BIOGEN IDEC INC.
Form PRE 14A
March 18, 2011

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
SCHEDULE 14A
PROXY STATEMENT PURSUANT TO SECTION 14(A) OF THE SECURITIES EXCHANGE ACT OF 1934

Filed by the Registrant þ
Filed by a Party other than the Registrant o
Check the appropriate box:
þ Preliminary Proxy Statement
o Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))
o Definitive Proxy Statement
o Definitive Additional Materials
o Soliciting Material Under § 240.14a-12

BIOGEN IDEC INC.

(Name of Registrant as Specified In Its Charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

Payment of Filing Fee (Check the appropriate box):

þ No fee required.

o Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.

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NOTICE OF 2011 ANNUAL MEETING OF STOCKHOLDERS
TO BE HELD ON JUNE 2, 2011

To our stockholders:

The annual meeting of stockholders of Biogen Idec Inc., a Delaware corporation, will be held at **9:00 a.m., local time, on Thursday, June 2, 2011 at our offices located at 15 Cambridge Center, Cambridge, Massachusetts 02142** for the following purposes:

1. If Proposal 5 is approved by our stockholders, to elect the twelve nominees identified in this Proxy Statement to our Board of Directors to serve for a one-year term extending until the 2012 annual meeting of stockholders and their successors are duly elected and qualified. If Proposal 5 is not approved, to elect the four nominees identified in this Proxy Statement as Class 2 directors to our Board of Directors to serve for a three-year term extending until the 2014 annual meeting of stockholders and their successors are duly elected and qualified.

2. To ratify the selection of PricewaterhouseCoopers LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2011.

3. To hold an advisory vote on executive compensation.

4. To hold an advisory vote on the frequency of the advisory vote on executive compensation.

5. To approve an amendment to our Amended and Restated Certificate of Incorporation eliminating the classification of our Board of Directors.

6. To transact such other business as may be properly brought before the meeting and any adjournments or postponements.

Only Biogen Idec stockholders of record at the close of business on April 4, 2011 will be entitled to vote at the meeting.

Our Board of Directors recommends voting FOR the election of all of the director nominees listed in Proposal 1, FOR Proposals 2, 3 and 5, and for the ONE YEAR option for Proposal 4.

Your vote is extremely important regardless of the number of shares you own. Whether or not you expect to attend the annual meeting in person, we urge you to vote as promptly as possible by telephone or by Internet or by signing, dating and returning a printed proxy card or voting instruction form, as applicable. If your shares are held in street name in a stock brokerage account or by a bank or other nominee, you must provide your broker with instructions on how to vote your shares in order for your shares to be voted on important matters presented at the annual meeting.

BY ORDER OF OUR BOARD OF DIRECTORS,

Susan H. Alexander,
Secretary

133 Boston Post Road

Weston, Massachusetts 02493
April , 2011

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Biogen Idec Inc.
133 Boston Post Road
Weston, Massachusetts 02493

PROXY STATEMENT FOR 2011 ANNUAL MEETING OF STOCKHOLDERS TO BE HELD ON JUNE 2, 2011

GENERAL INFORMATION ABOUT THE MEETING AND VOTING

We are making this Proxy Statement and other annual meeting materials available to you on the Internet or, upon your request, sending printed versions of these materials to you by mail, because the Board of Directors of Biogen Idec Inc. (Biogen Idec or Company) is soliciting your proxy to vote at our 2011 annual meeting of stockholders (Annual Meeting) to be held at 9:00 a.m., local time, on Thursday, June 2, 2011 at our offices located at 15 Cambridge Center, Cambridge, Massachusetts 02142 for the purposes summarized in the accompanying Notice of 2011 Annual Meeting of Stockholders. Our 2010 Summary Annual Report and 2010 Annual Report on Form 10-K are also available with this Proxy Statement.

Who can vote?

Each share of our common stock that you own as of the close of business on the record date of April 4, 2011 (Record Date) entitles you to one vote on each matter to be voted upon at the Annual Meeting. As of the Record Date, shares of our common stock were outstanding and entitled to vote. We are making this Proxy Statement and other Annual Meeting materials available on the Internet or, upon request, sending printed versions of these materials on or about April , 2011 to all stockholders of record as of the Record Date. For 10 days before the Annual Meeting, a list of stockholders entitled to vote will be available for inspection at our offices located at 133 Boston Post Road, Weston, Massachusetts 02493. If you would like to review the list, please call our Investor Relations department at (781) 464-2442.

Who can attend the Annual Meeting?

Attendance at the Annual Meeting will be limited to stockholders of Biogen Idec as of the Record Date (or their authorized representatives). If your shares are held by a bank, broker or other nominee, please bring to the Annual Meeting your bank or broker statement evidencing your beneficial ownership of Biogen Idec stock to gain admission to the Annual Meeting. Stockholders who plan to attend the Annual Meeting must present valid photo identification. Stockholders of record will be verified against an official list available at the registration area. We reserve the right to deny admittance to anyone who cannot show sufficient proof of share ownership as of the Record Date.

How do proxies work?

Our Board of Directors is asking for your proxy authorizing us to vote your shares at the Annual Meeting in the manner you direct. You may abstain from voting on any matter. If you submit your proxy without specifying your voting instructions, we will vote your shares as follows:

> ***Election of Directors:*** FOR the election of all of our director nominees, consisting of (a) 12 nominees to serve for a one-year term if the amendment to our Amended and Restated Certificate of Incorporation eliminating the classification of our Board of Directors is approved by our stockholders or (b) 4 nominees to serve as Class 2 directors for a three-year term if the amendment to our Amended and Restated Certificate of

Incorporation is not approved by our stockholders;

Ratification of PricewaterhouseCoopers LLP: FOR the ratification of the selection of PricewaterhouseCoopers LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2011;

Advisory Vote on Executive Compensation: FOR the advisory vote on executive compensation;

Advisory Vote on Frequency of Executive Compensation Advisory Vote: For the ONE YEAR option as the frequency of the advisory vote on executive compensation;

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Amendment to Certificate of Incorporation: FOR the approval of an amendment to our Amended and Restated Certificate of Incorporation eliminating the classification of our Board of Directors; and

As to any other matter that may properly come before the meeting or any adjournment or postponement, in accordance with our best judgment.

Shares represented by valid proxies received in time for the Annual Meeting and not revoked before the Annual Meeting will be voted at the Annual Meeting. You can revoke your proxy and change your vote in the manner described below in the subsection titled How can I change my vote? If your shares are held through a bank, broker or other nominee, please follow the instructions provided by your bank, broker or other nominee.

How do I vote?

It is important that your shares are represented at the Annual Meeting, whether or not you attend the Annual Meeting in person.

If you are a registered stockholder (also called a record holder), there are four ways to vote:

Telephone: By calling the toll-free telephone number indicated on your Notice of Internet Availability of Proxy Materials or proxy card. Easy-to-follow voice prompts allow you to vote your shares and confirm that your instructions have been properly recorded.

Internet: By going to the Internet website indicated on your Notice of Internet Availability of Proxy Materials or proxy card. As with telephone voting, you can confirm that your instructions have been properly recorded.

Mail: By signing, dating and returning a printed proxy card.

In Person: By submitting a written ballot in person at the Annual Meeting. To obtain directions to attend the Annual Meeting, please contact our Investor Relations department at (781) 464-2442. We will pass out ballots at the Annual Meeting to anyone who wishes to vote in person.

If your shares are held in a brokerage account in your broker s name (this is called street name), please follow the voting instructions provided by your bank, broker or other nominee. In most cases, you may submit voting instructions by telephone or by Internet to your bank, broker or other nominee, or you can sign, date and return a voting instruction form to your bank, broker or other nominee. If you provide specific voting instructions by telephone, by Internet or by mail, your bank, broker or other nominee must vote your shares as you have directed. If you wish to vote in person at the Annual Meeting, you must request a legal proxy from your bank, broker or other nominee.

Why did I receive a one-page notice in the mail regarding the Internet availability of proxy materials instead of a full set of proxy materials?

We have elected to provide access to our proxy materials on the Internet, consistent with the rules of the Securities and Exchange Commission (SEC). Accordingly, in most instances we are mailing a Notice of Internet Availability of Proxy Materials to our stockholders. You can access our proxy materials on the website referred to in the Notice of Internet Availability of Proxy Materials or you may request printed versions of our proxy materials for the Annual Meeting. Instructions on how to access our proxy materials on the Internet or to request printed versions are provided in the Notice of Internet Availability of Proxy Materials. In addition, you may request to receive proxy materials in printed form by mail or electronically by email on an ongoing basis.

What does it mean if I receive more than one notice regarding the Internet availability of proxy materials or more than one set of printed proxy materials?

If you hold your shares in more than one account, you may receive a separate Notice of Internet Availability of Proxy Materials or a separate set of printed proxy materials, including a separate proxy card or voting instruction form, for each account. To ensure that all of your shares are voted, please vote by telephone or by Internet or sign, date and return a proxy card or voting instruction form for each account.

How can I change my vote?

You may revoke your proxy and change your vote at any time before the Annual Meeting by:

Re-voting by telephone or by Internet as instructed above. Only your latest telephone or Internet vote will be counted.

Signing and dating a new proxy card or voting instruction form and submitting it as instructed above. Only your latest proxy card or voting instruction form will be counted.

If your shares are registered in your name, delivering timely written notice of revocation to the Secretary, Biogen Idec Inc., 133 Boston Post Road, Weston, Massachusetts 02493.

Attending the Annual Meeting in person and voting in person. Attending the Annual Meeting in person will not in and of itself revoke a previously submitted proxy unless you specifically request it. If your shares are held in street name by a bank, broker or other nominee, you must request a legal proxy from your bank, broker or other nominee to vote in person at the Annual Meeting.

Only your latest vote, in whatever form, will be counted.

Will my shares be counted if I do not vote?

If you are a record holder and do not vote by telephone or by Internet or by signing, dating and returning a printed proxy card, your shares will not be voted.

If you are the beneficial owner of shares held in street name, your bank, broker or other nominee, as the record holder of the shares, is required to vote those shares in accordance with your instructions. If no voting instructions are provided, these record holders can vote your shares only on discretionary, or routine, matters and not on non-discretionary, or non-routine, matters. Uninstructed shares whose votes cannot be counted on non-routine matters result in what are commonly referred to as broker non-votes.

If you do not give your broker voting instructions, your broker will be entitled to vote your shares only on the routine matter of the ratification of our independent accounting firm. All of the other proposals the election of directors, advisory vote on executive compensation, advisory vote on the frequency of executive compensation advisory vote and amendment to our Amended and Restated Certificate of Incorporation are non-routine matters and your broker will not be able to vote on them without your instructions. We urge you to provide instructions to your bank, broker or other nominee so that your votes may be counted on all of these important matters.

You should vote your shares by telephone or by Internet according to the instructions provided by your bank, broker or other nominee or by signing, dating and returning a printed voting instruction form to your bank, broker or other nominee to ensure that your shares are voted on your behalf.

How many shares must be present to hold the Annual Meeting?

A majority of our outstanding shares of common stock as of the Record Date must be present at the Annual Meeting to hold the Annual Meeting and conduct business. This is called a quorum. Shares voted in the manner described above (under How do I vote?) will be counted as present at the Annual Meeting. Shares that are present and entitled to vote on one or more of the matters to be voted upon are counted as present for establishing a quorum. If a quorum is not present, we expect that the Annual Meeting will be adjourned until we obtain a quorum.

What vote is required to approve each proposal and how are votes counted?

Election of Directors: Directors are elected by majority vote that is, if more votes are cast for that director s election than against. Abstentions and broker non-votes, if any, are not counted for purposes of electing directors and will have no effect on the results of this vote.

Ratification of PricewaterhouseCoopers LLP: The affirmative vote of a majority of shares present in person or represented by proxy at the Annual Meeting and entitled to vote on the proposal is required to ratify

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PricewaterhouseCoopers LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2011. Abstentions will have the effect of votes against this proposal. Brokers generally have discretionary authority to vote on the ratification of our independent accounting firm, thus we do not expect any broker non-votes on this proposal. To the extent there are any broker non-votes, they will have no effect on the results of this vote.

Advisory Vote on Executive Compensation: Because this proposal asks for a non-binding, advisory vote, there is no required vote that would constitute approval. We value the opinions expressed by our stockholders in this advisory vote, and our Compensation and Management Development Committee, which is responsible for overseeing and administering our executive compensation programs, will consider the outcome of the vote when designing our compensation programs and making future compensation decisions for our named executive officers. Abstentions and broker non-votes, if any, will not have any effect on the results of those deliberations.

Advisory Vote on the Frequency of Executive Compensation Advisory Vote: This proposal also calls for a non-binding, advisory vote. Our Board of Directors has recommended an annual vote, and we believe that stockholders will overwhelmingly support that recommendation. However, if another frequency receives more votes, our Board of Directors will take that fact into account when making its decision on how often to hold executive compensation advisory votes. Abstentions and broker non-votes, if any, will not have any effect on the results of those deliberations.

Amendment to Certificate of Incorporation: The affirmative vote of the holders of a majority of the stock issued and outstanding and entitled to vote on the proposal is required to approve the amendment to our Amended and Restated Certificate of Incorporation eliminating the classification of our Board of Directors. Abstentions and broker non-votes, if any, will have the effect of votes against this proposal.

Are there other matters to be voted on at the Annual Meeting?

We do not know of any other matters that may come before the Annual Meeting. If any other matters are properly presented to the Annual Meeting, your proxy authorizes us to vote, or otherwise act, in accordance with our best judgment.

Where do I find the voting results of the Annual Meeting?

We will publish voting results in a Current Report on Form 8-K filed with the SEC within four business days after the end of the Annual Meeting. You may request a copy of this Form 8-K by contacting Investor Relations, Biogen Idec Inc., 133 Boston Post Road, Weston, Massachusetts 02493, (781) 464-2442. You will also be able to find a copy of this Form 8-K on the Internet through the SEC s electronic data system called EDGAR at *www.sec.gov* or through the Investors section of our website, *www.biogenidec.com.*

Who should I call if I have any questions?

If you have any questions or require any assistance with voting your shares, please contact your bank, broker or other nominee holding your shares, or our Investor Relations department at (781) 464-2442.

Important Notice Regarding the Availability of Proxy Materials for Annual Meeting of Stockholders To Be Held on June 2, 2011: The Notice of 2011 Annual Meeting of Stockholders, Proxy Statement, 2010 Summary Annual Report and 2010 Annual Report on Form 10-K are available at the following website: .

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PROPOSAL 1 ELECTION OF DIRECTORS

Our Board of Directors currently consists of three Classes of directors with each director serving a staggered three-year term as follows:

Class 1 Directors Term Expires at 2013 Annual Meeting	Class 2 Directors Term Expires at this Annual Meeting	Class 3 Directors Term Expires at 2012 Annual Meeting
Nancy L. Leaming	Caroline D. Dorsa	Alexander J. Denner
Brian S. Posner	Stelios Papadopoulos	Richard C. Mulligan
Eric K. Rowinsky	George A. Scangos	Robert W. Pangia
Stephen A. Sherwin	Lynn Schenk	William D. Young

As described below under *Proposal 5 Approval of Amendment to Certificate of Incorporation*, our Board of Directors is recommending that stockholders approve the declassification of our Board of Directors so that all directors will be elected annually. This Proposal 1 concerns the election of directors under two alternative scenarios:

1. If stockholders approve Proposal 5, the amendment to our Amended and Restated Certificate of Incorporation will eliminate our classified Board structure, which will have the effect of reducing the current terms of our four incumbent Class 1 directors and four incumbent Class 3 directors so that they expire at the Annual Meeting. Accordingly, if stockholders approve Proposal 5, the following twelve individuals recommended by our Board of Directors are standing for election to serve a one-year term extending until the 2012 annual meeting of stockholders and until their successors are duly elected and qualified, unless they resign or are removed: Alexander J. Denner, Caroline D. Dorsa, Nancy L. Leaming, Richard C. Mulligan, Robert W. Pangia, Stelios Papadopoulos, Brian S. Posner, Eric K. Rowinsky, George A. Scangos, Lynn Schenk, Stephen A. Sherwin, William D. Young.

2. If stockholders do not approve Proposal 5, the election of our four Class 2 director nominees will proceed under our Amended and Restated Certificate of Incorporation as currently in effect and our Class 1 and Class 3 directors will continue to serve the remainder of their current three-year terms. Accordingly, if stockholders do not approve Proposal 5, the following four individuals recommended by our Board of Directors are standing for election as Class 2 directors to serve a three-year term extending until the 2014 annual meeting of stockholders and until their successors are duly elected and qualified, unless they resign or are removed: Caroline D. Dorsa, Stelios Papadopoulos, George A. Scangos, Lynn Schenk.

As described in detail below, our nominees have considerable professional and business expertise. The recommendation of our Board of Directors is based on its carefully considered judgment that the experience, qualifications, attributes and skills of our nominees qualify them to serve on our Board of Directors.

If any of our nominees is unable to serve on our Board of Directors, the shares represented by your proxy will be voted for the election of such other person as may be nominated by our Board of Directors. In addition, in full compliance with all applicable state and federal laws and regulations, we will file an amended proxy statement and proxy card that, as applicable, (1) identifies the alternate nominee(s), (2) discloses that such nominees have consented to being named in the revised proxy statement and to serve if elected and (3) includes the disclosure required by Item 7 of Schedule 14A with respect to such nominees. We know of no reason why any nominee would be unable to accept nomination or election. All nominees have consented to be named in this Proxy Statement and to serve if elected.

Our Nominees for Director

Alexander J. Denner, Ph.D. (Director since June 2009)	Dr. Denner, 41, has been serving as Managing Director of private investment funds affiliated with Carl C. Icahn since August 2006. From 2005 to May 2006, he served as a portfolio manager specializing in healthcare investments for Viking Global Investors, a private investment fund. Prior to that, Dr. Denner served in a variety of roles at Morgan Stanley, a financial services company, beginning in 1996, including as portfolio manager of healthcare and biotechnology mutual funds.

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	Dr. Denner is Chairman of Enzon Pharmaceuticals, Inc. and a member of the board of directors of Amylin Pharmaceuticals, Inc., both life sciences companies. During the past five years, Dr. Denner has also served as a director of ADVENTRX Pharmaceuticals, Inc. and ImClone Systems Incorporated, both life sciences companies. Dr. Denner has experience overseeing the operations and research and development of biopharmaceutical companies and evaluating corporate governance matters. He also has extensive experience as an investor, particularly with respect to healthcare companies, and possesses broad life sciences industry knowledge.
Caroline D. Dorsa (Director since January 2010)	Ms. Dorsa, 51, has been Executive Vice President and Chief Financial Officer of Public Service Enterprise Group Incorporated, a diversified energy company, since April 2009 and served on that company s board of directors from 2003 to April 2009. From February 2008 to April 2009, she served as Senior Vice President, Global Human Health, Strategy and Integration at Merck & Co., Inc., a pharmaceutical company. From November 2007 to January 2008, Ms. Dorsa served as Senior Vice President and Chief Financial Officer of Gilead Sciences, Inc., a life sciences company. From February 2007 to November 2007, she served as Senior Vice President and Chief Financial Officer of Avaya, Inc., a telecommunications company. From 1987 to January 2007, Ms. Dorsa held various financial and operational positions at Merck & Co., Inc., including Vice President and Treasurer, Executive Director of U.S. Customer Marketing and Executive Director of U.S. Pricing and Strategic Planning. Ms. Dorsa has financial and accounting expertise and a deep knowledge of the pharmaceutical industry. Her strategic perspective on the industry is particularly valuable to our Board of Directors as it oversees our growth initiatives and reviews both internal development projects and external opportunities.
Nancy L. Leaming (Director since January 2008)	Ms. Leaming, 63, has been an independent consultant since 2005. From 2003 to 2005, she served as the Chief Executive Officer and President of Tufts Health Plan, a provider of healthcare insurance. From 1986 to 2003, Ms. Leaming served in several executive positions at Tufts Health Plan, including President, Chief Operating Officer and Chief Financial Officer. Ms. Leaming is a member of the boards of directors of Hologic, Inc., a provider of diagnostic and surgical products, and Edgewater Technology, Inc., a technology management consulting firm. Ms. Leaming has well-developed leadership skills and financial acumen and provides insights into the healthcare reimbursement and payor market, where she served for 20 years in senior operational, financial and managerial roles.
Richard C. Mulligan, Ph.D. (Director since June 2009)	Dr. Mulligan, 56, has been the Mallinckrodt Professor of Genetics at Harvard Medical School and Director of the Harvard Gene Therapy Initiative since 1996. Prior to that, he was Professor of Molecular Biology at the Massachusetts Institute of Technology, a member of the Whitehead Institute for Biomedical Research, and Chief Scientific Officer of Somatix Therapy Corporation, a drug discovery and development company that he founded. Dr. Mulligan was named a MacArthur Foundation Fellow in 1981. Dr. Mulligan is Vice Chairman of Enzon Pharmaceuticals, Inc. and a member of the board of directors of Cellectis SA, both life sciences companies. During the past five years, Dr. Mulligan has also served as a director of ImClone Systems Incorporated, a

life sciences company.

Dr. Mulligan has scientific expertise in the areas of molecular biology, genetics, gene therapy and biotechnology, as well as extensive experience within the life sciences industry, including overseeing the operations and research and development of biopharmaceutical companies.

Robert W. Pangia (Director since 1997)	Mr. Pangia, 59, has been a partner in Ivy Capital Partners, LLC, the general partner of Ivy Healthcare Capital, L.P., a private equity fund specializing in healthcare investments, since 2003. From October 2007 to October 2009, he served as the Chief Executive Officer of Highlands Acquisition Corp., a special purpose acquisition company. From 1996 to 2003, Mr. Pangia was self-employed as an investment banker. From 1987 to 1996, he held various senior management positions at PaineWebber, including Executive Vice President and Director of Investment Banking for PaineWebber Incorporated of New York, member of the board of directors of PaineWebber, Inc., Chairman of PaineWebber Properties, Inc., and member of several of PaineWebber s executive and operating committees. Mr. Pangia is a member of the board of directors of McAfee, Inc., a security technology company. During the past five years, Mr. Pangia has also served as a director of Icos Corporation, a life sciences company. Mr. Pangia has significant financial acumen, breadth of expertise within the healthcare industry, and extensive knowledge of Biogen Idec derived from his 14 year tenure as a director.
Stelios Papadopoulos, Ph.D. (Director since July 2008)	Dr. Papadopoulos, 62, is Chairman of Exelixis, Inc., a drug discovery and development company that he co-founded in 1994. Previously, he was an investment banker with Cowen & Co., LLC, a financial services company, focusing on the biotechnology and pharmaceutical sectors, from 2000 until his retirement as Vice Chairman in August 2006. Prior to joining Cowen & Co., Dr. Papadopoulos served for 13 years as an investment banker at PaineWebber, Inc., a financial services company, where he was most recently Chairman of PaineWebber Development Corp., a PaineWebber subsidiary focusing on biotechnology. Dr. Papadopoulos is Chairman of Anadys Pharmaceuticals, Inc., a drug discovery and development company he co-founded, and a member of the board of directors of BG Medicine, Inc., a life sciences company. During the past five years, Dr. Papadopoulos has also served as a director of GenVec, Inc. and SGX Pharmaceuticals, Inc., both life sciences companies. Having founded multiple life sciences companies and worked as an investment banker focused on the life sciences industry, Dr. Papadopoulos brings to our Board of Directors a first-hand understanding of the demands of establishing, growing and running life sciences businesses.
Brian S. Posner (Director since July 2008)	Mr. Posner, 49, has been a private investor since March 2008 and is the President of Point Rider Group LLC, a consulting and advisory services firm within the financial services industry. From 2005 to March 2008, Mr. Posner served as the Chief Executive Officer and co-Chief Investment Officer of ClearBridge Advisors LLC, an asset management company and a wholly-owned subsidiary of Legg Mason. Prior to that, Mr. Posner co-founded Hygrove Partners LLC, a private investment fund, in 2000 and served as its Managing Partner for five years. He served as a portfolio manager and an analyst at Fidelity Investments, a financial services company, from 1987 to 1996 and, from 1997 to 1999, at Warburg Pincus Asset Management/Credit Suisse Asset Management where he also served as co-Chief Investment Officer and Director of Research. Mr. Posner is a member of the board of directors of Arch Capital Group Ltd., an insurance company.

Given his substantial experience as a leading institutional investment manager and advisor, Mr. Posner brings a professional investor s perspective and financial expertise that is valuable to our Board of Directors as it oversees our strategy for enhancing shareholder value.

Eric K. Rowinsky, M.D. (Director since March 2010)	Dr. Rowinsky, 54, has been an independent consultant since January 2010. Since August 2010, he has also been the Chief Executive Officer of Primrose Therapeutics, Inc., a start-up biotechnology company focusing on the development of therapeutics for polycystic kidney disease. Dr. Rowinsky is also an Adjunct Professor of Medicine at New York University. From February 2005 to December 2009, he served as Chief Medical Officer and Executive Vice President of ImClone Systems Incorporated, a life sciences company. Prior to that, from 1996 to 2004, Dr. Rowinsky held several positions at the Cancer Therapy & Research Center s Institute for Drug Development, including Director of the Institute and Director of Clinical Research. During that time, he held the SBC Endowed Chair for Early Drug Development and Clinical Professor of Medicine in the Division of Medical Oncology at the University of Texas Health Science Center at San Antonio. Dr. Rowinsky was an Associate Professor of Oncology at the Johns Hopkins School of Medicine and on the staff of the Johns Hopkins Hospital from 1988 to 1996. Dr. Rowinsky is a member of the board of directors of ADVENTRX Pharmaceuticals, Inc., a life sciences company, and Neoprobe Corporation, a biomedical company. During the past five years, Dr. Rowinsky has also served as a director of Tapestry Pharmaceuticals, Inc., a life sciences company. Dr. Rowinsky has extensive research and drug development experience, oncology expertise, and broad scientific and medical knowledge.
George A. Scangos, Ph.D. (Director since July 2010)	Dr. Scangos, 62, is our Chief Executive Officer and has served in this position since July 2010. Prior to that, Dr. Scangos served as President and Chief Executive Officer of Exelixis, Inc., a drug discovery and development company, since October 1996. From 1993 to 1996, Dr. Scangos served as President of Bayer Biotechnology, where he was responsible for research, business development, process development, manufacturing, engineering and quality assurance of Bayer s biological products. Before joining Bayer in 1987, Dr. Scangos was a Professor of Biology at Johns Hopkins University for six years. Dr. Scangos served as the Chair of the California Healthcare Institute in 2010 and was a member of the Board of the Global Alliance for TB Drug Development until 2010. He is also a member of the Board of Visitors of the University of California, San Francisco School of Pharmacy, and the National Board of Visitors of the University of California, Davis School of Medicine, and is an Adjunct Professor of Biology at Johns Hopkins. Dr. Scangos is a member of the board of directors of Exelixis, Inc. During the past five years, Dr. Scangos has also served as a director of Anadys Pharmaceuticals, Inc., a drug discovery and development company. Dr. Scangos has extensive training as a scientist, significant knowledge and experience with respect to the biotechnology, healthcare and pharmaceutical industries, and a comprehensive leadership background resulting from service on various boards and as an executive in the pharmaceutical industry.
Lynn Schenk (Director since 1995)	Ms. Schenk, 66, is an attorney and consultant in private practice with extensive public policy and business experience. From 1999 to 2003, she served as Chief of Staff to the Governor of California, during which time she led the effort to create the Institutes for Science and Innovation at the University of California. From 1993 to 1995, Ms. Schenk was a Member of the United States House of Representatives, representing San Diego, California and served on the House Energy & Commerce Committee with a special

emphasis on biotechnology. From 1980 to 1983, she was the California Secretary of Business, Transportation and Housing.

Ms. Schenk is a member of the board of directors of Sempra Energy, an energy services and development company.

	Ms. Schenk s strong public policy, government, legal and private sector experience provides vital insights to our Board of Directors about significant issues affecting the highly regulated life sciences industry. She brings public sector operations and management expertise to our Board of Directors and has extensive knowledge of Biogen Idec derived from her 16 year tenure as a director.
Stephen A. Sherwin, M.D. (Director since March 2010)	Dr. Sherwin, 62, has been Chairman of Ceregene, Inc., a life sciences company that he co-founded, since 2001. From 1990 to October 2009, he served as the Chief Executive Officer of Cell Genesys, Inc., a life sciences company, and was the company s Chairman from 1994 to October 2009. Prior to that, he held various positions at Genentech, Inc., a life sciences company, most recently as Vice President, Clinical Research. Dr. Sherwin is board certified in internal medicine and medical oncology. Dr. Sherwin is a member of the board of directors of BioSante Pharmaceuticals, Inc., a pharmaceutical company, Neurocrine Biosciences, Inc., a life sciences company, and Rigel Pharmaceuticals, Inc., a life sciences company. He is also Chairman of the Biotechnology Industry Organization. Dr. Sherwin has extensive knowledge of the life sciences industry and brings more than 25 years of experience in senior leadership positions at large and small publicly traded life sciences companies to our Board of Directors.
William D. Young (Director since 1997)	Mr. Young, 66, has served as our independent Chairman since January 2010. He has also been a venture partner in Clarus Ventures, LLC, a life sciences venture capital firm, since March 2010 and has served as the Executive Chairman of NanoString Technologies, Inc., a provider of molecular diagnostics and a portfolio company of Clarus Ventures, since February 2010. From 1999 to August 2009, Mr. Young served as the Chief Executive Officer of Monogram Biosciences, Inc., a provider of molecular diagnostics, and as its Chairman from 1998 to August 2009. From 1980 to 1999, he held several positions at Genentech, Inc., a life sciences company, and served as its Chief Operating Officer from 1997 to 1999. Prior to joining Genentech, Mr. Young was with Eli Lilly & Co., a pharmaceutical company, for 14 years. He was elected to the National Academy of Engineering in 1993 for his contributions to biotechnology. Mr. Young is a member of the board of directors of Theravance, Inc. and BioMarin Pharmaceutical Inc., both life sciences companies. During the past five years, Mr. Young has also served as a director of Human Genome Sciences, Inc., a life sciences company. Mr. Young has extensive operational experience, leadership skills and knowledge of the life sciences industry through service on boards and as an executive as well as a broad understanding of Biogen Idec through his service as a director over the past 14 years.

OUR BOARD OF DIRECTORS RECOMMENDS THAT STOCKHOLDERS VOTE FOR THE ELECTION OF EACH DIRECTOR NOMINEE NAMED ABOVE.

PROPOSAL 2 RATIFICATION OF THE SELECTION OF OUR INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Finance and Audit Committee has selected PricewaterhouseCoopers LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2011. PricewaterhouseCoopers served as our independent registered public accounting firm in connection with the audit for the fiscal year ended December 31, 2010. Although stockholder approval of the Finance and Audit Committee s selection of PricewaterhouseCoopers is not required, our Board of Directors believes that it is a matter of good corporate practice to solicit stockholder ratification of this selection. If our stockholders do not ratify the selection of PricewaterhouseCoopers as our independent registered public accounting firm, the Finance and Audit Committee will reconsider its selection. Even if the selection is ratified, the Finance and Audit Committee always has the ability to change the engagement of PricewaterhouseCoopers if it determines that a change is in Biogen Idec s best interest. Representatives of PricewaterhouseCoopers will attend the Annual Meeting, have the opportunity to make a statement if they so desire, and be available to respond to appropriate questions.

Audit and Other Fees

The following table shows fees for professional audit services billed to us by PricewaterhouseCoopers for the audit of our annual consolidated financial statements for the years ended December 31, 2010 and December 31, 2009, and fees billed to us by PricewaterhouseCoopers for other services provided during 2010 and 2009:

Fees	**2010**	**2009**
Audit fees	$ 3,440,307	$ 3,116,797
Audit-related fees	61,304	131,766
Tax fees*	1,632,008	1,995,053
All other fees	8,715	78,106
Total	$ 5,142,334	$ 5,321,722

* Includes tax compliance fees of $1,291,040 in 2010 and $1,416,418 in 2009.

Audit fees are fees for the audit of our 2010 and 2009 consolidated financial statements included in our Annual Reports on Form 10-K, reviews of consolidated financial statements included in our Quarterly Reports on Form 10-Q, review of the consolidated financial statements incorporated by reference into our outstanding registration statements, and statutory audit fees in overseas jurisdictions.

Audit-related fees are fees that principally relate to assurance and related services that are reasonably related to the performance of the audits and reviews of our consolidated financial statements, including audits of employee benefit plan information.

Tax fees are fees for tax compliance and planning services.

All other fees are fees that principally relate to audit procedures performed in connection with one of our collaboration agreements in 2009 and educational resources in 2010 and 2009.

Policy on Pre-Approval of Audit and Non-Audit Services

The Finance and Audit Committee has the sole authority to approve the scope of the audit and any audit-related services as well as all audit fees and terms. The Finance and Audit Committee must pre-approve any audit and non-audit services provided by our independent registered public accounting firm. The Finance and Audit Committee will not approve the engagement of the independent registered public accounting firm to perform any services that the independent registered public accounting firm would be prohibited from providing under applicable securities laws, NASDAQ requirements or Public Company Accounting Oversight Board rules. In assessing whether to approve the use of our independent registered public accounting firm to provide permitted non-audit services, the Finance and Audit Committee tries to minimize relationships that could appear to impair the objectivity of our independent registered public accounting firm. The Finance and Audit Committee will approve permitted non-audit

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services by our independent registered public accounting firm only when it will be more effective or economical to have such services provided by our independent registered public accounting firm than by another firm.

The Finance and Audit Committee annually reviews and pre-approves the audit, audit-related, tax, and other permissible non-audit services that can be provided by the independent registered public accounting firm. Any proposed services exceeding pre-set levels or amounts will require separate pre-approval by the Finance and Audit Committee, although the Chief Accounting Officer can approve up to an additional $50,000 in the aggregate per calendar year for categories of services that the Finance and Audit Committee has pre-approved. In addition, any pre-approved services for which no pre-approved cost level has been set or which would exceed the pre-approved cost by an amount that would cause the aggregate $50,000 amount to be exceeded must be separately pre-approved by the Finance and Audit Committee.

The Finance and Audit Committee has delegated pre-approval authority to the chair of the Finance and Audit Committee within the guidelines discussed above. The chair of the Finance and Audit Committee is required to inform the Finance and Audit Committee of each pre-approval decision at the next regularly scheduled Finance and Audit Committee meeting.

All of the services provided by PricewaterhouseCoopers during 2010 were pre-approved in accordance with this policy.

OUR BOARD OF DIRECTORS RECOMMENDS THAT STOCKHOLDERS VOTE FOR THE RATIFICATION OF THE SELECTION OF PRICEWATERHOUSECOOPERS LLP AS OUR INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM FOR THE FISCAL YEAR ENDING DECEMBER 31, 2011.

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PROPOSAL 3 ADVISORY VOTE ON EXECUTIVE COMPENSATION

Our Compensation Discussion and Analysis, which appears later in this Proxy Statement, describes our executive compensation program and the compensation decisions that the Compensation and Management Development Committee and our Board of Directors made in 2010 with respect to the compensation of our named executive officers (listed in the Summary Compensation Table). As required pursuant to Section 14A of the Securities Exchange Act, our Board of Directors is asking that stockholders cast a non-binding, advisory vote FOR the following resolution:

RESOLVED, that the compensation paid to the Company s named executive officers, as disclosed pursuant to Item 402 of Regulation S-K, including the Compensation Discussion and Analysis, compensation tables and narrative discussion, is hereby APPROVED.

As we describe in our Compensation Discussion and Analysis, our executive compensation program embodies a pay-for-performance philosophy that supports our business strategy and aligns the interests of our executives with our stockholders. In particular, our compensation program rewards financial, strategic and operational performance and the goals set for each performance category support our long-range plans. In light of our strong performance in 2010, we believe that the compensation paid to our named executive officers was appropriate. Highlights of our 2010 performance include: our revenue and earnings per share (EPS) for 2010 exceeded the targets we set for our compensation programs; our compensation measure for revenue increased by 11% in 2010 and our compensation measure for EPS increased by 10% in 2010; and stock price performance increased 25% in 2010. In addition, to discourage excessive risk taking, we maintain policies for share ownership and recoupment of compensation; cap payments under our annual cash incentive plan; and require multi-year vesting of long-term incentive awards.

For these reasons, our Board of Directors is asking that stockholders support this proposal. Although the vote you are being asked to cast is non-binding, we value the views of our stockholders, and the Compensation and Management Development Committee and our Board of Directors will consider the outcome of the vote when making future compensation decisions for our named executive officers.

OUR BOARD OF DIRECTORS RECOMMENDS THAT STOCKHOLDERS VOTE <u>FOR</u> THE ADVISORY VOTE ON EXECUTIVE COMPENSATION.

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PROPOSAL 4 ADVISORY VOTE ON FREQUENCY OF ADVISORY VOTE ON EXECUTIVE COMPENSATION

Proposal 3 above requests that you cast an advisory vote for the compensation disclosed in this Proxy Statement that we paid in 2010 to our named executive officers. That advisory vote is referred to as a say-on-pay vote. In this Proposal 4, as required pursuant to Section 14A of the Securities Exchange Act, our Board of Directors is asking that stockholders cast a non-binding, advisory vote on how frequently we should have say-on-pay votes in the future. You can vote to hold say-on-pay votes every one, two or three years, or you can abstain from voting.

Our Board of Directors believes that say-on-pay votes should be held annually to give stockholders the opportunity to provide regular input on our executive compensation programs and increase our Board s accountability for its compensation decisions and therefore recommends that stockholders vote for the one-year option. This vote, like the say-on-pay vote itself, is non-binding. If a choice other than one year receives the most votes, our Board of Directors will take the voting results into consideration in determining how frequently we will present you with a say-on-pay vote.

OUR BOARD OF DIRECTORS RECOMMENDS THAT STOCKHOLDERS VOTE FOR THE ONE-YEAR OPTION AS THE FREQUENCY OF THE ADVISORY VOTE ON EXECUTIVE COMPENSATION.

PROPOSAL 5 APPROVAL OF AMENDMENT TO CERTIFICATE OF INCORPORATION

Article VII of our Amended and Restated Certificate of Incorporation (Certificate of Incorporation) divides our Board of Directors into three Classes of directors (Class 1, Class 2 and Class 3) with terms of three years each. Generally, absent the earlier resignation or removal of a director, the terms of these Classes are staggered so that one Class stands for re-election at each annual meeting of stockholders. The current terms of our director Classes expire as follows: Class 1 director term expires at the 2013 annual meeting of stockholders; Class 2 director term expires at this Annual Meeting; Class 3 director term expires at the 2012 annual meeting of stockholders.

Our Board of Directors has approved and declared advisable an amendment to Article VII of our Certificate of Incorporation (Charter Amendment) to declassify our Board of Directors and institute annual voting for each director to serve a one-year term beginning with the 2011 Annual Meeting. The form of Charter Amendment, which is subject to stockholder approval, is set forth in Appendix A to this Proxy Statement. Our Board of Directors also has approved, subject to the Charter Amendment becoming effective, certain conforming amendments to our Second Amended and Restated Bylaws (Bylaw Amendment) to remove references to a classified Board and to reflect stockholders ability to remove directors on a declassified Board with or without cause.

Our Board of Directors recommends that stockholders support Board declassification. Declassification of our Board of Directors would further our goal of ensuring that our corporate governance policies maximize Board accountability to stockholders and would allow stockholders the opportunity each year to register their views on the composition of our Board of Directors.

If stockholders approve the Charter Amendment, our classified Board structure will be eliminated, which will have the effect of reducing the current terms of our Class 1 and Class 3 directors so that they expire at the Annual Meeting, and all twelve members of our Board of Directors will stand for election to a one-year term at the Annual Meeting. The Bylaw Amendment will also become effective. The incumbent Class 1 and Class 3 directors have indicated their support for the declassification of our Board of Directors by agreeing to resign from their current three-year terms if stockholders approve the Charter Amendment, effective upon filing of the Charter Amendment.

If stockholders do not approve the Charter Amendment, the election of our four Class 2 director nominees to a three-year term will proceed under the Certificate of Incorporation as currently in effect, our Class 1 and Class 3 directors will continue to serve the remainder of their respective three-year terms, and the Bylaw Amendment will not become effective.

If approved and adopted by stockholders, the Charter Amendment will be filed with the Secretary of State of the State of Delaware immediately following certification of the voting results and will be in effect immediately upon such filing.

OUR BOARD OF DIRECTORS RECOMMENDS THAT STOCKHOLDERS VOTE FOR THE APPROVAL OF AN AMENDMENT TO OUR CERTIFICATE OF INCORPORATION ELIMINATING THE CLASSIFICATION OF OUR BOARD OF DIRECTORS.

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STOCK OWNERSHIP

The following table and accompanying notes provide information about the beneficial ownership of our common stock by:

- each stockholder known by us to be the beneficial owner of more than 5% of our common stock;
- each of our named executive officers (listed in the Summary Compensation Table);
- each of our directors and nominees for director; and
- all of our directors and executive officers as a group.

Except as otherwise noted, the persons identified have sole voting and investment power with respect to the shares of our common stock beneficially owned. Beneficial ownership is determined in accordance with the rules of the SEC and includes voting and investment power with respect to the shares. Except as otherwise noted, the information below is as of March 8, 2011 (Ownership Date).

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ASC 718 requires measurement of compensation cost for all stock-based awards at fair value on date of grant and recognition of compensation over the requisite service period for awards expected to vest. The fair value of restricted stock and restricted stock units is determined based on the number of shares granted and the quoted price of the Company s common stock on the date of grant. The determination of grant-date fair value for stock option awards is estimated using the Black-Scholes model, which includes variables such as the expected volatility of our share price, the anticipated exercise behavior of our employees, interest rates, and dividend yields. These variables are projected based on our historical data, experience, and other factors. Changes in any of these variables could result in material adjustments to the expense recognized for share-based payments. Such value is recognized as expense over the requisite service period, net of estimated forfeitures, using the straight-line attribution method. The estimation of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from current estimates, such amounts are recorded as a cumulative adjustment in the period estimates are revised. The Company considers many factors when estimating expected forfeitures, including type of awards granted employee class, and historical experience. Actual results and future estimates may differ substantially from current estimates.

Segments

The Company has determined its reportable segments in accordance with ASC 280, *Segment Reporting* (ASC 280) and related disclosures about products, services, geographic areas and major customers. After considering its business activities and geographic reach, the Company has concluded that it operates in just one operating segment being the discovery, development and commercialization of novel, mechanism-targeted drugs to treat cancer and other serious disorders, with development operations in two geographic areas, namely the United States and the United Kingdom.

Net Loss per Common Share

The Company calculates net loss per common share in accordance with ASC 260, *Earnings Per Share* (ASC 260). Basic and diluted net loss per common share were determined by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding during the period. The Company s potentially dilutive shares, which include outstanding common stock options, restricted stock, restricted stock units, convertible preferred stock, and common stock warrants, have not been included in the computation of diluted net loss per share for all periods as the result would be anti-dilutive.

	June 30, 2010	**June 30, 2011**
Stock options	3,187,291	3,543,529
Restricted stock and restricted stock units	75,515	44,255
Convertible preferred stock	516,228	516,228
Options to purchase common stock and common stock warrants issued in connection with the October 2010 financing		6,242,398
Common stock warrants	5,843,597	10,005,192
Total shares excluded from calculation	9,622,631	20,351,602

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Comprehensive Income (Loss)

In accordance with ASC 220, *Comprehensive Income* (ASC 220) all components of comprehensive income (loss), including net income (loss), are reported in the financial statements in the period in which they are recognized. ASC 220 defines comprehensive income (loss) as the change in equity during a period from transactions and other events and circumstances from nonowner sources. Net income (loss) and other comprehensive income (loss), including foreign currency translation adjustments, are reported, net of any related tax effect, to arrive at comprehensive income (loss). No taxes were recorded on items of other comprehensive income.

	Three Months Ended June 30,		Six Months Ended June 30,		Period from August 13, 1996 (inception) to June 30,
	2010	2011	2010	2011	2011
			$000		
Net loss	(3,933)	(3,552)	(9,040)	(8,140)	(246,446)
Translation adjustment	(19)	139	4,001	(2,826)	5,952
Unrealized foreign exchange (loss) gain on intercompany loans	9	(108)	(3,979)	2,834	(5,913)
Comprehensive loss	(3,943)	(3,521)	(9,018)	(8,132)	(246,407)

3. FAIR VALUE MEASUREMENTS

As defined in ASC 820, fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, ASC 820 establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Inputs other than quoted prices within Level 1 that are observable for the asset or liability, either directly or indirectly.

Level 3: Unobservable inputs that are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value. Financial assets and liabilities carried at fair value on a recurring basis as of December 31, 2010 are classified in the table below in one of the three categories described above:

	Level 1 $000	Level 2 $000	Level 3 $000	Total $000
Cash equivalents	29,066			29,066
Warrants			680	680
Total	29,066		680	29,746

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Financial assets and liabilities carried at fair value on a recurring basis as of June 30, 2011 are classified in the table below in one of the three categories described above:

	Level 1 $000	Level 2 $000	Level 3 $000	Total $000
Cash equivalents	17,333			17,333
Warrants			477	477
Total	17,333		477	17,810

Warrants Liability

The Company issued warrants to purchase shares of common stock under the registered direct financing completed in February 2007. These warrants are being accounted for as a liability in accordance with ASC 815, *Derivatives and Hedging* (ASC 815). At the date of the transaction, the fair value of the warrants of $6.8 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate 4.68%, expected volatility 85%, expected dividend yield 0%, and a contractual life of 7 years. The fair value of the warrant is being re-measured each reporting period, with a derivative gain or loss recognized in the consolidated statement of operations. Such gains or losses will continue to be reported until the warrants are exercised or expired. The Company used the Black-Scholes option-pricing model with the following assumptions to value the warrants:

	December 31, 2010	June 30, 2011
Exercise price	$ 8.44	$ 8.44
Expected term	3.13 Yrs.	2.63 Yrs.
Risk free interest rate	1.02%	0.68%
Expected volatility	121%	118%
Expected dividend yield over expected term		

During the three months ended June 30, 2010 and 2011, the Company recognized the change in the value of warrants of approximately $0.3 million and $0.1 million, respectively, as a gain on the consolidated statement of operations. During the six months ended June 30, 2010, the Company recognized the $0.5 million increase in the value of warrants as a loss on the consolidated statement of operations. During the six months ended June 30, 2011, the Company recognized the $0.2 million decrease in the value of warrants as a gain on the consolidated statement of operations. The following table reconciles the beginning and ending balance of Level 3 inputs for the six months ended June 30, 2011:

	Level 3 $000
Balance as of December 31, 2010	680
Gain from change in valuation of warrants liability reported in earnings	(203)
Balance as of June 30, 2011	477

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4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consist of the following:

	December 31, 2010	June 30, 2011
	($000s)	
Research and development tax credit receivable	660	998
Prepayments	317	476
Other current assets	405	214
Total prepaid expenses and other current assets	1,382	1,688

5. ACCRUED LIABILITIES AND OTHER CURRENT LIABILITIES

Accrued and other current liabilities consisted of the following:

	December 31, 2010	June 30, 2011
	($000s)	
Accrued research and development	2,793	3,343
Other current liabilities	1,339	1,116
	4,132	4,459

6. STOCK BASED COMPENSATION

Stock based compensation has been reported within expense line items on the consolidated statement of operations for the three months ended June 30, 2010 and 2011 as shown in the following table:

	For the three months ended June 30,		For the six months ended June 30,	
	2010	2011	2010	2011
	($000s)			
Research and development	93	41	165	90
General and administrative	374	164	621	365
Stock-based compensation costs before income taxes	467	205	786	455

Under the 2006 Plan, 5,200,000 shares of the Company s common stock have been reserved. The awards granted under the 2006 Plan have a maximum maturity of 10 years and generally vest over a four-year period from the date of grant.

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A summary of activity for the options under the Company s 2006 Plan for the six months ended June 30, 2011 is as follows:

	Options		Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in $000s)
Options outstanding at December 31, 2010	3,489,932	$	3.96	7.22	938
Granted	199,500	$	1.52		
Exercised	(6,638)	$	0.41		
Expired					
Cancelled / forfeited	(139,265)	$	6.32		
Options outstanding at June 30, 2011	3,543,529	$	3.74	6.95	828
Unvested at June 30, 2011	968,024	$	1.83	8.75	153
Vested and exercisable at June 30, 2011	2,575,505	$	4.45	6.27	675

ASC 718 requires compensation expense associated with share-based awards to be recognized over the requisite service period, which for the Company is the period between the grant date and the date the award vests or becomes exercisable. Most of the awards granted by the Company (and still outstanding), vest ratably over four years, with 1/4 of the award vesting one year from the date of grant and 1/48 of the award vesting each month thereafter. However, certain awards made to executive officers vest over three to five years, depending on the terms of their employment with the Company. In addition, recent awards made to other employees vest ratably over four years, with 1/48 of the award vesting each month.

Effective January 1, 2006, the Company elected to recognize all share-based awards issued after the adoption of ASC 718 under the straight-line attribution method. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. This analysis is evaluated quarterly and the forfeiture rate adjusted as necessary. Ultimately, the actual expense recognized over the vesting period is based on only those shares that vest.

The Company used the Black-Scholes option-pricing model with the following assumptions for stock option grants to employees and directors for the six months ended June 30, 2010 and 2011:

	For the six months ended June 30, 2010	For the six months ended June 30, 2011
Expected term	5 6Yrs 2.37	5 6Yrs 1.47
Risk free interest rate	2.96%	2.29%
Expected volatility	90 100%	93 99%
Expected dividend yield over expected term		
Resulting weighted average grant fair value	$1.80	$1.15

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There were 199,500 options granted during the six months ended June 30, 2011. For grants made during the six months ended June 30, 2010 and June 30, 2011, the expected term assumption was estimated using past history of early exercise behavior and estimated expectations of future exercise behavior. Starting with the December 2010 annual grants to the Company s employees, the Company relied exclusively on its historical volatility as an input to the option pricing model as the Company s management believes that this rate will be representative of future volatility over the expected term of the options. Prior to December 2010, because the Company had been publicly traded for a limited period, the expected volatility assumption was based on the historical volatility of peer companies over the expected term of the option awards.

Estimates of pre-vesting option forfeitures are based on the Company s experience. For outstanding options, the Company uses a forfeiture rate of 0 50% depending on when and to whom the options are granted. The Company adjusts its estimate of forfeitures over the requisite service period based on the extent to which actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures are recognized through a cumulative adjustment in the period of change and may impact the amount of compensation expense to be recognized in future periods.

The weighted average risk-free interest rate represents interest rate for treasury constant maturities published by the Federal Reserve Board. If the term of available treasury constant maturity instruments is not equal to the expected term of an employee option, Cyclacel uses the weighted average of the two Federal Reserve securities closest to the expected term of the employee option.

During the six months ended June 30, 2011, 6,638 stock options were exercised resulting in approximately $3,000 of cash proceeds to the Company. During the six months ended June 30, 2010, there were 124,277 stock options exercised for proceeds of approximately $0.1 million. As the Company presently has tax loss carry forwards from prior periods and expects to incur tax losses in 2011, the Company is not able to benefit from the deduction for exercised stock options in the current reporting period.

Restricted Stock

In November 2008, the Company issued restricted common stock to an employee subject to certain forfeiture provisions. Specifically, one quarter of the award vested one year from the date of grant and 1/48 of the award effectively vests each month thereafter. This restricted stock grant is accounted for at fair value at the date of grant and an expense is recognized during the vesting term. Summarized information for the restricted stock grant for the six months ended June 30, 2011 is as follows:

	Restricted Stock	**Weighted Average Grant Date Value Per Share**
Non-vested at December 31, 2010	23,954	$ 0.44
Vested	(6,252)	$ 0.44
Non-vested at June 30, 2011	17,702	$ 0.44

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Restricted Stock Units

Restricted stock units were issued to senior executives of the Company in November 2008, which entitle the holders to receive a specified number of shares of the Company s common stock over the four year vesting term. A restricted stock unit grant is accounted for at fair value at the date of grant which is equivalent to the market price of a share of the Company s common stock, and an expense is recognized during the vesting term. There were no restricted stock unit grants prior to November 2008. Summarized information for restricted stock grants for the six months ended June 30, 2011 is as follows:

	Restricted Stock Units	Weighted Average Grant Date Value Per Share
Non-vested at December 31, 2010	35,931	$ 0.44
Vested	(9,378)	$ 0.44
Non-vested at June 30, 2011	26,553	$ 0.44

7. COMMITMENTS AND CONTINGENCIES

Licensing Agreements

The Company has entered into licensing agreements with academic and research organizations. Under the terms of these agreements, the Company has received licenses to technology and patent applications. The Company is required to pay royalties on future sales of product employing the technology or falling under claims of patent applications. Pursuant to the Daiichi Sankyo license under which the Company licenses certain patent rights for sapacitabine, its lead drug candidate, the Company is under an obligation to use reasonable endeavors to develop a product and obtain regulatory approval to sell a product and has agreed to pay Daiichi Sankyo an up-front fee, reimbursement for Daiichi Sankyo s enumerated expenses, milestone payments and royalties on a country-by-country basis. Under this agreement, aggregate milestone payments totaling $11.7 million could be payable subject to achievement of all the specific contractual milestones and the Company s decision to continue with these projects. The up-front fee and certain past reimbursements have been paid and, as a result of the SEAMLESS trial entering Phase 3 during the first quarter of 2011, $1.6 million was paid in July 2011. Following these milestone payments, a further $9.3 million in aggregate milestone payments could be payable. Royalties are payable in each country for the term of patent protection in the country or for ten years following the first commercial sale of licensed products in the country, whichever is later. Royalties are payable on net sales. Net sales are defined as the gross amount invoiced by the Company or its affiliates or licensees, less discounts, credits, taxes, shipping and bad debt losses. The agreement extends from its commencement date to the date on which no further amounts are owed under it. If the Company wishes to appoint a third party to develop or commercialize a sapacitabine-based product in Japan, within certain limitations, Daiichi Sankyo must be notified and given a right of first refusal to develop and/or commercialize in Japan. In general, the license may be terminated by the Company for technical, scientific, efficacy, safety, or commercial reasons on six months notice, or twelve months, if after a launch of a sapacitabine-based product, or by either party for material default. Effective July 11, 2011, the license agreement was amended to irrevocably waive a termination right Daiichi Sankyo possessed under a provision of the agreement that required the Company to obtain regulatory approval to sell sapacitabine in at least one country by September 2011, and releases the Company from all claims and liability of any kind arising under such provision. The amendment further provides that the royalty due from the Company to Daiichi Sankyo on future net sales of sapacitabine be increased by a percentage between 1.25% and 1.50% depending on the level of net sales of sapacitabine realized.

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Guarantee

On July 28, 2005 and as amended on March 27, 2006, Cyclacel Group plc (Group) signed a convertible Loan Note Instrument constituting convertible unsecured loan notes (the Loan) and entered into a Facility Agreement (Agreement) with Scottish Enterprise (SE), as lender, whereby SE subscribed for £5 million, or approximately $9 million at the time, of the convertible loan notes. The loan was subsequently converted into 1,231,527 preferred D shares of the Group in satisfaction of all amounts owed by Group under the convertible loan notes. The number of preferred D shares that SE received was calculated by dividing the principal amount outstanding under the loan note by £4.06. The preferred D shares were exchanged for shares in Xcyte Therapies, Inc. on March 27, 2006 as part of the transaction between Xcyte and Cyclacel Limited. However, Scottish Enterprise retained the ability it had under the Agreement to receive a cash payment should the research operations in Scotland be significantly reduced. The Company had guaranteed approximately £5 million, the amount potentially due to SE, which will be calculated as a maximum of £5 million less the market value of the shares held by SE at the time of any significant reduction in research facilities.

On June 22, 2009, the Company amended the Agreement with SE (the Amendment), in order to allow the Company to implement a reduction of the Company s research operations located in Scotland in exchange for the parties agreement to modify the payment terms of the Agreement in the principal amount of £5 million (approximately $8.0 million at December 31, 2009), which SE had previously entered into with the Company. The Agreement provided for repayment of £5 million in the event the Company significantly reduced its Scottish research operations. Pursuant to the terms of the Amendment, in association with Cyclacel s material reduction in staff at its Scottish research facility, the parties agreed to a modified payment of £1 million (approximately $1.7 million at June 22, 2009) payable in two equal tranches. On July 1, 2009, the first installment of £0.5 million (approximately $0.8 million) was paid and the remaining amount of £0.5 million (approximately $0.8 million) was paid on January 6, 2010. In addition, should a further reduction below current minimum staff levels be effectuated before July 2014 without SE s prior consent, the Company will guarantee approximately £4 million, the amount potentially due to SE, which will be calculated as a maximum of £4 million less the market value of the shares held by SE at the time of any further reduction in research facilities.

This arrangement is accounted for as a liability and is measured at fair value. Changes in fair value are recognized in earnings. Due to the nature of the associated contingency and the likelihood of occurrence, the Company has concluded the fair value of this liability is immaterial as of December 31, 2010 and June 30, 2011.

Legal proceedings

On April 27, 2010, the Company was served with a complaint filed by Celgene Corporation in the United States District Court for the District of Delaware seeking a declaratory judgment that four of its own patents, claiming the use of romidepsin injection in T-cell lymphomas, are invalid and not infringed by Celgene s products, but directly involve the use and administration of Celgene s ISTODAX® (romidepsin for injection) product. On June 17, 2010, the Company filed its answer and counterclaims to the declaratory judgment complaint. The Company filed counterclaims charging Celgene with infringement of each of the Company s four patents and seeking damages for Celgene s infringement as well as injunctive relief. The four patents directly involve the use and administration of Celgene s ISTODAX® (romidepsin for injection) product.

8. STOCKHOLDERS EQUITY

Preferred Stock

As of June 30, 2011, there were 1,213,142 shares of Preferred Stock issued and outstanding at an issue price of $10.00 per share. Dividends on the Preferred Stock are cumulative from the date of original issuance at the annual rate of 6% of the liquidation preference of the Preferred Stock, payable quarterly on the first day of February, May, August and November, commencing February 1, 2005. Any dividends must be declared by the Company s Board of Directors and must come from funds that are legally available for dividend payments. The Preferred Stock has a liquidation preference of $10 per share, plus accrued and unpaid dividends.

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The Preferred Stock is convertible at the option of the holder at any time into the Company s shares of common stock at a conversion rate of approximately 0.42553 shares of common stock for each share of Preferred Stock based on a price of $23.50. During 2010, 833,671 shares of Preferred Stock were converted into 1,655,599 shares of the Company s common stock, which is described in more detail below. Since inception through June 30, 2011, holders have voluntarily converted 1,776,858 shares of Preferred Stock into common stock. The Company has reserved 516,228 shares of common stock for issuance upon conversion of the remaining shares of Preferred Stock outstanding at June 30, 2011. The converted shares of Preferred Stock have been retired and canceled and shall upon cancellation be restored to the status of authorized but unissued shares of preferred stock, subject to reissuance by the Board of Directors as shares of Preferred Stock of one or more series.

The Company may automatically convert the Preferred Stock into common stock if the closing price of the Company s common stock has exceeded $35.25, which is 150% of the conversion price of the Preferred Stock, for at least 20 trading days during any 30-day trading period, ending within five trading days prior to notice of automatic conversion.

The Certificate of Designations governing the Preferred Stock provides that if the Company fails to pay dividends on its Preferred Stock for six quarterly periods, holders of Preferred Stock are entitled to nominate and elect two directors to the Company s Board of Directors. This right accrued to the holders of Preferred Stock as of August 2, 2010 and two directors were nominated and elected at the annual meeting held on May 24, 2011.

The Preferred Stock has no maturity date and no voting rights prior to conversion into common stock, except under limited circumstances.

From November 6, 2007, the Company may, at its option, redeem the Preferred Stock in whole or in part, out of funds legally available at the redemption prices per share stated below, plus an amount equal to accrued and unpaid dividends up to the date of redemption:

Year from November 1, 2010 to October 31, 2011	$	10.24
Year from November 1, 2011 to October 31, 2012	$	10.18
Year from November 1, 2012 to October 31, 2013	$	10.12
Year from November 1, 2013 to October 31, 2014	$	10.06
November 1, 2014 and thereafter	$	10.00

The Preferred Stock is exchangeable, in whole but not in part, at the option of the Company on any dividend payment date beginning on November 1, 2005 (the Exchange Date) for the Company s 6% Convertible Subordinated Debentures (Debentures) at the rate of $10 principal amount of Debentures for each share of Preferred Stock. The Debentures, if issued, will mature 25 years after the Exchange Date and have terms substantially similar to those of the Preferred Stock.

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Conversion of Convertible Preferred Stock

During the first and second quarters of 2010, Cyclacel entered into agreements to exchange shares of the Company s Preferred Stock into shares of common stock. There were no such conversions for the six months ended June 30, 2011. The table below provides details of the aggregate activities in 2010:

	For the three months ended June 30, 2010	For the six months ended June 30, 2010
Preferred shares exchanged	710,271	833,671
Common shares issued:		
At stated convertible option	302,242	354,752
Incremental shares issued under an inducement offer	1,113,961	1,300,847
Total common shares issued	1,416,203	1,655,599

ASC 260, EITF Topic D-42, *The Effect of the Calculation of Earnings per Share for the Redemption or Induced Conversion of Preferred Stock* (ASC 260) requires that if convertible preferred stock is converted to other securities pursuant to an inducement offer, the Company should record the excess of (1) the fair value of all securities and other consideration transferred to the holders of the convertible preferred stock and (2) the fair value of securities issuable to the original conversion terms as an increase to net loss to arrive at a net loss attributable to common shareholders. The stockholder received more shares of the Company s common stock than would have been delivered pursuant to the original conversion terms of the Preferred Stock, pursuant to a short term inducement offer. The excess of the fair value of the common stock transferred to the stockholder over the carrying amount of the preferred stock in the Company s balance sheet at the time of the transfer was considered to be an additional return to the holder of the Preferred Stock. Specifically, the Company recorded deemed dividends related to the additional shares issued under the exchange transactions of approximately $2.5 million and $2.9 million for the three and six months ended June 30, 2010, respectively.

Common Stock

October 2010 Private Placement

On October 7, 2010, the Company completed a private placement pursuant to which it sold approximately $15.2 million of its units to several institutional investors, for net proceeds of approximately $14.0 million. The units consist of one share of common stock and 0.5 of a warrant, with each whole warrant representing the right to purchase one share of common stock at an exercise price of $1.92 per share for a period of five years. As of June 30, 2011, all options and warrants issued to the investors are outstanding and have been classified as equity. The investors purchased a total of 8,323,190 units at a price of $1.82625 per unit. The investors also have the right to acquire up to 4,161,595 additional units at a price of $1.67 per unit (for $6.9 million in gross proceeds) at any time up to nine months after closing or by July 6, 2011. As of June 30, 2011, none of the additional units had been exercised and, as of July 6, 2011, the right to acquire the additional units lapsed. The transaction date fair value of the warrants and additional optional units was $5.1 million and $2.8 million, respectively. Net proceeds of approximately $14.0 million were allocated based on relative transaction date fair values in the following manner: $8.9 million ($1.07 per share), $3.3 million ($0.79 per warrant) and $1.8 million ($0.43 per optional unit) to common shares, warrants and the additional optional units, respectively.

In connection with the October 2010 private placement, the Company granted to the investors certain registration rights pursuant to a Registration Rights Agreement, dated October 7, 2010, in which the Company agreed, among other things, to register all of the shares of common stock acquired from the Company (including upon exercise of the warrants and/or the options) within thirty calendar days after the Company becomes eligible to use a registration statement on Form S-3, and use commercially reasonable efforts to have the registration statement declared effective as promptly as practicable thereafter. Upon the Company s failure to comply with the terms of the Registration Rights Agreement and certain other conditions, the Company will be required to make pro rata payments to each investor, as liquidated damages, in an amount equal to 1.5% of the aggregate purchase price paid by such investor. The Company also agreed to other customary obligations regarding registration, including indemnification and maintenance of the effectiveness of the registration statement. The Company is currently in compliance with the applicable terms of the Registration Rights Agreement, and the securities that were registrable under the terms of the Registration Rights Agreement are currently subject to an effective registration statement.

January 2010 Registered Direct Financings

On January 25, 2010, the Company completed the sale of 2,350,000 units in a registered direct offering at a purchase price of $2.50 per unit to certain institutional investors of the Company for gross proceeds of approximately $5.9 million. Each unit consisted of one share of the Company s common stock and one warrant to purchase 0.30 of one share of its common stock. The warrants have a five-year term from the date of issuance, are exercisable beginning six months from the date of issuance at an exercise price of $2.85 per share of common stock. As of June 30, 2011, warrants issued to the investors have been classified as equity. The transaction date fair value of the warrants of $1.0 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate 2.39%, expected volatility 90%, expected dividend yield 0%, and a remaining contractual life of 5.00 years. As of June 30, 2011, all the warrants are outstanding. Net proceeds of approximately $5.4 million were allocated based on relative transaction date fair values in the following manner: $4.5 million ($1.93 per share) to common shares and $0.9 million ($1.29 per warrant) to the warrants.

On January 13, 2010, the Company completed the sale of 2,850,000 units in a registered direct offering to certain institutional investors. Each unit was sold at a purchase price of $2.51 per unit and consists of one share of the Company s common stock and one warrant to purchase 0.25 of one share of its common stock for gross proceeds of approximately $7.2 million. The warrants have a five-year term from the date of issuance, are exercisable beginning six months from the date of issuance at an exercise price of $3.26 per share of common stock. As of June 30, 2011, warrants issued to the investors have been classified as equity. The transaction date fair value of the warrants of $1.3 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate 2.55%, expected volatility 90%, expected dividend yield 0%, and a remaining contractual life of 5.00 years. As of June 30, 2011, all the warrants are outstanding. Net proceeds of approximately $6.5 million were allocated based on relative transaction date fair values in the following manner: $5.6 million ($1.95 per share) to common shares and $0.9 million ($1.32 per warrant) to the warrants.

July 2009 Registered Direct Financing

On July 29, 2009, the Company sold its securities to select institutional investors consisting of 4,000,000 units in a registered direct offering at a purchase price of $0.85 per unit. Each unit consisted of (i) one share of the Company s common stock, (ii) one warrant to purchase 0.625 of one share of common stock (a Series I Warrant) and (iii) one warrant to purchase 0.1838805 of one share of common stock (a Series II Warrant). The Series I Warrants had a seven-month term from the date of issuance, were exercisable beginning six months from the date of issuance at an exercise price of $1.00 per share of common stock. During the first quarter of 2010, all of the Series I Warrants were exercised for $2.5 million. The Series II Warrants have a five-year term from the date of issuance, are exercisable beginning six months from the date of issuance at an exercise price of $1.00 per share of common stock. During the first quarter of 2010, 43,266 common shares were issued upon exercise of Series II Warrants with proceeds of $43,266. There were no exercises during the six months ended June 30, 2011.

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The net proceeds to the Company from the sale of the units, after deducting for the placement agent s fees and offering expenses, were approximately $2.9 million. As of June 30, 2011, the remaining Series II Warrants outstanding and exercisable into 692,256 of the Company s shares of common stock have been classified as equity. The transaction date fair value of the Series II Warrants of $0.6 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate 2.69%, expected volatility 90%, expected dividend yield 0%, and a remaining contractual life of 5.00 years.

December 2007 Committed Equity Financing Facility

On December 10, 2007 and as amended on November 24, 2009, Cyclacel entered into a Committed Equity Financing Facility, or CEFF, with Kingsbridge, in which Kingsbridge committed to purchase the lesser of 4,084,590 shares of common stock or $60 million of common stock from Cyclacel over a three-year period. The CEFF lapsed on December 10, 2010.

During March 2010, the Company sold 1,563,208 shares of its common stock to Kingsbridge under the CEFF, in consideration of aggregate proceeds of $3.1 million. During December 2009 and January 2010, the Company sold an aggregate of 1,583,626 shares of its common stock to Kingsbridge under the terms of the CEFF in consideration of an aggregate of $1.3 million, of which approximately $1.0 million was received in 2009, with the balance of $0.3 million in respect of common shares subscribed but unissued at December 31, 2009, received by the Company in January 2010.

Common Stock Warrants

In connection with the Company s February 16, 2007 registered direct offering the Company issued to investors warrants to purchase 1,062,412 shares of common stock. The warrants issued to the investors are being accounted for as a liability. At the date of the transaction, the fair value of the warrants of $6.8 million was determined utilizing the Black-Scholes option pricing model utilizing the following assumptions: risk free interest rate 4.58%, expected volatility - 85%, expected dividend yield 0%, and a remaining contractual life of 6.88 years. The value of the warrant is being marked to market each reporting period as a derivative gain or loss on the consolidated statement of operations until exercised or expiration. See Note 3 Fair Value for further details.

The following table summarizes information about warrants outstanding at June 30, 2011:

Issued in Connection With	Expiration Date	Common Shares Issuable	Weighted Average Exercise Price	
April 2006 stock issuance	2013	2,571,429	$	7.00
February 2007 stock issuance	2014	1,062,412	$	8.44
December 2007 CEFF	2013	100,000	$	1.40
July 2009 Series II stock issuance	2014	692,256	$	1.00
January 2010 stock issuance	2015	712,500	$	3.26
January 2010 stock issuance	2015	705,000	$	2.85
October 2010 stock issuance	2015	4,161,595	$	1.92
Total		10,005,192	$	4.01

Exercise of Stock Options

During the six months ended June 30, 2011, there were 5,131 stock option exercises totaling approximately $3,000. During the three months ended June 30, 2010, there were 124,277 stock option exercises totaling approximately $0.1 million.

9. SUBSEQUENT EVENTS

Preferred Stock Dividend

On July 8, 2011, the Board of Directors decided not to declare the quarterly cash dividend on the Preferred Stock with respect to the second quarter of 2011 that would have otherwise been payable on August 1, 2011.

The Board also did not declare the quarterly cash dividend with respect to each of the four quarters of fiscal year 2009 and the first, second and third quarters of 2010. To the extent that any dividends payable on the Preferred Stock are not paid, such unpaid dividends are added to the liquidity preference of the Preferred Stock. As the Company failed to pay in an aggregate amount equal to at least six quarterly dividends (whether or not consecutive) on the Preferred Stock, the size of the Company s Board was increased by two members and the holders of the Preferred Stock, voting separately as a class, voted on May 24, 2011 and elected two directors to fill the vacancies created thereby, which directorships shall terminate when the Company pays all accrued but unpaid dividends.

License Agreement

On July 11, 2011, the Company entered into an amendment to its license agreement with Daiichi Sankyo Company, Limited (Daiichi Sankyo), dated September 10, 2003, relating to certain rights which the Company has licensed from Daiichi Sankyo with regard to the Company s sapacitabine drug. Effective July 11, 2011, the license agreement was amended to irrevocably waive a termination right Daiichi Sankyo possessed under a provision of the agreement that required the Company to obtain regulatory approval to sell sapacitabine in at least one country by September 2011, and releases the Company from all claims and liability of any kind arising under such provision. The amendment further provides that the royalty due from the Company to Daiichi Sankyo on future net sales of sapacitabine be increased by a percentage between 1.25% and 1.50% depending on the level of net sales of sapacitabine realized.

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Financing

On July 7, 2011 the Company closed an underwritten offering for an aggregate of 7,617,646 units, at an offering price of $1.36 per unit, for gross proceeds of approximately $10.4 million. Each unit consists of (i) one share of common stock and (ii) a five-year warrant to purchase 0.5 of a share of common stock at an exercise price of $1.36 per share, exercisable beginning six months after the date of issuance. The shares of common stock and warrants were immediately separable and were issued separately such that no units were issued. The net proceeds, after underwriting discounts and commissions and other fees and expenses payable by the Company, were approximately $9.3 million.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, including, without limitation, Management s Discussion and Analysis of Financial Condition and Results of Operations, contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). We intend that the forward-looking statements be covered by the safe harbor for forward-looking statements in the Exchange Act. The forward-looking information is based on various factors and was derived using numerous assumptions. All statements, other than statements of historical fact, that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future are forward-looking statements. Such statements are based upon certain assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate. These forward-looking statements are usually accompanied by words such as believe, anticipate, plan, seek, expect, intend and similar expressions.

Forward-looking statements necessarily involve risks and uncertainties, and our actual results could differ materially from those anticipated in the forward looking statements due to a number of factors, including those set forth in Part I, Item 1A, entitled Risk Factors, of our Annual Report on Form 10-K for the year ended December 31, 2010, as updated and supplemented by Part II, Item 1A, entitled Risk Factors, of our Quarterly Reports on Form 10-Q and other reports we publicly file with the Securities and Exchange Commission, or the SEC. These factors as well as other cautionary statements made in this Quarterly Report on Form 10-Q, should be read and understood as being applicable to all related forward-looking statements wherever they appear herein. The forward-looking statements contained in this Quarterly Report on Form 10-Q represent our judgment as of the date hereof. We encourage you to read those descriptions carefully. We caution you not to place undue reliance on the forward-looking statements contained in this report. These statements, like all statements in this report, speak only as of the date of this report (unless an earlier date is indicated) and we undertake no obligation to update or revise the statements except as required by law. Such forward-looking statements are not guarantees of future performance and actual results will likely differ, perhaps materially, from those suggested by such forward-looking statements. In this report, Cyclacel, the Company, we, us, and our refer to Cyclacel Pharmaceuticals, Inc.

Overview

We are a biopharmaceutical company dedicated to the development and commercialization of novel, mechanism-targeted drugs to treat human cancers and other serious diseases. Our strategy is to build a diversified biopharmaceutical business focused in hematology and oncology based on a portfolio of commercial products and a development pipeline of novel drug candidates.

Our clinical development priorities are focused on sapacitabine in the following indications:

- Acute myeloid leukemia, or AML, in the elderly;
- Myelodysplastic syndromes, or MDS; and
- Non-small cell lung cancer, or NSCLC.

On January 11, 2011, the Company opened enrollment of the SEAMLESS pivotal Phase 3 trial for the Company s sapacitabine oral capsules as a front-line treatment of elderly patients aged 70 years or older with newly diagnosed AML who are not candidates for intensive induction chemotherapy. SEAMLESS is a registration-directed clinical trial and is conducted under a Special Protocol Assessment, or SPA, agreement with the U.S. Food and Drug Administration, or FDA. SEAMLESS is a randomized study against an active control drug with the primary objective of demonstrating an improvement in overall survival. SEAMLESS has two parts. The first part is a pilot study of a single arm of the trial. The study s Data Safety Monitoring Board, or DSMB, will review the data from the pilot study before we are allowed to enroll patients in the second part in which patients will be randomized either to an active or control treatment.

The Company has advanced two additional product candidates, seliciclib in Phase 2 for NSCLC and nasopharyngeal cancer or NPC, and CYC116 in Phase 1 clinical development. The combination of sapacitabine with seliciclib is also being evaluated in a Phase 1 clinical trial. The Company will determine the feasibility of pursuing further development and/or partnering these assets depending on the availability of funding and further clinical data. In addition, we market directly in the United States Xclair® Cream for radiation dermatitis and Numoisyn® Liquid and Numoisyn® Lozenges for xerostomia.

Recent Developments

On June 6, 2011, we announced interim results from an ongoing, multicenter, Phase 1/2 clinical trial examining the safety and effectiveness of oral sapacitabine, our lead product candidate, administered sequentially with decitabine. Thirty-day mortality from all causes was 4.5%; 60-day mortality from all causes was 9.5%. The overall response rate was 34.8%. An additional 26.1% of patients stayed on study for more than 4 cycles with a decrease in bone marrow blast counts despite not meeting criteria of response. Approximately 60.9% of patients received 4 or more cycles of the regimen.

The data was reported during a poster session at the 2011 American Society of Clinical Oncology, or ASCO, Annual Meeting in Chicago, Illinois. As reported at ASCO, no dose-limiting toxicities were observed in 21 patients treated with the regimen who have had at least 60 days of follow-up. The median age in the group is 76 years (range 72-88). Common adverse events regardless of cause included anemia, anorexia, dehydration, diarrhea, dyspnea, edema, hypocalcemia, nausea, febrile neutropenia, neutropenia, pneumonia, thrombocytopenia, and weakness, which were mostly moderate in intensity.

We believe, based on the interim results reported at ASCO that the sequential administration of sapacitabine and decitabine appears safe and active in elderly patients with newly diagnosed acute myeloid leukemia, or AML.

The treatment regimen under evaluation in this pilot study is being used as one of the arms in SEAMLESS, the registration-directed, Phase 3 study of sapacitabine in elderly patients with newly diagnosed AML who are not candidates for or have refused induction chemotherapy. SEAMLESS is being conducted under a Special Protocol Assessment agreement that Cyclacel reached with the US Food and Drug Administration.

Our pipeline and expertise in cell cycle biology

Our core area of expertise is in cell cycle biology and we focus primarily on the development of orally-available anticancer agents that target the cell cycle with the aim of slowing the progression or shrinking the size of tumors, and enhancing the quality of life and improving survival rates of cancer patients. We are generating several families of anticancer drug candidates that act on the cell cycle including nucleoside analogues, cyclin dependent kinase, or CDK inhibitors and Aurora kinase/Vascular Endothelial Growth Factor Receptor 2, or AK/VEGFR2 inhibitors. Although a number of pharmaceutical and biotechnology companies are currently attempting to develop nucleoside analogues, CDK inhibitor and AK inhibitor drugs, we believe that our drug candidates are differentiated in that they are orally-available and interact with unique target profiles and mechanisms. For example we believe that our sapacitabine is the only orally-available nucleoside analogue to be tested in a Phase 3 trial for AML and in a Phase 2 trial in MDS and seliciclib is the most advanced orally-available CDK inhibitor in Phase 2 trials.

Although our resources are primarily directed towards advancing our anticancer drug candidate sapacitabine through in-house development activities we are also progressing, but with minimal investment, our other novel drug series which are at earlier stages. As a consequence of our progress in sapacitabine clinical development, research and development expenditures for the six months ended June 30, 2011 increased by $1.5 million, or 42%, to $5.0 million, compared to $3.5 million for the six months ended June 30, 2010.

We have retained rights to commercialize our clinical development candidates and our business strategy is to enter into selective partnership arrangements with these programs.

Our corporate headquarters is located in Berkeley Heights, New Jersey, with a research facility located in Dundee, Scotland.

From our inception in 1996 through June 30, 2011, we have devoted substantially all our efforts and resources to our research and development activities. We have incurred significant net losses since inception. As of June 30, 2011, our accumulated deficit during the development stage was approximately $250.0 million. We expect to continue incurring substantial losses for the next several years as we continue to develop our clinical and preclinical drug candidates. Our operating expenses are comprised of research and development expenses and selling and general and administrative expenses.

To date, we have not generated significant product revenue but have financed our operations and internal growth through, among other things, public and private equity offerings, licensing revenue, interest on investments, government grants and research and development tax credits. Prior to October 2007, our revenue consisted of collaboration and grant revenue. Beginning in 2008, we recognized revenue from sales of commercial products, for the first time, following the ALIGN acquisition in October 2007. We have recognized revenues from inception through June 30, 2011 totaling approximately $9.4 million, of which approximately $2.7 million is derived from product sales, approximately $3.1 million from fees under collaborative agreements and approximately $3.6 million of grant revenue from various United Kingdom government grant awards.

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Subsequent Events

Preferred Stock Dividend

On July 8, 2011, our Board of Directors, or Board, decided not to declare the quarterly cash dividend on our 6% Convertible Exchangeable Preferred Stock, or Preferred Stock, with respect to the second quarter of 2011 that would have otherwise been payable on August 1, 2011.

The Board also did not declare the quarterly cash dividend with respect to each of the four quarters of fiscal year 2009 and the first, second and third quarters of 2010. To the extent that any dividends payable on the Preferred Stock are not paid, such unpaid dividends are added to the liquidity preference of the Preferred Stock. As we failed to pay in an aggregate amount equal to at least six quarterly dividends (whether or not consecutive) on the Preferred Stock, the size of the our Board was increased by two members and the holders of the Preferred Stock, voting separately as a class, voted on May 24, 2011 and elected two directors to fill the vacancies created thereby, which directorships shall terminate when we pay all accrued but unpaid dividends.

License Agreement

On July 11, 2011, we entered into an amendment to our license agreement with Daiichi Sankyo Company, Limited (Daiichi Sankyo), dated September 10, 2003, relating to certain rights which we have licensed from Daiichi Sankyo with regard to sapacitabine. Effective July 11, 2011, the license agreement was amended to irrevocably waive a termination right Daiichi Sankyo possessed under a provision of the agreement that required us to obtain regulatory approval to sell sapacitabine in at least one country by September 2011, and releases us from all claims and liability of any kind arising under such provision. The amendment further provides that the royalty due to Daiichi Sankyo on future net sales of sapacitabine be increased by a percentage between 1.25% and 1.50% depending on the level of net sales of sapacitabine realized.

Financing

On July 7, 2011, we closed an underwritten offering for an aggregate of 7,617,646 units, at an offering price of $1.36 per unit, for gross proceeds of $10.4 million. Each unit consists of (i) one share of common stock and (ii) a five-year warrant to purchase 0.5 of a share of common stock at an exercise price of $1.36 per share, exercisable beginning six months after the date of issuance. The shares of common stock and warrants were immediately separable and were issued separately such that no units were issued. The net proceeds, after underwriting discounts and commissions and fees and expenses, were approximately $9.3 million.

Results of Operations

Three Months Ended June 30, 2011 and 2010

Revenues

The following table summarizes the components of our revenues for the three months ended June 30, 2010 and 2011:

	Three Months Ended June 30, 2010	Three Months Ended June 30, 2011	Increase (Decrease) $	Increase (Decrease) %
	($000s)			
Collaboration and research and development revenue	$ 100	$	$ (100)	(100)%
Product revenue	19	168	149	784%
Total revenue	$ 119	$ 168	$ 49	41%

We recognized $0.1 million of collaboration and research and development revenue for the three months ended June 30, 2010, derived from an agreement with a pharmaceutical company under which we provided one of our compounds for evaluation in the field of eye care. We had no collaboration and research and development revenue for the three months ended June 30, 2011.

Product revenue is derived from the sale of Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges following the ALIGN asset acquisition on October 5, 2007. During the three months ended June 30, 2010 and 2011, we recognized approximately $19,000 and $0.2 million, respectively in accordance with our revenue recognition policy. Product revenue was lower by $0.2 million for the three months ended June 30, 2010 compared to the same period in 2011 as a result of recognizing $0.2 million in product returns during the three months ended June 30, 2010.

Grant revenue is recognized as we incur and pay for qualifying costs and services under the applicable grant. Grant revenue is primarily derived from various United Kingdom government grant awards. We have earned grant revenue in the past and will continue to pursue opportunities in the future but did not recognize any grant revenue for the three months ended June 30, 2010 or 2011 as a result of finalization of a three-year European Union grant in the first quarter of 2010.

The future

We expect to continue to maintain the sales of ALIGN products in 2011 through the support of a small sales and marketing infrastructure. We do not expect to earn any grant revenue during the remainder of year, as no awards are expected during the year ended December 31, 2011.

Cost of goods sold

The following table summarizes cost of goods sold for the six months ended June 30, 2010 and 2011:

	Three Months Ended June 30, 2010	Three Months Ended June 30, 2011	Increase (Decrease) $	Increase (Decrease) %
	($000s)			
Cost of goods sold	$ 92	$ 72	$ (20)	(22)%

Total cost of sales represented 43% of product revenue for the three months ended June 30, 2011. Total cost of sales was not a meaningful percentage of product revenue for the three months ended June 30, 2010 because of the low product revenue recognized during the period, as explained above.

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Research and development expenses

We expense all research and development costs as they are incurred. Research and development expenses primarily include:

- clinical trial and regulatory-related costs;
- payroll and personnel-related expenses, including consultants and contract research;
- preclinical studies and laboratory supplies and materials;
- technology license costs; and
- rent and facility expenses for our laboratories.

The following table provides information with respect to our research and development expenditure for the three months ended June 30, 2010 and 2011:

	Three Months Ended June 30, 2010	Three Months Ended June 30, 2011	Increase (Decrease) $	Increase (Decrease) %
	($000s)			
Sapacitabine	$ 1,186	$ 1,760	$ 574	48%
Seliciclib	72	16	(56)	(78)%
Other research and development costs	64	83	19	30%
Total research and development costs	$ 1,322	$ 1,859	$ 537	41%

Total research and development expenses represented 29% and 47% of our operating expenses for the three months ended June 30, 2010 and 2011, respectively.

Research and development expenditure increased by $0.5 million to $1.9 million for the three month period ended June 30, 2011 from $1.3 million for the three month period ended June 30, 2010. The increase in costs of $0.5 million is mostly due to a $0.6 million increase in sapacitabine-related expenses, primarily a $0.2 million increase in capsule manufacture and testing and a $0.2 million increase in clinical trial expenses, as a result of the SEAMLESS trial entering Phase 3. Seliciclib costs decreased $56,000, from $72,000 for the three months ended June 30, 2010, to $16,000 for the three months ended June 30, 2011, primarily due to the completion of clinical trials. Other research and development costs remained relatively flat, increasing $19,000 from approximately $0.1 million for the three months ended June 30, 2010 to approximately $0.1 million for three months ended June 30, 2011 as we have continued to concentrate financial resources on the development of sapacitabine and selectively invest in other compounds.

The future

We will continue to concentrate our resources on the development of sapacitabine. We anticipate that overall research and development expenditures in 2011 will increase as we enroll the SEAMLESS pivotal Phase 3 trial.

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Selling, general and administrative expenses

Selling, general and administrative expenses include costs for sales and marketing and administrative personnel, legal and other professional expenses and general corporate expenses. The following table summarizes the selling, general and administrative expenses for the three months ended June 30, 2010 and 2011:

	Three Months Ended June 30, 2010	Three Months Ended June 30, 2011	Increase (Decrease) $	Increase (Decrease) %
	($000s)			
Selling, general and administrative	$ 3,091	$ 2,034	$ (1,057)	(34)%

Total selling, general and administrative expenses represented 69% and 51% of our operating expenses for the three months ended June 30, 2010 and 2011, respectively. Our selling, general and administrative expenditure decreased by $1.1 million from $3.1 million for the three months ended June 30, 2010 to $2.0 million for the three months ended June 30, 2011. The decrease of $1.1 million in expenses was primarily attributable to a net decrease in professional and consultancy costs of $0.8, million, a decrease in stock compensation of $0.4 million, a decrease in rent expense of $0.1 million, a decrease in salaries of $0.1 million, and an increase in patent costs of $0.3 million.

The future

We expect our selling, general and administrative expenditures in 2011 to remain at the same level or to be less than our expenditures in 2010.

Other income (expense)

The following table summarizes other income (expense) for the three months ended June 30, 2010 and 2011:

	Three Months Ended June 30, 2010	Three Months Ended June 30, 2011	Increase (Decrease) $	Increase (Decrease) %
		($000s)		
Other income (expense):				
Change in valuation of warrants	$ 273	$ 125	$ (148)	(54)%
Foreign exchange (losses)/gains	(49)	(19)	30	(61)%
Interest income	8	13	5	63%
Interest expense	(9)		9	(100)%
Total other income (expense)	$ 223	$ 119	$ (104)	(47)%

Total other income and expense, net, decreased by approximately $0.1 million, from income of $0.2 million for the three months ended June 30, 2010, to income of $0.1 million for the three months ended June 30, 2011. The most significant impact is the change in the valuation of the warrant liability described below.

The change in valuation of warrants relates to the issue of warrants to purchase shares of our common stock under the registered direct financing completed in February 2007. The warrants issued to the investors meet the requirements of and are being accounted for as a liability in accordance with ASC 480, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock.* The fair value of the warrants is re-measured each reporting period with a derivative gain or loss recognized in the consolidated statement of operations. Such gains or losses will continue to be reported until the warrants are exercised or expired. For the three months ended June 30, 2010 and 2011, the change in the value of warrants was a $0.3 million increase and a $0.1 million decrease, respectively.

Foreign exchange gains (losses) decreased by $30,000 to a loss of $19,000 for the three months ended June 30, 2011 compared to a loss of $49,000 for the three months ended June 30, 2010. Foreign exchange gains/(losses) are reported in the consolidated statement of operations as a separate line item within other income (expense).

Interest income increased by approximately $5,000 to $13,000 for the three months to June 30, 2010 from $8,000 for the three months ended June 30, 2010. This is mostly attributed to a higher average daily balance of cash and cash equivalents during the three months ended June 30, 2011 compared to the same period in 2010.

Interest expense decreased by $9,000 from $9,000 for the three months ended June 30, 2010 to $0 for the three months ended June 30, 2011. This reduction was primarily due to the elimination of the accretion expense associated with the restructured Bothell lease, which expired in December 2010.

The future

The valuation of the warrant liability will continue to be re-measured at the end of each reporting period. The valuation of the warrants is dependent upon many factors, including our stock price, interest rates and the remaining term of the instrument and may fluctuate significantly, which may have a significant impact on our statement of operations.

Income tax benefit

Credit is taken for research and development tax credits, which are claimed from the United Kingdom s revenue and customs authority, or HMRC, in respect of qualifying research and development costs incurred.

The following table summarizes research and development tax credits for the three months ended June 30, 2010 and 2011:

	Three Months Ended June 30, 2010	Three Months Ended June 30, 2011	Increase (Decrease) $	Increase (Decrease) %
	($000s)			
Income tax benefit	$ 230	$ 126	$ (104)	(45)%

Research and development tax credits recoverable decreased by $0.1 million to $0.1 million for the three months ended June 30, 2011 from $0.2 million for three months ended June 30, 2010. The level of tax credits recoverable is linked directly to qualifying research and development expenditure incurred in any one year, but restricted to payroll taxes paid by us in the United Kingdom in that same year. The $0.1 million decrease between the three months ended June 30, 2010 and 2011 is due to lower payroll taxes paid as a result of lower headcount in 2011.

The future

We expect to continue to be eligible to receive United Kingdom research and development tax credits for the foreseeable future and will elect to do so.

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Six Months Ended June 30, 2010 and 2011

Revenues

The following table summarizes the components of our revenues for the six months ended June 30, 2010 and 2011:

	Six Months Ended June 30, 2010	Six Months Ended June 30, 2011	Increase (Decrease) $	Increase (Decrease) %
		($000s)		
Collaboration and research and development revenue	$ 100	$	$ (100)	(100)%
Product revenue	273	360	87	32%
Grant revenue	16		(16)	(100)%
Total revenue	$ 389	$ 360	$ (29)	(7)%

We recognized $0.1 million of collaboration and research and development revenue for the six months ended June 30, 2010 derived from an agreement with a pharmaceutical company under which we provided one of our compounds for evaluation in the field of eye care. We had no collaboration and research and development revenue for the six months ended June 30, 2011.

Product revenue is derived from the sale of Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges. During the six months ended June 30, 2010 and 2011, we recognized product revenue of approximately $0.3 and $0.4 million, respectively, in accordance with our revenue recognition policy. Product revenue was lower by $0.1 million for the six months ended June 30, 2010 compared to the same period in 2011 due to $0.2 million in product returns during six month ended June 30, 2011.

Grant revenue is recognized as we incur and pay for qualifying costs and services under the applicable grant. Grant revenue is primarily derived from various United Kingdom government grant awards. We recognized $16,000 in grant revenue for the six months ended June 30, 2010. We did not recognize any grant revenue for the six months ended June 30, 2011 as a result of finalization of a three-year European Union grant in the first quarter of 2010.

Cost of goods sold

The following table summarizes cost of goods sold for the six months ended June 30, 2010 and 2011:

	Six Months Ended June 30, 2010	Six Months Ended June 30, 2011	Increase (Decrease) $	Increase (Decrease) %
		($000s)		
Cost of goods sold	$ 234	$ 178	$ (56)	(24)%

Total cost of sales represented 86% and 49% of product revenue for the six months ended June 30, 2010 and 2011, respectively. The high percentage for the six months ended June 30, 2010 is the result of lower product revenue driven by $0.2 million of product returns during the period, as described above.

Research and development expenses

We expense all research and development costs as they are incurred. Research and development expenses primarily include:

- clinical trial and regulatory-related costs;
- payroll and personnel-related expenses, including consultants and contract research;
- preclinical studies and laboratory supplies and materials;
- technology license costs; and
- rent and facility expenses for our laboratories.

The following table provides information with respect to our research and development expenditure for the six months ended June 30, 2010 and 2011:

	Six Months Ended June 30, 2010	Six Months Ended June 30, 2011	Increase (Decrease) $	Increase (Decrease) %
	($000s)			
Sapacitabine	$ 2,803	$ 4,731	$ 1,928	69%
Seliciclib	133	25	(108)	(81)%
Other research and development costs	561	183	(378)	(67)%
Total research and development expenses	$ 3,497	$ 4,939	$ 1,442	41%

Total research and development expenses represented 38% and 55% of our operating expenses for the six months ended June 30, 2010 and 2011, respectively.

Research and development expenditure increased by $1.4 million to $4.9 million for the six month period ended June 30, 2011 from $3.5 million for the six month period ended June 30, 2010. The increase in costs of $1.4 million is primarily due to a $1.9 million increase in sapacitabine related costs and decreases of $0.1 million and $0.4 million in seliciclib and other research and development costs, respectively, as we continue to focus on the development of sapacitabine. The $1.9 million increase in sapacitabine expenditures was primarily due to $1.6 million of contractual expenses, resulting from an achievement of a milestone triggered by the opening of enrollment in our SEAMLESS trial, pursuant to the Daiichi Sankyo license under which we license certain patent rights for sapacitabine, and a $0.4 million increase in capsule manufacturing and testing. Seliciclib costs decreased by $0.1 million from $133,000 for the six months ended June 30, 2010 to $25,000 for six months ended June 30, 2011 primarily due to the completion of clinical trials. Other research and development costs decreased $0.4 million to $0.2 million for the six months ended June 30, 2011 from $0.6 million for the six months ended June 30, 2010, as we have concentrated financial resources on the development of sapacitabine and reduced investment in other compounds.

Selling, general and administrative expenses

Selling, general and administrative expenses include costs for sales and marketing and administrative personnel, legal and other professional expenses and general corporate expenses. The following table summarizes the selling, general and administrative expenses for the six months ended June 30, 2010 and 2011:

	Six Months Ended June 30, 2010	Six Months Ended June 30, 2011	Increase (Decrease) $	Increase (Decrease) %
	($000s)			
Selling, general and administrative	$ 5,491	$ 3,840	$ (1,651)	(30)%

Total selling, general and administrative expenses represented 60% and 43% of our operating expenses for the six months ended June 30, 2010 and 2011, respectively. Our selling, general and administrative expenditure decreased by $1.7 million from $5.5 million for the six months ended June 30, 2010 to $3.8 million for the six months ended June 30, 2011. The decrease of $1.7 million in expenses was primarily attributable to a net decrease in professional and consultancy costs of $1.3 million, a decrease in salaries of $0.4 million, a decrease in rent of $0.2 million as a result of the expiration our lease on a facility in Bothell, Washington in December 2010, and a decrease in stock compensation of $0.3 million. These amounts were partially offset by a $0.4 million increase in patent-related costs.

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Other income (expense)

The following table summarizes other income (expense) for the three months ended June 30, 2010 and 2011:

	Six Months Ended June 30, 2010	Six Months Ended June 30, 2011	Increase (Decrease) $	Increase (Decrease) %
	($000s)			
Other income (expense):				
Change in valuation of warrants	$ (516)	$ 203	$ 719	139%
Foreign exchange (losses)/gains	(38)	(87)	(49)	(129)%
Interest income	17	24	7	41%
Interest expense	(33)		33	(100)%
Total other income (expense)	$ (570)	$ 140	$ 710	(125)%

Total other income and expense, net, increased by approximately $0.7 million, from an expense of $0.6 million for the six months ended June 30, 2010, to income of $0.1 million for the six months ended June 30, 2011. The most significant impact is the $0.7 million increase in the change in the valuation of the warrant liability, mostly due to the decrease in our common share price.

The change in valuation of warrants relates to the issue of warrants to purchase shares of our common stock under the registered direct financing completed in February 2007. The warrants issued to the investors meet the requirements of and are being accounted for as a liability in accordance with ASC 480, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock.* The fair value of the warrants is re-measured each reporting period with a derivative gain or loss recognized in the consolidated statement of operations. Such gains or losses will continue to be reported until the warrants are exercised or expired. For the six months ended June 30, 2010 and 2011, the change in the value of warrants was a $0.5 million increase and a $0.2 million decrease, respectively.

Foreign exchange gains (losses) increased by $49,000 to a loss of $87,000 for the six months ended June 30, 2011 compared to a loss of $38,000 for the six months ended June 30, 2010. Foreign exchange gains/(losses) are reported in the consolidated statement of operations as a separate line item within other income (expense).

Interest income increased by approximately $7,000 to $24,000 for the six months ended June 30, 2010 from $17,000 for the six months ended June 30, 2010. This is mostly attributed to a higher average daily balance of cash and cash equivalents during the three months ended June 30, 2011 compared to the same period in 2010.

Interest expense decreased by $33,000 from $33,000 for the six months ended June 30, 2010 to $0 for the six months ended June 30, 2011. This reduction was primarily due to the elimination of the accretion expense associated with the restructured Bothell lease, which expired in December 2010.

The future

The valuation of the warrant liability will continue to be re-measured at the end of each reporting period. The valuation of the warrants is dependent upon many factors, including our stock price, interest rates and the remaining term of the instrument and may fluctuate significantly, which may have a significant impact on our statement of operations.

Income tax benefit

Credit is taken for research and development tax credits, which are claimed from the United Kingdom s revenue and customs authority, or HMRC, in respect of qualifying research and development costs incurred.

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The following table summarizes research and development tax credits for the six months ended June 30, 2010 and 2011:

	Six Months Ended June 30, 2010	Six Months Ended June 30, 2011	Increase (Decrease) $	Increase (Decrease) %
	($000s)			
Income tax benefit	$ 363	$ 317	$ (46)	(13)%

Research and development tax credits recoverable decreased $46,000, from $0.4 million for the six months ended June 30, 2010, to $0.3 million for the six months ended June 30, 2011. The level of tax credits recoverable is linked directly to qualifying research and development expenditure incurred in any one year, but restricted to payroll taxes paid by us in the United Kingdom in that same year. The $46,000 decrease between the six months ended June 30, 2010 and 2011 is due to lower payroll taxes paid as a result of lower headcount in 2011.

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Liquidity and Capital Resources

The following is a summary of our key liquidity measures at December 31, 2010 and June 30, 2011:

	December 31, 2010	June 30, 2011	$ Difference	% Difference
		($000s)		
Cash and cash equivalents	$ 29,495	$ 20,614	$ (8,881)	(30)%
Working capital:				
Current assets	$ 31,051	$ 22,449	$ (8,602)	(28)%
Current liabilities	(6,535)	(6,040)	495	8%
Working capital	$ 24,516	$ 16,409	$ (8,107)	(33)%

The objectives of our cash management policy are to safeguard and preserve funds, to maintain liquidity sufficient to meet our cash flow requirements and to attain a market rate of return. At June 30, 2011, we had cash and cash equivalents of $20.6 million as compared to $29.5 million at December 31, 2010. The decrease in balance at June 30, 2010 was primarily due to normal cash outflows required to operate our business. Since our inception, we have not generated any significant revenue and have relied primarily on the proceeds from sales of equity and preferred securities to finance our operations and internal growth. Additional funding has come through interest on investments, licensing revenue, government grants and research and development tax credits. We have incurred significant losses since our inception. As of June 30, 2011, we had an accumulated deficit during the development stage of $250.0 million. We believe that existing funds together with cash generated from operations and recent financing activities are sufficient to satisfy our planned working capital, capital expenditures, debt service and other financial commitments for at least the next twelve months. Current business and capital market risks could have a detrimental effect on the availability of sources of funding and our ability to access them in the future which may delay or impede our progress of advancing our drugs currently in the clinic to approval by the FDA for commercialization.

Cash provided by (used in) operating, investing and financing activities

Cash provided by (used in) operating, investing and financing activities for the six months ended June 30, 2010 and 2011, is summarized as follows:

	Six months ended June 30, 2010	Six months ended June 30, 2011
	($000s)	
Net cash used in operating activities	(9,776)	(8,477)
Net cash provided by investing activities	27	
Net cash provided by (used in) financing activities	17,855	(441)

Operating activities

Net cash used in operating activities decreased $1.3 million, from $9.8 million for the six months ended June 30, 2010 to $8.5 million for the six months ended June 30, 2011. The decrease in cash outflow is primarily the result of better management of selling, general and administrative expenses as the result of our continued focus on sapacitabine.

Investing activities

Net cash provided by investing activities for the six months ended June 30, 2010 was $27,000 as a result of the sale of laboratory equipment. There were no cash flows from investing activities during the six months ended June 30, 2011.

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Financing activities
Net cash used in financing activities for the six months ended June 30, 2011 was $0.4 million. Net cash provided by financing activities was $17.9 million for the six months ended June 30, 2010. During the six months ended June 30, 2010, we completed two registered direct offerings in January 2010 for gross proceeds of approximately $13.0 million, drew down the Kingsbridge CEFF totaling approximately $2.8 million and had investors exercising warrants totaling $2.7 million. During the six months ended June 30, 2011, we paid a cash dividend to our holders of the Preferred Stock of approximately $0.4 million.

Operating Capital and Capital Expenditure Requirements
We expect to continue to incur substantial operating losses in the future. While we have generated modest product revenues from ALIGN product sales from October 2007 through June 30, 2011, we cannot guarantee that we will generate any significant product revenues until a product candidate has been approved by the FDA or similar regulatory agencies in other countries and successfully commercialized.

We currently anticipate that our cash and cash equivalents, including net proceeds of $9.3 million from the underwritten offering closed in July 2011, will be sufficient to fund our operations for at least the next 12 months. We cannot be certain that any of our programs will be successful or that we will be able to raise sufficient funds to complete the development and commercialize any of our product candidates currently in development, should they succeed. Additionally, we plan to continue to evaluate in-licensing and acquisition opportunities to gain access to new drugs or drug targets that would fit with our strategy. Any such transaction would likely increase our funding needs in the future.

Our future funding requirements will depend on many factors, including but not limited to:

- the rate of progress and cost of our clinical trials, preclinical studies and other discovery and research and development activities;
- the costs associated with establishing manufacturing and commercialization capabilities;
- the costs of acquiring or investing in businesses, product candidates and technologies;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the costs and timing of seeking and obtaining FDA and other regulatory approvals;
- the effect of competing technological and market developments; and
- the economic and other terms and timing of any collaboration, licensing or other arrangements into which we may enter.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through public or private equity offerings, debt financings or strategic collaborations. Although we are not reliant on institutional credit finance and therefore not subject to debt covenant compliance requirements or potential withdrawal of credit by banks, the current economic climate has also impacted the availability of funds and activity in equity markets. We do not know whether additional funding will be available on acceptable terms, or at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more of our clinical trials or research and development programs or make changes to our operating plan. In addition, we may have to partner one or more of our product candidate programs at an earlier stage of development, which would lower the economic value of those programs to us.

Off-Balance Sheet Arrangements
As of June 30, 2011, we have no off-balance sheet arrangements.

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Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and related disclosure of contingent assets and liabilities. We review our estimates on an ongoing basis. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. We believe the judgments and estimates required by the following accounting policies to be critical in the preparation of our consolidated financial statements.

Revenue Recognition

Product sales

We have adopted the following revenue recognition policy related to the sales of Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges. We recognize revenue from these product sales when persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the selling price is fixed and determinable; and collectability is reasonably assured.

As we offer a general right of return on these product sales, we must consider the guidance in ASC Topic 605. Under these guidelines, we account for all product sales using the sell-through method. Under the sell-through method, revenue is not recognized upon shipment of product to distributors. Instead, we record deferred revenue at gross invoice sales price and deferred cost of sales at the cost at which those goods were held in inventory. We recognize revenue when such inventory is sold through to pharmacies. To estimate products sold through to pharmacies, we rely on third-party information, including information obtained from significant distributors with respect to their inventory levels and sell-through to pharmacies. We estimate product returns based on historical returns experience and other factors that affect the demand for our products as well as the amount of product subject to return.

Stock-based Compensation

The Company grants stock options, restricted stock units and restricted stock to officers, employees, directors and consultants under the Company s 2006 Amended and Restated Equity Incentive Plan, which was amended and restated as of April 14, 2008. We also have outstanding options under various stock-based compensation plans for employees and directors.

ASC 718 requires measurement of compensation cost for all stock-based awards at fair value on date of grant and recognition of compensation over the requisite service period for awards expected to vest. The fair value of restricted stock and restricted stock units is determined based on the number of shares granted and the quoted price of our common stock on the date of grant. The determination of grant-date fair value for stock option awards is estimated using an option-pricing model, which includes variables such as the expected volatility of our share price, the anticipated exercise behavior of our employees, interest rates, and dividend yields. These variables are projected based on our historical data, experience, and other factors.

Such value is recognized as an expense over the requisite service period, net of estimated forfeitures, using the straight-line attribution method. The estimation of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from our current estimates, such amounts will be recorded as a cumulative adjustment in the period estimates are revised. We consider many factors when estimating expected forfeitures, including types of awards, employee class, and historical experience. If our actual forfeiture rate is materially different from our estimate, the stock-based compensation expense could be significantly different from what we have recorded in the current period.

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Warrants Liability

With respect to warrants issued in February 2007 as part of a financing and pursuant to ASC 815, since we are unable to control all the events or actions necessary to settle the warrants in registered shares the warrants have been recorded as a current liability at fair value. The fair value of the outstanding warrants is evaluated at each reporting period with any resulting change in the fair value being reflected in the consolidated statements of operations. During the three months ended June 30, 2010 and 2011, the Company recognized gains from the change in the value of warrants of approximately $0.3 million and $0.1 million, respectively. During the six months ended June 30, 2010, the Company recognized the change in the value of warrants as a loss of approximately $0.5 million. During the six months ended June 30, 2011, the Company recognized the change in the value of warrants as a gain of approximately $0.2 million. Fair value is estimated using an option-pricing model, which includes variables such as the expected volatility of our share price, interest rates, and dividend yields. These variables are projected based on our historical data, experience, and other factors. Changes in any of these variables could result in material adjustments to the expense recognized for changes in the valuation of the warrants liability.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to fluctuations in foreign currency exchange rates.

Foreign Currency Risk

We are exposed to foreign currency rate fluctuations related to the operation of our subsidiary in the United Kingdom. At the end of each reporting period, income and expenses of the subsidiary are re-measured into U.S. dollars using the average currency rate in effect for the period and assets and liabilities are re-measured into U.S. dollars using either historical rates or the exchange rate in effect at the end of the period. Intercompany loans with this subsidiary are denominated in U.S. dollars and unrealized foreign exchange gains and losses arising on these loans have been recorded in the consolidated statement of operations within the separate line item foreign exchange gains/(losses) within other income (expense) up to September 30, 2008.

We currently do not engage in foreign currency hedging. We enter into certain transactions denominated in foreign currencies in respect of underlying operations and, therefore, we are subject to currency exchange risks. We realized losses of $49,000 and gains of $2,000 for the three months ended June 30, 2010 and 2011, respectively. During the six months ended June 30, 2010 and 2011, we realized losses of $38,000 and $66,000, respectively.

Common Stock Price Risk

In February 2007, we issued common stock and warrants. Pursuant to ASC 815, we recorded the fair value of the warrants as a current liability. The fair value of the outstanding warrants is evaluated at each reporting period with any resulting change in the fair value being reflected in the condensed consolidated statements of operations. We recognized a loss of $0.3 million and a gain of $0.1 million on the consolidated statement of operations for the three months ended June 30, 2010 and 2011, respectively, related to the change in the value of warrants. We recognized a loss of $0.5 million and a gain of $0.2 million on the consolidated statement of operations for the six months ended June 30, 2010 and 2011, respectively, related to the change in the value of warrants. Fair value of the derivative instruments will be affected by estimates of various factors that may affect the respective instrument, including our stock price, the risk free rate of return and expected volatility in the fair value of our stock price. As the fair value of this derivative may fluctuate significantly from period to period, the resulting change in valuation may have a significant impact on our results of operations.

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Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial and accounting officer, we conducted an evaluation of the effectiveness, as of June 30, 2011, of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. The purpose of this evaluation was to determine whether as of the evaluation date our disclosure controls and procedures were effective to provide reasonable assurance that the information we are required to disclose in our filings with the SEC under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms and (ii) accumulated and communicated to our management, including our principal executive officer and principal financial and accounting officer, as appropriate to allow timely decisions regarding required disclosure. Based on that evaluation, management has concluded that as of June 30, 2011, our disclosure controls and procedures were not effective at the reasonable assurance level due to the material weaknesses in our internal controls described in the amendment to our Annual Report on Form 10-K for the year ended December 31, 2010 in the section captioned Item 9A Controls and Procedures Management s Annual Report on Internal Control Over Financial Reporting that remain present.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended June 30, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting other than those described below.

In response to the material weaknesses in our internal controls noted in our Annual Report on Form 10-K for the year ended December 31, 2010, filed on March 31, 2011, management presented a proposed remediation plan to our audit committee concerning our internal controls over financial reporting, and the audit committee adopted management s remediation plan. We have implemented the plan by hiring qualified finance professionals and retaining outside consultants. Remediation of the material weaknesses will require management time and attention over the coming quarters and will likely result in additional incremental expenses. Any failure on our part to remedy our identified weaknesses or any additional errors or delays in our financial reporting would have a material adverse effect on our business and results of operations and could have a substantial adverse impact on the trading price of our common stock.

Subject to oversight by our board of directors, our chief executive officer will be responsible for implementing management s internal control remediation plan, adopted by our audit committee and approved by our board of directors.

Specifically, the remediation plan consists of strengthening the financial reporting function through the hiring of qualified finance personnel, with experience in the interpretation and application of accounting principles generally accepted in the United States, or GAAP, and designing and placing into operation appropriate controls to prevent or detect on a timely basis any potential material misstatements in the accounting, presentation and disclosure of cumulative preferred dividends. It is anticipated that the remediation plan, once implemented, will materially affect our internal control over financial reporting.

We anticipate that the actions described above will remediate the material weakness described in our Annual Report on Form 10-K for the year ended December 31, 2010.

Inherent Limitation on the Effectiveness of Internal Controls

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurances. In addition, 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. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but cannot assure you that such improvements will be sufficient to provide us with effective internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1. Legal proceedings.

From time to time, we may be involved in routine litigation incidental to the conduct of our business. On April 27, 2010, we were served with a complaint filed by Celgene Corporation in the United States District Court for the District of Delaware seeking a declaratory judgment that four of our own patents, claiming the use of romidepsin injection in T-cell lymphomas, are invalid and not infringed by Celgene s products, but directly involve the use and administration of Celgene s ISTODAX® (romidepsin for injection) product. On June 17, 2010, we filed our answer and counterclaims to the declaratory judgment complaint. We have filed counterclaims charging Celgene with infringement of each of our four patents and seeking damages for Celgene s infringement as well as injunctive relief. The four patents directly involve the use and administration of Celgene s ISTODAX® (romidepsin for injection) product.

Item 1A. Risk Factors.

In analyzing our company, you should consider carefully the following risk factors, together with all of the other information included in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2010. Factors that could cause or contribute to differences in our actual results include those discussed in the following subsection, as well as those discussed above in Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere throughout this Quarterly Report on Form 10-Q. Each of the following risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock.

Risks Associated with Development and Commercialization of Our Drug Candidates

Clinical trial designs that were discussed with the authorities prior to their commencement may subsequently be considered insufficient for approval at the time of application for regulatory approval. Thus, our SPA regarding our SEAMLESS trial does not guarantee marketing approval or approval of our sapacitabine oral capsules for the treatment of acute myeloid leukemia.

On September 13, 2010, we reached agreement with the FDA regarding an SPA on the design of a pivotal Phase 3 trial for our sapacitabine oral capsules as a front-line treatment in elderly patients aged 70 years or older with newly diagnosed acute myeloid leukemia, or AML, who are not candidates for intensive induction chemotherapy, or the SEAMLESS trial. An SPA provides trial sponsors with an agreement from the FDA that the design and analysis of the trial adequately address objectives in support of a submission for a marketing application if the trial is performed according to the SPA. The SPA may only be changed through a written agreement between the sponsor and the FDA or if the FDA becomes aware of a substantial scientific issue essential to product efficacy or safety. On January 11, 2011, we opened enrollment of the SEAMLESS trial.

An SPA, however, neither guarantees approval nor provides any assurance that a marketing application would be approved by the FDA. There are companies that have been granted SPAs but have ultimately failed to obtain final approval to market their drugs. The FDA may revise previous guidance or decide to ignore previous guidance at any time during the course of clinical activities or after the completion of clinical trials. The FDA may raise issues relating to, among other things, safety, study conduct, bias, deviation from the protocol, statistical power, patient completion rates, changes in scientific or medical parameters or internal inconsistencies in the data prior to making its final decision. The FDA may also seek the guidance of an outside advisory committee prior to making its final decision. Even with successful clinical safety and efficacy data, including such data from a clinical trial conducted pursuant to an SPA, we may be required to conduct additional, expensive clinical trials to obtain regulatory approval.

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The development program for our lead drug candidate sapacitabine is based, in part, on intellectual property rights we license from others and any termination of this license could seriously harm our business.

Effective July 11, 2011, the Daiichi Sankyo license under which we license certain patent rights for sapacitabine, our lead drug candidate, was amended to irrevocably waive a termination right Daiichi Sankyo possessed under a provision of the agreement that required the Company to obtain regulatory approval to sell sapacitabine in at least one country by September 2011, and releases the Company from all claims and liability of any kind arising under such provision. The amendment further provides that the royalty due from the Company to Daiichi Sankyo on future net sales of sapacitabine be increased by a percentage between 1.25% and 1.50% depending on the level of net sales of sapacitabine realized.

In general, the license may be terminated by us for technical, scientific, efficacy, safety, or commercial reasons on six months notice, or twelve months if after a launch of a sapacitabine-based product, or by either party for material default.

Although we are currently in compliance with all of our material obligations under this license, if we were to breach any such obligations, our counterparty may be entitled to terminate the license. This would restrict or delay or eliminate our ability to develop and commercialize these drug candidates, which could adversely affect our business.

If we fail to enter into and maintain successful strategic alliances for our drug candidates, we may have to reduce or delay our drug candidate development or increase our expenditures.

An important element of our strategy for developing, manufacturing and commercializing our drug candidates is entering into strategic alliances with pharmaceutical companies or other industry participants to advance our programs and enable us to maintain our financial and operational capacity.

We face significant competition in seeking appropriate alliances. We may not be able to negotiate alliances on acceptable terms, if at all. In addition, these alliances may be unsuccessful. If we fail to create and maintain suitable alliances, we may have to limit the size or scope of, or delay, one or more of our drug development or research programs. If we elect to fund drug development or research programs on our own, we will have to increase our expenditures and will need to obtain additional funding, which may be unavailable or available only on unfavorable terms.

Clinical trials are expensive, time consuming, subject to delay and may be required to continue beyond our available funding.

Clinical trials are expensive, complex, can take many years to conduct and may have uncertain outcomes. We estimate that clinical trials of our most advanced drug candidates may be required to continue beyond our available funding and may take several years more to complete. The designs used in some of our trials have not been used widely by other pharmaceutical companies. Failure can occur at any stage of the testing and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of our current or future drug candidates, including but not limited to:

- delays in securing clinical investigators or trial sites for our clinical trials;
- delays in obtaining institutional review board, or IRB, and other regulatory approvals to commence a clinical trial;
- slower than anticipated rates of patient recruitment and enrollment, or reaching the targeted number of patients because of competition for patients from other trials or other reasons;
- negative or inconclusive results from clinical trials;
- unforeseen safety issues;
- uncertain dosing issues may or may not be related to suboptimal pharmacokinetic and pharmacodynamic behaviors;
- approval and introduction of new therapies or changes in standards of practice or regulatory guidance that render our clinical trial endpoints or the targeting of our proposed indications obsolete;
- inability to monitor patients adequately during or after treatment or problems with investigator or patient compliance with the trial protocols;
- inability to replicate in large controlled studies safety and efficacy data obtained from a limited number of patients in uncontrolled trials;
- inability or unwillingness of medical investigators to follow our clinical protocols; and
- unavailability of clinical trial supplies.

If we suffer any significant delays, setbacks or negative results in, or termination of, our clinical trials, we may be unable to continue development of our drug candidates or generate revenue and our development costs could increase significantly. Adverse events have been observed in our clinical trials and may force us to stop development of our product candidates or prevent regulatory approval of our product candidates.

Adverse or inconclusive results from our clinical trials may substantially delay, or halt entirely, any further development of our drug candidates. Many companies have failed to demonstrate the safety or effectiveness of drug candidates in later stage clinical trials notwithstanding favorable results in early stage clinical trials. Previously unforeseen and unacceptable side effects could interrupt, delay or halt clinical trials of our drug candidates and could result in the FDA or other regulatory authorities denying approval of our drug candidates. We will need to demonstrate safety and efficacy for specific indications of use, and monitor safety and compliance with clinical trial protocols throughout the development process. To date, long-term safety and efficacy has not been demonstrated in clinical trials for any of our drug candidates. Toxicity and serious adverse events as defined in trial protocols have been noted in preclinical and clinical trials involving certain of our drug candidates. For example, neutropenia and gastro-intestinal toxicity were observed in patients receiving sapacitabine and elevations of liver enzymes and decrease in potassium levels have been observed in patients receiving seliciclib.

In addition, we may pursue clinical trials for sapacitabine and seliciclib in more than one indication. There is a risk that severe toxicity observed in a trial for one indication could result in the delay or suspension of all trials involving the same drug candidate. Even if we believe the data collected from clinical trials of our drug candidates are promising with respect to safety and efficacy, such data may not be deemed sufficient by regulatory authorities to warrant product approval. Clinical data can be interpreted in different ways. Regulatory officials could interpret such data in different ways than we do which could delay, limit or prevent regulatory approval. The FDA, other regulatory authorities or we may suspend or terminate clinical trials at any time. Any failure or significant delay in completing clinical trials for our drug candidates, or in receiving regulatory approval for the commercialization of our drug candidates, may severely harm our business and reputation.

If our understanding of the role played by CDKs or AKs in regulating the cell cycle is incorrect, this may hinder pursuit of our clinical and regulatory strategy.

Our development of small molecule inhibitors of CDK and AK is based on our understanding of the mechanisms of action of CDK and AK inhibitors and their interaction with other cellular mechanisms. One of our drug candidates, seliciclib, is a CDK inhibitor, and CYC116 is an AK and VEGFR2 inhibitor. Although a number of pharmaceutical and biotechnology companies are attempting to develop CDK or AK inhibitor drugs for the treatment of cancer, no CDK or AK inhibitor has yet reached the market. If our understanding of the role played by CDK or AK inhibitors in regulating the cell cycle is incorrect, seliciclib and/or CYC116 may fail to produce therapeutically relevant results hindering our ability to pursue our clinical and regulatory strategy.

We are making use of biomarkers, which are not scientifically validated, and our reliance on biomarker data may thus lead us to direct our resources inefficiently.

We are making use of biomarkers in an effort to facilitate our drug development and to optimize our clinical trials. Biomarkers are proteins or other substances whose presence in the blood can serve as an indicator of specific cell processes. We believe that these biological markers serve a useful purpose in helping us to evaluate whether our drug candidates are having their intended effects through their assumed mechanisms, and thus enable us to identify more promising drug candidates at an early stage and to direct our resources efficiently. We also believe that biomarkers may eventually allow us to improve patient selection in connection with clinical trials and monitor patient compliance with trial protocols.

For most purposes, however, biomarkers have not been scientifically validated. If our understanding and use of biomarkers is inaccurate or flawed, or if our reliance on them is otherwise misplaced, then we will not only fail to realize any benefits from using biomarkers, but may also be led to invest time and financial resources inefficiently in attempting to develop inappropriate drug candidates. Moreover, although the FDA has issued for comment a draft guidance document on the potential use of biomarker data in clinical development, such data are not currently accepted by the FDA or other regulatory agencies in the United States, the European Union or elsewhere in applications for regulatory approval of drug candidates and there is no guarantee that such data will ever be accepted by the relevant authorities in this connection. Our biomarker data should not be interpreted as evidence of efficacy.

Due to our reliance on contract research organizations or other third parties to conduct clinical trials, we may be unable to directly control the timing, conduct and expense of our clinical trials.

We do not have the ability to independently conduct clinical trials required to obtain regulatory approvals for our drug candidates. We must rely on third parties, such as contract research organizations, data management companies, contract clinical research associates, medical institutions, clinical investigators and contract laboratories to conduct our clinical trials. In addition, we rely on third parties to assist with our preclinical development of drug candidates. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates.

To the extent we are able to enter into collaborative arrangements or strategic alliances, we will be exposed to risks related to those collaborations and alliances.

Although we are not currently party to any collaboration arrangement or strategic alliance that is material to our business, in the future we expect to be dependent upon collaborative arrangements or strategic alliances to complete the development and commercialization of some of our drug candidates particularly after the Phase 2 stage of clinical testing. These arrangements may place the development of our drug candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

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We may be unable to locate and enter into favorable agreements with third parties, which could delay or impair our ability to develop and commercialize our drug candidates and could increase our costs of development and commercialization. Dependence on collaborative arrangements or strategic alliances will subject us to a number of risks, including the risk that:

- we may not be able to control the amount and timing of resources that our collaborators may devote to the drug candidates;
- our collaborators may experience financial difficulties;
- we may be required to relinquish important rights such as marketing and distribution rights;
- business combinations or significant changes in a collaborator s business strategy may also adversely affect a collaborator s willingness or ability to complete our obligations under any arrangement;
- a collaborator could independently move forward with a competing drug candidate developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our drug candidates.

We have no manufacturing capacity and will rely on third party manufacturers for the late stage development and commercialization of any drugs or devices we may develop or sell.

We do not currently operate manufacturing facilities for clinical or commercial production of our drug candidates under development or our currently marketed ALIGN products. We currently lack the resources or the capacity to manufacture any of our products on a clinical or commercial scale. We depend upon a third party, Sinclair, to manufacture the commercial products sold by our ALIGN subsidiary and we cannot rely upon Sinclair to continue to supply the products. We anticipate future reliance on a limited number of third party manufacturers until we are able, or decide to, expand our operations to include manufacturing capacities. Any performance failure on the part of manufacturers could delay late stage clinical development or regulatory approval of our drug, the commercialization of our drugs or our ability to sell our commercial products, producing additional losses and depriving us of potential product revenues.

If the FDA or other regulatory agencies approve any of our drug candidates for commercial sale, or if we significantly expand our clinical trials, we will need to manufacture them in larger quantities and will be required to secure alternative third-party suppliers to our current suppliers. To date, our drug candidates have been manufactured in small quantities for preclinical testing and clinical trials and we may not be able to successfully increase the manufacturing capacity, whether in collaboration with our current or future third-party manufacturers or on our own, for any of our drug candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA and other regulatory bodies must review and approve. If we are unable to successfully increase the manufacturing capacity for a drug candidate whether for late stage clinical trials or for commercial sale or are unable to secure alternative third-party suppliers to our current suppliers, the drug development, regulatory approval or commercial launch of any related drugs may be delayed or blocked or there may be a shortage in supply. Even if any third party manufacturer makes improvements in the manufacturing process for our drug candidates, we may not own, or may have to share, the intellectual property rights to such innovation.

As we evolve from a company primarily involved in discovery and development to one also involved in the commercialization of drugs and devices, we may encounter difficulties in managing our growth and expanding our operations successfully.

In order to execute our business strategy, we will need to expand our development, control and regulatory capabilities and develop financial, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. If our operations expand, we expect that we will need to manage additional relationships with various collaborative partners, suppliers and other third parties. Our ability to manage our operations and any growth will require us to make appropriate changes and upgrades, as necessary, to our operational, financial and management controls, reporting systems and procedures wherever we may operate. Any inability to manage growth could delay the execution of our business plan or disrupt our operations.

The failure to attract and retain skilled personnel and key relationships could impair our drug development and commercialization efforts.

We are highly dependent on our senior management and key scientific, technical and sales and marketing personnel. Competition for these types of personnel is intense. The loss of the services of any member of our senior management, scientific, technical or sales or marketing staff may significantly delay or prevent the achievement of drug development and other business objectives and could have a material adverse effect on our business, operating results and financial condition. We also rely on consultants and advisors to assist us in formulating our strategy. All of our consultants and advisors are either self-employed or employed by other organizations, and they may have conflicts of interest or other commitments, such as consulting or advisory contracts with other organizations, that may affect their ability to contribute to us. The success of the commercialization of the ALIGN products depends, in large part, on our continued ability to develop and maintain important relationships with distributors and research and medical institutions. Failure to do that could have a material adverse effect on our ability to commercialize the ALIGN products.

We intend to expand and develop new drug candidates. We will need to hire additional employees in order to continue our clinical trials and market our drug candidates and medical devices. This strategy will require us to recruit additional executive management and scientific and technical personnel. There is currently intense competition for skilled executives and employees with relevant scientific and technical expertise, and this competition is likely to continue. The inability to attract and retain sufficient scientific, technical and managerial personnel could limit or delay our product development efforts, which would adversely affect the development of our drug candidates and commercialization of our potential drugs and growth of our business.

Our drug candidates are subject to extensive regulation, which can be costly and time-consuming, and we may not obtain approvals for the commercialization of any of our drug candidates.

The clinical development, manufacturing, selling and marketing of our drug candidates are subject to extensive regulation by the FDA and other regulatory authorities in the United States, the European Union and elsewhere. These regulations also vary in important, meaningful ways from country to country. We are not permitted to market a potential drug in the United States until we receive approval of an NDA from the FDA. We have not received an NDA approval from the FDA for any of our drug candidates.

Obtaining an NDA approval is expensive and is a complex, lengthy and uncertain process. The FDA approval process for a new drug involves completion of preclinical studies and the submission of the results of these studies to the FDA, together with proposed clinical protocols, manufacturing information, analytical data and other information in an Investigational New Drug, or IND, which must become effective before human clinical trials may begin. Clinical development typically involves three phases of study: Phase 1, 2 and 3. The most significant costs associated with clinical development are the pivotal or suitable for registration late Phase 2 or Phase 3 clinical trials as they tend to be the longest and largest studies conducted during the drug development process. After completion of clinical trials, an NDA may be submitted to the FDA.

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In responding to an NDA, the FDA may refuse to file the application, or if accepted for filing, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval. In addition, failure to comply with the FDA and other applicable foreign and U.S. regulatory requirements may subject us to administrative or judicially imposed sanctions. These include warning letters, civil and criminal penalties, injunctions, product seizure or detention, product recalls, total or partial suspension of production and refusal to approve either pending NDAs, or supplements to approved NDAs.

Despite the substantial time and expense invested in preparation and submission of an NDA or equivalents in other jurisdictions, regulatory approval is never guaranteed. The FDA and other regulatory authorities in the United States, the European Union and elsewhere exercise substantial discretion in the drug approval process. The number, size and design of preclinical studies and clinical trials that will be required for FDA or other regulatory approval will vary depending on the drug candidate, the disease or condition for which the drug candidate is intended to be used and the regulations and guidance documents applicable to any particular drug candidate. The FDA or other regulators can delay, limit or deny approval of a drug candidate for many reasons, including, but not limited to:

- those discussed in the risk factor which immediately follows;
- the fact that the FDA or other regulatory officials may not approve our or our third party manufacturer s processes or facilities; or
- the fact that new regulations may be enacted by the FDA or other regulators may change their approval policies or adoption of new regulations requiring new or different evidence of safety and efficacy for the intended use of a drug candidate.

With regard to the ALIGN products, and following regulatory approval of any of our drug candidates, we are subject to ongoing regulatory obligations and restrictions, which may result in significant expense and limit our ability to commercialize our potential products.

With regard to our ALIGN products and our drug candidates, if any, approved by the FDA or by another regulatory authority, we are held to extensive regulatory requirements over product manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping. Regulatory approvals may also be subject to significant limitations on the indicated uses or marketing of the drug candidates. Potentially costly follow-up or post-marketing clinical studies may be required as a condition of approval to further substantiate safety or efficacy, or to investigate specific issues of interest to the regulatory authority. Previously unknown problems with the product or drug candidate, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the drug or device, and could include withdrawal of the drug or device from the market.

In addition, the law or regulatory policies governing pharmaceuticals may change. New statutory requirements may be enacted or additional regulations may be enacted that could prevent or delay regulatory approval of our drug candidates. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or elsewhere. If we are not able to maintain regulatory compliance, we might not be permitted to market our drugs and our business could suffer.

Our applications for regulatory approval could be delayed or denied due to problems with studies conducted before we in-licensed the rights to some of our product candidates.

We currently license some of the compounds and drug candidates used in our research programs from third parties. These include sapacitabine which was licensed from Daiichi Sankyo. Our present research involving these compounds relies upon previous research conducted by third parties over whom we had no control and before we in-licensed the drug candidates. In order to receive regulatory approval of a drug candidate, we must present all relevant data and information obtained during our research and development, including research conducted prior to our licensure of the drug candidate. Although we are not currently aware of any such problems, any problems that emerge with preclinical research and testing conducted prior to our in-licensing may affect future results or our ability to document prior research and to conduct clinical trials, which could delay, limit or prevent regulatory approval for our drug candidates.

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We face intense competition and our competitors may develop drugs that are less expensive, safer, or more effective than our drug candidates.

A large number of drug candidates are in development for the treatment of leukemia, lung cancer, lymphomas and nasopharyngeal cancer. Several pharmaceutical and biotechnology companies have nucleoside analogs or other products on the market or in clinical trials which may be competitive to sapacitabine in both hematological and oncology indications. These include Celgene, Cephalon, Eisai, Johnson & Johnson, Eli Lilly, Genzyme, GlaxoSmithKline, Hospira, Onconova, Pfizer, Seattle Genetics and Sunesis. There are two other orally available CDK inhibitors in Phase 2 clinical trials. PD-0332991 (Pfizer/Onyx) and PHA-848125 (Nerviano Medical Sciences) target different subsets of kinase enzymes and have a different mechanism of action from seliciclib. We believe that seliciclib is currently the most advanced orally available CDK-specific agent in Phase 2 clinical trials but that there are a number of companies, including AstraZeneca, Astex Therapeutics, Bayer-Schering, Eisai, Merck, Nerviano Medical Sciences, Pfizer, Piramal Life Sciences, and Roche that are developing CDK inhibitors in early stage clinical trials in cancer patients. Although Aventis, a predecessor of Sanofi-Aventis, had previously announced that it has ceased Phase 2 development of alvocidib or flavopiridol, a CDK inhibitor, we believe that the National Cancer Institute s Cancer Therapy Evaluation Program, or CTEP, is continuing to enroll patients in a CTEP sponsored trial in patients with chronic leukemia. A number of companies are pursuing discovery and research activities in each of the other areas that are the subject of our research and drug development programs. We believe that Amgen, Astex Therapeutics, AstraZeneca, Entremed, Merck, jointly with Vertex, Nerviano Medical Sciences, Pfizer, Rigel, Sunesis and Takeda-Millennium have commenced Phase 1, Phase 2, or Phase 3 clinical trials of Aurora kinase inhibitors in patients with advanced cancers. Several companies have reported selection of Aurora kinase inhibitor candidates for development and may have started or are expected to start clinical trials within the next twelve months. We believe that Boehringer Ingelheim, GlaxoSmithKline, Merck, Nerviano Medical Sciences, Takeda-Millennium and Tekmira Pharmaceuticals Corporation have commenced Phase 1 or Phase 2 clinical trials with Plk inhibitor candidates for oncology indications. For our ALIGN products, we believe that Beiersdorf, Daiichi Sankyo, Eisai, Johnson & Johnson, MPM Medical and other companies market products for radiation dermatitis and xerostomia.

Our competitors, either alone or together with collaborators, may have substantially greater financial resources and research and development staff. Our competitors may also have more experience:

- developing drug candidates;
- conducting preclinical and clinical trials;
- obtaining regulatory approvals; and
- commercializing product candidates.

Our competitors may succeed in obtaining patent protection and regulatory approval and may market drugs before we do. If our competitors market drugs that are less expensive, safer, more effective or more convenient to administer than our potential drugs, or that reach the market sooner than our potential drugs, we may not achieve commercial success. Scientific, clinical or technical developments by our competitors may render our drug candidates obsolete or noncompetitive. We anticipate that we will face increased competition in the future as new companies enter the markets and as scientific developments progress. If our drug candidates obtain regulatory approvals, but do not compete effectively in the marketplace, our business will suffer.

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The commercial success of the ALIGN products and our drug candidates depends upon their market acceptance among physicians, patients, healthcare providers and payors and the medical community.

It is necessary that our and our distribution partners products, including Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges achieve and maintain market acceptance. If our drug candidates are approved by the FDA or by another regulatory authority, the resulting drugs, if any, may not gain market acceptance among physicians, healthcare providers and payors, patients and the medical community. The degree of market acceptance of any of our approved drugs or devices will depend on a variety of factors, including:

- timing of market introduction, number and clinical profile of competitive drugs;
- our ability to provide acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- cost-effectiveness;
- availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third party payors;
- prevalence and severity of adverse side effects; and
- other potential advantages over alternative treatment methods.

If our drugs fail to achieve market acceptance, we may not be able to generate significant revenue and our business would suffer.

If we are unable to compete successfully in our market place, it will harm our business.

There are existing products in the marketplace that compete with our products. Companies may develop new products that compete with our products. Certain of these competitors and potential competitors have longer operating histories, substantially greater product development capabilities and financial, scientific, marketing and sales resources. Competitors and potential competitors may also develop products that are safer, more effective or have other potential advantages compared to our products. In addition, research, development and commercialization efforts by others could render our products obsolete or non-competitive. Certain of our competitors and potential competitors have broader product offerings and extensive customer bases allowing them to adopt aggressive pricing policies that would enable them to gain market share. Competitive pressures could result in price reductions, reduced margins and loss of market share. We could encounter potential customers that, due to existing relationships with our competitors, are committed to products offered by those competitors. As a result, those potential customers may not consider purchasing our products.

There is uncertainty related to coverage, reimbursement and payment by healthcare providers and payors for the ALIGN products and newly approved drugs, if any. The inability or failure to obtain or maintain coverage could affect our ability to market the ALIGN products and our future drugs and decrease our ability to generate revenue.

The availability and levels of coverage and reimbursement of newly approved drugs by healthcare providers and payors is subject to significant uncertainty. The commercial success of the ALIGN products and our drug candidates in both the United States and international markets is substantially dependent on whether third party coverage and reimbursement is available. The United States Centers for Medicare and Medicaid Services, health maintenance organizations and other third party payors in the United States, the European Union and other jurisdictions are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs and, as a result, they may not cover or provide adequate payment for our potential drugs. The ALIGN products and our drug candidates may not be considered cost-effective and reimbursement may not be available to consumers or may not be sufficient to allow the ALIGN products or our drug candidates to be marketed on a competitive basis.

In some countries, pricing of prescription drugs is subject to government control. In such countries, pricing negotiations with governmental authorities can take three to 12 months or longer following application to the competent authorities. To obtain reimbursement or pricing approval in such countries may require conducting an additional clinical trial comparing the cost-effectiveness of the drug to other alternatives. In the United States, the Medicare Part D drug benefit implemented in 2006 will limit drug coverage through formularies and other cost and utilization management programs, while Medicare Part B limits drug payments to a certain percentage of average price or through restrictive payment policies of least costly alternatives and inherent reasonableness Our business could be materially harmed if coverage, reimbursement or pricing is unavailable or set at unsatisfactory levels.

Intellectual property rights and distribution rights for our drug candidate seliciclib and ALIGN products are licensed from others, and any termination of these licenses could harm our business.

We have in-licensed certain patent rights in connection with the development program of our drug candidate seliciclib. Pursuant to the CNRS and Institut Curie license under which we license seliciclib, we are obligated to pay license fees, milestone payments and royalties and provide regular progress reports. We are also obligated to use reasonable efforts to develop and commercialize products based on the licensed patents.

We have in-licensed from Sinclair the distribution rights to the ALIGN products. This license agreement imposes obligations on us and expires in 2015. Although we are currently in compliance with all of our material obligations under this license, if we were to breach any such obligations, Sinclair would be permitted to terminate the license. In addition, if we are unable to extend the term of the license agreement, it would prevent us from distributing the ALIGN products.

Although we are currently in compliance with all of our material obligations under these licenses, if we were to breach any such obligations our counterparties may be entitled to terminate the licenses. This would restrict or delay or eliminate our ability to develop and commercialize the seliciclib or sell the ALIGN products, which could adversely affect our business.

We may be exposed to product liability claims that may damage our reputation and we may not be able to obtain adequate insurance.

Because we conduct clinical trials in humans, we face the risk that the use of our drug candidates will result in adverse effects. We believe that we have obtained reasonably adequate product liability insurance coverage for our trials. We cannot predict, however, the possible harm or side effects that may result from our clinical trials. Such claims may damage our reputation and we may not have sufficient resources to pay for any liabilities resulting from a claim excluded from, or beyond the limit of, our insurance coverage.

As we market commercialized products through our ALIGN subsidiary we are exposed to additional risks of product liability claims. These risks exist even with respect to drugs and devices that are approved for commercial sale by the FDA or other regulatory authorities in the United States, the European Union or elsewhere and manufactured in facilities licensed and regulated by the FDA or other such regulatory authorities. We have secured limited product liability insurance coverage, but may not be able to maintain such insurance on acceptable terms with adequate coverage, or at a reasonable cost. There is also a risk that third parties that we have agreed to indemnify could incur liability. Even if we were ultimately successful in product liability litigation, the litigation would consume substantial amounts of our financial and managerial resources and may exceed insurance coverage creating adverse publicity, all of which would impair our ability to generate sales of the litigated product as well as our other potential drugs.

We may be required to defend lawsuits or pay damages in connection with the alleged or actual violation of healthcare statutes such as fraud and abuse laws, and our corporate compliance programs can never guarantee that we are in compliance with all relevant laws and regulations.

Our commercialization efforts in the United States are subject to various federal and state laws pertaining to promotion and healthcare fraud and abuse, including federal and state anti-kickback, fraud and false claims laws. Anti-kickback laws make it illegal for a manufacturer to offer or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase of a product. The federal government has published many regulations relating to the anti-kickback statutes, including numerous safe harbors or exemptions for certain arrangements. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third-party payers including Medicare and Medicaid, claims for reimbursed products or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services.

Our activities relating to the sale and marketing of our products will be subject to scrutiny under these laws and regulations. It may be difficult to determine whether or not our activities, comply with these complex legal requirements. Violations are punishable by significant criminal and/or civil fines and other penalties, as well as the possibility of exclusion of the product from coverage under governmental healthcare programs, including Medicare and Medicaid. If the government were to investigate or make allegations against us or any of our employees, or sanction or convict us or any of our employees, for violations of any of these legal requirements, this could have a material adverse effect on our business, including our stock price. Our activities could be subject to challenge for many reasons, including the broad scope and complexity of these laws and regulations, the difficulties in interpreting and applying these legal requirements, and the high degree of prosecutorial resources and attention being devoted to the biopharmaceutical industry and health care fraud by law enforcement authorities. During the last few years, numerous biopharmaceutical companies have paid multi-million dollar fines and entered into burdensome settlement agreements for alleged violation of these requirements, and other companies are under active investigation. Although we have developed and implemented corporate and field compliance programs as part of our commercialization efforts, we cannot assure you that we or our employees, directors or agents were, are or will be in compliance with all laws and regulations or that we will not come under investigation, allegation or sanction.

In addition, we may be required to prepare and report product pricing-related information to federal and state governmental authorities, such as the Department of Veterans Affairs and under the Medicaid program. The calculations used to generate the pricing-related information are complex and require the exercise of judgment. If we fail to accurately and timely report product pricing-related information or to comply with any of these or any other laws or regulations, various negative consequences could result, including criminal and/or civil prosecution, substantial criminal and/or civil penalties, exclusion of the approved product from coverage under governmental healthcare programs including Medicare and Medicaid, costly litigation and restatement of our financial statements. In addition, our efforts to comply with this wide range of laws and regulations are, and will continue to be, time-consuming and expensive.

If our supplier upon whom we rely fails to produce on a timely basis the finished goods in the volumes that we require or fails to meet quality standards and maintain necessary licensure from regulatory authorities, we may be unable to meet demand for our products, potentially resulting in lost revenues.

Our licensor and supplier Sinclair contracts with third party manufacturers to supply the finished goods to us to meet our needs. If any of Sinclair s third party manufacturers service providers do not meet our or our licensor s requirements for quality, quantity or timeliness, or do not achieve and maintain compliance with all applicable regulations, demand for our products or our ability to continue supplying such products could substantially decline. As the third party manufacturers are the sole supplier of the products any delays may impact our sales.

In all the countries where we sell or may sell our products, governmental regulations exist to define standards for manufacturing, packaging, labeling and storing. All of our suppliers of raw materials and contract manufacturers must comply with these regulations. Failure to do so could result in supply interruptions. In the United States, the FDA requires that all suppliers of pharmaceutical bulk material and all manufacturers of pharmaceuticals for sale in or from the United States achieve and maintain compliance with the FDA s Current Good Manufacturing Practice or cGMP regulations and guidelines. Failure of our third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on them or us, including fines, injunctions, civil penalties, disgorgement, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, before any product batch produced by our manufacturers can be shipped, it must conform to release specifications pre-approved by regulators for the content of the pharmaceutical product. If the operations of one or more of our manufacturers were to become unavailable for any reason, any required FDA review and approval of the operations of an alternative supplier could cause a delay in the manufacture of our products.

Our customer base is highly concentrated.

Our principal customers are a small number of wholesale drug distributors. These customers comprise a significant part of the distribution network for pharmaceutical products in the United States. Three large wholesale distributors, AmerisourceBergen Corporation, Cardinal Health, Inc. and McKesson Corporation, control a significant share of the market in the United States. Our ability to distribute any product, including Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges and to recognize revenues on a timely basis is substantially dependent on our ability to maintain commercially reasonable agreements with each of these wholesale distributors and the extent to which these distributors, over whom we have no control, comply with such agreements. Our agreements with wholesaler distributors may contain terms that are not favorable, given our relative lack of market leverage as a company with only three approved products or other factors, which could adversely affect our commercialization of Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges. The loss of any of these customers could materially and adversely affect our ability to distribute our products, resulting in a negative impact on our operations and financial condition.

We may be unable to accurately estimate demand and monitor wholesaler inventory of Xclair® Cream, Numoisyn® Liquid or Numoisyn® Lozenges. Although we attempt to monitor wholesaler inventory of Xclair® Cream, Numoisyn® Liquid or Numoisyn® Lozenges, we also rely on third party information, which is inherently uncertain and may not be accurate, to assist us in monitoring estimated inventory levels and prescription trends. Inaccurate estimates of the demand and inventory levels of the product may cause our revenues to fluctuate significantly from quarter to quarter and may cause our operating results for a particular quarter to be below expectations.

Inventory levels of Xclair® Cream, Numoisyn® Liquid or Numoisyn® Lozenges held by wholesalers can also cause our operating results to fluctuate unexpectedly. For the three months ended June 30, 2010 and 2011, approximately 91% and 90%, respectively, of our product sales in the United States were to three wholesalers, Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen. Inventory levels held by those wholesalers can cause our operating results to fluctuate unexpectedly if our sales to wholesalers do not match customer demand. We have entered into inventory management agreements with these U.S. wholesalers under which they provide us with data regarding inventory levels at these wholesalers. However, these wholesalers may not be completely effective in matching inventory levels to customer demand, as they make estimates to determine customer demand. In addition, inventory is held at retail pharmacies and other non-wholesaler locations, for which we have no inventory management agreements and have no control in respect to their buying patterns. Also, the non-retail sector in the United States, which includes government institutions and large health maintenance organizations, tends to be less consistent in terms of buying patterns, and often causes quarter-over-quarter fluctuations in inventory and ordering patterns. We attempt to monitor inventory of Xclair®, Numoisyn® Liquid or Numoisyn® Lozenges in the United States through the use of internal sales forecasts and the expiration dates of product shipped, among other factors.

The commercialization of our products is substantially dependent on our ability to develop effective sales and marketing capabilities.

Our successful commercialization of Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges in the United States will depend on our ability to establish and maintain effective sales and marketing initiatives in the United States. Although we launched the ALIGN products with a small specialty oncology sales force, we now sell and market our products via unique sales and marketing strategies in order to reduce costs. We contracted, trained and deployed additional telemarketing personnel to call on specialists who prescribe ALIGN products. We also utilize mailings, print advertising, sampling, trade show attendance and other unique marketing programs to reach our customer base. We may increase or decrease the size of our telemarketing sales force in the future, depending on many factors, including the effectiveness of the sales force, the level of market acceptance of Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges and the results of our clinical trials. Prior to our launches of these products, we had never sold or marketed any products.

For our product candidates currently under development, our strategy is to develop compounds through the Phase 2 stage of clinical testing and market or co-promote certain of our drugs on our own. We have limited sales, marketing or distribution capabilities. We will depend primarily on strategic alliances with third parties, which have established distribution systems and sales forces, to commercialize our drugs. To the extent that we are unsuccessful in commercializing any drugs or devices ourselves or through a strategic alliance, product revenues will suffer, we will incur significant additional losses and our share price will be negatively affected.

Defending against claims relating to improper handling, storage or disposal of hazardous chemical, radioactive or biological materials could be time consuming and expensive.

Our research and development involves the controlled use of hazardous materials, including chemicals, radioactive and biological materials such as chemical solvents, phosphorus and bacteria. Our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from those materials. Various laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development and production efforts.

Risks Related to Our Business and Financial Condition

The current economic conditions and financial market turmoil could adversely affect our business and results of operations.

Economic conditions remain difficult with the continuing uncertainty in the global credit markets, the financial services industry and the United States capital markets and with the United States economy as a whole experiencing a period of substantial turmoil and uncertainty characterized by unprecedented intervention by the United States federal government and the failure, bankruptcy, or sale of various financial and other institutions. We believe the current economic conditions and financial market turmoil could adversely affect our operations, business and prospects, as well as our ability to obtain funds. If these circumstances persist or continue to worsen, our future operating results could be adversely affected, particularly relative to our current expectations.

We are at an early stage of development as a company and we do not have, and may never have, any products that generate significant revenues.

We are at an early stage of development as a company and have a limited operating history on which to evaluate our business and prospects. While we have earned modest product revenues from the ALIGN business acquired in October 2007, since beginning operations in 1996, we have not generated any product revenues from our product candidates currently in development. We cannot guarantee that any of our product candidates currently in development will ever become marketable products and we do not anticipate material revenues from the ALIGN products in the foreseeable future.

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We must demonstrate that our drug candidates satisfy rigorous standards of safety and efficacy for their intended uses before the FDA, and other regulatory authorities in the United States, the European Union and elsewhere. Significant additional research, preclinical testing and clinical testing is required before we can file applications with the FDA or other regulatory authorities for premarket approval of our drug candidates. In addition, to compete effectively, our drugs must be easy to administer, cost-effective and economical to manufacture on a commercial scale. We may not achieve any of these objectives. Sapacitabine, our most advanced drug candidates for the treatment of cancer, is currently in Phase 3 for AML and Phase 2 for MDS. Seliciclib is currently in Phase 2 clinical trials. A combination trial of sapacitabine and seliciclib is currently in a Phase 1 clinical trial. We cannot be certain that the clinical development of these or any other drug candidates in preclinical testing or clinical development will be successful, that we will receive the regulatory approvals required to commercialize them or that any of our other research and drug discovery programs will yield a drug candidate suitable for investigation through clinical trials. Our commercial revenues from our product candidates currently in development, if any, will be derived from sales of drugs that will not become marketable for several years, if at all.

We have a history of operating losses and we may never become profitable. Our stock is a highly speculative investment.

We have incurred operating losses in each year since beginning operations in 1996 due to costs incurred in connection with our research and development activities and selling, general and administrative costs associated with our operations, and we may never achieve profitability. As of December 31, 2010 and June 30, 2011, our accumulated deficit was $241.8 million and $250.0 million, respectively. Our net loss for the six months ended June 30, 2010 and 2011 was $9.0 million and $8.1 million, respectively. Our net loss applicable to common stockholders from inception through June 30, 2011 was $291.3 million. Our drug candidates are in the mid-stages of clinical testing and we must conduct significant additional clinical trials before we can seek the regulatory approvals necessary to begin commercial sales of our drugs. We expect to incur continued losses for several years, as we continue our research and development of our drug candidates, seek regulatory approvals, commercialize any approved drugs and market and promote the ALIGN products: Xclair® Cream, Numoisyn® Liquid and Numoisyn® Lozenges. If our drug candidates are unsuccessful in clinical trials or we are unable to obtain regulatory approvals, or if our drugs are unsuccessful in the market, we will not be profitable. If we fail to become and remain profitable, or if we are unable to fund our continuing losses, particularly in light of the current economic conditions, you could lose all or part of your investment.

Capital markets are currently experiencing a period of disruption and instability, which has had and could continue to have a negative impact on the availability and cost of capital.

The general disruption in the United States capital markets has impacted the broader worldwide financial and credit markets and reduced the availability of debt and equity capital for the market as a whole. These global conditions could persist for a prolonged period of time or worsen in the future. Our ability to access the capital markets may be restricted at a time when we would like, or need, to access those markets, which could have an impact on our flexibility to react to changing economic and business conditions. The resulting lack of available credit, lack of confidence in the financial sector, increased volatility in the financial markets could materially and adversely affect the cost of debt financing and the proceeds of equity financing may be materially adversely impacted by these market conditions.

If we fail to comply with the continued listing requirements of the NASDAQ Global Market our common stock price may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Our common stock is currently listed for trading on the NASDAQ Global Market. We must satisfy NASDAQ s continued listing requirements, including among other things, a minimum stockholders equity of $10.0 million and a minimum bid price for our common stock of $1.00 per share, or risk delisting, which would have a material adverse effect on our business. A delisting of our common stock from the NASDAQ Global Market could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock.

In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. During 2009, Cyclacel received notification from the NASDAQ Stock Market that the Company was not in compliance with the minimum $10 million stockholders equity requirement for continued listing set forth in NASDAQ Marketplace Rule 5450(b)(1)(A). On January 27, 2010, NASDAQ notified the Company that it regained compliance with the minimum $50 million market value of listed securities requirement and that it currently complies with all other applicable standards for continued listing on The NASDAQ Global Market. Accordingly, the Company s shares of common and preferred stock will continue to trade on The NASDAQ Global Market.

Raising additional capital in the future may not be available to us on reasonable terms, if at all, when or as we require additional funding. If we issue additional shares of our common stock or other securities that may be convertible into, or exercisable or exchangeable for, our common stock, our existing stockholders would experience further dilution. If we fail to obtain additional funding, we may be unable to complete the development and commercialization of our lead drug candidate, sapacitabine, or continue to fund our research and development programs.

We have funded all of our operations and capital expenditures with proceeds from the issuance of public equity securities, private placements of our securities, interest on investments, licensing revenue, government grants, research and development tax credits and product revenue. In order to conduct the lengthy and expensive research, preclinical testing and clinical trials necessary to complete the development and marketing of our drug candidates, we will require substantial additional funds. Based on our current operating plans of focusing on the advancement of sapacitabine, we expect our existing resources to be sufficient to fund our planned operations for at least the next twelve months. To meet our long-term financing requirements, we may raise funds through public or private equity offerings, debt financings or strategic alliances. Raising additional funds by issuing equity or convertible debt securities may cause our stockholders to experience substantial dilution in their ownership interests and new investors may have rights superior to the rights of our other stockholders. Raising additional funds through debt financing, if available, may involve covenants that restrict our business activities and options. To the extent that we raise additional funds through collaborations and licensing arrangements, we may have to relinquish valuable rights to our drug discovery and other technologies, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. Additional funding may not be available to us on favorable terms, or at all, particularly in light of the current economic conditions. If we are unable to obtain additional funds, we may be forced to delay or terminate our current clinical trials and the development and marketing of our drug candidates including sapacitabine.

To the extent we elect to fund the development of a drug candidate or the commercialization of a drug at our expense, we will need substantial additional funding.

We plan to market drugs on our own, with or without a partner, that can be effectively commercialized and sold in concentrated markets that do not require a large sales force to be competitive. To achieve this goal, we will need to establish our own specialized sales force, marketing organization and supporting distribution capabilities. The development and commercialization of our drug candidates is very expensive, including our Phase 3 clinical trials for sapacitabine. To the extent we elect to fund the full development of a drug candidate or the commercialization of a drug at our expense, we will need to raise substantial additional funding to:

- fund research and development and clinical trials connected with our research;
- fund clinical trials and seek regulatory approvals;
- build or access manufacturing and commercialization capabilities;
- implement additional internal control systems and infrastructure;

- commercialize and secure coverage, payment and reimbursement of our drug candidates, if any such candidates receive regulatory approval;
- maintain, defend and expand the scope of our intellectual property; and
- hire additional management, sales and scientific personnel.

Our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- the costs and timing of seeking and obtaining regulatory approvals;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the costs associated with establishing sales and marketing capabilities;
- the costs of acquiring or investing in businesses, products and technologies;
- the effect of competing technological and market developments; and
- the payment, other terms and timing of any strategic alliance, licensing or other arrangements that we may establish.

If we are not able to secure additional funding when needed, especially in light of the current economic conditions and financial market turmoil, we may have to delay, reduce the scope of or eliminate one or more of our clinical trials or research and development programs or future commercialization efforts.

Any future workforce and expense reductions may have an adverse impact on our internal programs, strategic plans, and our ability to hire and retain key personnel, and may also be distracting to our management.

Further workforce and expense reductions in addition to those carried out in September 2008 and June 2009 could result in significant delays in implementing our strategic plans. In addition, employees, whether or not directly affected by such reduction, may seek future employment with our business partners or competitors. Although our employees are required to sign a confidentiality agreement at the time of hire, the confidential nature of certain proprietary information may not be maintained in the course of any such future employment. In addition, any additional workforce reductions or restructurings would be expected to involve significant expense as a result of contractual terms in certain of our existing agreements, including potential severance obligations as well as any payments that may, under certain circumstances, be required under our agreement with the Scottish Enterprise. Further, we believe that our future success will depend in large part upon our ability to attract and retain highly skilled personnel. We may have difficulty retaining and attracting such personnel as a result of a perceived risk of future workforce and expense reductions. Finally, the implementation of expense reduction programs may result in the diversion of the time and attention of our executive management team and other key employees, which could adversely affect our business.

Budget constraints resulting from our restructuring plan may negatively impact our research and development, forcing us to delay our efforts to develop certain product candidates in favor of developing others, which may prevent us from commercializing our product candidates as quickly as possible.

Research and development is an expensive process. As part of our restructuring plan, we have decided to focus our clinical development priorities on sapacitabine, while still possibly continuing to progress additional programs pending the availability of clinical data and the availability of funds, at which time we will determine the feasibility of pursuing, if at all, further advanced development of seliciclib, CYC116 or additional programs. Because we have had to prioritize our development candidates as a result of budget constraints, we may not be able to fully realize the value of our product candidates in a timely manner, if at all.

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We are exposed to risks related to foreign currency exchange rates.

Some of our costs and expenses are denominated in foreign currencies. Most of our foreign expenses are associated with our research and development operations of our United Kingdom-based wholly-owned subsidiary. When the United States dollar weakens against the British pound, the United States dollar value of the foreign currency denominated expense increases, and when the United States dollar strengthens against the British pound, the United States dollar value of the foreign currency denominated expense decreases. Consequently, changes in exchange rates, and in particular a weakening of the United States dollar, may adversely affect our results of operations

Risks Related to our Intellectual Property

We may be subject to damages resulting from claims that our employees or we have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper or prevent our ability to commercialize certain potential drugs, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

If we fail to enforce adequately or defend our intellectual property rights our business may be harmed.

Our commercial success depends in large part on obtaining and maintaining patent and trade secret protection for our drug candidates, the methods used to manufacture those drug candidates and the methods for treating patients using those drug candidates.

Specifically, sapacitabine is covered in granted, composition of matter patents that expire in 2014 in the United States and 2012 outside the United States. Sapacitabine is further protected by additional granted, composition of matter patents claiming certain, stable crystalline forms of sapacitabine and their pharmaceutical compositions and therapeutic uses that expire in 2022 and also patent applications claiming the combination of sapacitabine with decitabine which is being tested as one of the arms of the SEAMLESS Phase 3 trial . In early development, amorphous sapacitabine was used. We have used one of the stable, crystalline forms of sapacitabine in nearly all our Phase 1 and in all of our Phase 2 clinical studies. We have also chosen this form for commercialization. Additional patents claim certain medical uses and formulations of sapacitabine which have emerged in our clinical trials.

Seliciclib is protected by granted, composition of matter patents that expire in 2016. Additional patents claim certain medical uses which have emerged from our research programs.

Failure to obtain, maintain or extend the patents could adversely affect our business. We will only be able to protect our drug candidates and our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them.

Our ability to obtain patents is uncertain because legal means afford only limited protections and may not adequately protect our rights or permit it to gain or keep any competitive advantage. Some legal principles remain unresolved and the breadth or interpretation of claims allowed in patents in the United States, the European Union or elsewhere can still be difficult to ascertain or predict. In addition, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or in interpretations of patent laws in the United States, the European Union or elsewhere may diminish the value of our intellectual property or narrow the scope of our patent protection. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products and technologies. In addition, we generally do not control the patent prosecution of subject matter that we license from others and have not controlled the earlier stages of the patent prosecution. Accordingly, we are unable to exercise the same degree of control over this intellectual property as we would over our own.

Even if patents are issued regarding our drug candidates or methods of using them, those patents can be challenged by our competitors who may argue such patents are invalid and/or unenforceable. Patents also will not protect our drug candidates if competitors devise ways of making or using these product candidates without legally infringing our patents. The U.S. Federal Food, Drug and Cosmetic, or FD&C, Act and FDA regulations and policies and equivalents in other jurisdictions provide incentives to manufacturers to challenge patent validity or create modified, noninfringing versions of a drug in order to facilitate the approval of abbreviated new drug applications for generic substitutes. These same types of incentives encourage manufacturers to submit new drug applications that rely on literature and clinical data not prepared for or by the drug sponsor.

Proprietary trade secrets and unpatented know-how are also very important to our business. We rely on trade secrets to protect our technology, especially where we do not believe that patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party obtained illegally and is using trade secrets is expensive and time consuming, and the outcome is unpredictable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Intellectual property rights of third parties may increase our costs or delay or prevent us from being able to commercialize our drug candidates and/or the ALIGN products.

There is a risk that we are infringing or will infringe the proprietary rights of third parties because patents and pending applications belonging to third parties exist in the United States, the European Union and elsewhere in the world in the areas of our research and/or the ALIGN products. Others might have been the first to make the inventions covered by each of our or our licensors   pending patent applications and issued patents and might have been the first to file patent applications for these inventions. We are aware of several published patent applications, and understand that others may exist, that could support claims that, if granted, could cover various aspects of our developmental programs, including in some cases particular uses of our lead drug candidate sapacitabine, seliciclib or other therapeutic candidates, or gene sequences and techniques that we use in the course of our research and development. In addition, we understand that other applications and patents exist relating to potential uses of sapacitabine and seliciclib that are not part of our current clinical programs for these compounds. Numerous third-party United States and foreign issued patents and pending applications exist in the area of kinases, including CDK, AK and Plk for which we have research programs. For example, some pending patent applications contain broad claims that could represent freedom to operate limitations for some of our kinase programs should they be issued unchanged. Although we intend to continue to monitor these applications, we cannot predict what claims will ultimately be allowed and if allowed what their scope would be. In addition, because the patent application process can take several years to complete, there may be currently pending applications, unknown to us, which may later result in issued patents that cover the production, manufacture, commercialization or use of our drug candidates. If we wish to use the technology or compound claimed in issued and unexpired patents owned by others, we will need to obtain a license from the owner, enter into litigation to challenge the validity of the patents or incur the risk of litigation in the event that the owner asserts that we infringe its patents. In one case we have opposed a European patent relating to human aurora kinase and the patent has been finally revoked (no appeal was filed). We are also aware of a corresponding U.S. patent containing method of treatment claims for specific cancers using aurora kinase modulators which, if held valid, could potentially restrict the use of our aurora kinase inhibitors once clinical trials are completed.

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There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. Defending against third party claims, including litigation in particular, would be costly and time consuming and would divert management s attention from our business, which could lead to delays in our development or commercialization efforts. If third parties are successful in their claims, we might have to pay substantial damages or take other actions that are adverse to our business. As a result of intellectual property infringement claims, or to avoid potential claims, we might:

- be prohibited from selling or licensing any product that we may develop unless the patent holder licenses the patent to us, which it is not required to do;
- be required to pay substantial royalties or grant a cross license to our patents to another patent holder;
- decide to move some of our screening work outside Europe;
- be required to pay substantial damages for past infringement, which we may have to pay if a court determines that our product candidates or technologies infringe a competitor s patent or other proprietary rights; or
- be required to redesign the formulation of a drug candidate so it does not infringe, which may not be possible or could require substantial funds and time.

Risks Related to Securities Regulations and Investment in Our Securities

Failure to achieve and maintain internal controls is accordance with Sections 302 and 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse effect on our business and stock price.

During March 2011, we identified a deficiency in respect of our internal controls over financial reporting, specifically our controls over the accounting for cumulative preferred stock dividends, that constitutes a material weakness as described in the SEC s guidance regarding Management s Report on Internal Control Over Financial Reporting as of December 31, 2010. As a result of this deficiency, the financial statements included in our Form 10-K for the year ended December 31, 2009, filed on March 29, 2010, as amended by Amendment No. 1 to our Annual Report on Form 10-K/A for the year ended December 31, 2009 filed on May 17, 2010 and, as further amended by Amendment No. 2 to our Annual Report on Form 10-K/A for the year ended December 31, 2009 filed on May 19, 2010, included errors related to the presentation and disclosure of undeclared cumulative preferred stock dividends in the consolidated balance sheet and in the statement of stockholders equity. Unaudited balance sheets for the each of the first three quarters of 2009 and 2010 also contained errors. In addition, in May 2010, we filed an amendment to our Annual Report on Form 10-K for the year ended December 31, 2009, to report a restatement of our financial statements and report a material weakness in our internal control over financial reporting as of December 31, 2009, specifically related to the operational failure of the controls in place to ensure the correct computation of net loss per share and presentation of preferred stock dividends in the consolidated statement of cash flows. In March 2011, our auditors identified a further error in respect of the accounting, presentation and disclosure of cumulative undeclared preferred stock dividends, specifically the inclusion of undeclared cumulative preferred stock dividends as a current liability in its consolidated financial statements, which resulted from the same material weakness as described above. This has resulted in the restatement of our consolidated balance sheets as of March 31, 2009, June 30, 2009, September 30, 2009, December 31, 2009, March 31, 2010, June 30, 2010, and September 30, 2010 and consolidated statement of stockholders equity for the year ended December 31, 2009 and selected financial data as of and for the year ended December 31, 2009.

If we fail to maintain our internal controls or fail to implement required new or improved controls, as such control standards are modified, supplemented or amended from time to time, we may not be able to conclude on an ongoing basis that we have effective internal controls over financial reporting. Effective internal controls are necessary for us to produce reliable financial reports and are important in the prevention of financial fraud. If we cannot produce reliable financial reports or prevent fraud, our business and operating results could be harmed.

We incur increased costs and management resources as a result of being a public company, and we still may fail to comply with public company obligations.

As a public company, we face and will continue to face increased legal, accounting, administrative and other costs and expenses as a public company that we would not incur as a private company. Compliance with the Sarbanes Oxley Act of 2002, as well as other rules of the SEC, the Public Company Accounting Oversight Board and the NASDAQ Global Market resulted in a significant initial cost to us as well as an ongoing compliance costs. As a public company, we are subject to Section 404 of the Sarbanes Oxley Act relating to internal control over financial reporting. We have completed a formal process to evaluate our internal controls for purposes of Section 404, and we concluded that as of December 31, 2010, our internal control over financial reporting was ineffective. As our business grows and changes, there can be no assurances that we can maintain the effectiveness of our internal controls over financial reporting. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our operating results could be harmed. We have completed a formal process to evaluate our internal control over financial reporting. However, guidance from regulatory authorities in the area of internal controls continues to evolve and substantial uncertainty exists regarding our on-going ability to comply by applicable deadlines. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

Our common stock may have a volatile public trading price.

An active public market for our common stock has not developed. Our stock can trade in small volumes which may make the price of our stock highly volatile. The last reported price of our stock may not represent the price at which you would be able to buy or sell the stock. The market prices for securities of companies comparable to us have been highly volatile. Often, these stocks have experienced significant price and volume fluctuations for reasons that are both related and unrelated to the operating performance of the individual companies. In addition, the stock market as a whole and biotechnology and other life science stocks in particular have experienced significant recent volatility. Like our common stock, these stocks have experienced significant price and volume fluctuations for reasons unrelated to the operating performance of the individual companies. In addition, due to our existing stock price, we may not continue to qualify for continued listing on the NASDAQ Global Market. To maintain listing, we are required to maintain a minimum closing bid price of $1.00 per share and, among other requirements, to maintain a minimum stockholders equity value of $10 million. Factors giving rise to this volatility may include:

- disclosure of actual or potential clinical results with respect to product candidates we are developing;
- regulatory developments in both the United States and abroad;
- developments concerning proprietary rights, including patents and litigation matters;

public concern about the safety or efficacy of our product candidates or technology, or related technology, or new technologies generally;

concern about the safety or efficacy of our product candidates or technology, or related technology, or new technologies generally;

public announcements by our competitors or others; and

general market conditions and comments by securities analysts and investors.

Fluctuations in our operating losses could adversely affect the price of our common stock.

Our operating losses may fluctuate significantly on a quarterly basis. Some of the factors that may cause our operating losses to fluctuate on a period-to-period basis include the status of our preclinical and clinical development programs, level of expenses incurred in connection with our preclinical and clinical development programs, implementation or termination of collaboration, licensing, manufacturing or other material agreements with third parties, non-recurring revenue or expenses under any such agreement, and compliance with regulatory requirements. Period-to-period comparisons of our historical and future financial results may not be meaningful, and investors should not rely on them as an indication of future performance. Our fluctuating losses may fail to meet the expectations of securities analysts or investors. Our failure to meet these expectations may cause the price of our common stock to decline.

If securities or industry analysts do not publish research or reports about us, if they change their recommendations regarding our stock adversely or if our operating results do not meet their expectations, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us. If one or more of these analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Moreover, if one or more of the analysts who cover us downgrade our stock or if our operating results do not meet their expectations, our stock price could decline.

Anti-takeover provisions in our charter documents and provisions of Delaware law may make an acquisition more difficult and could result in the entrenchment of management.

We are incorporated in Delaware. Anti-takeover provisions of Delaware law and our amended and restated certificate of incorporation and amended and restated bylaws may make a change in control or efforts to remove management more difficult. Also, under Delaware law, our Board of Directors may adopt additional anti-takeover measures.

We have the authority to issue up to 5 million shares of preferred stock and to determine the terms of those shares of stock without any further action by our stockholders. If the Board of Directors exercises this power to issue preferred stock, it could be more difficult for a third party to acquire a majority of our outstanding voting stock and vote the stock they acquire to remove management or directors.

Our amended and restated certificate of incorporation and amended and restated bylaws also provides staggered terms for the members of our Board of Directors. Under Section 141 of the Delaware General Corporation Law, our directors may be removed by stockholders only for cause and only by vote of the holders of a majority of voting shares then outstanding. These provisions may prevent stockholders from replacing the entire board in a single proxy contest, making it more difficult for a third party to acquire control of us without the consent of our Board of Directors. These provisions could also delay the removal of management by the Board of Directors with or without cause. In addition, our directors may only be removed for cause and amended and restated bylaws limit the ability our stockholders to call special meetings of stockholders.

Under Section 203 of the Delaware General Corporation Law, a corporation may not engage in a business combination with any holder of 15% or more of its capital stock until the holder has held the stock for three years unless, among other possibilities, the Board of Directors approves the transaction. Our Board of Directors could use this provision to prevent changes in management. The existence of the foregoing provisions could limit the price that investors might be willing to pay in the future for shares of our common stock.

We have the authority to issue up to 5 million shares of preferred stock and to determine the terms of those shares of stock without any further action by our stockholders. If the Board of Directors exercises this power to issue preferred stock, it could be more difficult for a third party to acquire a majority of our outstanding voting stock and vote the stock they acquire to remove management or directors.

Our amended and restated certificate of incorporation and amended and restated bylaws also provides staggered terms for the members of our Board of Directors. Under Section 141 of the Delaware General Corporation Law, our directors may be removed by stockholders only for cause and only by vote of the holders of a majority of voting shares then outstanding. These provisions may prevent stockholders from replacing the entire board in a single proxy contest, making it more difficult for a third party to acquire control of us without the consent of our Board of Directors. These provisions could also delay the removal of management by the Board of Directors with or without cause. In addition, our directors may only be removed for cause and amended and restated bylaws limit the ability our stockholders to call special meetings of stockholders.

Under Section 203 of the Delaware General Corporation Law, a corporation may not engage in a business combination with any holder of 15% or more of its capital stock until the holder has held the stock for three years unless, among other possibilities, the Board of Directors approves the transaction. Our Board of Directors could use this provision to prevent changes in management. The existence of the foregoing provisions could limit the price that investors might be willing to pay in the future for shares of our common stock.

Certain severance-related agreements in our executive employment agreements may make an acquisition more difficult and could result in the entrenchment of management.

In March 2008 (as subsequently amended, most recently as of January 1, 2011), we entered into employment agreements with our President and Chief Executive Officer and our Executive Vice President, Finance, Chief Financial Officer and Chief Operating Officer, which contain severance arrangements in the event that such executive s employment is terminated without cause or as a result of a change of control (as each such term is defined in each agreement). The financial obligations triggered by these provisions may prevent a business combination or acquisition that would be attractive to stockholders and could limit the price that investors would be willing to pay in the future for our stock.

In the event of an acquisition of our common stock, we cannot assure our common stockholders that we will be able to negotiate terms that would provide for a price equivalent to, or more favorable than, the price at which our shares of common stock may be trading at such time.

We may not effect a consolidation or merger with another entity without the vote or consent of the holders of at least a majority of the shares of our preferred stock (in addition to the approval of our common stockholders), unless the preferred stock that remains outstanding and its rights, privileges and preferences are unaffected or are converted into or exchanged for preferred stock of the surviving entity having rights, preferences and limitations substantially similar, but no less favorable, to our convertible preferred stock.

In addition, in the event a third party seeks to acquire our company or acquire control of our company by way of a merger, but the terms of such offer do not provide for our preferred stock to remain outstanding or be converted into or exchanged for preferred stock of the surviving entity having rights, preferences and limitations substantially similar, but no less favorable, to our preferred stock, the terms of the Certificate of Designation of our preferred stock provide for an adjustment to the conversion ratio of our preferred stock such that, depending on the terms of any such transaction, preferred stockholders may be entitled, by their terms, to receive up to $10.00 per share in common stock, causing our common stockholders not to receive as favorable a price as the price at which such shares may be trading at the time of any such transaction.

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As of June 30, 2011, there were 1,213,142 shares of our preferred stock issued and outstanding. If the transaction were one in which proceeds were received by the Company for distribution to stockholders, and the terms of the Certificate of Designation governing the preferred stock were strictly complied with, approximately $13,344,563 would be paid to the preferred holders before any distribution to the common stockholders, although the form of transaction could affect how the holders of preferred stock are treated. In such an event, although such a transaction would be subject to the approval of our holders of common stock, we cannot assure our common stockholders that we will be able to negotiate terms that would provide for a price equivalent to, or more favorable than, the price at which our shares of common stock may be trading at such time. Thus, the terms of our preferred stock might hamper a third party s acquisition of our company.

Our certificate of incorporation and bylaws and certain provisions of Delaware law may delay or prevent a change in our management and make it more difficult for a third party to acquire us.

Our amended and restated certificate of incorporation and bylaws contain provisions that could delay or prevent a change in our Board of Directors and management teams. Some of these provisions:

- authorize the issuance of preferred stock that can be created and issued by the Board of Directors without prior stockholder approval, commonly referred to as blank check preferred stock, with rights senior to those of our common stock;
- provide for the Board of Directors to be divided into three classes; and
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit stockholder action by written consent.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of large stockholders to complete a business combination with, or acquisition of, us. These provisions may prevent a business combination or acquisition that would be attractive to stockholders and could limit the price that investors would be willing to pay in the future for our stock. These provisions also make it more difficult for our stockholders to replace members of our Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt to replace our current management team. Additionally, these provisions may prevent an acquisition that would be attractive to stockholders and could limit the price that investors would be willing to pay in the future for our common stock.

We may have limited ability to pay cash dividends on our preferred stock, and there is no assurance that future quarterly dividends will be declared.

Delaware law may limit our ability to pay cash dividends on our preferred stock. Under Delaware law, cash dividends on our preferred stock may only be paid from surplus or, if there is no surplus, from the corporation s net profits for the current or preceding fiscal year. Delaware law defines surplus as the amount by which the total assets of a corporation, after subtracting its total liabilities, exceed the corporation s capital, as determined by its Board of Directors.

Since we are not profitable, our ability to pay cash dividends will require the availability of adequate surplus. Even if adequate surplus is available to pay cash dividends on our preferred stock, we may not have sufficient cash to pay dividends on the preferred stock or we may choose not to declare the dividends.

On July 8, 2011, the Board of Directors decided not to declare the quarterly cash dividend on the preferred stock with respect to the second quarter of 2011 that would have otherwise been payable on August 1, 2011. In addition, the Board of Directors also did not declare the quarterly cash dividend with respect to each of the four quarters of fiscal year 2009 and the first, second and third quarters of 2010.

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We have granted additional rights to our holders of preferred stock with respect to the management of the Company as a result of having not declared quarterly dividends on our preferred stock for a total of six quarterly dividend periods.

As a result of having not declared quarterly dividends on our preferred stock for a total of six quarters, the size of the Company s Board was increased by two members and the holders of the preferred stock, voting separately as a class, voted on May 24, 2011 and elected two directors to fill the vacancies created thereby. The directors elected by the holders of the preferred stock will have the ability to participate in the management of the Company until all accrued but unpaid dividends have been paid in full.

Our common and convertible preferred stock may experience extreme price and volume fluctuations, which could lead to costly litigation for the Company and make an investment in the Company less appealing.

The market price of our common and convertible preferred stock may fluctuate substantially due to a variety of factors, including:

- additions to or departures of our key personnel;
- announcements of technological innovations or new products or services by us or our competitors;
- announcements concerning our competitors or the biotechnology industry in general;
- new regulatory pronouncements and changes in regulatory guidelines;
- general and industry-specific economic conditions;
- changes in financial estimates or recommendations by securities analysts;
- variations in our quarterly results;
- announcements about our collaborators or licensors; and
- changes in accounting principles.

The market prices of the securities of biotechnology companies, particularly companies like us without product revenues and earnings, have been highly volatile and are likely to remain highly volatile in the future. This volatility has often been unrelated to the performance of particular companies. In the past, companies that experience volatility in the market price of their securities have often faced securities class action litigation. Moreover, market prices for stocks of biotechnology-related and technology companies frequently reach levels that bear no relationship to the performance of these companies. These market prices generally are not sustainable and are highly volatile. Whether or not meritorious, litigation brought against us could result in substantial costs, divert our management s attention and resources and harm our financial condition and results of operations. In addition, due to our stock price from time to time, we may not continue to qualify for continued listing on the NASDAQ Global Market. Please see Risk Factor: *Our common stock may have a volatile public trading price.*

The future sale of our common and preferred stock and future issuances of our common stock upon conversion of our preferred stock could negatively affect our stock price and cause dilution to existing holders of our common stock.

If our common or preferred stockholders sell substantial amounts of our stock in the public market, or the market perceives that such sales may occur, the market price of our common and preferred stock could fall. For example, we were approached by a preferred stockholder that elected to convert 123,400 of its shares of preferred stock, which shares were converted into 239,396 shares of common stock in the first quarter of 2010. In addition, 710,271 shares of preferred stock were converted to 1,416,203 shares of common stock during the second quarter of 2010. If additional holders of preferred stock elect to convert their shares to shares of common stock at renegotiated prices, such conversion as well as the sale of substantial amounts of our common or preferred stock, could cause dilution to existing holders of our common stock, thereby also negatively affecting the price of our common stock.

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If we exchange the convertible preferred stock for debentures, the exchange will be taxable but we will not provide any cash to pay any tax liability that any convertible preferred stockholder may incur.

An exchange of convertible preferred stock for debentures, as well as any dividend make-whole or interest make-whole payments paid in our common stock, will be taxable events for United States federal income tax purposes, which may result in tax liability for the holder of convertible preferred stock without any corresponding receipt of cash by the holder. In addition, the debentures may be treated as having original issue discount, a portion of which would generally be required to be included in the holder s gross income even though the cash to which such income is attributable would not be received until maturity or redemption of the debenture. We will not distribute any cash to the holders of the securities to pay these potential tax liabilities.

If we automatically convert the convertible preferred stock, there is a substantial risk of fluctuation in the price of our common stock from the date we elect to automatically convert to the conversion date.

We may automatically convert the convertible preferred stock into common stock if the closing price of our common stock has exceeded $35.30. There is a risk of fluctuation in the price of our common stock between the time when we may first elect to automatically convert the preferred and the automatic conversion date.

We do not intend to pay cash dividends on our common stock in the foreseeable future.

We do not anticipate paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends will depend on our financial condition, results of operations, capital requirements, the outcome of the review of our strategic alternatives and other factors and will be at the discretion of our Board of Directors. Accordingly, investors will have to rely on capital appreciation, if any, to earn a return on their investment in our common stock. Furthermore, we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends.

The number of shares of common stock which are registered, including the shares to be issued upon exercise of our outstanding warrants, is significant in relation to our currently outstanding common stock and could cause downward pressure on the market price for our common stock.

The number of shares of common stock registered for resale, including those shares which are to be issued upon exercise of our outstanding warrants, is significant in relation to the number of shares of common stock currently outstanding. If the security holder determines to sell a substantial number of shares into the market at any given time, there may not be sufficient demand in the market to purchase the shares without a decline in the market price for our common stock. Moreover, continuous sales into the market of a number of shares in excess of the typical trading volume for our common stock, or even the availability of such a large number of shares, could depress the trading market for our common stock over an extended period of time.

If persons engage in short sales of our common stock, including sales of shares to be issued upon exercise of our outstanding warrants, the price of our common stock may decline.

Selling short is a technique used by a stockholder to take advantage of an anticipated decline in the price of a security. In addition, holders of options and warrants will sometimes sell short knowing they can, in effect, cover through the exercise of an option or warrant, thus locking in a profit. A significant number of short sales or a large volume of other sales within a relatively short period of time can create downward pressure on the market price of a security. Further sales of common stock issued upon exercise of our outstanding warrants could cause even greater declines in the price of our common stock due to the number of additional shares available in the market upon such exercise, which could encourage short sales that could further undermine the value of our common stock. You could, therefore, experience a decline in the value of your investment as a result of short sales of our common stock.

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We are exposed to risk related to the marketable securities we may purchase.

We may invest cash not required to meet short term obligations in short term marketable securities. We may purchase securities in United States government, government-sponsored agencies and highly rated corporate and asset-backed securities subject to an approved investment policy. Historically, investment in these securities has been highly liquid and has experienced only very limited defaults. However, recent volatility in the financial markets has created additional uncertainty regarding the liquidity and safety of these investments. Although we believe our marketable securities investments are safe and highly liquid, we cannot guarantee that our investment portfolio will not be negatively impacted by recent or future market volatility or credit restrictions.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults upon Senior Securities.

None.

Item 4. (Removed and Reserved).

Item 5. Other Information.

None.

Item 6. Exhibits.

1.1	Underwriting Agreement, dated as of June 30, 2011, by and among the Company, Leerink Swann LLC and Lazard Capital Markets LLC, as representative of the several underwriters named therein (previously filed as Exhibit 1.1 to the Registrant s Current Report on Form 8-K, originally filed with the SEC on July 1, 2011 (File No. 000-50625), and incorporated herein by reference).
4.1	Form of Warrant to purchase shares of Cyclacel Pharmaceuticals, Inc. Common Stock (previously filed as Exhibit 4.1 to the Registrant s Current Report on Form 8-K, originally filed with the SEC on July 1, 2011 (File No. 000-50625), and incorporated herein by reference).
10.1*	License Agreement between Sankyo Co., Ltd. and Cyclacel Limited, dated September 10, 2003, and letter amendments dated April 1, 2004 and April 28, 2004.
10.2*	Amendment No. 4 to License Agreement between Daiichi Sankyo Company, Limited and Cyclacel Limited, dated July 11, 2011.
31.1*	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a) As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(a) As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101***	The following materials from Cyclacel Pharmaceuticals, Inc. s Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Statements of Income, (ii) the Condensed Consolidated Balance Sheets, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) Notes to Condensed Consolidated Financial Statements.

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Certain portions of the exhibit have been omitted pursuant to a confidential treatment request filed separately with the Securities and Exchange Commission.

* Filed herein.

** Furnished herewith.

*** XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

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SIGNATURES

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

CYCLACEL PHARMACEUTICALS, INC.

Date: August 12, 2011

By: /s/ Paul McBarron
Paul McBarron
Chief Operating Officer, Chief Financial Officer and Executive Vice President, Finance

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