rights of return after they have accepted shipment of the product.

***Other Revenue.*** Other revenue includes contract payments for distribution rights amortized over the contract period and grant revenue. Contract revenues include payments associated with collaborations with third parties. Revenue is generally recognized when there is persuasive evidence of an arrangement, delivery has occurred or services have been rendered, the price is fixed or determinable, and collectibility is reasonably assured.

Revenue from non-refundable, upfront license fees where the Company has a continuing involvement is recognized ratably over the performance period. The Company periodically re-evaluates estimates of the performance period and revises assumptions as appropriate. These changes in assumptions may affect the amount of revenue recorded in financial statements in future periods.

Grant revenues are recognized as the Company provides the services stipulated in the underlying grant based on the time and materials incurred. Amounts received in advance of services provided are recorded as deferred revenue and amortized as revenue when the services are provided.

***Cost of Product Revenues.***

Cost of product revenue includes finished product costs, distribution expense related to product sales, including one-time start-up distribution expenses, and amortization of Solagé product rights.

***Research and Development Costs***

Costs to develop the Company's products are expensed as incurred. Assets acquired that are used for research and development and have no future alternative use are expensed as in-process research and development. There were no in-process research and development expenses recorded for the period ended December 31, 2005.

***Advertising Fees***

Advertising fees are expenses as incurred. Advertising costs were approximately $389,000 for the year ended December 31, 2005. There were no advertising costs for 2004 and 2003.

***Concentration of Credit Risk***

The Company's financial instruments that are exposed to concentration of credit risks consist primarily of cash and cash equivalents and marketable securities. The Company maintains its cash and cash equivalents in bank accounts which, at times, exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to significant credit risk on cash and cash equivalents and marketable securities.

The Company's trade accounts receivable are reported net of allowances for charge-backs, cash discounts and doubtful accounts. The Company performs ongoing credit evaluations of its customers and generally does not require collateral. The Company maintains reserves for doubtful accounts, the amount was not material for 2005.

In the United States and Canada, the Company sells products primarily to wholesalers and distributors, who, in turn, sell to pharmacies. In the United States, three wholesalers, Cardinal Health, McKesson and AmerisourceBergen make up approximately 85% of total product revenue.

***Income Taxes***

The Company accounts for income taxes under the asset and liability method whereby deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

***Foreign Currency Translation***

The functional currencies of the Company's foreign subsidiaries are the local currencies: the Euro and Canadian dollar. Assets and liabilities are translated into U.S. dollars at year-end exchange rates and equity accounts are translated at historical exchange rates. The Company translates income and expense

accounts at weighted average rates for each month and records gains and losses from the translation of financial statements in foreign currencies into U.S. dollars in other comprehensive income. Foreign exchange transaction gains and losses are included in the results of operations and are not material to the Company's consolidated financial statements.

***Comprehensive Loss***

Statement of Financial Accounting Standards No. 130, *Reporting Comprehensive Income*, requires components of other comprehensive loss, including unrealized gains and losses on available-for-sale securities and foreign currency translation, to be included as part of total comprehensive loss. The components of comprehensive loss are included in the statements of stockholders' equity (deficiency).

***Stock-Based Compensation***

As allowed by SFAS 123, the Company had elected to continue to apply the intrinsic value-based method of accounting prescribed in APB Opinion 25 and, accordingly, does not recognize compensation expense for stock option grants made at an exercise price equal to or in excess of the fair market value of the stock at the date of grant. For pro forma purposes the stock compensation expense is based on an accelerated vesting method.

Had compensation cost for the Company's outstanding employee stock options been determined based on the fair value at the grant dates for those options consistent with SFAS 123, the Company's net loss and basic and diluted net loss per share, would have been changed to the following pro forma amounts:

(In thousands, except per-share amounts)

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2005 | 2004 | 2003 |
| Net loss attributable to common stockholders | $ (45,241) | $ (44,335) | $ (28,647) |
| Add non-cash employee compensation as reported | 889 | 2,001 | 198 |
| Deduct total stock-based employee compensation expense determined under fair value based method for all awards | (5,095) | (3,871) | (273) |
| SFAS 123 pro forma net loss | $ (49,447) | $ (46,205) | $ (28,722) |
| Basic and diluted loss attributable per common share | $ (1.91) | $ (3.02) | $ (83.95) |
| Basic and diluted loss attributable to common stockholders per share, SFAS 123 pro forma | $ (2.09) | $ (3.15) | $ (84.17) |

SFAS 123 pro forma information regarding net loss is required by SFAS 123, and has been determined as if the Company had accounted for its stock-based employee compensation under the fair value method prescribed in SFAS 123. The fair value of the options was estimated using the Black-Scholes pricing model with the following assumptions:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2005 | 2004 | 2003 |
| Risk-free interest rate | 4.0% | 4.0% | 2.8-3% |
| Dividend yield | 0% | 0% | 0% |
| Expected life | 6.0 years | 8.5 years | 9.0 years |
| Volatility | 75% | 75% | 75% |

The effects of applying SFAS 123 in this pro forma disclosure are not indicative of future amounts. Stock option grants are expensed over their respective vesting periods.

The Company accounts for options issued to non-employees under SFAS 123 and EITF Issue 96-18, *Accounting for Equity Investments that are Issued to Other than Employees for Acquiring or in Conjunction with Selling Goods or Services* ("EITF 96-18"). As such, the value of such options is periodically remeasured during their vesting terms.

***Deferred Stock Compensation***

In connection with the grant of stock options to employees and directors, the Company recorded deferred stock compensation prior to the IPO. There was no deferred compensation related to options issued during 2005. In 2005, the Company reversed prior year deferred compensation of approximately $89,000 related to employee terminations. The deferred compensation amounts are included as a reduction of stockholders' equity and are being amortized over the vesting period of the individual options, generally four years, using an accelerated vesting method. The accelerated vesting method provides for vesting of portions of the overall award at interim dates and results in higher vesting in earlier years than straight-line vesting. During the year ended December 31, 2005, the Company recorded amortization of deferred stock compensation of $889,000. As of December 31, 2005, the Company recorded deferred stock compensation of $3.7 million, related amortization of $3.1 million, and reversed $0.1 million of prior year deferred compensation related to employee terminations. The Company is applying a graded vesting amortization policy for deferred compensation.

***Net Loss Per Common Share***

The Company computes basic net loss per common share ("Basic EPS") by dividing net loss by the weighted-average number of common shares outstanding. Diluted net loss per common share ("Diluted EPS") is computed by dividing net loss by the weighted-average number of common shares and dilutive common shares equivalents then outstanding. Common equivalent shares consist of the incremental common shares issuable upon the conversion of preferred stock, and the shares issuable upon the exercise of stock options. Diluted EPS is identical to Basic EPS since common equivalent shares are excluded from the calculations, as their effect is anti-dilutive. The following table summarizes the Company's calculation of net loss per common share:

(In thousands, except share and per-share amounts)

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2005 | 2004 | 2003 |
| Net loss attributable to common stockholders | $ (45,241) | $ (44,335) | $ (28,647) |
| Basic and diluted: | | | |
| Weighted-average shares of common stock outstanding | 23,798,922 | 14,988,799 | 822,500 |
| Less: weighted-average shares subject to repurchase | (142,616) | (311,089) | (481,244) |
| Shares used in computing basic and diluted net loss per common share | 23,656,306 | 14,677,710 | 341,256 |
| Basic and diluted net loss per common share | $ (1.91) | $ (3.02) | $ (83.95) |

The following table shows dilutive common share equivalents outstanding, which are not included in the above historical calculation, as the effect of their inclusion is anti-dilutive during each period.

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2005 | 2004 | 2003 |
| Preferred stock | — | — | 31,921,809 |
| Options | 1,819,587 | 1,438,937 | 878,583 |

***Recently Issued Accounting Pronouncements***

On December 16, 2004, the Financial Accounting Standards Board issued Statement No. 123, revised 2004, *Share-Based Payment*, which is a revision of FASB Statement No. 123, *Accounting for Stock-Based Compensation*. Statement 123(R) supersedes Accounting Principal Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends FASB No. 95, *Statement of Cash Flows*. Generally, the approach to accounting in Statement 123(R) is similar to the approach described in Statement 123. However, Statement 123(R) *requires* all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. On April 15, 2005, the Securities and Exchange Commission adopted a new rule that extended the compliance date for periods ending after January 1, 2006.

Currently the Company accounts for these payments under the intrinsic value provisions of APB No. 25. Effective January 1, 2006, the Company will adopt Statement 123(R) using the modified prospective method. The Company will commence the new method of valuing stock-based compensation as prescribed by Statement 123(R) on all stock-based awards granted after the effective date. The Company estimates that the 2006 expense associated with recognition of additional non-cash compensation expense related to such awards will be approximately $6 million.

## 2. Available for Sale Investments

The following is a summary of available for sale investments as of December 31, 2005 and December 31, 2004:

(In thousands)

| | Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|---|---|---|---|
| **December 31, 2005** | | | | |
| Maturities within one year: | | | | |
| Corporate notes | $ 36,273 | $ — | $ (73) | $ 36,200 |
| Federal agency notes | 11,397 | — | (16) | 11,381 |
| Asset-backed securities | 13,686 | — | (38) | 13,648 |
| Total | $ 61,356 | $ — | $ (127) | $ 61,229 |
| **December 31, 2004** | | | | |
| Maturities within one year: | | | | |
| Corporate notes | $ 56,245 | $ — | $ (173) | $ 56,072 |
| Federal agency notes | 16,431 | — | (12) | 16,419 |
| Asset-backed securities | 4,688 | — | (6) | 4,682 |
| Total | $ 77,364 | $ — | $ (191) | $ 77,173 |

Unrealized gains and losses are reported as a component of accumulated other comprehensive income (loss) in stockholders' equity. The amortized cost of debt securities is adjusted for amortization of premiums and discounts from the date of purchase to maturity. Such amortization is included in interest income as an addition to or deduction from the coupon interest earned on the investments. There are no realized gains or losses on marketable securities as the Company has not sold any marketable securities during the periods presented.

Unrealized losses in the Company's portfolio relate primarily to fixed income debt securities and all of the unrealized losses are one year or less. For these securities, the unrealized losses are due to increases in interest rates and not changes in credit risk. The gross unrealized losses in the portfolio of investments represent less than one percent of the total fair value of the portfolio. The Company has concluded that

the unrealized losses in its marketable securities are temporary and the Company has the ability to hold the securities to maturity or a planned forecasted recovery.

### 3. Property and Equipment

Fixed assets consist of the following:

| | Estimated Life | December 31, 2005 | December 31, 2004 |
|---|---|---|---|
| Furniture and fixtures | 5 years | $ 592 | $ 471 |
| Computer, laboratory and office equipment | 3 years | 770 | 703 |
| Computer software | 3 years | 468 | 468 |
| Leasehold improvements | (a) | 215 | 45 |
| | | 2,045 | 1,687 |
| Less accumulated depreciation | | (990) | (562) |
| | | $ 1,055 | $ 1,125 |

(a) Leasehold improvements are depreciated over the estimated useful lives of the assets or related initial lease terms, whichever is shorter.

Depreciation expense was approximately $428,000, $381,000 and $144,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

### 4. Intangible Assets

On February 7, 2005, the Company entered into a Product Acquisition Agreement with Moreland Enterprises, Ltd. ("Moreland"). Under the terms of the Product Acquisition Agreement, the Company acquired the United States and Canadian rights to Solagé (mequinol 2%, tretinoin 0.01%) Topical Solution, and all existing finished goods inventory. The Company was assigned all U. S. and Canadian marketing authorizations, patents, and trademarks for the product. The patent rights include U.S. and Canadian patents covering the pharmaceutical composition of Solagé and methods of use until at least 2013.

The Company acquired the intellectual property and finished goods inventory for $3.1 million and will make future payments totaling up to an additional $2.0 million, if certain sales targets are met. The total initial purchase price was allocated $3.0 million to product rights and $61,000 to inventory. During 2005, the Company recorded a liability and a corresponding increase to the intangible asset product rights of $100,000 for future amounts payable to Moreland based on product sales during the period. Product rights are being amortized on a straight-line basis over the life of the underlying patent, which expires in 2013.

The following information relates to acquired product rights as of December 31, 2005:

| (In Thousands) | Gross Carrying Amount | Accumulated Amortization |
|---|---|---|
| Product Rights | $ 3,100 | $ 320 |

Total accumulated amortization for intangible assets amounted to $320,000 at December 31, 2005. As of December 31, 2005, the estimated amortization expense for each of the five succeeding years will be $351,000 per year.

## 5. Balance Sheet Detail

Accrued liabilities consist of the following as of December 31:

| (In Thousands) | December 31, 2005 | December 31, 2004 |
|---|---|---|
| Accrued product costs | $ 566 | $ 2,316 |
| Accrued compensation and benefits | 2,027 | 1,698 |
| Accrued other | 1,553 | 673 |
| | $ 4,146 | $ 4,687 |

## 6. Notes Payable

In September 2003, the Company entered into an equipment and furniture financing arrangement with a third party for up to $750,000 which was increased to $1,500,000 in 2004, with an interest rate of 6.15% plus the three year Treasury Constant Maturities rates at the time of funding. Each time it receives funding, the Company will enter into a promissory note with a term of three years, collateralized by the related equipment and furniture.

In November 2003, the Company entered into a promissory note for $267,851, payable in 35 monthly installments of $8,498, including interest at 8.84%. In August 2004, the Company entered into a promissory note for $407,179, payable in 35 monthly installments of $12,939, including interest at 8.95%. In December 2004, the Company entered into a promissory note for $148,014, payable in 35 monthly installments of $4,732, including interest at 9.37%. In December 2005, the Company entered into a promissory note for $340,391, payable in 35 monthly installments of $11,067, including interest at 10.52%.

Principal payments under notes payable are as follows (in thousands):

| | |
|---|---|
| 2006 | $ 379 |
| 2007 | 279 |
| 2008 | 126 |
| | $ 784 |

## 7. Income Taxes

There is no tax provision for federal income taxes as the Company has incurred operating losses since inception. At December 31, 2005, the Company has net operating loss carry-forwards for federal income tax purposes of approximately $102,232,000, which begin to expire in 2021. The Company has research tax credit carryovers for federal income tax purposes at December 31, 2005 of approximately $4,000,000, which begin to expire in 2021.

During 2005, 2004 and 2003, the Company sold a portion of its unused New Jersey State operating loss carry-forwards, through a program sponsored by the State of New Jersey and the New Jersey Economic Development Authority. Cash proceeds of approximately $536,000, $367,000 and $217,000, net of fees of $63,000, $49,000 and $35,000, respectively, were received by the Company resulting in the recognition of a tax benefit.

The benefit for income taxes is as follows:

| (In Thousands) | Year Ended December 31, 2005 | 2004 | 2003 |
|---|---|---|---|
| Federal income taxes: | | | |
| Current expense | $ – | $ – | $ – |
| Deferred expense | – | – | – |
| State income taxes: | | | |
| Current benefit | 536 | 367 | 217 |
| Deferred expense | – | – | – |
| Foreign income taxes: | | | |
| Current expense | – | – | – |
| Deferred expense | – | – | – |
| Income tax benefit | $536 | $367 | $217 |

Utilization of the net operating loss carry-forwards and credits may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. The Company has not performed a detailed analysis to determine whether an ownership change under Section 382 of the Internal Revenue Code occurred. The effect of an ownership change would be the imposition of an annual limitation on the use of net operating loss carry-forwards attributable to periods before the change.

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company's deferred tax assets relate primarily to its net operating loss carry-forwards. At December 31, 2005 and 2004, a valuation allowance was recorded to fully offset the net deferred tax asset. The change in the valuation allowance for the years ended December 31, 2005 and 2004 was approximately $19,532,000 and $17,835,000, respectively. Significant components of the Company's deferred tax assets at December 31, 2005 and 2004 are as follows:

| (In Thousands) | Year Ended December 31, 2005 | 2004 |
|---|---|---|
| Deferred tax assets: | | |
| Net operating loss carry-forwards | $40,398 | $ 22,760 |
| Stock-based compensation | 358 | 1,232 |
| Research tax credits | 5,895 | 3,242 |
| Deferred revenue | 247 | 260 |
| Other | 526 | 407 |
| Total deferred tax asset | 47,424 | 27,901 |
| Deferred tax liabilities: | | |
| Depreciation | (93) | (102) |
| Total gross deferred tax liabilities | (93) | (102) |
| Less valuation allowance | (47,331) | (27,799) |
| Net deferred tax asset | $ — | $ — |

A reconciliation of the statutory tax rates and the effective tax rates for the years ended December 31, 2005 and 2004 is as follows:

| | Year Ended December 31, 2005 | 2004 |
|---|---|---|
| Statutory rate | (34)% | (34)% |
| State income tax | (7)% | (7)% |
| Research tax credits | (2)% | (5)% |
| Change in valuation allowance | 42% | 45% |
| Benefit for income tax | (1)% | (1)% |

## 8. Stockholders' Equity and Capital Structure

*Preferred Stock*

In connection with the IPO the Company's Series A, Series B, and Series C redeemable convertible preferred stock were converted into one share of common stock for each preferred share held by the investor. Fractional shares were redeemed for cash. Pursuant to the Company's Amended and Restated Certificate of Incorporation filed on May 3, 2004, the Company has 5,000,000 shares of authorized "blank-check" preferred stock. The Board of Directors is authorized to issue these shares in one or more series without stockholder approval. The Board of Directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences of each series of preferred stock.

*Common Stock*

The Company is authorized to issue 80,000,000 shares of common stock. The Company is required to, at all times, reserve and keep available out of its authorized but unissued shares of common stock sufficient shares to effect the conversion of the shares of the redeemable convertible preferred stock and stock options.

The restricted shares generally vest as follows: (a) 25% on the common stock shall vest on the date each founder commences employment with the Company, (b) 18.75% shall vest on the first anniversary of the date of employment, and (c) the remaining 56.25% shall vest in equal installments over a three year period beginning the month following the first anniversary.

*Employee Stock Purchase Plan*

The Company established an Employee Stock Purchase Plan (the "ESPP") in February 2004 which was approved by the stockholders in March 2004. The plan allows eligible employees the opportunity to acquire shares of Barrier's common stock (the "Common Stock") at periodic intervals through accumulated payroll deductions. These deductions will be applied at semi-annual intervals to purchase shares of Common Stock at a discount from the then current market price. The purchase price per share will be equal to 85% of the fair market value per share on the date in which the participant is enrolled, or, if lower, 85% of the fair market value per share on the semi-annual purchase date. Semi-annual purchase dates are the last business day of January and July each year.

Initially 200,000 shares were reserved for issuance. The number of shares reserved for the plan will be automatically increased each year on the first trading day in January by an amount equal to .5% of the total number of outstanding shares of common stock on the last trading day of December in the prior year,

not to exceed 150,000 shares. There is a 1,500 share purchase limitation per participant and 75,000 aggregate purchase limitation per purchase date.

As of December 31, 2005, a total of 21,574 shares of common stock were purchased under this plan; 4,050 shares were purchased at $8.94 per share, 7,354 shares were purchased at $9.35 per share and 10,170 shares were purchased at $7.97 per share.

*Stock Options*

On April 26, 2002, the Company's Board of Directors and stockholders approved the Company's 2002 Equity Compensation Plan (the "2002 Plan"). In March 2004, the Company's Board of Directors and stockholders approved the Company's 2004 Equity Compensation Plan (the "2004" Plan). On that date, the outstanding options under the 2002 Plan were transferred to the 2004 Plan, and no further options may be granted under the 2002 Plan. The 2002 Plan options will continue to be governed by their existing terms, unless the Board or its committee elects to extend one or more features of the 2004 Plan to these options. The options granted under the 2002 Plan have substantially the same terms as the options granted under the 2004 Plan.

The 2004 Plan provides for the granting of options to purchase shares of the Company's common stock to key employees, advisors and consultants at a price not less than the fair market value at the date of grant, or stock appreciation rights tied to the value of such common stock. The number of shares of common stock reserved for issuance under the 2004 Plan will automatically increase each year on the first trading day in January of each calendar year by an amount equal to 5% of the total number of shares of common stock outstanding on the last trading day in December, not in excess of 1,000,000 shares.

The 2004 Plan is intended to encourage ownership of stock by employees and consultants of the Company and to provide additional incentives for them to promote the success of the Company's business and is administered by the Board of Directors or committee consisting of members of the Board. Options granted pursuant to the 2004 Plan generally vest 25% after the first year, and the remaining 75% vest monthly over the next three years.

The following table summarizes information about stock options outstanding at December 31, 2005:

| | Shares Available for Grant | Options Outstanding: Number of Shares | Options Outstanding: Option Price Per Share Range | Options Outstanding: Weighted-Average Exercise Price |
|---|---|---|---|---|
| Balance at December 31, 2002 | 570,000 | 357,500 | 0.60 | 0.60 |
| Shares authorized | 500,000 | | — | — |
| Options granted | (521,083) | 521,083 | 0.80-3.00 | 0.88 |
| Options exercised | — | — | — | — |
| Options forfeited | — | — | — | — |
| Balance at December 31, 2003 | 548,917 | 878,583 | 0.60-3.00 | 0.88 |
| Shares authorized | 500,000 | — | — | — |
| Options granted | (691,050) | 691,050 | 3.50-17.70 | 8.50 |
| Options exercised | | (107,382) | 0.60-4.00 | 1.09 |
| Options forfeited | 23,314 | (23,314) | 0.60-3.50 | 0.94 |
| Balance at December 31, 2004 | 381,181 | 1,438,937 | 0.60-17.70 | 4.52 |
| Shares authorized | 1,000,000 | | — | — |
| Options granted | (713,800) | 713,800 | 7.05-19.98 | 14.12 |
| Options exercised | — | (183,521) | 0.60-14.74 | 2.35 |
| Options forfeited | 149,629 | (149,629) | 0.60-18.56 | 6.70 |
| Balance at December 31, 2005 | 817,010 | 1,819,587 | $0.60-19.98 | $ 8.32 |

The following table summarizes information about vested stock options outstanding:

| | December 31, 2005 | December 31, 2004 | December 31, 2003 |
|---|---|---|---|
| Vested stock options | 696,010 | 383,586 | 159,404 |
| Weighted-average exercise price | $ 4.68 | $ 1.09 | $ 0.68 |

The following table summarizes information about stock options outstanding at December 31, 2005:

| Exercise Price | Options Outstanding | Options Vested | Weighted-Average Remaining Contractual Life |
|---|---|---|---|
| $0.60 – $1.50 | 539,846 | 377,324 | 7.1 |
| 3.00 – 4.00 | 154,391 | 84,879 | 8.0 |
| 4.01 – 8.00 | 231,200 | 95,427 | 8.4 |
| 8.01 – 10.00 | 153,200 | 2,500 | 9.7 |
| 10.01 – 14.00 | 278,000 | 64,084 | 8.5 |
| 14.01 – 20.00 | 462,950 | 71,796 | 9.0 |
| | 1,819,587 | 696,010 | 8.3 |

The weighted-average fair value of options issued during 2005 and 2004 were $14.12 and $10.70, respectively.

Compensation expense of $378,000, $756,000 and $107,000 has been recognized in 2005, 2004 and 2003, respectively, for non-employee options granted.

## 9. Commitments and Contingencies

***Johnson & Johnson***

In addition to the Series A exchanged for the acquisition of in-process research and development, Janssen Pharmaceutica Products, L.P., Johnson & Johnson Consumer Companies, Inc., and Ortho-McNeil Pharmaceutical, Inc., received certain rights of first negotiation for the marketing and sales of those drugs which the Company successfully develops from that portfolio. The most significant terms of the license provide the following:

(a) the licenses are subject to a right of first negotiation for the marketing and sale of those drugs which the Company elects not to market itself or through contract sales organizations on a territory-by- territory basis,

(b) the licenses are royalty-free, except for the so-called "itraconazole melt extrusion", Hyphanox, which will require the payment of a royalty with respect to those sales not effectuated directly by the Company or through contract sales organizations on a territory-by-territory basis, and

(c) as to the "itraconazole melt extrusion" only, Janssen Pharmaceutica Products, L.P., Johnson & Johnson Consumer Companies, Inc., and Ortho-McNeil Pharmaceutical, Inc., has an option to acquire the marketing and sales rights on a territory-by-territory basis subject to payment to the Company of: fees as specified in the contract; all of the Company's development costs on such project; and a royalty on sales, as stated in the contract, depending on the duration from the date of delivery of materials until the Company's first major market filing for drug approval (NDA or equivalent).

In September 2005, Janssen notified the Company that it would not exercise its option and, as a result, the Company retains worldwide rights for all licensed indications for this product candidate.

## 10. Geographic Segments

The Company manages its business and operations as one segment and is focused on the development and commercialization of its product candidates and approved products for marketing. The Company operates in United States, Belgium and Canada.

The following table presents financial information based on the geographic location of the facilities of the Company and for the years ended (in thousands):

| December 31, 2005 | United States | International | Total |
|---|---|---|---|
| Total assets | $ 83,212 | $ 1,749 | $ 84,961 |
| Property and equipment, net | 831 | 224 | 1,055 |
| Product revenues | 684 | 108 | 792 |
| Grant revenues | — | 1,059 | 1,059 |
| Contract revenues | 660 | 29 | 689 |

| December 31, 2004 | United States | International | Total |
|---|---|---|---|
| Total assets | $ 91,679 | $ 1,105 | $92,784 |
| Property and equipment, net | 780 | 345 | 1,125 |
| Product revenues | — | — | — |
| Grant revenues | — | 797 | 797 |
| Contract revenues | 100 | — | 100 |

| December 31, 2003 | United States | International | Total |
|---|---|---|---|
| Total assets | $ 56,415 | $ 556 | $ 56,971 |
| Property and equipment, net | 600 | 245 | 845 |
| Product revenues | — | — | — |
| Grant revenues | — | 367 | 367 |
| Contract revenues | — | — | — |

## 11. Related Party Transactions

In July 2004, the Company entered into an agreement with Janssen Pharmaceutica, NV under which the Company committed to purchase € 1,000,000 (approximately $1,365,000) of inventory within the two-year period ending July 2008. The Company recorded approximately $57,000 in 2005 related to this agreement.

The Company expensed approximately $14,000, $21,000 and $1,607,000 for the purchase of raw materials and clinical supplies from a Janssen during 2005, 2004 and 2003, respectively.

## 12. Leases

The Company leases its U.S. corporate facilities in Princeton, New Jersey under a lease which expires in September 2010. The Company leases space in Geel, Belgium under a short-term service agreement with a monthly fee of approximately $13,800. Future minimum lease commitments are as follows:

| | |
|---|---|
| 2006 | $ 666,000 |
| 2007 | 632,000 |
| 2008 | 624,000 |
| 2009 | 631,000 |
| 2010 | 473,000 |
| Thereafter | - |
| | $ 3,026,000 |

Total rent expense was $743,000 in 2005, $425,000 in 2004, and $283,000 in 2003.

## 13. Benefit Plan

In July 2002, the Company established a 401(k) plan (the "Plan") covering all eligible employees. Beginning January 1, 2005, the Company elected to match a portion of the employee's contribution. The Company's contributions for 2005 were approximately $78,000.

## 14. Selected Quarterly Financial Data (Unaudited)

(In Thousands except per share amounts)

| | Quarter Ended | | | |
|---|---|---|---|---|
| | March 31, | June 30, | September 30, | December 31, |
| **2005** | | | | |
| Net revenue | $ 653 | $ 472 | $ 626 | $ 789 |
| Cost of product revenues | (82) | (103) | (163) | (195) |
| Total operating expenses | (13,403) | (12,026) | (13,437) | (12,328) |
| Net loss | (12,158) | (10,809) | (12,050) | (10,225) |
| Net loss attributable to common stockholders | (12,158) | (10,809) | (12,050) | (10,225) |
| Basic and diluted net loss per common share(1) | $ (0.53) | $ (0.45) | $ (0.50) | $ (0.43) |
| **2004** | | | | |
| Net revenue | $ 181 | $ 179 | $ 223 | $ 315 |
| Cost of product revenues | — | — | — | — |
| Total operating expenses | (7,870) | (9,247) | (10,806) | (14,456) |
| Net loss | (7,524) | (8,756) | (10,150) | (13,313) |
| Net loss attributable to common stockholders | (10,942) | (9,930) | (10,150) | (13,313) |
| Basic and diluted net loss per common share(1) (2) | $ (22.62) | $ (0.66) | $ (0.47) | $ (0.62) |

(1) Per common share amounts for the quarters and full years have been calculated separately. Accordingly, quarterly amounts do not add to the annual amount because of differences in the weighted-average common shares outstanding during each period principally due to the effect of the Company's issuing shares of its common stock during the year.

(2) The March 31, 2004 basic and diluted net loss per common share was prior to the Company's initial public offering.

Diluted EPS is identical to Basic EPS since common equivalent shares are excluded from the calculation, as their effect is anti-dilutive.

The above amounts are calculated independently for each of the quarters presented. The sum of the quarters may not equal the full year amounts.

## 15. Legal Matters

In October, 2005, a purported class action lawsuit was filed in the United States District Court for the District of New Jersey against the Company and certain of its officers on behalf of all persons who purchased or acquired securities of Barrier Therapeutics, Inc. between April 29, 2004 and June 29, 2005. At least four additional putative class action lawsuits have also been filed against the Company and certain of its officers, all pleading essentially the same allegations. In an Order entered on December 19, 2005, the Court consolidated these cases. By Order dated March 2, 2006, the Court appointed lead plaintiffs and approved co-lead counsel. The complaints filed allege violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, and under Sections 11, 12 and 15 of the Securities Exchange Act of 1933. Based on a preliminary review and analysis of the

complaints, the Company believes that each of the lawsuits is without merit and intends to defend each of these lawsuits vigorously. The Company is not presently able to estimate the potential losses, if any, related to these lawsuits.

**16. Subsequent Events (Unaudited)**

On February 16, 2006, the U.S. Food and Drug Administration (FDA) approved Vusion(TM) (0.25% miconazole nitrate, 15% zinc oxide and 81.35% white petrolatum) Ointment. Vusion was specifically formulated for the treatment of diaper dermatitis complicated by candidiasis (DDCC) in infants 4 weeks and older. This inflammatory condition occurs when diaper dermatitis, also known as diaper rash, is complicated with a fungal infection caused by yeast known as Candida. The existence of Candida is readily determined by microscopic evaluation for presence of pseudohyphae or budding yeast. Vusion is the only prescription product approved for the treatment of this condition in the United States.

## INDEX OF EXHIBITS

| Exhibit No. | Description |
|---|---|
| 3.1 | Amended and Restated Certificate of Incorporation, filed as Exhibit 3.2 to the Company's Registration Statement on Form S-1 (File No. 333-112539) |
| 3.2 | Amended and Restated Bylaws of the Registrant, filed as Exhibit 3.4 to the Company's Registration Statement on Form S-1 (File No. 333-112539) |
| 4.1 | Specimen copy of stock certificate for shares of Common Stock of the Registrant, filed as Exhibit 4.1 to the Company's Registration Statement on Form S-1 (File No. 333-112539) |
| 4.2 | Amended and Restated Investors Rights Agreement, dated as of April 20, 2004, by and among the Registrant and the Investors listed therein, filed as Exhibit 4.2 to the Company's Registration Statement on Form S-1 (File No. 333-112539) |
| 10.1† | 2002 Equity Compensation Plan, filed as Exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-112539) |
| 10.2*(1)* | Intellectual Property Transfer and License Agreement, dated as of May 6, 2002, by and between the Registrant and Johnson & Johnson Consumer Companies, Inc., filed as Exhibit 10.2 to the Company's Registration Statement on Form S-1 (File No. 333-112539) |
| 10.3 | Amendment No. 1 to the Intellectual Property Transfer and License Agreement dated as of September 7, 2004, by and between Barrier Therapeutics, Inc. and Johnson & Johnson Consumer Companies, Inc., filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 10, 2004 |
| 10.4*(1)* | Intellectual Property Transfer and License Agreement, dated as of May 6, 2002, by and among the Registrant and Janssen Pharmaceutica Products, L.P. and Ortho-McNeil Pharmaceutical, Inc., filed as Exhibit 10.3 to the Company's Registration Statement on Form S-1 (File No. 333-112539) |
| 10.5 | Amendment No. 1 to the Intellectual Property Transfer and License Agreement, dated as of September 7, 2004, by and between Barrier Therapeutics, Inc. and Janssen Pharmaceutica Products, L.P. , filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed on September 10, 2004 |
| 10.6† | Employment Agreement, effective as of April 1, 2004, by and between the Registrant and Geert Cauwenbergh, Ph.D., filed as Exhibit 10.4 to the Company's Registration Statement on Form S-1 (File No. 333-112539) |
| 10.7† | Employment Agreement, effective as of April 1, 2004, by and between the Registrant and Charles Nomides, filed as Exhibit 10.5 to the Company's Registration Statement on Form S-1 (File No. 333-112539) |
| 10.8† | Employment Agreement, effective as of April 1, 2004, by and between the Registrant and Anne M. VanLent, filed as Exhibit 10.6 to the Company's Registration Statement on Form S-1 (File No. 333-112539) |
| 10.9† | Employment Agreement, effective as of April 1, 2004, by and between the Registrant and Alfred Altomari |

| Exhibit No. | Description |
|---|---|
| 10.10† | Employment Agreement, effective as of April 1, 2004, by and between the Registrant and Albert Bristow |
| 10.11† | Restricted Stock Purchase Agreement, dated as of October 31, 2001, by and between the Registrant and Geert Cauwenbergh, Ph.D., filed as Exhibit 10.7 to the Company's Registration Statement on Form S-1 (File No. 333-112539) |
| 10.12† | Amendment No. 1 to Restricted Stock Purchase Agreement, dated as of May 7, 2002, by and between the Registrant and Geert Cauwenbergh, Ph.D., filed as Exhibit 10.8 to the Company's Registration Statement on Form S-1 (File No. 333-112539) |
| 10.13† | Amendment No. 2 to Restricted Stock Purchase Agreement, dated as of April 1, 2004, by and between the Registrant and Geert Cauwenbergh, Ph.D., filed as Exhibit 10.18 to the Company's Registration Statement on Form S-1 (File No. 333-112539) |
| 10.14† | Restricted Stock Purchase Agreement, dated as of February 20, 2002, by and between the Registrant and Charles Nomides, filed as Exhibit 10.9 to the Company's Registration Statement on Form S-1 (File No. 333-112539) |
| 10.15† | Amendment No. 1 to Restricted Stock Purchase Agreement, dated May 7, 2002, by and between the Registrant and Charles Nomides, filed as Exhibit 10.10 to the Company's Registration Statement on Form S-1 (File No. 333-112539) |
| 10.16† | Amendment No. 2 to Restricted Stock Purchase Agreement, dated as of April 1, 2004, by and between the Registrant and Charles Nomides, filed as Exhibit 10.19 to the Company's Registration Statement on Form S-1 (File No. 333-112539) |
| 10.17† | Restricted Stock Purchase Agreement, dated as of August 1, 2002, by and between the Registrant and Anne M. VanLent, filed as Exhibit 10.11 to the Company's Registration Statement on Form S-1 (File No. 333-112539) |
| 10.18† | Amendment No. 1 to Restricted Stock Purchase Agreement, dated as of April 1, 2004, by and between the Registrant and Anne M. VanLent, filed as Exhibit 10.20 to the Company's Registration Statement on Form S-1 (File No. 333-112539) |
| 10.19 | Lease Agreement, dated May 28, 2003, between the Registrant and Peregrine Investment Partners-I relating to property located at 600 College Road East, Princeton Forrestal Center, New Jersey, filed as Exhibit 10.12 to the Company's Registration Statement on Form S-1 (File No. 333-112539) |
| 10.20 | Amendment No. 1 dated November 6, 2003, to Lease Agreement, dated May 28, 2003, between the Registrant and Peregrine Investment Partners-I relating to property located at 600 College Road East, Princeton Forrestal Center, New Jersey, filed as Exhibit 10.13 to the Company's Registration Statement on Form S-1 (File No. 333-112539) |
| 10.21 | Master Security Agreement, dated as of August 21, 2003 and Amendment, dated as of September 3, 2003, between the Registrant and General Electric Capital Corporation, filed as Exhibit 10.14 to the Company's Registration Statement on Form S-1 (File No. 333-112539) |

| Exhibit No. | Description |
|---|---|
| 10.22*(1)* | Development and Supply Agreement, dated as of May 16, 2002, between the Registrant and Abbott GmbH & Co. KG, filed as Exhibit 10.15 to the Company's Registration Statement on Form S-1 (File No. 333-112539) |
| 10.23† | 2004 Stock Incentive Plan, filed as Exhibit 10.16 to the Company's Registration Statement on Form S-1 (File No. 333-112539) |
| 10.24† | Employee Stock Purchase Plan, filed as Exhibit 10.17 to the Company's Registration Statement on Form S-1 (File No. 333-112539) |
| 10.25 | Amendment No. 2 dated May 13, 2004, to Lease Agreement, dated May 28, 2003, between the Registrant and Peregrine Investment Partners-I relating to property located at 600 College Road East, Princeton Forrestal Center, New Jersey, filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 11, 2004. |
| 10.26*(1)* | Distribution and License Agreement dated November 4, 2004 between the Registrant and Grupo Ferrer Internacional, S.A., filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 9, 2004. |
| 10.27 | Finished Product Supply Agreement dated July 14, 2004 between the Registrant and Janssen Pharmaceutica, NV, filed as Exhibit 10.25 to the Company's Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-122261). |
| 10.28 | Product Acquisition Agreement dated February 5, 2005 between the Registrant and Moreland Enterprises Limited, filed as Exhibit 10.26 to the Company's Amendment No. 2 to the Registration Statement on Form S-1 (File No. 333-122261). |
| 10.29 | Amendment No. 2 to the Intellectual Property Transfer and License Agreement, dated as of May 12, 2005, by and between the Registrant and Janssen Pharmaceutica Products, L.P., filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 11, 2005. |
| 10.30 | Scientific Advisory Board Consulting Agreement dated as of August 1, 2005 by and between the Registrant and Carl W. Ehmann, M.D., filed as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 11, 2005. |
| 10.31 | Amendment dated as of August 26, 2005 to the Finished Product Supply Agreement by and between the Registrant and Janssen Pharmaceutica, NV, filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on November 14, 2005. |

| Exhibit No. | Description |
|---|---|
| *21 | List of Subsidiaries |
| *23.1 | Consent of Ernst & Young LLP |
| *23.2 | Power of Attorney (included on signature page) |
| *31.1 | Certification of principal executive officer required by Rule 13a-14(a) |
| *31.2 | Certification of principal financial officer required by Rule 13a-14(a) |
| ¤32.1 | Section 1350 Certification of principal executive officer |
| ¤32.2 | Section 1350 Certification of principal financial officer |

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* Filed herewith.

¤ Furnished herewith

† Compensation plans and arrangements for executives and others.

*(1)* Portions of the Exhibit have been omitted and have been filed separately pursuant to an application for confidential treatment granted by the Securities and Exchange Commission.

**EXHIBIT 21**

## LIST OF SUBSIDIARIES

Barrier Therapeutics, NV, a corporation organized under the laws of Belgium.

Barrier Therapeutics Canada, Inc., a corporation organized under the laws of Ontario, Canada.

**EXHIBIT 23.1**

## CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements (Form S-8 Nos. 333-125141 and 333-115597) pertaining to the 2004 Stock Incentive Plan and the Employee Stock Purchase Plan of Barrier Therapeutics, Inc. of our reports dated March 9, 2006, with respect to the consolidated financial statements of Barrier Therapeutics, Inc., Barrier Therapeutics, Inc. management's assessment of the effectiveness of internal control over financial reporting, and the effectiveness of internal control over financial reporting of Barrier Therapeutics, Inc. included in the Annual Report (Form 10-K) for the year ended December 31, 2005.

/s/ ERNST & YOUNG LLP

MetroPark, New Jersey
March 9, 2006

**EXHIBIT 31.1**

## CERTIFICATION

Geert Cauwenbergh, certify that:

1. I have reviewed this annual report on Form 10-K of Barrier Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

ate: March 14, 2006

GEERT CAUWENBERGH

Geert Cauwenbergh, Ph.D.
Chairman and Chief Executive Officer
(Principal Executive Officer)

**EXHIBIT 31.**

## CERTIFICATION

I, Anne M. VanLent, certify that:

1. I have reviewed this annual report on Form 10-K of Barrier Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented i this report our conclusions about the effectiveness of the disclosure controls and procedures, as o the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting tha occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (e) All significant deficiencies and material weaknesses in the design or operation of internal contro over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (f) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2006

ANNE M. VANLENT

Anne M. VanLent
Executive Vice President, Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)

**EXHIBIT 32.1**

**CERTIFICATION PURSUANT TO**
**18 U.S.C. SECTION 1350,**
**AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Barrier Therapeutics, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2005 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Geert Cauwenbergh, Chairman and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, based on my knowledge, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

GEERT CAUWENBERGH
Geert Cauwenbergh, Ph.D.
Chairman and Chief Executive Officer
(Principal Executive Officer)

March 14, 2006

**EXHIBIT 32.**

**CERTIFICATION PURSUANT TO**
**18 U.S.C. SECTION 1350,**
**AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Barrier Therapeutics, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2005 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I Anne M. VanLent, Executive Vice president, Chief Financial Officer and Treasurer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, based on my knowledge, that:

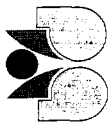
(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

ANNE M. VANLENT

Anne M. VanLent
Executive Vice President, Chief Financial Officer and
Treasurer
(Principal Financial and Accounting Officer)

March 14, 2006



**Barrier** *Therapeutics, Inc.*

# LETTER FROM OUR CHAIRMAN

Barrier Therapeutics was built on the [illegible] that, at a time when many companies in dermatology are moving into the cosmetics and esthetics field, more emphasis was needed on advancing the state of the art in therapeutic dermatology. The skin is a key organ through which we function and is fundamental to the way we perceive ourselves and interact with others. Understandably, there is a desire to enhance the features of normal skin through cosmetic and esthetic means. At Barrier Therapeutics, we seek to go beyond this. Our focus is on developing novel therapeutic approaches for patients who require actual treatment to combat skin diseases that affect their physical, social and emotional well-being.

We are fortunate to have an extraordinary group of [illegible] at Barrier who provide the knowledge and experience to build upon our vision. Committed to delivering excellence, they each possess a significant record of accomplishment and have the unique ability to work as top professionals in interdependent teams. Our talented people have joined forces behind the Barrier vision to develop products with meaningful clinical value in terms of safety, efficacy and convenience. Because of this, they have become the driving force behind the broad areas of progress our company has made since we began operations just four years ago.

Our goal as a company is to create [illegible] for patients, physicians, and other health care providers as well as shareholders and employees. We believe that true product differentiation is critical to the overall value creation for the company and its many stakeholders. We are pleased with the progress that we have made during the past year and we will continue to focus our efforts to deliver sustainable [illegible] and long-term shareholder value.

mequinol 2% tretinoin 0.01%

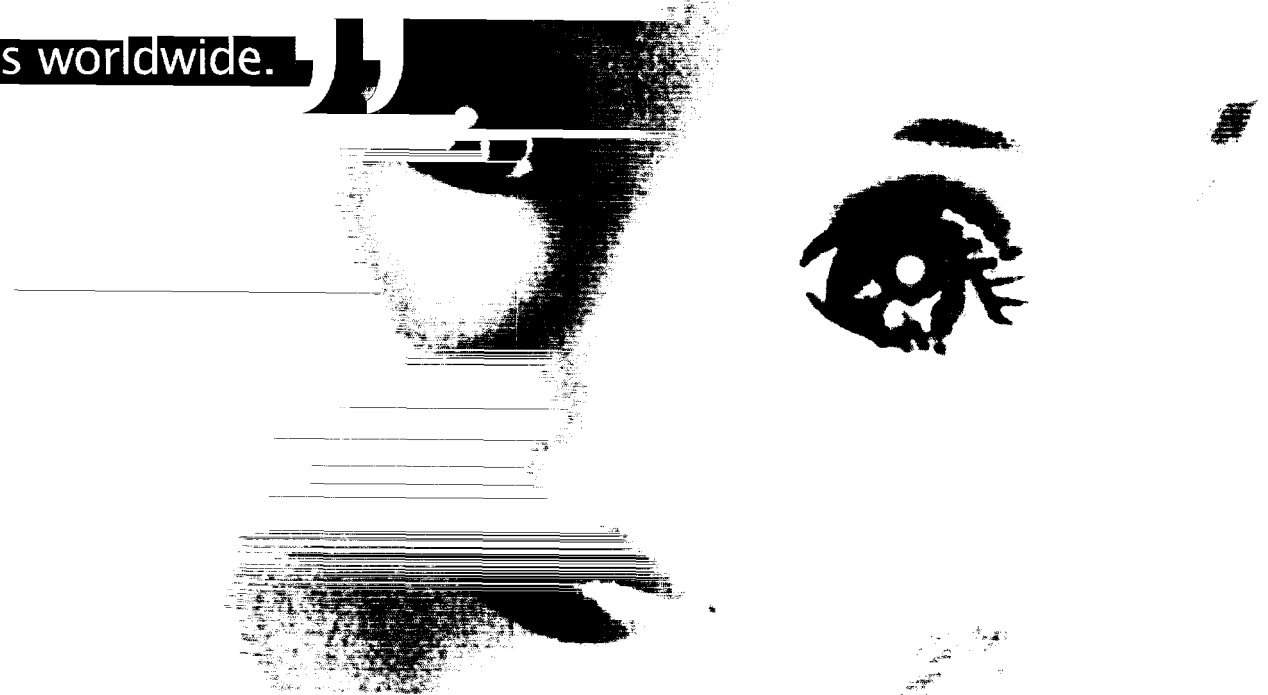
Solagé® Solution is indicated for the treatment of solar lentigines as part of a comprehensive skin care and sun avoidance program. The unique combination of mequinol and tretinoin, together with a special contoured applicator tip, make Solagé ideal for treating the growing number of patients who experience these lesions. Last summer, Barrier re-positioned Solagé to be "The At-Home Procedure Between Procedures." Dermatologists have since embraced Solagé as a complement to the growing number of in-office procedures they perform and new prescriptions have been steadily increasing.


2005 has been a rewarding as well as a challenging year for Barrier Therapeutics. Through the acquisition of Solagé® which we market in the United States and Canada, and our distribution arrangement for VANIQA® in Canada, we have achieved a strategic goal to initiate sales and marketing activities in our core market, North America. We believe that by launching our initial sales team to market Solagé, we have built a strong foundation that will support our future commercial growth.

In May 2005, we were disappointed to receive a not approvable letter for our first New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA) for Vusion™ (0.25% miconazole nitrate, 15% zinc oxide and 81.35% white petrolatum) Ointment, our topical antifungal treatment for diaper dermatitis complicated by candidiasis. However, through commitment and concentrated interaction with the FDA, we submitted a complete response to the one issue that caused this action letter, and Vusion was ultimately approved in February 2006. This approval marks a significant milestone, making Vusion the first product from the Barrier pipeline to obtain FDA approval and enter the market.

During 2005, our dedicated research and development teams continued to make important progress with our product pipeline. We reported promising, positive data on our key mid-term products: Azoline, an oral broad-spectrum antifungal for the treatment of common fungal infections and Rambazole™, an innovative new treatment in both oral

"Our team is dedicated to developing therapeutics to improve the health of skin for patients worldwide."



and topical formulations, for psoriasis, acne and possibly photo-damage. In addition, in late September, we filed an NDA with the FDA for our most advanced product candidate Sebazole™, a gel for the treatment of seborrheic dermatitis.

Hyphanox™ continues to be a valuable asset for the company. Even though we could not seek marketing approval based on the results of our Phase 3 study in the treatment of vaginal candidiasis, which we announced in June 2005, we are seeking a partner for the future development of this indication. More importantly, we are continuing to move forward with a Phase 3 clinical study in toe nail fungus, also known as onychomycosis, which is the largest dermatology indication for oral antifungals. We plan to start that study in mid-2006.

The current year promises to be exciting as we aim to achieve several additional major milestones. The approval of Vusion has allowed us to continue the transition from a development stage company into an integrated commercial entity. In addition, we expect an action letter later in 2006 on the NDA submission for Sebazole. If approved, Sebazole would provide us with a second product to launch in 2006. Additionally, once we obtain the results from the ongoing dose finding studies with oral Azoline and oral Rambazole, we plan to move forward in 2007 to seek strong partners for the development of these valuable assets outside of our North American market.

Vusion
(0.25% miconazole nitrate/1.5% zinc oxide/
81.35% white petrolatum) Ointment

**Vusion™ Ointment is the first and only prescription product in the United States indicated and specifically formulated for the treatment of diaper dermatitis complicated by candidiasis (DDCC)* in children as young as four weeks of age. Until now, common treatment options have included the use of antifungal products, steroids and combination products not specifically approved for the treatment of this condition or for use on infants.**

* The existence of *Candida* is readily determined by microscopic evaluation for presence of pseudohyphae or budding yeast.

| PRODUCT | INDICATIONS | PHASE |
|---|---|---|
| **Vusion™** | Diaper Dermatitis Complicated by Candidiasis* | |
| **Solagé®** | Age Spots* | |
| **Sebazole™** | Seborrheic Dermatitis | |
| **Hyphanox™** | Nail Fungus | |
| **Azoline** | Fungal Infections | |
| **Rambazole™** | Oral–Acne and Psoriasis | |
| | Topical–Acne and Psoriasis | |
| **Hivenyl™** | Skin Allergies | |

## CANADA ONLY

| | | |
|---|---|---|
| **VANIQA®** | Hair Growth Suppression | |
| **Denavir®** | Cold Sores | |

### Vusion™ (0.25% miconazole nitrate, 15% zinc oxide and 81.35% white petrolatum) Ointment*

Vusion was specifically formulated for the treatment of diaper dermatitis complicated by candidiasis (DDCC) *in infants 4 weeks and older. This* inflammatory condition occurs when diaper dermatitis, also known as diaper rash, is complicated with a fungal infection caused by yeast known as *Candida.* The existence of *Candida* is readily determined by microscopic evaluation for presence of pseudo-hyphae or budding yeast. Vusion was approved by the FDA in February, 2006 and is the only prescription product approved for the treatment of this condition in the United States.

### Solagé® (mequinol 2%, tretinoin 0.01%) Topical Solution*

Barrier acquired the U.S. and Canadian rights to Solagé and began marketing the product in February 2005. The product contains two active ingredients, mequinol and tretinoin. In *the United States, Solagé is indicated* for the treatment of solar lentigines, commonly known as "age spots," while the Canadian indication also includes use for related hyperpigmented lesions. Currently, Solagé is the only combination product approved for the treatment of solar lentigines.

### Sebazole™

Sebazole is an anhydrous gel formulation containing 2.0% of the antifungal agent ketoconazole which has been developed for the treatment of seborrheic dermatitis. Seborrheic dermatitis is a type of eczema characterized by inflammation and scaling of the skin, principally of the scalp, face and chest. Sebazole has been studied for once a day treatment for a period of two weeks, as compared to the twice a day four week treatment regimen for the currently marketed ketoconazole creams. The product is currently under FDA review following the filing of an NDA for Sebazole in late September 2005.

### Hyphanox™

*Hyphanox is a unique 200 mg* tablet formulation of the oral antifungal itraconazole that we are developing for the treatment of onychomycosis, commonly known as nail fungus. Itraconazole is known to be effective in treating this type of fungal infection. We plan to commence Phase 3 clinical trials for Hyphanox for the treatment of toe nail onychomycosis during 2006, following completion of our current discussions with the FDA.

### Azoline

Azoline is an oral formulation of pramiconazole, a novel antifungal agent that we are developing as a treatment for skin, nail and mucosal fungal infections. Preclinical testing has shown Azoline to be more potent than itraconazole against dermatological fungal infections and less interactive than itraconazole with the metabolism of other drugs. Results from pilot phase 2a clinical studies in four acute infections indicate that Azoline may be an effective short course oral treatment for fungal infections. We are currently conducting Phase 2b dose ranging studies outside the U.S. with Azoline in patients with tinea versicolor.

*** For full prescribing information for these products, please see their respective package inserts which can be found on our website at www.barriertherapeutics.com.**

| PHASE 2 | PHASE 3 | NDA REVIEW | MARKETED |
|---|---|---|---|

launch—03.2006

### Oral Rambazole™

We are developing an oral formulation of Rambazole for the treatment of psoriasis and severe acne. Results from pilot Phase 2a efficacy studies with oral Rambazole in both severe psoriasis and severe acne have shown encouraging results. We are currently conducting a Phase 2b dose finding study outside the U.S. in patients with severe plaque psoriasis.

### Topical Rambazole™

We are developing topical Rambazole for dermatological indications including common forms of acne and psoriasis. Early studies indicate that topical Rambazole may produce the same therapeutic results as retinoic acid but with potentially less irritation. We are currently testing topical Rambazole in a Phase 2a trial in Europe for mild to moderate acne.

### Hivenyl™

Hivenyl is an oral formulation of vapitadine dihydrochloride, an antihistamine that we are developing as a treatment for allergic reactions of the skin, such as those associated with hives and for the itch associated with atopic dermatitis. The results of two dose escalation Phase 1 clinical trials suggest that Hivenyl inhibits allergic reactions, has a fast onset of action and does not cause sedation. In these trials, no cardiovascular side effects or sedation were experienced at doses of five to 15 times those that elicited an antihistamine response. We are currently conducting Phase 2a clinical trials in Europe for Hivenyl.

## Products Distributed in Canada Only

### VANIQA® (eflornithine hydrochloride) Cream, 13.9%

Barrier acquired the Canadian distribution rights for VANIQA from Shire Pharmaceuticals in June 2005. VANIQA is the only prescription product approved by Health Canada for slowing the growth of unwanted facial hair in women. VANIQA works during the growth phase of the hair cycle by blocking an enzyme that is necessary for hair growth. VANIQA does not remove facial hair; instead, it is designed to reduce the rate of growth of facial hair and increase the interval between periods of hair removal. We launched this product in Canada during the fourth quarter of 2005.

### Denavir® (penciclovir cream) 1%

Barrier acquired the Canadian distribution rights for Denavir from Novartis Consumer Health Canada, Inc., in March 2006. Denavir is the only topical antiviral prescription medication approved by Health Canada for the treatment of herpes labialis, also known as cold sores, in adults. Denavir is a non-greasy cream specially formulated for use on the lips and face and contains an antiviral agent, penciclovir, which is active against the HSV1 virus. Denavir works by penetrating the area to block the virus that causes cold sores. We expect to launch this product in Canada in the third quarter of 2006.

Our commitment to create a corporate culture that encourages leadership and self-motivation is exemplified by our X5 initiative which was introduced at our first sales force launch meeting. It's the philosophy that drives our team to succeed beyond the competition bringing greater value to our customers, employees and shareholders.

Our broad and deep product pipeline continues to be one of our greatest points of differentiation as a company. We firmly believe, however, that our pipeline and product offerings need to be a balance between internally developed products and products available through licensing opportunities and acquisition. During the past year, we made significant progress in research and development that has resulted in advancing our internal product candidates closer to market, culminating in the approval of Vusion. Concurrently, through our business development activities, we have obtained the rights to marketed products that provide value to patients and physicians, and more significantly, have allowed us to begin commercialization activities in North America. Because of these accomplishments, we believe that we are well positioned to achieve significant growth in 2006 and beyond.

Over the next few years, we anticipate achieving sustainable revenue growth from our commercial organization through the marketing of our own products as well as from those obtained through business development activities. This commercial growth will contribute significantly to the funding of our important research and development activities. These activities will focus on the advancement of our high potential product candidates Azoline, oral Rambazole, and topical Rambazole as they advance into Phase 3 clinical testing or beyond.

"Rambazole appears to be a promising and exciting alternative to exogenous retinoic acid treatments because it may offer similar benefits but with a more favorable safety profile."

GROWTH

Novel therapeutic approaches for the treatment of skin conditions are our focus. We understand that skin diseases, while rarely fatal, are often chronic in nature with underlying causes that require intermittent therapy over extended periods. We believe that chronic and highly visible illnesses of the skin often have a devastating effect on self-esteem and quality of life. Therefore, at Barrier Therapeutics, we view effective treatments in dermatology as quality-of-life-saving – not just for a few months or years, but in some cases where it is a genetic condition, for a lifetime. Modern medicine has started to lose sight of this, and we are committed to filling that void.

As we move forward, we will continue to be guided by our core values. We are proud that just four years after beginning operations, Barrier Therapeutics has begun to realize its **vision**, thanks to its **people** striving every day to create long-term **value**. Because of support from you, our many and varied stakeholders, our marketed products and our product pipeline have positioned us to generate solid **growth** in the years ahead.

My sincere thanks to all of you for helping us make this possible.

**Geert Cauwenbergh, Ph.D.**
Chairman and Chief Executive Officer
April, 2006

**The basis of the initiative focuses on 3 points and drives our sales team members and employees to:**

- e**X**pect – **more, perfection and leadership**
- e**X**tend – **themselves, their knowledge and their ethics**

**and to:**

- e**X**cel – **in business, at home and in life.**

# BOARD OF DIRECTORS

**Geert Cauwenbergh, Ph.D.**
Chairman & Chief Executive Officer
Barrier Therapeutics, Inc.

**Robert Campbell**
Lead Director
Retired Vice Chairman
Johnson & Johnson

**Srinivas Akkaraju, M.D., Ph.D.**
Partner
JP Morgan Partners, LLC

**Carl W. Ehmann, M.D.**
Industry Consultant
Member, Barrier Scientific Advisory Board

**Edward L. Erickson**
Chairman of the Board
Immunicon Corporation

**Peter Ernster**
Retired Senior Vice President
Merck & Co., Inc.

**Charles F. Jacey, Jr.**
Retired Senior Partner
Coopers & Lybrand, LLP

**Carol Raphael**
President & CEO
Visiting Nurse Service of NY

**Nicholas J. Simon III**
Managing Director
Clarus Ventures, LLC

# CORPORATE INFORMATION

### CORPORATE HEADQUARTERS

Barrier Therapeutics, Inc.
600 College Road East
Suite 3200
Princeton, NJ 08540-6697

### CANADIAN OFFICE

Barrier Therapeutics Canada Inc.
PO Box 2730
Richmond Hill
Ontario
Canada L4E 1A7

### EUROPEAN OFFICE

Barrier Therapeutics, n.v.
Cipalstr. 3
B-2440 Geel
Belgium

### ANNUAL MEETING

The annual meeting of stockholders will be held at 11:00 a.m. on June 21, 2006, at the Doral Forrestal Conference Center in Princeton, New Jersey.

### STOCK LISTING

Barrier Therapeutics common stock is traded on the Nasdaq National Market under the ticker symbol BTRX.

### STOCK TRANSFER AGENT AND REGISTRAR

Communications concerning stockholder address changes, stock transfers, changes of ownership, lost stock certificates or other account services should be directed to American Stock Transfer & Trust Company, 59 Maiden Lane, Plaza Level, New York, NY 10038, shareholder toll free line 866-668-6550, worldwide 718-921-8346, or at www.amstock.com.

### INVESTOR AND MEDIA INFORMATION

Members of the financial community are invited to contact Anne VanLent, Executive Vice President and Chief Financial Officer at 609-945-1202. Correspondence can be sent to Barrier Therapeutics, Inc., Investor Relations, 600 College Road East, Suite 3200, Princeton, New Jersey 08540-6697, or emailed to **ir@barriertherapeutics.com.**

### ANNUAL REPORT ON FORM 10-K

A copy of Barrier Therapeutics' Annual Report on Form 10-K for fiscal year ended December 31, 2005, is included with this 2005 Annual Review. A copy of this 2005 Annual Review and the Form 10-K, filed with the Securities and Exchange Commission, are available online at **www.barriertherapeutics.com.** Please contact Barrier Therapeutics, Inc., Investor Relations, 600 College Road East, Suite 3200, Princeton, NJ 08540-6697, or email **ir@barriertherapeutics.com**, if you would like to receive a printed copy.

### INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

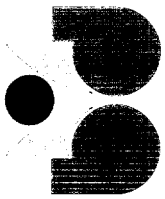
Ernst & Young LLP
Iselin, New Jersey

### COMPANY COUNSEL

Morgan, Lewis & Bockius LLP
Princeton, New Jersey

### SAFE HARBOR STATEMENT

*This Annual Review contains forward-looking statements including statements regarding ou project development goals, the timing of the initiation and completion of clinical trials, the timing of regulatory submissions, the potentia regulatory approval of our submissions, the timing of potential regulatory approval of our product candidates, the possible advantages o our product candidates, if approved, and our commercial strategy, including our sales and marketing plans, business development opportunities, and prospects for generating and increasing revenue. Forward-looking statements provide Barrier's current expectations or forecasts of future events and are subject to risks and uncertainties. Barrier's performance and financial results could differ materially from those reflected in these forward-looking statements due to risks both known and unknown including the outcome of clinical trials, actions of regulatory agencies, the acceptance of our products in the marketplace and general financial, economic, regulatory and political conditions affecting the biotechnology and pharmaceutical industries generally. For a discussion of these and other risks and uncertainties that may affect the forward-looking statements, please see the risk factors in our Annual Report on Form 10-K, which is on file with the Securities and Exchange Commission. In addition, please note that success in earlier clinical trials does not mean that subsequent trials will confirm earlier findings. No assessment of the efficacy or safety of any product candidate can be considered definitive until all clinical trials needed to support a submission for marketing approval are complete. Acceptance for filing an NDA by the FDA does not mean that the NDA has been or will be approved, nor does it represent an evaluation of the adequacy of th data submitted.*



**Barrier** Therapeutics, Inc.

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