CELL THERAPEUTICS INC
Form 424B5
December 09, 2011
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PROSPECTUS SUPPLEMENT
(To Prospectus dated October 25, 2011)

Filed Pursuant to Rule 424(b)(5)
Registration Statement No.: 333-177506

CELL THERAPEUTICS, INC.

20,000 Shares of Series 14 Preferred Stock

Warrants to Purchase 6,956,522 Shares of Common Stock

Pursuant to this prospectus supplement and the accompanying prospectus, we are offering 20,000 shares of Series 14 Convertible Preferred Stock, or the Series 14 Preferred Stock, and warrants to purchase up to 6,956,522 shares of common stock, or the warrants (and the approximately 24,347,826 shares of common stock issuable from time to time upon conversion of the Series 14 Preferred Stock and exercise of the warrants), to certain institutional investors, or collectively, the Initial Purchasers. The purchase price for each share of Series 14 Preferred Stock and a warrant to purchase approximately 348 shares of common stock is $1,000. Each warrant to purchase shares of our common stock will have an exercise price of $1.45 per share. The warrants are exercisable beginning six months and one day after the date of issuance and expire five years and one day after the date of issuance.

For a more detailed description of the Series 14 Preferred Stock and warrants, see the sections entitled Description of Series 14 Preferred Stock and Description of Warrants beginning on pages S-30 and S-33, respectively, of this prospectus supplement. For a more detailed description of our common stock issuable upon conversion of the Series 14 Preferred Stock and exercise of the warrants, see the section entitled Description of Capital Stock beginning on page S-34 of this prospectus supplement.

Rodman & Renshaw, LLC acted as the sole placement agent and book runner on this transaction. The placement agent is not purchasing or selling any other securities nor is it required to sell any specific number or dollar amount of securities, but has agreed to use its reasonable best efforts to sell the securities offered by this prospectus supplement. This prospectus supplement and the accompanying prospectus also cover the sale of these securities to the public.

The Series 14 Preferred Stock and warrants will not be listed on any national securities exchange. Our common stock is quoted on The NASDAQ Capital Market and on the Mercato Telematico Azionario, or the MTA, stock market in Italy under the symbol CTIC. On December 8, 2011, the last reported sale price of our common stock on The NASDAQ Capital Market was $1.38.

Investing in our securities involves a high degree of risk. See the section entitled Risk Factors beginning on page S-7 of this prospectus supplement and in the documents we incorporate by reference in this prospectus supplement to read about factors you should consider before investing in our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Shares of Series 14 Preferred Stock and warrants	Per share of Series 14 Preferred Stock and warrant(1)	Total
Offering price of the Series 14 Preferred Stock and warrants	20,000	$ 1,000	$ 20,000,000
Placement agent fees(2)		$ 47.50	$ 950,000
Total proceeds to us before other expenses		$ 952.50	$ 19,050,000

(1) Table excludes shares of common stock issuable upon conversion of the Series 14 Preferred Stock and exercise of the warrants offered hereby.

(2) A fee equal to 4.75% of the aggregate proceeds raised in this offering will be payable to the placement agent.

In addition to the placement agent fees, the placement agent will receive warrants (the Placement Agent Warrants) to purchase up to 347,826 shares of common stock for placement services. Trout Capital LLC will also receive a cash fee of $125,000, plus warrants (the Trout Warrants) to purchase up to 173,913 shares of common stock for financial advisory services. The Placement Agent Warrants, the Trout Warrants and the shares of common stock issuable upon exercise of the Placement Agent Warrants and the Trout Warrants are registered pursuant to this prospectus supplement.

The Series 14 Preferred Stock and warrants will be delivered to the Initial Purchasers on or about December 13, 2011.

This prospectus supplement is dated December 8, 2011.

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You should rely only on the information contained or incorporated by reference in this prospectus supplement or the accompanying prospectus. We have not authorized anyone to provide you with different information.

We are not making an offer of the Series 14 Preferred Stock and warrants (or the shares of common stock issuable from time to time upon conversion of the Series 14 Preferred Stock and exercise of the warrants) covered by this prospectus supplement in any jurisdiction where the offer is not permitted.

The information contained in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference is accurate only as of its respective date, regardless of the time of delivery of this prospectus supplement and the accompanying prospectus, or of any sale of the Series 14 Preferred Stock and warrants (or the shares of common stock issuable from time to time upon conversion of the Series 14 Preferred Stock and exercise of the warrants). You should not assume that the information contained in or incorporated by reference in this prospectus supplement or the accompanying prospectus is accurate as of any date other than the respective dates thereof.

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ABOUT THIS PROSPECTUS SUPPLEMENT

This document is in two parts. The first part is this prospectus supplement, which describes the specific terms of this offering of Series 14 Preferred Stock and warrants (and the shares of common stock issuable from time to time upon conversion of the Series 14 Preferred Stock and exercise of the warrants) and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference. The second part is the accompanying prospectus, which gives more general information. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or any document incorporated by reference, on the other hand, you should rely on the information in this prospectus supplement.

You should read this prospectus supplement, the accompanying prospectus and the documents incorporated by reference before making an investment decision. You should also read and consider the information in the documents we have referred you to in the section of this prospectus supplement entitled Incorporation of Certain Documents by Reference.

In this prospectus supplement, the terms CTI, Company, we, us, our and similar terms refer to Cell Therapeutics, Inc., a Washington corpora and its subsidiaries, unless the context otherwise requires.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the information requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act. In accordance with the Exchange Act, we file reports, proxy statements and other information with the Securities and Exchange Commission, or the SEC. Such reports, proxy statements and other information filed by us are available to the public free of charge at www.sec.gov. Copies of certain information filed by us with the SEC are also available on our website at www.celltherapeutics.com. You may also read and copy any document we file with the SEC at the public reference facilities maintained by the SEC at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the public reference facilities by calling the SEC at 1-800-SEC-0330.

This prospectus supplement and the accompanying prospectus are part of a registration statement that we filed with the SEC. This prospectus supplement and the accompanying prospectus omit some information contained in the registration statement in accordance with SEC rules and regulations. You should review the information and exhibits in the registration statement for further information about us and the securities being offered hereby. Statements in this prospectus supplement or the accompanying prospectus concerning any document we filed as an exhibit to the registration statement or that we otherwise filed with the SEC are not intended to be comprehensive and are qualified by reference to these filings. You should review the complete document to evaluate these statements.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

SEC rules allow us to incorporate by reference into this prospectus supplement and the accompanying prospectus much of the information we file with the SEC, which means that we can disclose important information to you by referring you to those publicly available documents. The information that we incorporate by reference into this prospectus supplement and the accompanying prospectus is considered to be part of this prospectus supplement and the accompanying prospectus. This prospectus supplement and the accompanying prospectus incorporate by reference the documents listed below and any future filings we make with the SEC under Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act (in each case, other than those documents or the portions of those documents deemed to be furnished and not filed in accordance with SEC rules) until the offering of the securities under the registration statement is terminated or completed:

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2010 filed with the SEC on February 16, 2011;
- our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2011, June 30, 2011 and September 30, 2011 filed with the SEC on April 26, 2011, July 28, 2011 and October 25, 2011, respectively;
- our Current Reports on Form 8-K filed with the SEC on January 18, 2011 (as amended by our Current Report on Form 8-K/A filed with the SEC on January 28, 2011), February 24, 2011 (as amended by our Current Report on Form 8-K/A filed with the SEC on March 7, 2011), March 14, 2011, March 15, 2011, March 22, 2011, May 2, 2011, May 3, 2011, May 6, 2011, May 18, 2011, June 17, 2011, June 29, 2011, July 6, 2011, August 31, 2011, September 26, 2011, November 15, 2011 and December 1, 2011; and

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the description of our capital stock contained in our Registration Statement on Form 10 filed with the SEC on June 27, 1996, as amended.

Because we are incorporating by reference future filings with the SEC, this prospectus supplement and the accompanying prospectus are continually updated and later information filed with the SEC may update and supersede some of the information included or incorporated by reference in this prospectus supplement and the accompanying prospectus. This means that you must look at all of the SEC filings that we incorporate by reference to determine if any of the statements in this prospectus supplement and the accompanying prospectus or in any document previously incorporated by reference have been modified or superseded.

We will provide without charge to each person, including any beneficial owners, to whom this prospectus supplement is delivered, upon his or her written or oral request, a copy of any or all documents referred to above which have been or may be incorporated by reference into this prospectus supplement and the accompanying prospectus but not delivered with this prospectus supplement, excluding exhibits to those documents unless they are specifically incorporated by reference into those documents. You may request a copy of these documents by writing or telephoning us at the following address:

Cell Therapeutics, Inc.

501 Elliott Avenue West, Suite 400

Seattle, Washington 98119

(206) 282-7100

Attention: Investor Relations

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus and the documents incorporated by reference may contain forward-looking statements within the meaning the federal securities laws. All statements other than statements of historical fact are forward-looking statements , including, without limitation:

any statements regarding future operations, plans, regulatory filings or approvals;

any statements regarding the performance, or likely performance, or outcomes or economic benefit of any licensing or other agreement, including any agreement with Novartis International Pharmaceutical Ltd., or Norvartis, or its affiliates, or Chroma Therapeutics Ltd., or Chroma, or its affiliates, including whether or not such partner will elect to participate, terminate or otherwise make elections under any such agreement or whether any regulatory authorizations required to enable such agreement will be obtained;

any projections of cash resources, revenues, operating expenses or other financial terms;

any statements of the plans and objectives of management for future operations or programs;

any statements concerning proposed new products or services;

any statements on plans regarding proposed or potential preclinical development, clinical trials or new drug filing strategies or timelines;

any statements regarding compliance with the listing standards of The NASDAQ Stock Market, or NASDAQ;

any statements regarding pending or future mergers or acquisitions; and

any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing.

In some cases, forward-looking statements can be identified by terms such as anticipates, believes, continue, could, estimates, expects, i may, plans, potential, predicts, projects, should or will or the negative thereof, variations thereof and similar expressions. Such stateme based on management s current expectations and are subject to risks and uncertainties which may cause actual results to differ materially from those set forth in the forward-looking statements. There can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including, but not limited to, the risk factors

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described in the section of this prospectus supplement entitled Risk Factors. All forward-looking statements and reasons why results may differ included in this prospectus supplement are made as of the date hereof, and we assume no obligation to update any such forward-looking statement or reason why actual results might differ, except to the extent required by law.

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SUMMARY

The following summary highlights information contained elsewhere, or incorporated by reference, in this prospectus supplement and the accompanying prospectus. The following summary does not contain all of the information that you should consider before investing in our securities. To understand this offering fully, you should read this entire prospectus supplement and the accompanying prospectus carefully, including the financial statements and the documents incorporated by reference.

Our Company

We develop, acquire and commercialize novel treatments for cancer. Our goal is to build a leading biopharmaceutical company with a diversified portfolio of proprietary oncology drugs. Our research, development, acquisition and in-licensing activities concentrate on identifying and developing new, less toxic and more effective ways to treat cancer. Our operations are primarily conducted in the United States. We are currently focusing our efforts on Pixuvri (pixantrone dimaleate), OPAXIO (paclitaxel poliglumex), tosedostat, brostallicin and bisplatinates.

Corporate Information

We were incorporated in the State of Washington in 1991. Our shares of common stock trade on The NASDAQ Capital Market and the MTA in Italy under the symbol CTIC. Our principal executive offices are located at 501 Elliott Avenue West, Suite 400, Seattle, Washington 98119, and our phone number is (206) 282-7100. Our website is located at www.celltherapeutics.com; however, the information in, or that can be accessed through, our website is not part of this prospectus supplement or the accompanying prospectus.

Recent Developments

OPAXIO

On August 18, 2011, we announced that enrollment had opened for a randomized phase II clinical study of OPAXIO, which is being conducted by a consortium of leading medical centers led by Brown University Oncology Group, comparing the combination of OPAXIO and radiation to the combination of temozolomide and radiation for patients with newly diagnosed glioblastoma, a high-grade malignant brain tumor.

Pixuvri

European Medicines Agency

On December 5, 2011, we announced that we had received the day-180 list of outstanding issues from the European Medicines Agency s, or the EMA s, Committee for Medicinal Products for Human Use, or the CHMP, in regard to our Marketing Authorization Application, or MAA, for Pixuvri in Europe to treat relapsed or refractory aggressive non-Hodgkin s lymphoma, or NHL, which contained only one remaining major clinical objection to our MAA and items not deemed to be major issues. To address the remaining major objection, the CHMP required that we provide a literature review of mechanisms of rituximab resistance and analyses that demonstrate the efficacy of Pixuvri in patients with prior rituximab treatment. In addition, the CHMP required that we provide information to address some additional questions that were not deemed to be major issues and could be addressed by additional analyses of currently available data. On November 29, 2011, we met with the rapporteurs and team members from the EMA for a clarification meeting at which we and our clinical expert presented the results of our literature review, additional supportive analyses regarding the efficacy of Pixuvri across response rates and progression free survival in patients with prior rituximab treatment, as well as its other proposed responses to the list of outstanding issues. We are required to submit our response to the day-180 list by December 19, 2011 and currently expect to be able to meet that deadline. If the responses satisfy the outstanding objections and the CHMP does not require an oral explanation, a positive recommendation on the approval of Pixuvri could be made at the January 19, 2012 meeting of the CHMP.

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Food & Drug Administration

On October 25, 2011, we announced the resubmission of our new drug application, or NDA, for Pixuvri to the U.S. Food and Drug Administration s, or FDA s, Division of Oncology Drug Products, or DODP, for accelerated approval to treat relapsed or refractory aggressive NHL in patients who failed two or more lines of prior therapy. On December 6, 2011, we announced that the FDA s Division of Oncology Products 1 had notified us that the resubmitted NDA is a complete, Class 2 response to the Complete Response Letter that we received in April 2010 for the NDA and that the FDA has set a set a Prescription Drug User Fee Act, or PDUFA, goal date of April 24, 2012 for a decision on the NDA. However, you should not infer that the aforementioned developments increase the likelihood of FDA approval of the NDA or that the FDA, the FDA s Office of New Drugs, or OND, or the DODP will not require additional actions or information.

Tosedostat

In March 2011, we entered into a co-development and license agreement with Chroma providing us with exclusive marketing and co-development rights to Chroma s drug candidate tosedostat in North, Central and South America. Tosedostat is an oral, aminopeptidase inhibitor that has demonstrated significant anti-tumor responses in blood related cancers and solid tumors in phase I-II clinical trials. Interim results from the phase II OPAL study of tosedostat in elderly patients with relapsed or refractory acute myeloid leukemia, or AML, were presented in June 2011 at the 2011 Annual Meeting of the American Society of Clinical Oncology. These results showed that once-daily, oral doses of tosedostat was well-tolerated and demonstrated encouraging response rates at the interim evaluation time point including a high-response rate among patients who received prior hypomethylating agents, which are used to treat myelodysplastic syndrome, or MDS, a precursor of AML. Based on these results, and pending discussions with the FDA, we, in collaboration with Chroma, anticipate initiating a phase III study for patients with relapsed or refractory MDS in the second quarter of 2012.

Amendments to Articles of Incorporation and Equity Incentive Plan

On November 11, 2011, at our annual meeting of shareholders, or the Annual Meeting, our shareholders approved a proposal to amend our articles of incorporation to reflect an increase in the total number of authorized shares from 284,999,999 to 384,999,999 and an increase in our authorized shares of common stock from 283,333,333 to 383,333,333.

Also, at the Annual Meeting our shareholders approved amendments to our 2007 Equity Incentive Plan, as amended and restated, or the 2007 Equity Plan. The amendments (i) increased the number of shares of our common stock that may be delivered pursuant to awards granted under the 2007 Equity Plan by an additional 14,000,000 shares, (ii) limited the number of shares of common stock that may be subject to stock options and stock appreciation rights granted under the 2007 Equity Plan to any individual in a calendar year to 13,500,000 shares and (iii) limited the number of shares that may be subject to awards intended to qualify as performance-based compensation under Section 162(m) of the Internal Revenue Code of 1986, as amended (other than stock options and stock appreciation rights), granted under the 2007 Equity Plan to any individual in a calendar year to 13,500,000 shares.

We previously adopted a long-term incentive program that provided for grants of performance-based equity awards (including the performance-based restricted stock awards granted by us in July 2010) to our executive officers and directors. These awards are scheduled to expire (and the approximately 5.6 million unvested shares subject to the July 2010 performance-based restricted stock awards would be forfeited) on December 31, 2011 to the extent the related performance goals have not been attained. On November 22, 2011, the Compensation Committee of our board of directors, or the Compensation Committee, approved a new three-year performance-based equity compensation program, which provides for the grant of performance-based equity awards scheduled to be effective on the first business day of January 2012 to James A. Bianco, our Chief Executive Officer, Louis A. Bianco, our Executive Vice President, Finance and Administration, Dan Eramian, our Executive Vice President, Corporate Communications, Craig W. Philips, the Company s President, and Jack W. Singer, M.D., our Executive President, Chief Medical Officer, our Executive Officers.

On November 29, 2011, our board of directors approved the grant of performance-based equity awards to our directors who are not employed by us, including John H. Bauer, Vartan Gregorian, Richard L. Love, Mary O. Mundinger, Phillip N. Nudelman, Frederick W. Telling and Reed V. Tuckson, or the Non-Employee Directors. Each of these awards for the Executive Officers and Non-Employee Directors is scheduled to be effective on the first business day of January 2012. In addition, on November 29, 2011, the Compensation Committee approved awards of restricted stock to each of the Executive Officers as follows: Dr. Bianco 1,685,626 shares; Mr. Bianco 505,688 shares; Mr. Eramian 505,688 shares; Mr. Philips 1,011,376 shares; and Dr. Singer 505,688 shares. Each of these awards was effective on the date of grant and will vest in three semi-annual installments over 18 months after the date of grant, subject to the Executive Officer s continued employment with us through the applicable vesting date. On November 29, 2011,

our board of directors also approved an award of 280,938 shares to Dr. Nudelman and awards of 187,292 shares to each of the other Non-Employee Directors. Each of these awards to the Non-Employee Directors was fully vested on the date of grant. On November 29, 2011, the Compensation Committee also approved a bonus of $150,000 to James A. Bianco, M.D., our Chief Executive Officer, in recognition of his 20 years of service to us.

Value Added Tax Assessment

On April 14, 2009 and December 21, 2009, the Italian Tax Authority, or the ITA, issued notices of assessment to CTI (Europe) based on the ITA s audit of CTI (Europe) s VAT returns for the years 2003 and 2005, respectively. On June 25, 2010, the ITA issued notices of assessment to CTI (Europe) for the years 2006 and 2007 based on similar findings for the 2003 and 2005 assessments. The ITA audits concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian clients for services performed by CTI (Europe). The assessments, including interest and penalties, for the years 2003, 2005, 2006 and 2007 are 0.5 million, 5.5 million, 2.5 million and 0.8 million, or approximately $0.7 million, $7.4 million, $3.4 million and $1.1 million converted using the currency exchange rate as of September 30, 2011, respectively. We believe that the services invoiced were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed. We are vigorously defending ourselves against the assessments both on procedural grounds and on the merits of the case. If the decisions of the Provincial Tax Court of Milan, or the Tax Court, for the different VAT cases are unfavorable, then we expect to appeal to the higher courts in order to further defend our interests. However, if we are unable to successfully defend ourselves against the assessments issued by the ITA, we may be requested to pay to the ITA an amount ranging from 4.9 million to 9.4 million, or approximately $6.6 million to $12.6 million converted using the currency exchange rate as of September 30, 2011, plus collection fees, notification expenses and additional interest for the period lapsed between the date in which the assessments were issued and the date of effective payment. On February 2, 2011, we paid to the ITA the required deposit in respect of the 2005 VAT in the amount of 1.5 million, or approximately $2.1 million converted using the currency exchange rate as of February 2, 2011. On March 4, 2011, we paid to the ITA the required deposit in respect of the 2006 VAT in the amount of 0.4 million, or approximately $0.6 million converted using the currency exchange rate as of March 4, 2011. On September 26, 2011, we paid to the ITA the required deposit in respect of the 2007 VAT in the amount of 0.1 million, or approximately $0.1 million converted using the currency exchange rate as of September 26, 2011.

2003 VAT. As of the date of this prospectus supplement, we have not received a notice from the ITA requesting a deposit payment for the VAT based on the 2003 assessment. The first hearing for the discussion of the merits of the case was held on March 18, 2011 in front of the Provincial Tax Court of Milan. On September 13, 2011, the Tax Court issued decision no. 229/3/2011 in which the Tax Court (i) fully accepted the merits of our appeal, (ii) declared that no penalties can be imposed against us, and (iii) found the Tax Office liable to pay us 10,000, or approximately $14,000 converted using the currency exchange rate as of September 13, 2011, as partial refund of the legal expenses we incurred for our appeal. The Tax Office is entitled to appeal this decision to a higher court within six months. We have not been notified of any appeal from the Tax Office.

2005 VAT. On July 14, 2010, the ITA issued a notice requiring a deposit payment for the VAT to CTI (Europe) based on the 2005 assessment, including 50% of the assessed VAT, interest and collection fees for an amount of 1.5 million, or approximately $2.1 million converted using the currency exchange rate as of September 30, 2011. We filed a petition with the Tax Court for suspension of the 2005 notice of deposit payment. On September 28, 2010, the merits of the case for the year 2005 were discussed in a public hearing before the Tax Court. On January 13, 2011, the Tax Court issued decision no. 4/2010 in which the Tax Court (i) partially accepted our appeal and declared that no penalties can be imposed against us, (ii) confirmed the right of the Italian Tax Authorities to reassess the VAT (plus interest) in relation to the transactions identified in the 2005 notice of assessment and (iii) repealed the suspension of the notice of deposit payment. As a result of this decision, our exposure for 2005 VAT assessment is currently reduced by the waiver of penalties of 2.6 million, or approximately $3.5 million converted using the currency exchange rate as of September 30, 2011. On February 2, 2011, we paid the required VAT deposit of 1.5 million, or approximately $2.1 million converted using the currency exchange rate as of February 2, 2011, prior to the due date of February 6, 2011. On March 25, 2011, we paid to the Italian collection agent an additional 0.1 million, or approximately $0.1 million converted using the currency exchange rate as of March 25, 2011. The additional payment was for interest and collection fees during the suspension period. We do not believe this additional payment was due and we intend to pursue recovery of such payment through litigation. In July 2011, we were notified by our Italian counsel of the ITA s appeal regarding the January 2011 decision that no penalties could be imposed on the Company. We do not believe that the Tax Court has carefully reviewed all of our arguments, relevant documents and other supporting evidence that our counsel filed and

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presented during the hearing, including an appraisal from an independent expert, and, therefore, that there are grounds of appeal in order to ask the judges of the higher court to further consider all of our arguments in support of invalidating the entire notice of assessment. Accordingly, we filed an appeal with the Tax Office on July 7, 2011 and intend to file a complaint with the European Commission.

While we contend that services invoiced were non-VAT taxable consulting services and that the VAT returns are correct as originally filed, we have recorded a reserve for VAT assessed, interest and collection fees totaling 2.6 million, or approximately $3.6 million as of September 30, 2011, of which $3.1 million is included in long-term obligations, less current portion and $0.5 million of the reserve is accounted for as an offset to VAT receivable included in other assets.

2006 VAT. On January 10, 2011, we received a notice from the ITA requiring a deposit payment for VAT to CTI (Europe) based on the 2006 assessment, including 50% of the assessed VAT, interest and collection fees for an amount of 0.4 million, or approximately $0.6 million converted using the currency exchange rate as of January 10, 2011, payable in the first quarter 2011. We filed a request for suspension of the collection of such amount, which was rejected. On March 4, 2011, we paid to the ITA the required deposit in respect of the 2006 VAT in the amount of 0.4 million, or approximately $0.6 million converted using the currency exchange rate as of March 4, 2011. The first hearing for the discussion of the merits of the case was held on May 27, 2011 (jointly with the 2007 VAT case). On October 18, 2011, the Tax Court issued decision no. 276/21/11 (jointly with the 2007 VAT case) in which the Tax Court (i) fully accepted the merits of our appeal, (ii) declared that no penalties can be imposed against us, and (iii) found for the 2006 and 2007 VAT cases the Tax Office liable to pay us 10,000, or approximately $14,000 converted using the currency exchange rate as of October 18, 2011, as partial refund of the legal expenses we incurred for our appeal. The Tax Office is entitled to appeal this decision to a higher court within 60 days from November 11, 2011 (the date on which we served the decision on the Tax Office). We have not been notified of any appeal from the Tax Office.

2007 VAT. The first hearing for the discussion of the merits of the case was held on May 27, 2011 (jointly with the 2006 VAT case). On August 4, 2011, we received a notice from the ITA requiring a deposit payment for VAT to CTI (Europe) based on the 2007 assessment, including 50% of the assessed VAT, interest and collection fees for an amount of 0.1 million, or approximately $0.1 million converted using the currency exchange rate as of August 4, 2011, payable in the third quarter 2011. On September 26, 2011, we paid to the ITA the required deposit in respect of the 2007 VAT in the amount of 0.1 million or approximately $0.1 million converted using the currency exchange rate as of September 26, 2011. On October 18, 2011, the Tax Court issued decision no. 276/21/11 (jointly with the 2006 VAT case) in which the Tax Court (i) fully accepted the merits of our appeal, (ii) declared that no penalties can be imposed against us, and (iii) found for the 2006 and 2007 VAT cases the Tax Office liable to pay us 10,000, or approximately $14,000 converted using the currency exchange rate as of October 18, 2011, as partial refund of the legal expenses we incurred for our appeal. The Tax Office is entitled to appeal this decision to a higher court within 60 days from November 11, 2011 (the date on which we served the decision on the Tax Office). We have not been notified of any appeal from the Tax Office.

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THE OFFERING

The following is a brief summary of some of the terms of this offering and is qualified in its entirety by reference to the more detailed information appearing elsewhere in this prospectus supplement and the accompanying prospectus.

Securities we are offering	20,000 shares of Series 14 Preferred Stock and warrants to purchase up to 6,956,522 shares of common stock (and the approximately 24,347,826 shares of common stock issuable from time to time upon conversion of the Series 14 Preferred Stock and exercise of the warrants). The purchase price for each share of Series 14 Preferred Stock and a warrant to purchase approximately 348 shares of common stock is $1,000. Each warrant will have an exercise price of $1.45 per share. The shares of Series 14 Preferred Stock and warrants will be issued separately, but can only be purchased together in this offering.
Description of the Series 14 Preferred Stock Dividends	Holders of the Series 14 Preferred Stock are entitled to receive dividends equal (on an as if converted to common stock basis) to and in the same form as dividends actually paid on shares of common stock or other junior securities, as and if such dividends are paid. We have never declared or paid any cash dividends on our common stock and do not currently anticipate declaring or paying cash dividends on our common stock in the foreseeable future. See Dividend Policy.
Optional conversion	The Series 14 Preferred Stock can be converted at the holder s option at any time after issuance into the number of shares of common stock determined by dividing the stated value of the Series 14 Preferred Stock of $1,000 per share to be converted by the conversion price, which is initially $1.15. The initial conversion price is subject to adjustment in certain events (including certain fundamental changes), which are explained in more detail under the section entitled Description of Series 14 Preferred Stock.
Automatic conversion	On the first to occur of (i) the one month anniversary of the original issuance date of the Series 14 Preferred Stock, (ii) the date on which 1,000 or less shares of Series 14 Preferred Stock remain outstanding or (iii) the adoption by our board of directors of a resolution that it intends to adopt an amendment to the articles of incorporation without shareholder approval to effect a reverse stock split with respect to our common stock in order to achieve compliance with the listing rules of The NASDAQ Capital Market or for other good faith business reasons, all outstanding shares of Series 14 Preferred Stock shall automatically convert into the number of shares of common stock determined by dividing the aggregate stated value of the Series 14 Preferred Stock being converted by the conversion price then in effect, subject only to the limitations on conversion described below.
Limitations on conversion	We cannot effect a conversion of the Series 14 Preferred Stock, and no holder may request a conversion of its Series 14 Preferred Stock, to the extent such conversion would result in the holder and its affiliates beneficially owning more than 4.99% of our common stock, provided that a holder may elect to increase the conversion threshold to 9.99% of our common stock by providing us with 61 days prior notice. In addition, in the event of an automatic conversion, the conversion threshold will increase to 19.99% without any further action on the part of a holder.
Liquidation preference	In the event of our voluntary or involuntary dissolution, liquidation or winding up, each holder of Series 14 Preferred Stock will be entitled to be paid a liquidation preference equal to the initial stated value of such holder s Series 14 Preferred Stock of $1,000 per share, plus accrued and unpaid dividends and any other payments that may be due on such shares, before any distribution of assets may be made to holders of capital stock ranking junior to the Series 14 Preferred Stock.

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Voting rights	The Series 14 Preferred Stock will have no voting rights, except as otherwise expressly provided in our articles of incorporation or as otherwise required by law. However, so long as at least 20% of the aggregate originally issued shares of the Series 14 Preferred Stock are outstanding, we cannot amend our articles of incorporation, our second amended and restated bylaws, or our bylaws, or other charter documents in each case so as to materially, specifically and adversely affect the rights of the Series 14 Preferred Stock, to repay, repurchase or offer to repay or repurchase or otherwise acquire any of our common stock or other securities junior to the Series 14 Preferred Stock, except in certain limited circumstances, to authorize or create any class of senior preferred stock or to enter into any agreement or understanding with respect to any of the foregoing, in each case without the affirmative written consent of holders of a majority of the outstanding shares of Series 14 Preferred Stock.
Description of the warrants	The Initial Purchasers will receive warrants to purchase approximately 348 shares of common stock for each share of Series 14 Preferred Stock purchased in this offering. The warrants are exercisable at an exercise price of $1.45 per share of common stock. The warrants are exercisable beginning six months and one day after the date of issuance and expire five years and one day after the date of issuance. See Description of Warrants.
Limitations on exercise	No holder may exercise its warrants to the extent that the exercise would result in the holder and its affiliates beneficially owning 4.99% or more of our common stock, provided that a holder may elect to increase the exercise threshold to 9.99% of our common stock by providing us with 61 days prior notice.
Use of proceeds after expenses	We will use a portion of the net proceeds from this offering for general corporate purposes, which may include, among other things, paying interest on and/or retiring portions of our outstanding debt, funding research and development, preclinical and clinical trials, the preparation and filing of new drug applications and general working capital. We may use a portion of the net proceeds from this offering to fund possible investments in, or acquisitions of, complementary businesses, technologies or products. See Use of Proceeds.
Market for the Series 14 Preferred Stock and warrants	There is no established public trading market for the Series 14 Preferred Stock or warrants and we do not expect a market to develop. In addition, we do not intend to apply for listing the Series 14 Preferred Stock or warrants on any securities exchange.
Market for our common stock	Our common stock is quoted on The NASDAQ Capital Market and on the MTA stock market in Italy under the symbol CTIC. On December 8, 2011, the last reported sale price of our common stock on The NASDAQ Capital Market was $1.38.
Risk factors	See the Risk Factors section contained in this prospectus supplement and in the documents we incorporate by reference in this prospectus supplement and the accompanying prospectus to read about factors you should consider before investing in our securities.

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RISK FACTORS

You should carefully consider the risks under the heading Risk Factors beginning on page 17 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2010, filed with the SEC on February 16, 2011, and our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2011, June 30, 2011 and September 30, 2011, filed with the SEC on April 26, 2011, July 28, 2011 and October 25, 2011, respectively, which information is incorporated by reference in this prospectus supplement, and the additional risks described below and other information in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference before deciding to invest in our securities. If any of the identified risks actually occur, they could materially adversely affect our business, financial condition, operating results or prospects and the trading price of our securities. Additional risks and uncertainties that we do not presently know or that we currently deem immaterial may also impair our business, financial condition, operating results and prospects and the trading price of our securities.

Risks Related to Our Company

We need to raise additional funds and expect that we will need to continue to raise funds in the future, and additional funds may not be available on acceptable terms, or at all; failure to raise significant additional funds may cause us to cease development of our products and operations.

We have substantial operating expenses associated with the development of our product candidates and as of September 30, 2011, we had cash and cash equivalents of $45.2 million. This amount does not include $8.2 million received in October 2011 related to our settlement with The Lash Group, Inc.

As of September 30, 2011, our total current liabilities were $30.8 million, including $10.9 million outstanding principal balance related to our 5.75% convertible senior notes, which are due December 2011. We do not expect that our existing cash and cash equivalents, including additional funds received to date, will provide sufficient working capital to fund our presently anticipated operations beyond the first quarter of 2012.

Even if we are able to raise additional capital through this offering, we will need to find other ways of raising additional capital, which will likely require that we issue additional shares of our common stock. In light of this offering, and because of the number of shares reserved for issuance under various convertible securities, derivative securities and otherwise, we have very few authorized shares of common stock available for issuance and it is difficult for us to obtain an increase in our authorized shares. If we do not have enough shares authorized to effect a future equity financing, our ability to raise capital through equity financings may be adversely affected.

To the extent that we raise additional capital through this offering or the sale of equity securities or securities convertible into our equity securities, our shareholders may experience dilution of their proportionate ownership of us. There can be no assurance that this offering will be consummated or that we will have sufficient earnings, access to liquidity or cash flow in the future to meet our operating expenses and other obligations, including our debt service obligations.

We may not be able to raise such capital or, if we can, it may not be on favorable terms. We may seek to raise additional capital through public or private equity financings, partnerships, joint ventures, dispositions of assets, debt financings or restructurings, bank borrowings or other sources. To obtain additional funding, we may need to enter into arrangements that require us to relinquish rights to certain technologies, drug candidates, products and/or potential markets. In addition, some financing alternatives may require us to meet additional regulatory requirements in the E.U. (including Italy) and the United States and we may be subject to certain contractual limitations, which may increase our costs and harm our ability to obtain additional funding. If adequate funds are not otherwise available, we will further curtail operations significantly, including the delay, modification or cancellation of operations and plans related to Pixuvri, OPAXIO, tosedostat, brostallicin and bisplatinates and may be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection. Bankruptcy may result in the termination of agreements pursuant to which we license certain intellectual property rights, including the rights to Pixuvri, OPAXIO, tosedostat, brostallicin and bisplatinates.

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We need to implement a reduction in expenses across our operations.

Even if we complete this offering, we need substantial additional capital to fund our current operations. If we are unable to secure additional financing on acceptable terms in the near future, we will need to implement additional cost reduction initiatives, such as further reductions in the cost of our workforce and the discontinuation of a number of business initiatives to further reduce our rate of cash utilization and extend our existing cash balances. We believe that these additional cost reduction initiatives, if undertaken, could provide us with additional time to continue our pursuit of additional funding sources and also strategic alternatives. In the event that we are unable to obtain financing on acceptable terms and reduce our expenses, we may be required to limit or cease our operations, pursue a plan to sell our operating assets, seek bankruptcy protection, or otherwise modify our business strategy, which could materially harm our future business prospects.

Our common stock is listed on The NASDAQ Capital Market and the MTA in Italy and we may not be able to maintain those listings or trading on these exchanges may be halted or suspended, which may make it more difficult for investors to sell shares of our common stock.

Effective with the opening of trading on January 8, 2009, the U.S. listing of our common stock was transferred to The NASDAQ Capital Market, subject to meeting a minimum market value of listed securities of $35.0 million. NASDAQ s Listing Qualifications Panel, or the Panel, approved this transfer after our market capitalization did not comply with the minimum market capitalization required for companies listed on The NASDAQ Global Market, and we presented a plan to the Panel for regaining compliance with the NASDAQ Marketplace Rules. On January 23, 2009, we received an Additional Staff Determination Letter from NASDAQ that stated that the NASDAQ staff had concluded that we had violated NASDAQ Marketplace Rule 4350(i)(1)(C) (now NASDAQ Marketplace Rule 5635), which requires shareholder approval in connection with an acquisition if the issuance or potential issuance is greater than 20% of the pre-acquisition shares outstanding, and that we had at times not complied with Marketplace Rule 4310(c)(17) regarding submission of a Listing of Additional Shares form. On February 18, 2009, we updated the Panel on our plan for regaining compliance and requested an extension of the deadline to regain compliance with the minimum market capitalization requirement for The NASDAQ Capital Market. On March 6, 2009, we were notified by NASDAQ that the Panel determined to continue the listing of our common stock on The NASDAQ Capital Market, subject to the condition that, on or before April 6, 2009, we demonstrated compliance with all applicable standards for continued listing on The NASDAQ Capital Market, including the $35.0 million minimum market capitalization requirement. In addition, the Panel issued a public reprimand for our prior failures to comply with the shareholder approval requirements and late filing of Listing of Additional Shares forms. On April 2, 2009, we were notified by NASDAQ that we had complied with the Panel s decision dated March 6, 2009, and, accordingly, the Panel determined to continue the listing of our common stock on The NASDAQ Capital Market.

NASDAQ reinstated the $1.00 minimum bid price requirement on August 3, 2009. On May 3, 2010, we received notice from NASDAQ indicating that for the last 30 consecutive business days the closing bid price of our common stock was below the minimum $1.00 per share requirement for continued listing of our common stock on The NASDAQ Capital Market under NASDAQ Marketplace Rule 5550(a)(2). This notification had no immediate effect on the listing of or the ability to trade our common stock on The NASDAQ Capital Market. In accordance with NASDAQ Marketplace Rule 5810(c)(3)(A), we were provided a grace period of 180 calendar days, or until November 1, 2010, to regain compliance. We would have achieved compliance if the bid price of our common stock closed at $1.00 per share or more for a minimum of ten consecutive trading days before November 1, 2010. In addition, we were eligible for an additional 180-day grace period if we met all of the initial listing standards of NASDAQ, with the exception of the closing bid price. On November 2, 2010, we received notice from NASDAQ that it granted us an additional 180 days, or until May 2, 2011, to regain compliance with the minimum $1.00 per share requirement for continued listing of our common stock on The NASDAQ Capital Market under NASDAQ Marketplace Rule 5550(a)(2).

On May 3, 2011, we received a notice from NASDAQ stating that we had not regained compliance with NASDAQ s $1.00 minimum bid price rule under NASDAQ Marketplace Rule 5550(a)(2). On May 5, 2011, in an effort to regain compliance with the NASDAQ listing requirements and increase the per-share trading price of our common stock, our board of directors approved a 1-for-6 reverse stock split. The reverse stock split became effective on May 15, 2011. On June 1, 2011, we announced that we received a letter from NASDAQ indicating that as of that date we had regained compliance with NASDAQ Marketplace Rule 5550(a)(2) and that as of that date we were in compliance with all applicable listing standards. As a result, our common stock will continue to be listed and traded on The NASDAQ Capital Market. However, notwithstanding our current compliance with NASDAQ listing standards, there can be no assurance that we will be able to maintain our continued listing on The NASDAQ Capital Market in the future.

The level of trading activity of our common stock may decline if it is no longer listed on The NASDAQ Capital Market. Furthermore, our failure to maintain a listing on The NASDAQ Capital Market may constitute an event of default under certain of our indebtedness which would accelerate the maturity date of such debt. As such, if our common stock ceases to be listed for trading on

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The NASDAQ Capital Market for any reason, it may harm our stock price, increase the volatility of our stock price and make it more difficult for investors to sell shares of our common stock. In the event our common stock is delisted from The NASDAQ Capital Market, we currently expect that our common stock would be eligible to be listed on the OTC Bulletin Board or Pink Sheets. We do not know what impact delisting from The NASDAQ Capital Market may have on our listing with the Borsa Italiana. Although we continue to be listed on The NASDAQ Capital Market, trading in our common stock may be halted or suspended due to market conditions or if NASDAQ, CONSOB or the Borsa Italiana determine that trading in our common stock is inadvisable. Trading in our common stock was halted by the Borsa Italiana on February 10, 2009, and, as a consequence, trading in our common stock was also halted by NASDAQ. After we provided CONSOB with additional information and clarification on our business operations and financial condition, as requested, and published a press release containing such information in Italy, the Borsa Italiana, and NASDAQ lifted the trading halts on our common stock. In addition, on March 23, 2009, the Borsa Italiana halted trading of our common stock on the MTA and resumed trading prior to the opening of the MTA the next day after we filed a press release regarding the explanatory paragraph in our auditor s reports on our December 31, 2008 and 2007 consolidated financial statements regarding their substantial doubt as to our ability to continue as a going concern. As a consequence, NASDAQ also halted trading in our common stock on March 23, 2009, but re-initiated trading later that day. Although we file press releases with CONSOB at the end of each month regarding our business and financial condition, CONSOB may make additional inquiries about our business and financial condition at any time, and there can be no guarantee that the Borsa Italiana, CONSOB or NASDAQ will not halt trading in our shares again in the future.

If our common stock ceases to be listed for trading on The NASDAQ Capital Market or the MTA, or both, for any reason, or if trading in our stock is halted or suspended on The NASDAQ Capital Market or the MTA, or both, such events may harm the trading price of our securities, increase the volatility of the trading price of our securities and make it more difficult for investors to buy or sell shares of our common stock. Moreover, if our common stock ceases to be listed for trading on The NASDAQ Capital Market or if trading in our stock is halted or suspended on The NASDAQ Capital Market, we may become subject to certain obligations. In addition, if we are not listed on The NASDAQ Capital Market and/or if our public float falls below $75 million, we will be limited in our ability to file new shelf registration statements on SEC Form S-3 and/or to fully use one or more registration statements on SEC Form S-3. We have relied significantly on shelf registration statements on SEC Form S-3 for most of our financings in recent years, so any such limitations may harm our ability to raise the capital we need.

We may be unable to obtain a quorum for meetings of our shareholders or obtain necessary shareholder approvals and therefore be unable to take certain corporate actions.

At our Annual Meeting held on November 11, 2011, our shareholders approved a proposal to amend our articles of incorporation to reflect an increase in the total number of authorized shares from 284,999,999 to 384,999,999 and an increase in our authorized shares of common stock from 283,333,333 to 383,333,333. However, in the future, if we are unable to obtain a quorum at our shareholder meetings, including the Annual Meeting, and/or fail to obtain shareholder approval of corporation actions, such failure could harm us. Our amended and restated articles of incorporation, or our articles of incorporation, require that a quorum, generally consisting of one-third of the outstanding shares of voting stock, be represented in person, by telephone or by proxy in order to transact business at a meeting of our shareholders. In addition, amendments to our articles of incorporation, such as an amendment to increase our authorized capital stock, generally require the approval of a majority of our outstanding shares. As a result, there is a risk that we may not get shareholder approval for amendments to our articles of incorporation, including amendments to increase the number of authorized shares of common stock at a time when we need those shares to effect a future equity financing. If we do not receive shareholder approval for such increase in authorized shares, our ability to raise capital through equity financings will be significantly harmed.

A substantial majority of our common shares are held by Italian institutions and, under Italian laws and regulations, it is difficult to communicate with the beneficial holders of those shares to obtain votes. In 2006, when a quorum required a majority of the outstanding shares of our voting stock be represented in person or by proxy, we scheduled two annual meetings of shareholders, but were unable to obtain quorum at either meeting. Following that failure to a obtain quorum, we contacted certain depository banks in Italy where significant numbers of shares of our common stock were held and asked them to cooperate by making a book-entry transfer of their share positions at Monte Titoli to their U.S. correspondent bank, who would then transfer the shares to an account of the Italian bank at a U.S. broker-dealer that is an affiliate of that bank. Certain of the banks contacted agreed to make the share transfer pursuant to these arrangements as of the record date of the meeting, subject to the relevant beneficial owner being given notice before such record date and taking no action to direct the voting of such shares. We were able to obtain a quorum to hold special meetings of the shareholders in April 2007, January 2008, March 2009 and June 2011 and annual meetings of the shareholders in September 2007, June 2008, October 2009 and September 2010. Nevertheless, obtaining a quorum at future meetings even at the lower threshold and obtaining necessary shareholder approvals will depend in part upon the willingness of the Italian depository banks to continue

participating in the custody transfer arrangements, and we cannot be assured that those banks that have participated in the past will continue to participate in custody transfer arrangements in the future. We are continuing to explore other alternatives to achieve a quorum for and shareholder representation at our meetings; however, we cannot be certain that we will find an alternate method if we are unable to continue to use the custody transfer arrangements. As a result, we may be unable to obtain a quorum at future annual or special meetings of shareholders or obtain shareholder approval of proposals when needed.

Even if we obtain a quorum at our shareholder meetings, we may not obtain enough votes to approve matters to be resolved upon at those meetings. Under Rule 452 of the New York Stock Exchange, or Rule 452, the U.S. broker-dealer may only vote shares absent direction from the beneficial owner on certain specified routine matters, such as certain amendments to our articles of incorporation to increase authorized shares that are to be used for general corporate purposes and the ratification of our auditors. If our shareholders do not instruct their brokers on how to vote their shares on non-routine matters, then we may not obtain the necessary number of votes for approval. Non-routine matters include, for example, proposals that relate to the authorization or creation of indebtedness or preferred stock. Revisions to Rule 452 that further limit matters for which broker discretionary voting is allowed, such as the recent revisions imposed by the Dodd-Frank Act to prohibit broker discretionary voting on matters related to executive compensation and in the election of directors, may further harm our ability to obtain a quorum and shareholder approval of certain matters. Therefore it is possible that even if we are able to obtain a quorum for our meetings of the shareholders we still may not receive enough votes to approve proxy proposals presented at such meeting and, depending on the proposal in question, including if a proposal is submitted to our shareholders to increase the number of authorized shares of common stock, such failure could harm us. For example, a proposal to approve a reverse stock split failed to receive sufficient votes to pass at the March 2009 shareholders meeting.

We may continue to incur net losses, and we may never achieve profitability.

We were incorporated in 1991 and have incurred a net operating loss every year since our formation. As of September 30, 2011, we had an accumulated deficit of $1.7 billion. We are pursuing regulatory approval for Pixuvri, OPAXIO, tosedostat, brostallicin and bisplatinates. We will need to conduct research, development, testing and regulatory compliance activities and undertake manufacturing and drug supply activities the costs of which, together with projected general and administrative expenses, may result in operating losses for the foreseeable future. We may never become profitable even if we are able to commercialize products currently in development or otherwise.

Our debt and operating expenses exceed our net revenues.

We have a substantial amount of debt outstanding, and our annual interest expense with respect to our debt is significant. Unless we raise substantial additional capital and reduce our operating expenses, we may not be able to pay all of our operating expenses or repay our debt or the interest on our debt, liquidated damages or other payments that may become due with respect to our debt. In the event we are unable to reduce our expenses and/or repay our debt or the interest on our debt, we may be required to limit or cease our operations, pursue a plan to sell our operating assets, seek bankruptcy protection, or otherwise modify our business strategy, which could materially harm our future business prospects. Bankruptcy may result in the termination of agreements pursuant to which we license certain intellectual property rights, including the rights to Pixuvri, OPAXIO, tosedostat, brostallicin and bisplatinates.

We may be unable to use our net operating losses to reduce future income tax liability.

We have substantial tax loss carryforwards for U.S. federal income tax purposes. As a result of prior changes in the stock ownership of the Company, our ability to use such carryforwards to offset future income or tax liability is limited under section 382 of the Internal Revenue Code of 1986, as amended. Moreover, future changes in the ownership of our stock, including those resulting from the issuance of shares of our common stock upon exercise of outstanding warrants, may further limit our ability to use our net operating losses.

We have received audit reports with a going concern disclosure on our consolidated financial statements.

As we may need to raise additional financing to fund our operations and satisfy obligations as they become due, our independent registered public accounting firm has included an explanatory paragraph in their reports on our December 31, 2010, 2009 and 2008 consolidated financial statements regarding their substantial doubt as to our ability to continue as a going concern. This may have a negative impact on the trading price of our common stock and we may have a more difficult time obtaining necessary financing.

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If we make any acquisitions, we will incur a variety of costs and may never realize the anticipated benefits.

If appropriate opportunities become available, we may attempt to acquire businesses and assets that we believe are a strategic fit with our business. We currently have no agreements to consummate any pending material acquisitions. If we pursue any such transaction, the process of negotiating the acquisition and integrating an acquired business and assets may result in operating difficulties and expenditures and may require significant management attention that would otherwise be available for ongoing development of our business, whether or not any such transaction is ever consummated. Moreover, we may never realize the anticipated benefits of any acquisition. Future acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities and/or amortization expenses related to goodwill and other intangible assets, which could harm our business, financial condition, operating results and prospects and the trading price of our securities.

The global financial crisis may have an impact on our business and financial condition in ways that we currently cannot predict, and may further limit our ability to raise additional funds.

The ongoing credit crisis and related turmoil in the global financial system has had and may continue to have an impact on our business and our financial condition. We may face significant challenges if conditions in the financial markets do not improve or continue to worsen. In particular, our ability to access the capital markets and raise funds required for our operations may be severely restricted at a time when we would like, or need, to do so, which could have an adverse effect on our ability to meet our current and future funding requirements and on our flexibility to react to changing economic and business conditions.

We are required to comply with the regulatory structure of Italy because our stock is traded on the MTA which could result in administrative and other challenges and additional expenses.

Our common stock is traded on the MTA and we are required to also comply with the rules and regulations of CONSOB and the Borsa Italiana, which ensures the development of the managed market in Italy. Collectively, these entities regulate companies listed on Italy s public markets. Conducting our operations in a manner that complies with all of the applicable laws and rules requires us to devote additional time and resources to regulatory compliance matters. For example, the process of seeking to understand and comply with the laws of each country, including tax, labor and regulatory laws, might require us to incur the expense of engaging additional outside counsel, accountants and other professional advisors and might result in delayed business initiatives as we seek to ensure that each new initiative will comply with all of the applicable regulatory regimes. In addition, the Borsa Italiana and CONSOB have made several requests for information asking us to provide additional clarifications about our business operations and financial condition, and we have complied with such requests and have met with CONSOB on several occasions to answer questions. Compliance with Italian regulatory requirements may delay additional issuances of our common stock; we are currently taking steps to attempt to conform to the requirements of the Italian stock exchange and CONSOB to allow such additional issuances.

In addition, under Italian law, we must publish a listing prospectus that has been approved by CONSOB prior to issuing common stock that exceeds, in any twelve-month period, 10% of the number of shares of our common stock outstanding at the beginning of that period (except for certain applicable exceptions).

If we are unable to maintain a listing prospectus to cover general financing efforts under Italian law, we may be required to raise money using alternative forms of securities. For example, we may need to use convertible preferred stock and convertible debt since the common stock resulting from the conversion of such securities, subject to the provisions of European Directive No. 71/2003 and according to the interpretations of the Committee of European Securities Regulators, is not subject to the 10% limitation imposed by EU and Italian law.

Moreover, on December 10, 2009, CONSOB sent us a notice claiming two violations of the provisions of Section 114, paragraph 1 of the Italian Legislative Decree no. 58/98 due to the asserted late disclosure of certain information then reported, at CONSOB s request, in press releases disseminated on December 19, 2008 and March 23, 2009. Such information concerned, respectively: (i) the conversion by BAM Opportunity Fund LP of 9.66% notes into shares of common stock that occurred between October 24, 2008 and November 19, 2008; and (ii) the contents of the opinion expressed by Stonefield Josephson, Inc., an independent registered public accounting firm, with respect to our 2008 financial statements. The sanctions established by Section 193, paragraph 1 of the Italian Legislative Decree no. 58/98 for such violations are pecuniary administrative sanctions amounting to between 5,000 and 500,000, or approximately $7,000 to $672,000 converted using the currency exchange rate as of September 30, 2011, applicable to each of the two asserted violations. According to the applicable Italian legal provisions, CONSOB may impose such administrative sanctions by means of a decree stating the grounds of its decision only after evaluating our possible defenses that

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were submitted to CONSOB on January 8, 2010 (within 30 days of December 10, 2009, the notification date of the relevant charges, according to the applicable Italian rules). On July 12, 2010, CONSOB (a) notified us that it had begun the preliminary investigation for its decision on these administrative proceedings and (b) provided us with a preliminary investigation report in response to our defenses submitted on January 8, 2010. On August 12, 2010 (within 30 days of July 12, 2010, the notification date of the beginning of the aforesaid preliminary investigation, according to the applicable Italian rules), we submitted further defenses that CONSOB would have to evaluate before imposing any possible administrative sanctions. In a letter dated March 10, 2011, CONSOB notified us of a resolution confirming the occurrence of the violation asserted in clause (i) above and applied a fine in the amount of 40,000, or approximately $55,000 converted using the foreign currency exchange rate as of March 10, 2011, which we paid on April 5, 2011. CONSOB has not yet notified us of a resolution with respect to the violation asserted in clause (ii) above, but based on our assessment, we believe the likelihood that a pecuniary administrative sanction will be imposed on the Company for such asserted violation (ii) is probable.

Our assets and liabilities that remain in our Italian branches make us subject to increased risk regarding currency exchange rate fluctuations.

We are exposed to risks associated with the translation of euro-denominated financial results and accounts into U.S. dollars. As long as we continue to have assets and liabilities held in our Italian branches the carrying value of these assets and liabilities will be affected by fluctuations in the value of the U.S. dollar as compared to the euro. Changes in the value of the U.S. dollar as compared to the euro might have an adverse effect on our reported results of operations and financial condition.

We may owe additional amounts for value added taxes related to our operations in Europe.

Our European operations are subject to value added tax, or VAT, which is usually applied to all goods and services purchased and sold throughout Europe. The VAT receivable is $5.2 million and 5.3 million as of September 30, 2011 and December 31, 2010, respectively. On April 14, 2009 and December 21, 2009, the ITA issued notices of assessment to CTI (Europe) based on the ITA s audit of CTI (Europe) s VAT returns for the years 2003 and 2005, respectively. On June 25, 2010, the ITA issued notices of assessment to CTI (Europe) for the years 2006 and 2007 based on similar findings for the 2003 and 2005 assessments. The ITA audits concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian clients for services performed by CTI (Europe). The assessments, including interest and penalties, for the years 2003, 2005, 2006 and 2007 are 0.5 million, 5.5 million, 2.5 million and 0.8 million, or approximately $0.7 million, $7.4 million, $3.4 million and $1.1 million converted using the currency exchange rate as of September 30, 2011, respectively. We believe that the services invoiced were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed. We are vigorously defending ourselves against the assessments both on procedural grounds and on the merits of the case. If the decisions of the Provincial Tax Court of Milan, or the Tax Court, for the different VAT cases are unfavorable, then we expect to appeal to the higher courts in order to further defend our interests. However, if we are unable to successfully defend ourselves against the assessments issued by the ITA, we may be requested to pay to the ITA an amount ranging from 4.9 million to 9.4 million, or approximately $6.6 million to $12.6 million converted using the currency exchange rate as of September 30, 2011, plus collection fees, notification expenses and additional interest for the period lapsed between the date in which the assessments were issued and the date of effective payment. On February 2, 2011, we paid to the ITA the required deposit in respect of the 2005 VAT in the amount of 1.5 million, or approximately $2.1 million converted using the currency exchange rate as of February 2, 2011. On March 4, 2011, we paid to the ITA the required deposit in respect of the 2006 VAT in the amount of 0.4 million, or approximately $0.6 million converted using the currency exchange rate as of March 4, 2011. On March 25, 2011, we paid to the Italian collection agent an additional 0.1 million, or approximately $0.1 million converted using the currency exchange rate as of March 25, 2011. On September 26, 2011, we paid to the ITA the required deposit in respect of the 2007 VAT in the amount of 0.1 million or approximately $0.1 million converted using the currency exchange rate as of September 26, 2011. Further information pertaining to these cases can be found in this prospectus supplement under Summary Recent Developments and is incorporated by reference herein.

Our financial condition may be adversely affected if third parties default in the performance of contractual obligations.

Our business is dependent on the performance by third parties of their responsibilities under contractual relationships and if third parties default on their performance of their contractual obligations, we could suffer significant financial losses and operational problems, which could in turn adversely affect our financial performance, cash flows or results of operations and may jeopardize our ability to maintain our operations.

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We may not realize any royalties, milestone payments or other benefits under the License and Co-Development Agreement entered into with Novartis.

We have entered into a License and Co-Development agreement related to OPAXIO and Pixuvri with Novartis pursuant to which Novartis received an exclusive worldwide license for the development and commercialization of OPAXIO and an option to enter into an exclusive worldwide license to develop and commercialize Pixuvri. We will not receive any royalty or milestone payments under this agreement unless Novartis exercises its option related to Pixuvri and we are able to reach a definitive agreement or Novartis elects to participate in the development and commercialization of OPAXIO. Novartis is under no obligation to make such election and enter into a definitive license agreement or exercise such right and may never do so. In addition, even if Novartis exercises such rights, any royalties and milestone payments we may be eligible to receive from Novartis are subject to the receipt of the necessary regulatory approvals and the attainment of certain sales levels. We may never receive the necessary regulatory approvals and our products may not reach the necessary sales levels to generate royalty or milestone payments even if Novartis elects to exercise its option with regard to Pixuvri and enter into a definitive license agreement or to participate in the development and commercialization of OPAXIO. Novartis has the right under the agreement in its sole discretion to terminate such agreement at any time upon written notice to us.

In the event Novartis does not elect to participate in the development of OPAXIO or Pixuvri, we may not be able to find another suitable partner for the commercialization and development of those products, which may have an adverse effect on our ability to bring those drugs to market. In addition, we would need to obtain a release from Novartis prior to entering into any agreement to develop and commercialize Pixuvri or OPAXIO with a third party. Further information about the status of the regulatory approval for Pixuvri can be found in Risk Factors Risks Related to Our Company We cannot guarantee that we will obtain regulatory approval to manufacture or market any of our drug candidates.

We cannot guarantee that we will obtain regulatory approval to manufacture or market any of our drug candidates.

Obtaining regulatory approval to market drugs to treat cancer is expensive, difficult and risky. Preclinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval. Negative or inconclusive results or adverse medical events during a clinical trial could delay, limit or prevent regulatory approval.

At the ODAC meeting on March 22, 2010, the ODAC panel did not recommend approval of our NDA for Pixuvri. Subsequently, in April 2010, we received a Complete Response Letter from the FDA regarding our NDA for Pixuvri. The FDA cited as its primary reason for the action its concerns previously raised at the ODAC meeting on March 22, 2010, and recommended that we conduct one additional clinical trial to demonstrate the safety and efficacy of Pixuvri. In December 2010, we filed an appeal with the OND s Center for Drug Evaluation and Research regarding the FDA s April 2010 decision to not approve Pixuvri for relapsed or refractory aggressive NHL. We filed our appeal under the FDA s formal dispute resolution process asking the OND to conclude that PIX301 demonstrated efficacy.

On May 3, 2011, we announced that the OND responded to our December 2010 appeal of the FDA s April 2010 decision to not approve Pixuvri for relapsed or refractory aggressive NHL. In its response, the OND indicated that after considering the data available in the appeal, it does not believe that accelerated approval of our NDA is necessarily out of reach based on a single controlled clinical trial, provided that two key matters can be resolved satisfactorily. First, the circumstances of stopping the PIX301 trial early must be resolved to assure that ongoing results assessment were not dictating the decision to stop. Second, ascertainment of the primary endpoint in the PIX301 study must be determined to have been sound and not subject to bias. The OND also indicated that our request that the OND find that the data in the NDA demonstrate efficacy and return the NDA to the Office of Oncology Drug Products for consideration of safety and other issues was denied because the OND was not able to conclude that efficacy had been demonstrated. However, the OND also did not find that it could be concluded that PIX301 was a failed study, which warranted application of interim analysis statistical thresholds.

On June 14, 2011, we announced that we had met with the DODP in a meeting that focused on the documents we proposed to provide regarding the circumstances of stopping the enrollment of PIX301 prior to achieving the original planned patient accrual and the make-up of the new radiology expert panel as well as our plan to address items noted in the FDA s Complete Response Letter. The DODP confirmed that the NDA would be reviewed within six months from the resubmission of the NDA. On October 25, 2011, we announced the resubmission of the NDA to the DODP for accelerated approval to treat relapsed or refractory aggressive NHL in patients who failed two or more lines of prior therapy. On December 6, 2011, we announced that the FDA s Division of Oncology Products 1 had notified us that the resubmitted NDA is a complete, Class 2 response to the Complete Response Letter for the NDA and that the FDA has set a set a PDUFA goal date of April 24, 2012 for a decision on the NDA. However, you should not infer that the aforementioned developments increase the likelihood of FDA approval of the NDA or that the FDA, OND or DODP will not require additional actions or information.

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Moreover, the FDA may request that we conduct more clinical trials in addition to PIX-R to obtain FDA approval of our NDA for Pixuvri and we do not know what this trial will cost or how long it would take to execute this study and provide additional information to the FDA. In March 2011, we initiated a randomized pivotal trial of Pixuvri for the treatment of relapsed or refractory DLBCL. This clinical trial, referred to as PIX306 or PIX-R, is now open to patient enrollment. PIX-R will compare a combination of Pixuvri plus rituximab to a combination of gemcitabine plus rituximab in patients with relapsed or refractory DLBCL who have received one to three prior lines of therapy. We cannot predict the outcome of PIX-R or whether PIX-R will serve as either a post-marketing commitment trial or as a pivotal trial. We may also need to take additional steps to obtain regulatory approval of Pixuvri. The expense to design and conduct clinical trials are substantial and any additional clinical trials or actions we may need to pursue to obtain approval of our NDA for Pixuvri may negatively affect our business, financial condition and results of operations.

We may be delayed, limited or precluded from obtaining regulatory approval of OPAXIO as a maintenance therapy for advanced stage ovarian cancer.

Our future financial success depends in part on obtaining regulatory approval of OPAXIO. We are currently focusing our development of OPAXIO as a potential maintenance therapy for women with advanced stage ovarian cancer who achieve a complete remission following first-line therapy with paclitaxel and carboplatin. This study, the GOG0212 trial, is under the control of the GOG and is expected to enroll 1,100 patients with 817 patients enrolled as of September 30, 2011. The GOG Data Monitoring Committee plans to conduct an interim analysis of overall survival and, based on feedback provided by the GOG, an interim analysis is currently expected in mid-2012. If successful, we could utilize those results to form the basis of an NDA for OPAXIO. However, prior clinical trials for OPAXIO have not been successful. In March 2005, we announced the results of STELLAR 3, and in May 2005, we announced the results of STELLAR 2 and 4, our phase III clinical trials of OPAXIO in NSCLC. All three trials failed to achieve their primary endpoints of superior overall survival compared to current marketed agents for treating NSCLC. Accordingly, there can be no assurance that the GOG0212 will provide compelling evidence or any positive results, which would preclude our planned submission of an NDA to the FDA. In addition, we cannot predict the outcome of the GOG0212 study and that study may not demonstrate or be adequate to support regulatory approval of OPAXIO by the FDA.

In March 2008, we submitted an MAA to the EMA for first-line treatment of patients with advanced NSCLC who are poor performance status, or PS2, based on a non-inferior survival and improved side effect profile which we believe was demonstrated in our previous clinical trials. The application was based on a positive opinion we received from the SAWP; the EMA agreed that switching the primary endpoint from superiority to non-inferiority is feasible if the retrospective justification provided in the marketing application is adequate. In September 2009, we notified the EMA of our decision to withdraw the MAA and we refocused our resources on the approval of OPAXIO for its potential superiority indication in maintenance therapy for ovarian cancer and as a radiation sensitizer in the treatment of esophageal cancer.

We are subject to extensive government regulation.

We are subject to rigorous and extensive regulation by the FDA in the United States and by comparable agencies in other states and countries, including the EMA s review of our MAA for Pixuvri. Failure to comply with regulatory requirements could result in various adverse consequences, including possible delay in approval or refusal to approve a product, withdrawal of approved products from the market, product seizures, injunctions, regulatory restrictions on our business and sales activities, monetary penalties, or criminal prosecution.

Our products may not be marketed in the United States until they have been approved by the FDA and may not be marketed in other countries until they have received approval from the appropriate agencies. None of our current product candidates have received approval for marketing in any country. On April 13, 2009, we began submission of a rolling NDA to the FDA for Pixuvri to treat relapsed or refractory aggressive NHL. We completed the submission in June 2009 and as announced on April 9, 2010, we received a Complete Response Letter from the FDA regarding our NDA for Pixuvri. The FDA cited as its primary reason for the action its concerns previously raised at the ODAC meeting on March 22, 2010 and recommended that we conduct an additional trial to demonstrate the safety and effectiveness of Pixuvri. In December 2010, we filed an appeal with the OND s Center for Drug Evaluation and Research regarding the FDA s April 2010 decision to not approve Pixuvri for relapsed or refractory aggressive NHL. We filed our appeal under the FDA s formal dispute resolution process asking the OND to conclude that PIX301 demonstrated efficacy.

On May 3, 2011, we announced that the OND responded to our December 2010 appeal of the FDA s April 2010 decision to not approve Pixuvri for relapsed or refractory aggressive NHL. In its response, the OND indicated that after considering the data available in the appeal, it does not believe that accelerated approval of our NDA is necessarily out of reach based on a single

controlled clinical trial, provided that two key matters can be resolved satisfactorily. First, the circumstances of stopping the PIX301 trial early must be resolved to assure that ongoing results assessment were not dictating the decision to stop. Second, ascertainment of the primary endpoint in the PIX301 study must be determined to have been sound and not subject to bias. The OND also indicated that our request that the OND find that the data in the NDA demonstrate efficacy and return the NDA to the Office of Oncology Drug Products for consideration of safety and other issues was denied because the OND was not able to conclude that efficacy had been demonstrated. However, the OND also did not find that it could be concluded that PIX301 was a failed study, which warranted application of interim analysis statistical thresholds. The OND further indicated that we could re-submit the NDA for a re-review of the safety and efficacy, provided that the two key matters can be resolved satisfactorily.

On June 14, 2011, we announced that we had met with the DODP in a meeting that focused on the documents we proposed to provide regarding the circumstances of stopping the enrollment of PIX301 prior to achieving the original planned patient accrual and the make-up of the new radiology expert panel. The DODP confirmed that the NDA would be reviewed within six months from the resubmission of the NDA. On October 25, 2011, we announced the resubmission of the NDA to the DODP for accelerated approval to treat relapsed or refractory aggressive NHL in patients who failed two or more lines of prior therapy. On December 6, 2011, we announced that the FDA s Division of Oncology Products 1 had notified us that the resubmitted NDA is a complete, Class 2 response to the Complete Response Letter for the NDA and that the FDA has set a set a PDUFA goal date of April 24, 2012 for a decision on the NDA. However, you should not infer that the aforementioned developments increase the likelihood of FDA approval of the NDA.

Obtaining regulatory approval requires substantial time, effort and financial resources, and we may not be able to obtain approval of any of our products on a timely basis, or at all. In addition, data obtained from preclinical and clinical trials are susceptible to varying interpretations, and government regulators and our collaborators may not agree with our interpretation of our clinical trial results. If our products are not approved quickly enough to provide net revenues to defray our debt and operating expenses, our business, financial condition and results of operations will be adversely affected.

In the event that we receive marketing approval for any of our product candidates, we will be subject to numerous regulations and statutes regulating the manner of selling and obtaining reimbursement for those products. For example, federal statutes generally prohibit providing certain discounts and payments to physicians to encourage them to prescribe our product. Violations of such regulations or statutes may result in treble damages, criminal or civil penalties, fines or exclusion of us or our employees from participation in federal and state health care programs. Although we have policies prohibiting violations of relevant regulations and statutes, unauthorized actions of our employees or consultants, or unfavorable interpretations of such regulations or statutes may result in third parties or regulatory agencies bringing legal proceedings or enforcement actions against us. Because we will likely need to develop a new sales force for any future marketed products, we may have a greater risk of such violations from lack of adequate training or experience. The expense to retain and pay legal counsel and consultants to defend against any such proceedings would be substantial, and together with the diversion of management s time and attention to assist in any such defense, may negatively affect our business, financial condition and results of operations.

In addition, both before and after approval, our contract manufacturers and our products are subject to numerous regulatory requirements covering, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, distribution and export. Manufacturing processes must conform to current Good Manufacturing Practice, or cGMPs. The FDA and other regulatory authorities periodically inspect manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort to maintain compliance. Failure to comply with FDA, EMA or other applicable regulations may cause us to curtail or stop the manufacture of such products until we obtain regulatory compliance.

The marketing and promotion of pharmaceuticals is also heavily regulated, particularly with regard to prohibitions on the promotion of products for off-label uses. In April 2007, we paid a civil penalty of $10.6 million and entered into a settlement agreement with the United States Attorney s Office for the Western District of Washington arising out of their investigation into certain of our prior marketing practices relating to TRISENOX, which was divested to Cephalon Inc. in July 2005. As part of that settlement agreement and in connection with the acquisition of Zevalin, we also entered into a corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services, which required us to establish a compliance committee and compliance program and adopt a formal code of conduct.

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We face direct and intense competition from our competitors in the biotechnology and pharmaceutical industries, and we may not compete successfully against them.

Competition in the oncology market is intense and is accentuated by the rapid pace of technological development. We anticipate that we will face increased competition in the future as new companies enter the market. Our competitors in the United States and elsewhere are numerous and include, among others, major multinational pharmaceutical companies, specialized biotechnology companies and universities and other research institutions. Specifically:

- If we are successful in bringing Pixuvri to market, Pixuvri will face competition from currently marketed anthracyclines, such as mitoxantrone (Novantrone®), and new anti-cancer drugs with reduced toxicity that may be developed and marketed.

- If we are successful in bringing OPAXIO to market, we will face direct competition from oncology-focused multinational corporations. OPAXIO will compete with other taxanes. Many oncology-focused multinational corporations currently market or are developing taxanes, epothilones, and other cytotoxic agents, which inhibit cancer cells by a mechanism similar to taxanes, or similar products. Such corporations include, among others, Bristol-Myers Squibb Co. and others, which market paclitaxel and generic forms of paclitaxel; Sanofi-Aventis, which markets docetaxel; Genentech, Roche and OSI Pharmaceuticals, which market Tarceva ; Genentech and Roche, which market Avastin ; Eli Lilly, which markets Alimta®; and Abraxis, which markets Abraxane . In addition, other companies such as NeoPharm Inc. and Telik, Inc. are also developing products, which could compete with OPAXIO.

- If we are successful in bringing tosedostat to market, we will face direct competition from oncology-focused multinational corporations including Eisai, Sanofi-Aventis, Celgene, and others. Currently some generic compounds are also available which may be used in treating conditions where tosedostat may have application, this could result in additional competitive pressure on price and volume. Additionally there are other products in development for AML from both large and small pharmaceutical companies which may compete with tosedostat.

- If we are successful in bringing brostallicin to market, we will face direct competition from other minor groove binding agents including Yondelis®, which is currently developed by PharmaMar and has received Authorization of Commercialization from the European Commission for soft tissue sarcoma.

Many of our competitors, particularly the multinational pharmaceutical companies, either alone or together with their collaborators, have substantially greater financial resources and substantially larger development and marketing teams than us. In addition, many of our competitors, either alone or together with their collaborators, have significantly greater experience than we do in developing, manufacturing and marketing products. As a result, these companies products might come to market sooner or might prove to be more effective, less expensive, have fewer side effects or be easier to administer than ours. In any such case, sales of our current or future products would likely suffer and we might never recoup the significant investments we are making to develop these product candidates.

Uncertainty regarding third-party reimbursement and healthcare cost containment initiatives may limit our returns.

The ongoing efforts of governmental and third-party payors to contain or reduce the cost of healthcare may affect our ability to commercialize our products successfully. Governmental and other third-party payers continue to attempt to contain healthcare costs by:

- challenging the prices charged for health care products and services;

- limiting both coverage and the amount of reimbursement for new therapeutic products;

denying or limiting coverage for products that are approved by the FDA but are considered experimental or investigational by third-party payors;

refusing in some cases to provide coverage when an approved product is used for disease indications in a way that has not received FDA marketing approval; and

denying coverage altogether.

The continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners and the availability of capital. In the United States, given the comprehensive health care reform legislation that the President signed into law on March 23, 2010, under the Patient Protection

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and Affordable Care Act (HR 3590), or the PPACA, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of healthcare services and products and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of these proposals could significantly influence the purchase of healthcare services and products, resulting in lower prices and reducing demand for our products. In addition, in almost all European markets, pricing and choice of prescription pharmaceuticals are subject to governmental control. Therefore, the price of our products and their reimbursement in Europe will be determined by national regulatory authorities.

Even if we succeed in bringing any of our proposed products to the market, they may not be considered cost-effective and third-party reimbursement might not be available or sufficient. If adequate third-party coverage is not available, we may not be able to maintain price levels sufficient to realize an appropriate return on our investment in research and product development. In addition, legislation and regulations affecting the pricing of pharmaceuticals may change in ways adverse to us before or after any of our proposed products are approved for marketing.

If users of our products are unable to obtain adequate reimbursement from third-party payers, or if new restrictive legislation is adopted, market acceptance of our products may be limited and we may not achieve anticipated revenues.

Our ability to commercialize our products will depend in part on the extent to which appropriate reimbursement levels for the cost of our products and related treatment are obtained by governmental authorities, private health insurers and other organizations, such as health maintenance organizations, or HMOs. Third-party payers are increasingly challenging the prices charged for medical care. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and products, as well as legislative proposals to further reform health care or reduce government insurance programs, may all result in lower prices for our products if approved for commercialization. The cost containment measures that health care payers and providers are instituting and the effect of any health care reform could materially harm our ability to sell our products at a profit.

Products that appear promising in research and development may be delayed or fail to reach later stages of development or the market.

The successful development of pharmaceutical products is highly uncertain and obtaining regulatory approval to market drugs to treat cancer is expensive, difficult and risky. Products that appear promising in research and development may be delayed or fail to reach later stages of development or the market for several reasons, including:

- clinical trial results may show the product to be less effective than desired or to have harmful or problematic side effects;
- preclinical tests may show the product to be toxic or lack efficacy in animal models;
- failure to receive the necessary U.S. and international regulatory approvals or a delay in receiving such approvals;
- difficulties in formulating the product, scaling the manufacturing process or getting approval for manufacturing;
- manufacturing costs, pricing, reimbursement issues or other factors may make the product uneconomical to commercialize;
- other companies or people have or may have proprietary rights to a product candidate, such as patent rights, and will not let the product candidate be sold on reasonable terms, or at all; or
- the product candidate is not cost effective in light of existing therapeutics.

Preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Negative or inconclusive results or adverse medical events during a clinical trial could delay, limit or prevent regulatory approval. In addition, any significant problem in the production of our products, such as the inability of a supplier to provide raw materials or supplies used to manufacture our products, equipment obsolescence, malfunctions or failures, product quality or contamination problems, or changes in regulatory requirements or standards that require modifications to our manufacturing process could delay, limit or prevent regulatory approval which could harm our business, financial condition and results or the trading price of our securities. There can be no assurance as to whether or when we will receive regulatory approvals for our products.

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If any of our license agreements for intellectual property underlying Pixuvri, OPAXIO, tosedostat, brostallicin, bisplatinates or any other products are terminated, we may lose the right to develop or market that product.

We have licensed intellectual property, including patent applications relating to intellectual property for Pixuvri, tosedostat, brostallicin and bisplatinates. We have also in-licensed the intellectual property for our drug delivery technology relating to OPAXIO which uses polymers that are linked to drugs, known as polymer-drug conjugates. Some of our product development programs depend on our ability to maintain rights under these licenses. Each licensor has the power to terminate its agreement with us if we fail to meet our obligations under these licenses. We may not be able to meet our obligations under these licenses. If we default under any license agreement, we may lose our right to market and sell any products based on the licensed technology.

We hold rights under numerous patents that protect inventions originating from our research and development, and the expiration of any one or more of these patents may allow our competitors to copy the inventions that are currently protected.

We dedicate significant resources to protecting our intellectual property, which is important to our business. We have filed numerous patent applications in the U.S. and various other countries seeking protection of inventions originating from our research and development and we have also obtained rights to various patents and patent applications under licenses with third parties. Patents have been issued on many of these applications. We have issued patents pending or issued in the U.S. and foreign countries directed to Pixuvri, OPAXIO, brostallicin, bisplatinates and other product candidates. However, the lives of these patents are limited. Patents for the individual products extend for varying periods according to the date of the patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The Pixuvri-directed patents will expire in 2014; the OPAXIO-directed patents will expire on various dates ranging from 2017 through 2018; and the brostallicin-directed patents will expire on various dates ranging from 2017 to 2023. Although such patent expiration ranges are only for U.S. issued patents and do not account for potential extensions that may be available in certain countries (for example, certain Pixuvri-directed patents may be subject to possible patent-term extensions that could provide extensions through 2019 in the U.S. and 2021 in Europe), there can be no assurance that such extensions will be obtained. The expiration of these patents may allow our competitors to copy the inventions that are currently protected and better compete with us.

If there is an adverse outcome in the securities class actions and shareholder derivative litigation that have been filed against us, our business may be harmed.

In March 2010, three purported securities class action complaints were filed against the Company and certain of its officers and directors in the United States District Court for the Western District of Washington. On August 2, 2010, Judge Marsha Pechman consolidated the actions, appointed lead plaintiffs, and approved lead plaintiffs counsel. On September 27, 2010, lead plaintiff filed an amended consolidated complaint, captioned Sabbagh v. Cell Therapeutics, Inc. (Case No. 2:10-cv-00414-MJP), naming the Company, Dr. James A. Bianco, Louis A. Bianco, and Craig W. Philips as defendants. The amended consolidated complaint alleges that defendants violated the federal securities laws by making certain alleged false and misleading statements related to the FDA approval process for pixantrone. The action seeks damages on behalf of purchasers of the Company s stock during a purported class period of March 25, 2008 through March 22, 2010. On October 27, 2010, defendants moved to dismiss the amended consolidated complaint. On February 4, 2011, the Court denied in large part the defendants motion. Defendants answered the amended consolidated complaint on March 28, 2011. Discovery has commenced, and the Court has set a trial date of June 25, 2012.

In April 2010, three shareholder derivative complaints were filed against the Company and certain of its officers and directors in the United States District Court for the Western District of Washington. These derivative complaints allege that defendants breached their fiduciary duties to the Company by making or failing to prevent the issuance of certain alleged false and misleading statements related to the FDA approval process for pixantrone. The allegations in the derivative actions are substantially similar to those in the securities action. On May 10, 2010, Judge Marsha Pechman consolidated the shareholder derivative actions under the caption Shackleton v. Bauer (Case No. 2:10-cv-00414-MJP), and appointed the law firms of Robbins Umeda LLP and Federman & Sherwood as co-lead counsel for derivative plaintiffs. Three more derivative complaints were filed in June, July and October 2010, and they have also been consolidated with Shackleton v. Bauer. The parties have agreed to coordinate discovery in the derivative and securities actions. Pursuant to the parties stipulation, the Court has stayed the deadline for the derivative plaintiffs to file an amended complaint until March 12, 2012 (45 days after the scheduled close of discovery in the securities class action), and briefing on any motion to dismiss will follow. The court has set a trial date of December 3, 2012 for the shareholder derivative action. As with any litigation proceeding, we cannot predict with certainty the eventual outcome of pending litigation. Furthermore, we may have to incur substantial expenses in connection with these lawsuits. In the event of an adverse outcome, our business could be materially harmed.

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If we fail to adequately protect our intellectual property, our competitive position could be harmed.

Development and protection of our intellectual property are critical to our business. If we do not adequately protect our intellectual property, competitors may be able to practice our technologies. Our success depends in part on our ability to:

- obtain patent protection for our products or processes both in the United States and other countries;
- protect trade secrets; and
- prevent others from infringing on our proprietary rights.

When polymers are linked, or conjugated, to drugs, the results are referred to as polymer-drug conjugates. We are developing drug delivery technology that links chemotherapy to biodegradable polymers. For example, OPAXIO is paclitaxel, the active ingredient in Taxol®, one of the world s best selling cancer drugs, linked to polyglutamate. We may not receive a patent for all of our polymer-drug conjugates and we may be challenged by the holder of a patent covering the underlying drug and/or methods for its use or manufacture.

The patent position of biopharmaceutical firms generally is highly uncertain and involves complex legal and factual questions. The U.S. Patent and Trademark Office has not established a consistent policy regarding the breadth of claims that it will allow in biotechnology patents. If it allows broad claims, the number and cost of patent interference proceedings in the United States and the risk of infringement litigation may increase. If it allows narrow claims, the risk of infringement may decrease, but the value of our rights under our patents, licenses and patent applications may also decrease. Patent applications in which we have rights may never issue as patents and the claims of any issued patents may not afford meaningful protection for our technologies or products. In addition, patents issued to us or our licensors may be challenged and subsequently narrowed, invalidated or circumvented. Litigation, interference proceedings or other governmental proceedings that we may become involved in with respect to our proprietary technologies or the proprietary technology of others could result in substantial cost to us. Patent litigation is widespread in the biotechnology industry, and any patent litigation could harm our business. Costly litigation might be necessary to protect a patent position or to determine the scope and validity of third-party proprietary rights, and we may not have the required resources to pursue any such litigation or to protect our patent rights. Any adverse outcome in litigation with respect to the infringement or validity of any patents owned by third parties could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using a product or technology.

We also rely upon trade secrets, proprietary know-how and continuing technological innovation to remain competitive. Third parties may independently develop such know-how or otherwise obtain access to our technology. While we require our employees, consultants and corporate partners with access to proprietary information to enter into confidentiality agreements, these agreements may not be honored.

Our products could infringe upon the intellectual property rights of others, which may cause us to engage in costly litigation and, if unsuccessful, could cause us to pay substantial damages and prohibit us from selling our products.

We attempt to monitor patent filings for patents that may be relevant to our products and product candidates in an effort to guide the design and development of our products to avoid infringement, but have not conducted an exhaustive search. We may not be able to successfully challenge the validity of these patents and could be required to pay substantial damages, possibly including treble damages, for past infringement and attorneys fees if it is ultimately determined that our products infringe a third-party s patents. Further, we may be prohibited from selling our products before we obtain a license, which, if available at all, may require us to pay substantial royalties. Moreover, third parties may challenge the patents that have been issued or licensed to us. Even if infringement claims against us are without merit, or if we challenge the validity of issued patents, lawsuits take significant time, may be expensive and may divert management attention from other business concerns.

We could fail in financing efforts or be delisted from NASDAQ if we fail to receive shareholder approval when needed.

We are required under the NASDAQ Marketplace Rules to obtain shareholder approval for any issuance of additional equity securities that would comprise more than 20% of the total shares of our common stock outstanding before the issuance of such securities sold at a discount to the greater of book or market value in an offering that is not deemed to be a public offering by the NASDAQ Marketplace Rules or NASDAQ. Funding of our operations in the future may require issuance of additional equity securities that would comprise more than 20% of the total shares of our common stock outstanding, but we might not be successful in

obtaining the required shareholder approval for such an issuance, particularly in light of the difficulties we have experienced in obtaining a quorum and holding shareholder meetings as outlined above. If we are unable to obtain financing due to shareholder approval difficulties, such failure may harm our ability to continue operations.

We may be unable to obtain the raw materials necessary to produce our OPAXIO product candidate in sufficient quantity to meet demand when and if such product is approved.

We may not be able to continue to purchase the materials necessary to produce OPAXIO, including paclitaxel, in adequate volume and quality. Paclitaxel is derived from certain varieties of yew trees and the supply of paclitaxel is controlled by a limited number of companies. We purchase the raw materials paclitaxel and polyglutamic acid from single sources. Should the paclitaxel or polyglutamic acid purchased from our sources prove to be insufficient in quantity or quality, should a supplier fail to deliver in a timely fashion or at all, or should these relationships terminate, we may not be able to qualify and obtain a sufficient supply from alternate sources on acceptable terms, or at all.

Our dependence on third-party manufacturers means that we do not always have direct control over the manufacture, testing or distribution of our products.

We do not currently have internal analytical laboratory or manufacturing facilities to allow the testing or production and distribution of drug products in compliance with cGMPs. Because we do not directly control our suppliers, these vendors may not be able to provide us with finished product when we need it.

We will be dependent upon these third parties to supply us in a timely manner with products manufactured in compliance with cGMPs or similar manufacturing standards imposed by United States and/or foreign regulatory authorities where our products will be tested and/or marketed. While the FDA and other regulatory authorities maintain oversight for cGMP compliance of drug manufacturers, contract manufacturers and contract service providers may at times violate cGMPs. The FDA and other regulatory authorities may take action against a contract manufacturer who violates cGMPs. Failure to comply with FDA, EMA or other applicable regulations may cause us to curtail or stop the manufacture of such products until we obtain regulatory compliance.

In addition, one of our other products under development, OPAXIO, has a complex manufacturing process and supply chain, which may prevent us from obtaining a sufficient supply of drug product for the clinical trials and commercial activities currently planned or underway on a timely basis, if at all. The active pharmaceutical ingredients and drug products for Pixuvri and brostallicin are both manufactured by a single vendor. Finished product manufacture and distribution for both Pixuvri and brostallicin are to be manufactured and distributed by different single vendors. We are currently disputing our right to cancel the exclusive manufacturing contract between us and the former manufacturer of Pixuvri. We assert multiple grounds for terminating this exclusive manufacturing agreement, which the former manufacturer disputes. The former manufacturer has asserted that we do not have the right to terminate the manufacturing contracts and has filed a lawsuit in the Court of Milan to compel us to source Pixuvri from that manufacturer. A hearing was held on January 21, 2010 to discuss preliminary matters and set a schedule for future filings and hearings. On November 11, 2010 a hearing was held aimed at examining and discussing the requests for evidence submitted by the parties in the briefs filed pursuant to article 183, paragraph 6 of the Italian code of civil procedure. At the hearing of November 11, the judge declared that the case does not require any discovery or evidentiary phase, as it may be decided on the basis of the documents and pleadings filed by the parties. The judge fixed accordingly the last hearing for October 11, 2012, for the parties to definitively submit to the judge their requests.

Even if our drug candidates are successful in clinical trials, we may not be able to successfully commercialize them.

Since our inception in 1991, we have dedicated substantially all of our resources to the research and development of our technologies and related compounds. All of our compounds currently are in research or development, and have not received marketing approval.

Prior to commercialization, each product candidate requires significant research, development and preclinical testing and extensive clinical investigation before submission of any regulatory application for marketing approval. The development of anti-cancer drugs, including those we are currently developing, is unpredictable and subject to numerous risks. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons including that they may:

- be found ineffective or cause harmful side effects during preclinical testing or clinical trials;

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fail to receive necessary regulatory approvals;

be difficult to manufacture on a scale necessary for commercialization;

be uneconomical to produce;

fail to achieve market acceptance; or

be precluded from commercialization by proprietary rights of third parties.

The occurrence of any of these events could adversely affect the commercialization of our products. Products, if introduced, may not be successfully marketed and/or may not achieve customer acceptance. If we fail to commercialize products or if our future products do not achieve significant market acceptance, we will not likely generate significant revenues or become profitable.

If we do not successfully develop our product candidates into marketable products, we may be unable to generate significant revenue or become profitable.

We divested our commercial product, TRISENOX, in July 2005 and fully divested our commercial product, Zevalin, in March 2009. Currently, we do not have a marketed product, and unless we are able to develop one of our product candidates, such as Pixuvri, into an approved commercial product, we will not generate any significant revenues from product sales, royalty payments, license fees or otherwise. Pixuvri, OPAXIO, tosedostat and brostallicin are currently in clinical trials and bisplatinates are in preclinical development; the development and clinical trials of these products may not be successful and, even if they are, we may not be successful in developing any of them into a commercial product. For example, our STELLAR phase III clinical trials for OPAXIO for the treatment of non-small cell lung cancer failed to meet their primary endpoints. In addition, a number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in advanced clinical trials, even after reporting promising results in earlier trials. We will need to commit significant time and resources to develop these and any additional product candidates. Even if our trials are viewed as successful, we may not get regulatory approval. Our product candidates will be successful only if:

our product candidates are developed to a stage that will enable us to commercialize them or sell related marketing rights to pharmaceutical companies;

we are able to commercialize product candidates in clinical development or sell the marketing rights to third parties; and

our product candidates, if developed, are approved by the regulatory authorities.

We are dependent on the successful completion of these goals in order to generate revenues. The failure to generate such revenues may preclude us from continuing our research and development of these and other product candidates.

If we are unable to enter into new in-licensing arrangements, our future product portfolio and potential profitability could be harmed.

One component of our business strategy is in-licensing drug compounds developed by other pharmaceutical and biotechnology companies or academic research laboratories. All of our product candidates in clinical and preclinical development are in-licensed from a third-party, including Pixuvri, OPAXIO, tosedostat, brostallicin and bisplatinates.

Competition for new promising compounds and commercial products can be intense. If we are not able to identify future in-licensing opportunities and enter into future licensing arrangements on acceptable terms, our future product portfolio and potential profitability could be harmed.

We may take longer to complete our clinical trials than we expect, or we may not be able to complete them at all.

Before regulatory approval for any potential product can be obtained, we must undertake extensive clinical testing on humans to demonstrate the safety and efficacy of the product. Although for planning purposes we forecast the commencement and completion of clinical trials, the actual timing of these events can vary dramatically due to a number of factors. For example:

- we may not obtain authorization to permit product candidates that are already in the preclinical development phase to enter the human clinical testing phase;

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- the FDA or the EMA may object to proposed protocols;
- there may be shortages of available product supplies or the materials that are used to manufacture the products;
- the quality or stability of the product candidates may fall below acceptable standards;
- authorized preclinical or clinical testing may require significantly more time, resources or expertise than originally expected to be necessary;
- clinical testing may not show potential products to be safe and efficacious and, as with many drugs, may fail to demonstrate the desired safety and efficacy characteristics in human clinical trials;
- clinical testing may show that potential products are not appropriate for the specific indication for which they are being tested;
- the results from preclinical studies and early clinical trials may not be indicative of the results that will be obtained in later-stage clinical trials;
- we or regulatory authorities may suspend clinical trials at any time on the basis that the participants are being exposed to unacceptable health risks or for other reasons; and
- the rates of patient recruitment and enrollment of patients who meet trial eligibility criteria may be lower than anticipated, which is a function of many factors, including the number of patients with the relevant conditions, the nature of the clinical testing, the proximity of patients to clinical testing centers, the eligibility criteria for tests as well as competition with other clinical testing programs involving the same patient profile but different treatments.

We have limited experience in conducting clinical trials. We expect to continue to rely on third parties, such as contract research organizations, academic institutions and/or cooperative groups, to conduct, oversee and monitor clinical trials as well as to process the clinical results and manage test requests, which may result in delays or failure to complete trials if the third parties fail to perform or to meet the applicable standards.

If we fail to commence, complete, experience delays in any of our present or planned clinical trials or need to perform more or larger clinical trials than planned, our development costs may increase and/or our ability to commercialize our product candidates may be adversely affected. If delays or costs are significant, our financial results and our ability to commercialize our product candidates may be adversely affected.

If we fail to establish and maintain collaborations or if our partners do not perform, we may be unable to develop and commercialize our product candidates.

We have entered into collaborative arrangements with third-parties to develop and/or commercialize product candidates and are currently seeking additional collaborations. For example, we entered into an agreement with the GOG to perform a phase III trial of OPAXIO in patients with ovarian cancer. Additional collaborations might be necessary in order for us to fund our research and development activities and third-party manufacturing arrangements, seek and obtain regulatory approvals and successfully commercialize our existing and future product candidates. If we fail to enter into additional collaborative arrangements or fail to maintain our existing collaborative arrangements, the number of product candidates from which we could receive future revenues would decline. For example, in 2005 we sold our product TRISENOX to Cephalon and, pursuant to the terms of the purchase agreement under which TRISENOX was sold, we are entitled to receive milestone payments upon the approval by the FDA of new labeled uses for TRISENOX; however, Cephalon may decide not to submit any additional information to the FDA to apply for label expansion of TRISENOX, in which case we would not receive a milestone payment under the agreement.

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Our dependence on collaborative arrangements with third parties will subject us to a number of risks that could harm our ability to develop and commercialize products, including that:

- collaborative arrangements may not be on terms favorable to us;
- disagreements with partners may result in delays in the development and marketing of products, termination of our collaboration agreements or time consuming and expensive legal action;
- we cannot control the amount and timing of resources partners devote to product candidates or their prioritization of product candidates and partners may not allocate sufficient funds or resources to the development, promotion or marketing of our products, or may not perform their obligations as expected;
- partners may choose to develop, independently or with other companies, alternative products or treatments, including products or treatments which compete with ours;
- agreements with partners may expire or be terminated without renewal, or partners may breach collaboration agreements with us;
- business combinations or significant changes in a partner s business strategy might adversely affect that partner s willingness or ability to complete its obligations to us; and
- the terms and conditions of the relevant agreements may no longer be suitable.

The occurrence of any of these events could adversely affect the development or commercialization of our products.

Because we base several of our drug candidates on unproven technologies, we may never develop them into commercial products.

We base several of our product candidates upon novel technologies that we are using to develop drugs for the treatment of cancer. These technologies have not been proven. Furthermore, preclinical results in animal studies may not predict outcomes in human clinical trials. Our product candidates may not be proven safe or effective. If these technologies do not work, our drug candidates will not develop into commercial products.

Because there is a risk of product liability associated with our products, we face potential difficulties in obtaining insurance.

Our business exposes us to potential product liability risks inherent in the testing, manufacturing and marketing of human pharmaceutical products, and we may not be able to avoid significant product liability exposure. While we have insurance covering the product use in our clinical trials for our product candidates, it is possible that we will not be able to maintain such insurance on acceptable terms or that any insurance obtained will not provide adequate coverage against potential liabilities. Our inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or limit the commercialization of any products we develop. A successful product liability claim in excess of our insurance coverage could exceed our net worth.

Since we use hazardous materials in our business, we may be subject to claims relating to improper handling, storage or disposal of these materials.

Our research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds. We are subject to international, federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by the regulations, the risk of accidental contamination or injury from these materials cannot be eliminated completely.

In the event of such an accident, we could be held liable for any damages that result and any such liability not covered by insurance could exceed our resources. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts.

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We may not be able to conduct animal testing in the future, which could harm our research and development activities.

Certain of our research and development activities involve animal testing. Such activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting activities through protests and other means. To the extent the activities of these groups are successful, our business could be materially harmed by delaying or interrupting our research and development activities.

The unfavorable outcome of litigation and other claims against us could harm our financial condition and results of operations.

We are subject to a variety of claims and lawsuits from time to time, some of which arise in the ordinary course of our business. Adverse outcomes in some or all of such pending cases may result in significant monetary damages or injunctive relief against us. While we currently believe that resolution of these matters, individually or in the aggregate, will not have a material adverse impact on our financial position, results of operations or trading price of our securities, the ultimate outcome of litigation and other claims is subject to inherent uncertainties, and our view of these matters may change in the future. It is possible that our financial condition and results of operations could be harmed in any period in which the effect of an unfavorable final outcome becomes probable and reasonably estimable.

Our financial condition and results of operations could be adversely affected by public health issues, wars and other military action, as well as terrorist attacks and threats and government responses thereto, especially if any such actions were directed at us or our facilities or customers.

Public health issues, terrorist attacks in the United States and elsewhere, government responses thereto, and military actions in Iraq, Afghanistan and elsewhere, may disrupt our operations or those of our customers and suppliers and may affect the availability of materials needed to manufacture our products or the means to transport those materials to manufacturing facilities and finished products to customers. A health pandemic could cause damage or disruption to international commerce by creating economic and political uncertainties that may have a strong negative impact on the global economy, us, and our customers or suppliers. Should a severe public health issues arise, we could be negatively impacted by the need for more stringent employee travel restrictions, additional limitations in the availability of freight services, governmental actions limiting the movement of products between various regions and disruptions in the operations of our customers or suppliers. The long-term effects public health issues, the terrorist attacks, and the ongoing war on terrorism on our business and on the global economy remain unknown. In addition, any of these events could increase volatility in the United States and world financial markets which may depress the price of our common stock and may limit the capital resources available to us or our customers or suppliers, which could result in decreased orders from customers, less favorable financing terms from suppliers, and scarcity or increased costs of materials and components of our products. Additionally, terrorist attacks directly upon us may significantly disrupt our ability to conduct our business. Any of these occurrences could have a significant impact on our operating results, revenues and costs and may result in increased volatility of the trading price of our securities.

Higher health care costs could adversely affect our business.

We will be impacted by the recent passage of the PPACA. Under the PPACA, we may be required to amend our health care plans to, among other things, provide affordable coverage, as defined in the PPACA, to all employees, or otherwise be subject to a payment per employee based on the affordability criteria in the Act: cover adult children of our employees to age 26; delete lifetime limits; and delete pre-existing condition limitations. Many of these requirements will be phased in over a period of time. Additionally, some states and localities have passed state and local laws mandating the provision of certain levels of health benefits by some employers. Increased health care costs could harm our business, financial condition and results of operations.

Risks Related to this Offering

There is no public market for the Series 14 Preferred Stock or warrants being offered in this offering.

There is no established public trading market for the Series 14 Preferred Stock or warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series 14 Preferred Stock or warrants on any securities exchange. Without an active market, the liquidity of the Series 14 Preferred Stock and warrants will be limited.

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Purchasers of Series 14 Preferred Stock and warrants who convert their shares of Series 14 Preferred Stock into common stock or exercise their warrants for shares common stock will incur immediate dilution.

Upon conversion or exercise of your shares of Series 14 Preferred Stock or warrants, as the case may be, you will experience immediate and substantial dilution because the per share conversion price of your shares of Series 14 Preferred Stock and the exercise price of your warrants will be higher than the net tangible book value per share of the outstanding common stock immediately after this offering. In addition, you will experience dilution when we issue additional shares of common stock that we are permitted or required to issue under outstanding options and warrants and under our stock option plan or other employee or director compensations plans.

Holders of our Series 14 Preferred Stock will have no rights as a holder of common stock until they acquire common stock.

Until you acquire shares of common stock upon conversion or exercise of the Series 14 Preferred Stock and warrants, as the case may be, you will have no rights with respect to our common stock, other than the right of the convertible preferred stock to receive dividends equal to and in the same term as dividends actually paid on common stock, including rights to vote or respond to tender offers. Upon conversion or exercise of your Series 14 Preferred Stock or warrants, as the case may be, you will be entitled to exercise the rights of a holder of common stock only as to matters for which the record date occurs after the conversion or exercise date.

Since we have broad discretion in how we use the net proceeds from this offering, we may use the net proceeds in ways in which you disagree.

We will use a portion of the net proceeds from this offering for general corporate purposes. We may use a portion of the net proceeds from this offering to fund possible investments in, or acquisitions of, complementary businesses, technologies or products. See Use of Proceeds. We have not allocated specific amounts of the net proceeds from this offering for any specific purpose. Accordingly, our management will have significant flexibility in applying the net proceeds of this offering. You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for our company. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flow.

Risks Related to Holders of our Common Stock

Shares of common stock are equity securities and are subordinate to our existing and future indebtedness.

Shares of our common stock are common equity interests. This means that our common stock ranks junior to the Series 14Preferred Stock and any other preferred stock that we may issue in the future, to our indebtedness and to all creditor claims and other non-equity claims against us and our assets available to satisfy claims on us, including claims in a bankruptcy or similar proceeding. Our existing and future indebtedness and our preferred stock may restrict payment of dividends on our common stock.

Additionally, unlike indebtedness, where principal and interest customarily are payable on specified due dates, in the case of our common stock, (i) dividends are payable only when and if declared by our board of directors or a duly authorized committee of our board of directors, and (ii) as a corporation, we are restricted to making dividend payments and redemption payments out of legally available assets. We have never paid a dividend on our common stock and have no current intention to pay dividends in the future. Furthermore, our common stock places no restrictions on our business or operations or on our ability to incur indebtedness or engage in any transactions, subject only to the voting rights available to shareholders generally.

The market price of shares of our common stock may be adversely affected by market conditions affecting the stock markets in general, including price and trading fluctuations on The NASDAQ Capital Market.

The market price of our common stock may be adversely affected by market conditions affecting the stock markets in general, including price and trading fluctuations on The NASDAQ Capital Market. These conditions may result in (i) volatility in the level of, and fluctuations in, the market prices of stocks generally and, in turn, our shares of common stock, and (ii) sales of substantial amounts of our common stock in the market, in each case that could be unrelated or disproportionate to changes in our operating performance.

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There may be future sales or other dilution of our equity, which may adversely affect the market price of shares of our common stock.

We are not restricted from issuing additional shares of common stock or preferred stock, including any securities that are convertible into or exchangeable for, or that represent the right to receive, shares of common stock or preferred stock, or any substantially similar securities. The market price of our shares of common stock or preferred stock could decline as a result of sales of a large number of shares of our common stock or preferred stock or similar securities in the market, or the perception that such sales could occur in the future.

The market price of shares of our common stock is extremely volatile, which may affect our ability to raise capital in the future and may subject the value of your investment in our securities to sudden decreases.

The market price for securities of biopharmaceutical and biotechnology companies, including ours, historically has been highly volatile, and the market from time to time has experienced significant price and volume fluctuations that are unrelated to the operating performance of such companies. For example, during the 12-month period ended December 8, 2011, our stock price has ranged from a low of $0.95 to a high of $3.30 (as adjusted to reflect the 1-for-6 reverse stock split effected on May 15, 2011). Fluctuations in the trading price or liquidity of our common stock may adversely affect the value of your investment in our common stock.

Factors that may have a significant impact on the market price and marketability of our securities include:

- announcements by us or others of results of preclinical testing and clinical trials and regulatory actions;
- announcements of technological innovations or new commercial therapeutic products by us, our collaborative partners or our present or potential competitors;
- our issuance of additional debt, equity or other securities, which we need to pursue in 2011 to generate additional funds to cover our current debt and operating expenses;
- our quarterly operating results;
- developments or disputes concerning patent or other proprietary rights;
- developments in our relationships with collaborative partners;
- acquisitions or divestitures;
- litigation and government proceedings;
- adverse legislation, including changes in governmental regulation;
- third-party reimbursement policies;

changes in securities analysts recommendations;

short selling;

changes in health care policies and practices;

halting or suspension of trading in our common stock by NASDAQ, CONSOB or the Borsa Italiana;

economic and other external factors; and

general market conditions.

In the past, following periods of volatility in the market price of a company s securities, securities class action litigation has often been instituted. For example, in the case of our company, we and certain of our officers and directors are named as defendants in purported securities class action and shareholder derivative lawsuits brought on behalf of a putative class of purchasers of our

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securities from March 25, 2008 through March 22, 2010. These lawsuits seek unspecified damages and, as with any litigation proceeding, we cannot predict with certainty the eventual outcome of pending litigation. Furthermore, we may have to incur substantial expenses in connection with these lawsuits and our management s attention and resources could be diverted from operating our business as we respond to the litigation. We maintain significant insurance to cover these risks for us and our directors and officers, but our insurance is subject to high deductibles to reduce premium expense, and there is no guarantee that the insurance will cover any specific claim that we currently face or may face in the future, or that it will be adequate to cover all potential liabilities and damages.

Anti-takeover provisions in our charter documents, in our Shareholder Rights Agreement, or rights plan, and under Washington law could make removal of incumbent management or an acquisition of us, which may be beneficial to our shareholders, more difficult.

Provisions of our articles of incorporation and amended and restated bylaws may have the effect of deterring or delaying attempts by our shareholders to remove or replace management, to commence proxy contests, or to effect changes in control. These provisions include:

- a classified board so that only approximately one third of our board of directors is elected each year;