CELL THERAPEUTICS INC Form S-3ASR July 31, 2009 Table of Contents

As filed with the Securities and Exchange Commission on July 31, 2009

Registration No. 333-\_\_\_\_

# **UNITED STATES**

# **SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

# FORM S-3

# **REGISTRATION STATEMENT**

UNDER

**THE SECURITIES ACT OF 1933** 

# **CELL THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

Washington (State of other jurisdiction of

Incorporation or Organization)

2834 (Primary Standard Industrial

**Classification Code Number**)

91-1533912 (I.R.S. Employer Identification No.)

Table of Contents

# Edgar Filing: CELL THERAPEUTICS INC - Form S-3ASR

501 Elliott Avenue West, Suite 400

Seattle, Washington 98119

(206) 282-7100

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

James A. Bianco, M.D.

**Chief Executive Officer** 

**Cell Therapeutics, Inc.** 

501 Elliott Avenue West, Suite 400

Seattle, Washington 98119

(206) 282-7100

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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#### Approximate date of commencement of proposed sale to the public:

From time to time after the effective date of this registration statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. "

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If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. x

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definition of accelerated filer, large accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer "

Non-accelerated filer " (Do not check if a smaller reporting company)

CALCULATION OF REGISTRATION FEE

Title of Each Class of			Proposed Maximum Aggregate Offering	
	Amount to be			Amount of
Securities To Be Registered	Registered (1)	Price Per Unit	Price (2)	<b>Registration Fee</b>
Common Stock, no par value per share	8,432,981	\$1.485	\$12,522,977	\$699

- (1) Pursuant to Rule 416(a) under the Securities Act, this registration statement shall be deemed to cover any additional shares of common stock that become issuable as a result of stock dividends, stock splits and similar transactions effected without receipt of consideration that result in an increase in the number of outstanding shares of the registrant s common stock.
- (2) Estimated solely for purposes of calculating the amount of the registration fee pursuant to Rule 457(c) under the Securities Act based on the average of the high and low sale prices of the registrant s common stock on the NASDAQ Capital Market on July 30, 2009.

Accelerated filer x

Smaller reporting company

### PROSPECTUS

Making cancer more treatable

### Up to 8,432,981 Shares of Common Stock

This prospectus relates to up to 8,432,981 shares of our common stock, no par value, to be offered from time to time by us upon the exercise of warrants issued and sold by us in connection with our underwritten public offering of shares of common stock and the warrants on July 22, 2009.

Each warrant described in this prospectus entitles its holder to purchase .25 shares of common stock at an exercise price of \$1.70 per share of common stock. The warrants are currently exercisable and must be exercised on or before April 28, 2010.

The warrants are not listed on any national securities exchange. Our common stock is quoted on The NASDAQ Capital Market and on the MTA stock market in Italy under the symbol CTIC . On July 30, 2009, the last reported sale price of our common stock on The NASDAQ Capital Market was \$1.49.

Investing in our securities involves a high degree of risk. See <u>Risk Factors</u> beginning on page 7 for a discussion of material risks 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 is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is July 31, 2009

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

We are not making an offer of our common stock covered by this prospectus in any jurisdiction where the offer is not permitted.

You should not assume that the information contained in or incorporated by reference in this prospectus is accurate as of any date other than the respective dates thereof.

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## **ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or the SEC, utilizing a shelf registration process. This prospectus relates to the offer of up to 8,432,981 shares of our common stock to be offered from time to time by us upon the exercise of warrants issued and sold by us in connection with our underwritten public offering of shares of common stock and the warrants on July 22, 2009.

You should read this prospectus and the documents that we incorporate by reference in this prospectus, and the additional information described below under Where You Can Find More Information before making an investment decision. You should rely only on the information contained or incorporated by reference in this prospectus. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

You should not assume that the information in this prospectus or any documents we incorporate by reference is accurate as of any date other than the date on the front of those documents only. Our business, financial condition, results of operations and prospectus may have changed since those dates.

This prospectus contains and incorporates by reference market data, industry statistics and other data that have been obtained from, or compiled from, information made available by third parties. We have not independently verified their data.

In this prospectus, the terms CTI, Company, we, us, our and similar terms refer to Cell Therapeutics, Inc., a Washington corporation, 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 SEC. Such reports, proxy statements and other information filed by us are available to the public free of charge at http://www.sec.gov. Copies of certain information filed by use with the SEC are also available on our website at http://www.celltherapeutics.com. You may also read and copy any document we file 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.

Because our common stock is listed on The NASDAQ Capital Market, you may also inspect such reports, proxy statements and other information concerning us at the offices of The NASDAQ Stock Market, 1735 K Street, N.W., Washington, D.C. 20006.

This prospectus is part of a registration statement we filed with the SEC. This prospectus omits 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 we are offering. Statements in this 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.

### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Exchange Act. All statements other than statements of historical fact are forward-looking statements for purposes of these provisions, including:

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 regarding future operations, plans, regulatory filings or approvals;

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

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, estimates, continue. could. expects. potential, predicts, should or will or the negative thereof or other comparable terms. Such statements are based on management s cur plans, 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 described in the section of this prospectus entitled Risk Factors. All forward-looking statements and reasons why results may differ included in this prospectus 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.

### SUMMARY

The following summary highlights information contained elsewhere, or incorporated by reference, in this 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, including the financial statements and the documents incorporated by reference.

### **Our Company**

We focus on the development, acquisition and commercialization of drugs for the treatment of cancer. Our principal business strategy is focused on cancer therapeutics; an area with significant market opportunity that we believe is not adequately served by existing therapies. Our operations are primarily conducted in the United States and we are winding down our operations in Italy. During 2008, we had one approved drug, Zevalin<sup>®</sup> (ibritumomab tiuxetan), or Zevalin, which we acquired in 2007, generating product sales. We contributed Zevalin to a joint venture, RIT Oncology, LLC, or RIT Oncology, upon its formation in December 2008 and in March 2009 we finalized the sale of our 50% interest in RIT Oncology to the other member of the joint venture, Spectrum Pharmaceuticals, Inc., or Spectrum. All of our current product candidates, including pixantrone, OPAXIO and brostallicin are under development.

### **Recent Developments**

### Debt and Equity Restructurings

In February 2009, 200 shares of Series A Preferred Stock, 2,218 shares of Series B Preferred Stock and 4,284 shares of Series C Preferred Stock were exchanged for 6,702 shares of Series F Preferred Stock.

On April 1 and 2, 2009, all shares of Series F Preferred Stock were converted into 47,871,425 shares of common stock.

On April 7, 2009, we issued 288,517 shares of common stock in exchange for 100 shares of Series A Preferred Stock and associated warrants to purchase 747 shares of common stock.

On April 17, 2009, we issued 3,452,493 shares of common stock in exchange for 1,000 shares of Series D Preferred Stock and associated warrants to purchase 19,138 shares of common stock.

On April 13, 2009, we entered into a securities purchase agreement by and between the Company and a single institutional investor pursuant to which we agreed to issue in a registered offering 15,000 shares of Series 1 Preferred Stock, no par value, or the Series 1 Preferred, convertible into 50,000,000 shares of common stock at a conversion price of \$0.30 per share, for a purchase price of \$1,000 per share of Series 1 Preferred and associated warrants, Class A warrants to purchase 9,183,562 shares of common stock and Class B Warrants to purchase 13,316,438 shares of common stock. In addition, the original holder of the Series 1 Preferred had, pursuant to the terms of the Series 1 Preferred, the right to purchase up to 5,000 additional shares of Series 1 Preferred in April 2009. The Class A Warrants were exercisable immediately, and on May 6, 2009, the holder exercised all of the Class A Warrants resulting in our issuance of 9,183,562 shares of common stock and our receipt of approximately \$3.8 million in proceeds from the exercise thereof. The Class B Warrants will become exercisable beginning on October 14, 2009 and will terminate on October 14, 2014. The exercise price per share of common stock issuable upon exercise of the Class B Warrants is \$0.41 per share of common stock (subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting shares of common stock). In connection with the offering described above, we expect to recognize a deemed dividend on the Series 1 Preferred of approximately \$8.2 million in our consolidated statement of operations for the three and six months ended June 30, 2009.

On May 11, 2009, we received aggregate gross proceeds of \$20.0 million in connection with our issuance of 16,000,000 shares of common stock and warrants to purchase 4,800,000 shares of common stock sold pursuant to a purchase agreement we entered into on that date.

On June 22, 2009, we exchanged \$7,117,336.50 in cash and 24,235,986 shares of common stock for \$52,917,000.00 aggregate principal amount of outstanding various series of convertible notes in connection with our five separate concurrent exchange offers for any and all of such convertible notes. The exchange offers commenced on May 12, 2009 and expired on June 16, 2009. All notes accepted by us in the exchange offers have been cancelled.

On July 28, 2009, we received aggregate gross proceeds of approximately \$43.9 million in connection with our underwritten public offering of 33,731,923 shares of common stock and the warrants described in this prospectus to purchase up to 8,432,981 shares of common stock.

### **Restructuring of Resources**

In connection with the sale of our 50% interest in RIT Oncology to Spectrum as discussed above, we announced an immediate reduction in force and plans for an additional reduction of employees following the termination of services to RIT Oncology. These positions were directly and indirectly involved in the sales and marketing, medical affairs and other operations of Zevalin. As of March 31, 2009, 22 employees had been terminated, with nine of these employees receiving employment or consulting positions with Spectrum.

During the first quarter of 2009, we announced that we had engaged the services of a strategic advisory consulting firm to assist in developing strategic options for a partnership, asset divestment or joint venture for our Italian branch. As of May 5, 2009, we had exhausted our efforts in finding a partner or buyer and the termination of our Bresso employees was planned. On May 13, 2009, we entered into an agreement with the unions representing the employees of the Bresso facility in connection with the closure of that facility. The agreement relates to a reduction of our total headcount in Italy by 56 positions in the immediate months. We have also sent notices of termination to the six managers of the Bresso facility and will seek to enter into separate severance arrangements with these managers.

## Lack of Liquidity

Our available cash and cash equivalents are approximately \$0.7 million as of March 31, 2009. In addition, in April 2009, we received \$6.5 million in gross proceeds from Spectrum in connection with the sale of our 50% interest in RIT Oncology to Spectrum, as well as \$20.0 million in gross proceeds from the issuance of 20,000 shares of our Series 1 Preferred Stock. We also received \$3.8 million in May 2009 for the exercise of all Class A Warrants related to our Series 1 Preferred Stock. On May 11, 2009, we received aggregate gross proceeds of \$20.0 million in connection with our issuance of common stock and warrants to purchase common stock. On June 22, 2009, we paid approximately \$7.1 million in cash in connection with our separate concurrent exchange offers for any and all of our outstanding various series of convertible notes. On July 28, 2009, we received aggregate gross proceeds of approximately \$43.9 million in connection with our underwritten public offering of shares of common stock and the warrants described in this prospectus. Even with these additional financings, we expect to have sufficient cash to fund our planned operations through January 2010. Accordingly, we have implemented cost saving initiatives to reduce operating expenses, including the reduction of employees related to Zevalin operations and our planned closure of our operations in Italy, and we continue to seek additional areas for cost reductions. However, we will also need to raise additional funds and are currently exploring alternative sources of equity or debt financing. We may seek to raise such capital through public or private equity financings, partnerships, joint ventures, dispositions of assets, debt financings or restructurings, bank borrowings or other sources. Additional funding may not be available on favorable terms or at all, and we are subject to certain regulatory and contractual limitations on our financing activities, which may limit our ability to raise additional funding. If additional funds are raised by issuing equity securities, substantial dilution to existing shareholders may result. If we fail to obtain additional capital when needed, we may be required to delay, scale back, or eliminate some or all of our research and development programs.

### **Corporate Information**

We were incorporated in the State of Washington in 1991. Our shares of common stock trade on The NASDAQ Capital Market 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 http://www.celltherapeutics.com; however, the information in, or that can be accessed through, our website is not part of this prospectus.

# THE OFFERING

Securities we are offering pursuant to this prospectus	Up to 8,432,981 shares of common stock to be offered by us from time to time upon the exercise of warrants issued and sold in connection with our underwritten public offering of shares of common stock and warrants on July 22, 2009. Each warrant entitles the holder to purchase .25 shares of common stock at an exercise price of \$1.70 per share of common stock. The warrants are currently exercisable and must be exercised on or before April 28, 2010.
Use of proceeds after expenses	We intend to use the proceeds we receive from the issuance of common stock upon the exercise of warrants, if any, for working capital and 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. See Use of Proceeds.
Risk factors	This investment involves a high degree of risk. See Risk Factors beginning on page 7 of this prospectus.
Market for the common stock and warrants	The warrants are not listed on any national securities exchange. Our common stock is quoted on The NASDAQ Capital Market and on the MTA stock market in Italy under the symbol CTIC. On July 30, 2009, the last reported sale price of our common stock on The NASDAQ Capital Market was \$1.49.
Common stock to be outstanding after this offering	544,492,556 shares (assuming all of the warrants described in this prospectus are exercised).

The number of shares of common stock that will be outstanding immediately after this offering is based on 536,059,575 shares of common stock outstanding as of July 30, 2009 and excludes the following:

outstanding options to purchase a total of 426,042 shares of common stock at a weighted-average exercise price of \$122.41 per share;

21,735,218 shares of common stock issuable from time to time upon exercise of warrants outstanding prior to this offering other than the warrants described in this prospectus;

80,301 shares of common stock issuable upon conversion of our outstanding 4% convertible senior subordinated notes due 2010;

363,766 shares of common stock issuable upon conversion of our outstanding 5.75% convertible senior notes due 2011;

14,264 shares of common stock issuable upon conversion of our outstanding 6.75% convertible senior notes due 2010; and

122,620 shares of common stock issuable upon conversion of our outstanding 7.5% convertible senior notes due 2011.

## **RISK FACTORS**

You should carefully consider the risks described below and other information in this prospectus and the documents incorporated by reference before deciding to invest in our securities. If any of the following risks actually occur, they could materially adversely affect our business, financial condition, operating results or prospects. 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.

## **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 the shares of our common stock rank junior to any 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 may restrict payment of dividends on our shares of common stock.

Additionally, unlike indebtedness, where principal and interest customarily are payable on specified due dates, in the case of shares 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 shares of common stock and have no current intention to pay dividends in the future. Further, our shares of common stock place 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.

### There may be future sales or other dilution of our equity, which may adversely affect the market price of our shares of 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 after consummation of this offering or the perception that such sales could occur in the future.

# The market price for our shares of 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 twelve month period ended July 30, 2009, our stock price has ranged from a low of \$0.05 to a high of \$3.80. 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 2009 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, beginning in March 2005, several class action lawsuits were instituted against us and certain of our directors and officers and a derivative action lawsuit was filed against our full board of directors. While these lawsuits were dismissed with prejudice, as a result of these types of lawsuits, we could incur substantial legal fees 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 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 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 amended and restated 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 of directors so that only approximately one third of our board of directors is elected each year;

elimination of cumulative voting in the election of directors;

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procedures for advance notification of shareholder nominations and proposals;

the ability of our board of directors to amend our amended and restated bylaws without shareholder approval; and

the ability of our board of directors to issue shares of preferred stock without shareholder approval upon the terms and conditions and with the rights, privileges and preferences as the board of directors may determine.

In addition, as a Washington corporation, we are subject to Washington law which imposes restrictions on some transactions between a corporation and certain significant shareholders. These provisions, alone or together, could have the effect of deterring or delaying changes in incumbent management, proxy contests or changes in control.

## **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.

We have substantial operating expenses associated with the development of our product candidates. As of March 31, 2009, we had cash and cash equivalents of approximately \$0.7 million, which does not take into account \$6.5 million in gross proceeds received from Spectrum on April 3, 2009 in connection with the sale of our 50% interest in RIT Oncology to Spectrum, as well as \$20.0 million in gross proceeds received in April 2009 for the issuance of 20,000 shares of our Series 1 Preferred Stock, Class A Warrants and Class B Warrants. In May 2009, we received \$3.8 million in connection with the exercise of all Class A Warrants issued in connection with our issuance of Series 1 Preferred Stock, Class A Warrants and Class B Warrants, and \$20.0 million in gross proceeds in connection with our issuance of 16,000,000 shares of common stock and warrants to purchase 4,800,000 shares of common stock sold pursuant to a purchase agreement we entered into on May 11, 2009. In June 2009, we completed the exchange offers pursuant to which we exchanged approximately \$7.1 million in cash and approximately 24.2 million shares of common stock for approximately \$52.9 million aggregate principal amount of our outstanding various series of convertible notes. On July 28, 2009, we received aggregate gross proceeds of approximately \$43.9 million in connection with our underwritten public offering of shares of common stock and the warrants described in this prospectus.

As of March 31, 2009, our total current liabilities were approximately \$36.9 million and we also had a substantial amount of debt outstanding. Subsequent to the exchange offers, the aggregate principal balance of our outstanding various series of convertible notes as of June 30, 2009 was approximately \$66.1 million with interest rates ranging from 4% to 7.5%. We expect that our existing cash and cash equivalents, securities available-for-sale, interest receivable and proceeds received from our offerings to date will provide sufficient working capital to fund our presently anticipated operations through January 2010 and we therefore need to raise additional capital. We also have substantial existing debt. There can be no assurance 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.

# Additional funds may not be available on acceptable terms, or at all; if we fail to raise significant additional funds we may be forced to cease development of our products and operations.

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. However, additional funding may not be available on favorable terms or at all and we are subject to certain regulatory and contractual limitations on our financing activities, which may limit our ability to raise 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 pixantrone, OPAXIO and brostallicin, and may be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection.

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, such as our transfer of Zevalin assets to RIT Oncology and our subsequent sale of our 50% interest in RIT Oncology.

In addition, some financing alternatives may require us to meet additional regulatory requirements in Italy and the United States, which may increase our costs and adversely affect our ability to obtain financing. To the extent that we raise additional capital through the sale of equity securities, or securities convertible into our equity securities, our shareholders may experience dilution of their proportionate ownership of us.

## If we are unable to obtain financing, we may need to implement a reduction in expenses across our operations.

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 may need to implement a number of 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, would 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, or otherwise modify our business strategy, which could materially harm our future business prospects.

We are currently in the process of closing down our Italian operations that were used primarily for pre-clinical research and were underutilized due to our current focused business model on the development of late-stage compounds and their commercialization. On May 13, 2009, we entered into an agreement with the unions representing the employees of the Bresso facility in connection with the closure of that facility. The agreement relates to a reduction of our total headcount in Italy by 56 positions in the immediate months, and is expected to save us approximately \$14 million in annual operating expenses going forward. In addition, we have sent notices of termination to the six managers of the Bresso facility and will seek to enter into separate severance arrangements with these managers. We expect to complete the closure of the Bresso facility by October 2009.

### 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 March 31, 2009, we had an accumulated deficit of approximately \$1.3 billion. We are pursuing regulatory approval for pixantrone, OPAXIO and brostallicin. We will need to conduct research, development, testing and regulatory compliance activities and undertake manufacturing and drug supply activities, expenses 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 and we need to raise capital to continue to fund our operations. Unless we raise substantial additional capital and reduce our operating expenses, we will not be able to pay all of our operating expenses or repay our debt or the interest, liquidated damages or other payments that may become due with respect to our debt.

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

Due to our 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, 2008 and December 31, 2007 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.

# Our common stock is listed on The NASDAQ Capital Market and the MTA stock market in Milan, 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 million. The NASDAQ 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, or the Determination Letter, from The NASDAQ Stock Market, or NASDAQ, that stated the NASDAQ staff had concluded that we had violated Marketplace Rule 4350(i)(1)(C) (now 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 had 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 demonstrate compliance with all applicable standards for continued listing on The NASDAQ Capital Market, including the \$35 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 had determined to continue the listing of our common stock on The NASDAQ Stock Market.

As of May 5, 2009, our stock price was below \$1.00. Although NASDAQ has suspended the \$1.00 minimum bid price requirement through July 31, 2009, there can be no assurances that our stock price will be above \$1.00 when the minimum bid price requirement is reinstated, nor can there be any assurance that NASDAQ will further extend the suspension of such requirement. At our Special Meeting of Shareholders held on March 24, 2009, the proposal to allow the Board, in its discretion, to effect a reverse stock split of our common stock was not approved by the shareholders. In the event that our stock price is below \$1.00 when the minimum bid price requirement is reinstated, we may not be able to effect a reverse stock split to increase our stock price if we are unable to obtain shareholder approval of a reverse stock split in the future.

In the event our common stock is delisted from the NASDAQ markets, 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 markets 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 determines 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 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, CONSOB and NASDAQ lifted the trading halt on our stock. In addition, on March 23, 2009, the Borsa Italiana halted trading of our common stock on the MTA stock market and resumed trading prior to 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 December 31, 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 conditions at any time, and there can be no guarantee that 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 Stock Market, the MTA or both for any reason or if trading in our stock is halted or suspended on The NASDAQ Stock Market, the MTA or both, such events may harm our stock price, increase the volatility of our stock price 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 Stock Market or if trading in our stock is halted or suspended on The NASDAQ Stock Market, we may become subject to certain obligations. In addition, if we are not listed on The NASDAQ Stock 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 have a material adverse effect on our ability to raise the capital we need.

# 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 challenges.

Our stock is traded on the Italian MTA stock market in Milan, Italy, and we are required to also comply with the rules and regulations of CONSOB, which is the public authority responsible for regulating the Italian securities market, 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 common stock outstanding at the beginning of that period. We have attempted to publish a listing prospectus in Italy to cover our general offerings for the past two years beginning in April 2007. After working with CONSOB to meet its requirements to publish that listing prospectus for the remainder of 2007, we were finally able to publish a listing prospectus in January 2008; however, that listing prospectus was limited to shares to be issued to Société Générale under the Step-Up Equity Financing Agreement we entered into with Société Générale in 2006, which has since terminated. After meeting with CONSOB in 2008 to further discuss its requirements for a more general listing prospectus, we filed a new listing prospectus on December 31, 2008, which was rejected by CONSOB on January 16, 2009. On January 28, 2009, we filed a registration document (*i.e.*, one of the three documents that, according to European Regulation No. 809/2004 and together with our related securities note and summary, constitute a listing prospectus, which can be separately filed, examined and eventually approved by CONSOB).

On July 2, 2009, after several requests of supplements, clarifications and submissions of new drafts of our registration document, CONSOB informed us that the relevant administrative procedure for CONSOB s authorization to publish the registration document had expired since CONSOB alleged that we had not amended the text of the registration document to provide certain information CONSOB had requested. We are planning to file a new draft of the registration document, securities note and summary. Nevertheless, pending the clearance of these documents, which together constitute a complete listing prospectus that will permit the Company to issue common stock in an amount that exceeds in any twelve month period 10% of the number of shares of our common stock outstanding at the beginning of that period, we are required to raise money using alternative forms of securities. For example, we use convertible preferred stock and convertible debt in lieu of common stock because convertible preferred stock and convertible debt, subject to the provisions of European Directive No. 71/2003 and according to the interpretations of the Committee of European Securities Regulators (CESR), are not subject to the 10% limitation imposed by European Union and Italian law.

# We are subject to additional legal duties, additional operational challenges and additional political and economic risks related to our operations in Italy.

A portion of our business is currently based in Italy, although we are in the process of shutting down our operations in Italy. However, as long as we continue to have operations in Italy, we are subject to duties and risks arising from doing business in Italy. As long as we continue to have a portion of our business in Italy, we are subject to operational challenges. We may not succeed in addressing these challenges, risks and duties, any of which may be exacerbated by the geographic separation of our operations in Italy. These risks related to doing business in Italy could harm our business, financial condition and results of operations.

### Our operations in Italy make us subject to increased risk regarding currency exchange rate fluctuations.

As long as we continue to have operations in Italy, we are exposed to risks associated with foreign currency transactions insofar as we use U.S. dollars to make contract payments denominated in euros or vice versa. As the net positions of our foreign currency transactions might fluctuate, our earnings might be negatively affected. In addition, we are exposed to risks associated with the translation of euro-denominated financial results and accounts into U.S. dollars. Our reporting currency will remain as the U.S. dollar; however, so long as we continue to have operations in Italy, a portion of our consolidated financial obligations will arise in euros. In addition, as long as we continue to have operations in Italy, the carrying value of some of our 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 approximately \$6.5 million and \$6.3 million as of June 30, 2009 and December 31, 2008, respectively. On March 26, 2009, the Italian Tax Authority, or ITA, issued a notice of assessment to CTI (Europe) based on their audit of VAT returns for the year 2003. The ITA audit concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian clients for services performed by CTI (Europe). In addition, the ITA has issued a pre-assessment of VAT filings for the year 2005 noting findings similar to the 2003 year. The assessment for the year 2003 is approximately \$0.7 million including interest and penalties. We believe that the services were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed and we intend to vigorously defend ourselves against the assessment and request a dismissal on procedural grounds and merits of the case. However, if we are unable to defend ourselves against the year 2003 assessment and if we receive an assessment for subsequent years, including the year 2005, it may harm our results of operations and financial condition.

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

Because we do not currently have any marketed products producing revenue, 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.

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

We have entered into a License and Co-Development agreement related to OPAXIO and pixantrone with Novartis International Pharmaceutical Ltd., or 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 pixantrone. We will not receive any royalty or milestone payments under this agreement unless Novartis exercises its option related to pixantrone 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. In the event Novartis does not elect to participate in the development of OPAXIO or pixantrone, 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 pixantrone or OPAXIO with a third party. 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 pixantrone 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.

# We may be delayed, limited or precluded from obtaining regulatory approval of OPAXIO given that our three STELLAR phase III clinical trials for the treatment of non-small cell lung cancer did not meet their primary endpoints.

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.

Our future financial success depends in part on obtaining regulatory approval of OPAXIO. 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 non-small cell lung cancer. All three trials failed to achieve their primary endpoints of superior overall survival compared to current marketed agents for treating NSCLC.

In December 2006, we closed the PIONEER clinical trial, and in 2007 we initiated a new study in the United States, PGT307, which focuses on the primary efficacy endpoint of survival in women with NSCLC and pre-menopausal estrogen levels. To conserve limited financial resources, we have decided not to initiate an additional study, the PGT306 trial, for which we have submitted a special protocol assessment, or SPA. We also feel that compelling evidence from one trial, the PGT307 trial, along with supporting evidence from earlier clinical trials, may be adequate to submit an NDA for OPAXIO even though the FDA has established a requirement that two adequate and well-controlled pivotal studies demonstrating a statistically significant improvement in overall survival will be required for approval of OPAXIO in the NSCLC setting. We may not receive compelling evidence or any positive results from the PGT307 trial, which would preclude our planned submission of an NDA to the FDA, and would preclude us from marketing OPAXIO in the United States.

Based on discussions with the EMEA Scientific Advice Working Party, we submitted an MAA for OPAXIO in Europe on March 4, 2008 based on results of the STELLAR trials. In April 2008, the MAA was accepted for review by the EMEA and we expect to receive an opinion from the EMEA by the fourth quarter of 2009. However a successful regulatory outcome from the EMEA is not assured as the EMEA s final opinion cannot be predicted until they have had the opportunity to complete a thorough review of the clinical data that was presented in the MAA.

### 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. 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. In March 2008, we submitted an MAA to the EMEA for OPAXIO. In April 2008, the EMEA accepted the MAA for review and we expect to receive an opinion from the EMEA in the fourth quarter of 2009. In addition, on April 13, 2009, we began submission of a rolling NDA to the FDA for pixantrone to treat relapsed aggressive NHL and completed the submission and requested priority review in June 2009. If priority review status is granted, the FDA could provide a decision on the NDA as early as six months after the final submission 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 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, EMEA 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 \$10.5 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.

# 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:

Because pixantrone is intended to provide less toxic treatments to patients who have failed standard chemotherapy treatment, if we are successful in bringing pixantrone to market, it is not expected to compete directly with many existing chemotherapies. However, pixantrone will face competition from currently marketed anthracyclines, such as mitoxantrone (Novantrone<sup>®</sup>), 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 oncology-focused multinational corporations include, among others, Bristol-Myers Squibb Co., which markets paclitaxel and generic forms of paclitaxel; Aventis, which markets docetaxel; Genentech, Roche and OSI Pharmaceuticals, which market Tarceva<sup>TM</sup>; Genentech and Roche, which market Avastin<sup>TM</sup>, Eli Lilly, which markets Alimta<sup>®</sup>, and American Pharmaceutical Partners, which markets Abraxane<sup>TM</sup>. 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 brostallicin to market, we will face direct competition from other minor groove binding agents including Yondelis<sup>®</sup>, 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 payors 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;

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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 trend toward managed healthcare in the United States, the growth of organizations such as health maintenance organizations, and legislative proposals to reform healthcare and government insurance programs 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.

### 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;

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 any of our license agreements for intellectual property underlying pixantrone, OPAXIO, brostallicin, 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 pixantrone and brostallicin. 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.

### 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 other 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<sup>®</sup>, 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 upon 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 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.

Our amended and restated articles of incorporation require that a quorum, consisting of one-third of the outstanding shares of voting stock, be represented in person or by proxy in order to transact business at a meeting of our shareholders. In addition, amendments to our amended and restated articles of incorporation, such as an amendment to increase our authorized capital stock, require the approval of a majority of our outstanding shares. 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 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 taking no action to direct the voting of such shares. Under Rule 452 of the New York Stock Exchange, the U.S. broker-dealer may vote shares absent direction from the beneficial owner on certain matters, such as the uncontested election of directors, an amendment to our amended and restated articles of incorporation to increase authorized shares that are to be used for general corporate purposes, and the ratification of our auditors. As a result of this custody transfer, we were able to hold special meetings of the shareholders in April 2007, January 2008 and March 2009 and annual meetings of the shareholders in September 2007 and June 2008. At the meeting in June 2008, our shareholders approved a proposal to reduce our quorum requirement from a majority of outstanding voting shares to one-third of outstanding voting shares. However, 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 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.

If we are unable to obtain a quorum at our shareholder meetings and thus fail to get shareholder approval of corporate actions, such failure could have a materially adverse effect on us. In addition, brokers may only vote on those matters for which broker discretionary voting is allowed under Rule 452 of the New York Stock Exchange, and we may not be able to obtain the required number of votes to approve certain proposals that require a majority of all outstanding shares to approve the proposal due to our reliance on broker discretionary voting. 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, such failure could have a material adverse effect on 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 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 our total shares of 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 NASDAQ. Funding of our operations in the future may require issuance of additional equity securities that would comprise more than 20% of our total shares of 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 have a material adverse effect on 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. Paclitaxel is available and we have purchased it from several sources. 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 U.S. 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. One of our 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 pixantrone and brostallicin are both manufactured by a single vendor. Finished product manufacture and distribution for both pixantrone 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 pixantrone. We assert multiple grounds for terminating this exclusive manufacturing agreement, which the former manufacturer disputes.

# If we do not successfully develop our products 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 pixantrone, into an approved commercial product, we will not generate any significant revenues from product sales, royalty payments, license fees or otherwise. Pixantrone, OPAXIO and brostallicin are currently in clinical trials; these clinical trials 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. 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 development are in-licensed from a third-party, including pixantrone, OPAXIO and brostallicin.

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;

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

completion of clinical trials depends on, among other things, the number of patients available for enrollment in a particular trial, 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 Gynecologic Oncology Group 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.

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.

### 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.

## We may be unable to use our net operating losses.

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 common stock upon exercise of the warrants offered in this offering, may further limit our ability to use our net operating losses.

#### **USE OF PROCEEDS**

We intend to use the proceeds we receive from the issuance of common stock upon the exercise of warrants, if any, for working capital and 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. Set forth below are details of certain of our outstanding indebtedness that we may retire, in whole or in part, with the net proceeds from this offering (principal amounts as of June 30, 2009):

our approximately \$43.4 million 4% Convertible Senior Subordinated Notes due 2010, which mature on July 1, 2010;

our approximately \$1.5 million 6.75% Convertible Senior Notes due 2010, which mature on October 31, 2010;

our approximately \$10.3 million 7.5% Convertible Senior Notes due 2011, which mature on April 30, 2011; and

our approximately \$10.9 million 5.75% Convertible Senior Notes due 2011, which mature on December 15, 2011. Because we will not receive any proceeds from the offering of shares of common stock described in this prospectus unless the warrants are exercised, we cannot estimate precisely the amount, if any, or the allocation of any proceeds from the issuance of shares of common stock upon the exercise of warrants. The amount of any proceeds and the amounts and timing of expenditures may vary significantly, depending on numerous factors, including, without limitation, the extent to which the warrants are exercised, the progress of our clinical trials and other development efforts, as well as the amount of cash used in our operations. Accordingly, our management will have broad discretion in the application of any proceeds. We reserve the right to change the use of any proceeds as a result of certain contingencies, such as competitive developments, opportunities to acquire technologies or products and other factors. Pending the uses described above, we may temporarily invest any proceeds in short- and medium-term interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

# **DIVIDEND POLICY**

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. We currently intend to retain all of our future earnings, if any, to finance operations. Any future determination relating to our dividend policy will be made at the discretion of our board of directors and will depend on a number of factors, including future earnings, capital requirements, financial conditions, future prospects, contractual restrictions and other factors that our board of directors may deem relevant.

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#### DESCRIPTION OF CAPITAL STOCK

This summary does not purport to be complete and is subject to, and qualified in its entirety by, the provisions of our amended and restated articles of incorporation, our bylaws, as amended, and all applicable provisions of Washington law.

# General

We are authorized to issue 800,000,000 shares of common stock, no par value, and 10,000,000 shares of preferred stock, no par value. As of July 30, 2009, there were 536,059,575 shares of common stock outstanding, warrants to purchase 21,735,218 shares of common stock outstanding (excluding the warrants described in this prospectus) and no shares of preferred stock outstanding.

On April 15, 2007, we effected a one-for-four reverse stock split of our common stock and on August 31, 2008, we effected a 1-for-10 reverse split of our common stock.

#### **Common Stock**

Each holder of common stock is entitled to one vote for each share held on all matters to be voted upon by the shareholders and there are no cumulative voting rights. Subject to preferences that may be applicable to any outstanding preferred stock, holders of common stock are entitled to receive ratably the dividends, if any, that are declared from time to time by the board of directors out of funds legally available for that purpose. In the event of our liquidation, dissolution or winding up, the holders of common stock are entitled to share in our assets remaining after the payment of liabilities and the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock. Holders of common stock have no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to our common stock. All outstanding shares of common stock are fully paid and nonassessable. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

#### **General Description of Preferred Stock**

Our board of directors has the authority, without action by the shareholders, to designate and issue preferred stock in one or more series and to designate the rights, preferences and privileges of each series, which may be greater than the rights of our common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock upon the rights of holders of our common stock until the board of directors determines the specific rights of the holders of this preferred stock. However, the effects might include, among other things:

restricting dividends on our common stock;

diluting the voting power of our common stock;

impairing the liquidation rights of our common stock; or

delaying or preventing a change in control of our company without further action by the shareholders. Anti-Takeover Effects of Provisions of Washington Law and our Charter and Bylaws

Washington law contains certain provisions that may have the effect of delaying, deterring or preventing a change in control of the Company. Chapter 23B.19 of the Washington Business Corporation Act prohibits us, with certain exceptions, from engaging in certain significant business transactions with an acquiring person (defined as a person or group of persons who acquire 10% or more of our voting securities without the prior approval of the our board of directors) for a period of five years following the acquiring person s share acquisition date. The prohibited transactions include, among others, a merger or consolidation with, disposition of assets to, or issuance or redemption of stock to or from, the acquiring person, or otherwise allowing the acquiring person to receive a disproportionate benefit as a shareholder. Exceptions to this statutory prohibition include approval of the transaction

at a shareholders meeting by holders of not less than a two-thirds of the shares held by each voting group entitled to vote on the transaction, not counting shares as to which the acquiring person has beneficial ownership or voting control, transactions approved by the board of directors prior to the acquiring person first becoming an acquiring person, or, with respect to a merger, share exchange, consolidation, liquidation or distribution entered into with the acquiring person, transactions where certain other requirements regarding the fairness of the consideration to be received by the shareholders have been met. We may not exempt ourselves from coverage of this statute. These statutory provisions may have the effect of delaying, deterring or preventing a change in control of the Company.

Our board of directors is divided into three approximately equal classes of directors serving staggered three-year terms. In addition, our amended and restated articles of incorporation provide that directors may be removed from office only at a meeting of the shareholders called expressly for that purpose and only for cause. Our amended and restated articles of incorporation limit cause to willful misfeasance having a material adverse effect on us or conviction of a felony, provided that any action by a director shall not constitute cause if, in good faith, the director believed the action to be in or not opposed to our best interests or if the director is entitled to be indemnified with respect to such action under applicable law, our amended and restated articles of incorporation or amended and restated bylaws, or a contract with us. Further, our amended and restated bylaws require a shareholder to provide notice to us of such shareholder s intention to nominate a person or persons for election as directors not later than 90 days prior to the first anniversary of the previous year s annual meeting or, in the case of an election to be held at a special meeting of the shareholders. A shareholder must also provide us with notice of such shareholder s intent to make any proposal at an annual meeting of shareholders not later than 90 days prior to the first anniversary of the previous year s annual meeting of shareholders. These may have the effect of deterring hostile takeovers or delaying change in control of our management.

#### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Computershare Investor Services, LLC.

#### **DESCRIPTION OF WARRANTS**

The material terms and provisions of the warrants are summarized below. This summary is subject to, and qualified in its entirety by, the terms set forth in the Common Stock Purchase Warrant filed as an exhibit to our Current Report on Form 8-K filed with the SEC on July 28, 2009.

# General

We issued and sold the warrants described in this prospectus in connection with our underwritten public offering of shares of common stock and the warrants on July 22, 2009. Each purchaser of a share of common stock in the public offering received a warrant to purchase .25 shares of common stock at an exercise price of \$1.70 per share of common stock. The warrants are currently exercisable and must be exercised on or before April 28, 2010.

The warrants are exercisable, at the option of the holder, upon the surrender of the warrants to us and the payment in cash of the exercise price of the shares of common stock being acquired upon exercise of the warrants. However, if at the time of exercise there is no effective registration statement registering the issuance of the shares of common stock issuable upon exercise of the warrants to the holder and all such shares are not then registered for resale by the holder, the holder may exercise the warrants by means of a cashless exercise or net exercise. The warrants will not be listed on any national securities exchange.

The exercise price per share of common stock purchasable upon exercise of the warrants is \$1.70 per share of common stock being purchased. The exercise price is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock. The holders of the warrants are entitled to 20 days notice before the record date for certain distributions to holders of our common stock. If certain fundamental transactions occur, such as a merger, consolidation, sale of substantially all of our assets in one transaction or a series of related transactions, tender offer or exchange offer with respect to our common stock pursuant to which holders of our common stock are permitted to tender or exchange a material portion of shares of our common stock for other securities, cash or property, or reclassification of our common stock or any compulsory share exchange pursuant to which our common stock is effectively converted into or exchanged for other securities, cash or property, the holders of the warrants will be entitled to receive thereafter in lieu of our common stock, the consideration (if different from common stock) that the holders of the warrants would have been entitled to receive upon the occurrence of the fundamental transaction as if the warrant had been exercised immediately before the fundamental transaction. In addition, if any holder of

fundamental transaction as if the warrant had been exercised immediately before the fundamental transaction. In addition, if any holder of common stock is given a choice of consideration to be received in the fundamental transaction, then the holders of the warrants shall be given the same choice upon the exercise of the warrants following the fundamental transaction.

As of July 30, 2009, other warrants to purchase 21,735,218 shares of common stock were outstanding.

# PLAN OF DISTRIBUTION

This prospectus relates to up to 8,432,981 shares of common stock to be offered from time to time by us upon the exercise of warrants issued and sold by us in connection with our underwritten public offering of shares of common stock and the warrants on July 22, 2009.

We will issue or cause to be delivered the shares of common stock to which this prospectus relates to holders of the warrants upon the exercise of the warrants. No underwriters, dealers or agents will participate in the distribution of the shares of common stock.

# LEGAL MATTERS

Certain legal matters in connection with the securities offered hereby will be passed upon for us by O Melveny & Myers LLP of San Francisco, California.

# EXPERTS

Stonefield Josephson, Inc., an independent registered public accounting firm, has audited our consolidated financial statements and consolidated financial statement schedule at December 31, 2008, and for each of the three years in the period ended December 31, 2008, included in our Annual Report on Form 10-K for the year ended December 31, 2008, as set forth in its report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Such consolidated financial statements and consolidated financial statement schedule are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

#### INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

SEC rules allow us to incorporate by reference into this 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 in this prospectus is considered to be part of this prospectus. This prospectus incorporates 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 not deemed to be filed) 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, 2008;

our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2009;

our definitive Proxy Statement on Schedule 14A, dated and filed with the SEC on January 14, 2009 for a Special Meeting of Shareholders, as amended by Amendment No. 1 to the definitive Proxy Statement on Schedule 14A, dated as of February 4, 2009 and filed with the SEC on February 5, 2009 and Definitive Additional Materials filed with the SEC on January 26, 2009, February 27, 2009 and March 9, 2009;

our Current Reports on Form 8-K filed on January 6, 2009, January 8, 2009, January 29, 2009, February 9, 2009, February 23, 2009, March 6, 2009, March 16, 2009 (Items 1.01 and 2.01 only), March 27, 2009, April 13, 2009, April 14, 2009, April 17, 2009, May 12, 2009 (Item 1.01 only), May 15, 2009, May 20, 2009, May 28, 2009, May 29, 2009, June 10, 2009, June 26, 2009, July 7, 2009 and July 28, 2009; and

the description of our capital stock contained in our Registration Statements on Form 10 filed with the SEC on June 27, 1996, including any amendment or reports filed for the purpose of updating that description.

Because we are incorporating by reference future filings with the SEC, this prospectus is continually updated and those future filings may modify or supersede some of the information included or incorporated by reference in this 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 or in any document previously incorporated by reference have been modified or superseded.

You may request a copy of these filings, at not cost, 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

## PART II

# INFORMATION NOT REQUIRED IN PROSPECTUS

#### Item 14. Other Expenses of Issuance and Distribution

The following table sets forth an estimate of the fees and expenses payable by the Registrant in connection with the offering described in this Registration Statement.

Securities and Exchange Commission registration fee	\$699
Legal fees and expenses	50,000
Accounting fees and expenses	20,000
Miscellaneous expenses	25,000
Total	\$95,699

#### Item 15. Indemnification of Directors and Officers

Sections 23B.08.500 through 23B.08.600 of the Washington Business Corporation Act, or the WBCA, authorize a court to award, or a corporation s board of directors to grant, indemnification to directors and officers on terms sufficiently broad to permit indemnification under certain circumstances for liabilities arising under the Securities Act of 1933. Article IX of the Registrant s Restated Bylaws provides for indemnification of the Registrant s directors, officers, employees and agents to the maximum extent permitted by Washington law. The directors and officers of the Registrant also may be indemnified against liability they may incur for serving in such capacity pursuant to a liability insurance policy we maintain for such purpose.

Section 23B.08.320 of the WBCA authorizes a corporation to limit a director s liability to the corporation or its shareholders for monetary damages for acts or omissions as a director, except in certain circumstances involving intentional misconduct, knowing violations of law or illegal corporate losses or distributions, or any transaction from which the director personally receives a benefit in money, property or services to which the director is not legally entitled. Article VII of the Registrant s Restated Articles of Incorporation contains provisions implementing, to the fullest extent permitted by Washington law, such limitations on a director s liability to the Registrant and its shareholders.

The Registrant has entered into an indemnification agreement with each of its executive officers and directors in which the Registrant agrees to hold harmless and indemnify the officer or director to the fullest extent permitted by Washington law. The Registrant agrees to hold harmless and indemnify the officer or director against any and all losses, claims, damages, liabilities or expenses incurred in connection with any actual, pending or threatened action, suit, claim or proceeding, whether civil, criminal, administrative or investigative and whether formal or informal, in

which the officer or director is, was or becomes involved by reason of the fact that the officer or director is or was a director, officer, employee, trustee or agent of the Registrant or any related company, partnership or enterprise, including service with respect to an employee benefit plan, whether the basis of such proceeding is alleged action (or inaction) by the officer or director in an official capacity and any action, suit, claim or proceeding instructed by or at the direction of the officer or director unless such action, suit, claim or proceeding is or was authorized by the Registrant s Board of Directors. No indemnity pursuant to the indemnification agreements shall be provided by the Registrant on account of any suit in which a final, unappealable judgment is rendered against the officer or director for an accounting of profits made from the purchase or sale by the officer or director of securities of the Registrant in violation of the provisions of Section 16(b) of the Securities Exchange Act of 1934, and amendments thereto, or for damages that have been paid directly to the officer or director by an insurance carrier under a policy of directors and officers liability insurance maintained by the Registrant.

#### Item 16. **Exhibits and Financial Statement Schedules** (a) Exhibits

Exhibit Number 1.1	<b>Description</b> Underwriting Agreement. (4)
4.1	Registrant s Amended and Restated Articles of Incorporation, as amended. (1)
4.2	Registrant s Amended and Restated Bylaws. (2)
4.3	Specimen Common Stock Certificate. (3)
4.4	Form of Common Stock Warrant. (4)
5.1	Opinion of O Melveny & Myers LLP.

- 23.1 Consent of Stonefield Josephson, Inc., Independent Registered Public Accounting Firm.
- 23.2 Consent of O Melveny & Myers LLP (included in Exhibit 5.1).
- 24.1 Power of Attorney (included on signature page of the Registration Statement hereto).
- (1) Incorporated by reference to Exhibit 4.1 to the Registrant s Registration Statement on Form S-3 (File No. 333-153358), Exhibit 3.1 to the Registrant s Current Report on Form 8-K, filed on February 9, 2009, Exhibit 3.1 to the Registrant s Current Report on Form 8-K, filed on March 27, 2009, and Exhibit 3.1 to the Registrant s Current Report on Form 8-K, filed on April 13, 2009.
- (2) Incorporated by reference to Exhibit 3.2 to the Registrant s Current Report on Form 8-K, filed on July 25, 2008.
- (3) Incorporated by reference to exhibits to the Registrant s Registration Statement on Form 10 filed on June 27, 1996, as amended.
- (4) Incorporated by reference to exhibits to the Registrant s Current Report on Form 8-K, filed on July 28, 2009.

#### Item 17. Undertakings

(a) The undersigned registrant hereby undertakes:

1. To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

*provided, however*, that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

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2. That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

3. To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

4. That, for the purposes of determining liability under the Securities Act of 1933 to any purchaser:

(i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or prospectus that was part of the registration statement or prospectus that was part of the registration statement or prospectus that was part of the registration statement or prospectus that was part of the registration statement or prospectus that was part of the registration statement or prospectus that was part of the registration statement or prospectus that was part of the registration statement or prospectus that was part of the registration statement or prospectus that was part of the registration statement or prospectus that was part of the registration statement or prospectus that was part of the registration statement or prospectus that was part of the registration statement or prospect

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant s annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan s annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

#### SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant named below certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3, and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Seattle, state of Washington, on this 31<sup>st</sup> day of July, 2009.

#### **CELL THERAPEUTICS, INC.**

By: /s/ James A. Bianco James A. Bianco, M.D. Chief Executive Officer

# POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that the undersigned officers and directors of Cell Therapeutics, Inc., a Washington corporation, do hereby constitute and appoint James A. Bianco, M.D. and Louis A. Bianco, and each of them individually, the lawful attorneys-in-fact and agents, each with full power of substitution or re-substitution, with full power and authority to do any and all acts and things and to execute any and all instruments which said attorneys-in-fact and agents, or either one of them, determine may be necessary or advisable or required to enable said corporation to comply with the Securities Act of 1933, as amended, and any rules or regulation or requirements of the Securities and Exchange Commission in connection with this registration statement. Without limiting the generality of the foregoing power and authority, the powers granted include the power and authority to sign the names of the undersigned officers and directors in the capacities indicated below to this registration statement, to any and all amendments, both pre-effective and post-effective, and supplements to this registration statement and to any and all instruments or documents filed as part of or in conjunction with this registration statement or amendments or supplements thereto, and each of the undersigned hereby ratifies and confirms all that said attorneys-in-fact and agents, or either one of them, shall do or cause to be done by virtue hereof. This power of attorney may be signed in several counterparts.

IN WITNESS WHEREOF, each of the undersigned has executed this power of attorney as of the date indicated.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed below by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Phillip M. Nudelman Phillip M. Nudelman, Ph.D.	Chairman of the Board	July 31, 2009
/s/ James A. Bianco James A. Bianco, M.D.	Chief Executive Officer and Director (Principal Executive Officer)	July 31, 2009
/s/ Louis A. Bianco Louis A. Bianco, M.D.	Executive Vice President, Finance and Administration (Principal Financial Officer and Principal Accounting Officer)	July 31, 2009
/s/ John H. Bauer		L 1 21 2000
John H. Bauer	Director	July 31, 2009
/s/ Vartan Gregorian Vartan Gregorian, Ph.D.	Director	July 31, 2009
/s/ Richard L. Love Richard L. Love	Director	July 31, 2009

Signature	Title	Date
/s/ Mary O. Mundinger Mary O. Mundinger, Dr. PH	Director	July 31, 2009
/s/ Jack W. Singer Jack W. Singer, M.D.	Director	July 31, 2009
/s/ Frederick W. Telling Frederick W. Telling, Ph.D.	Director	July 31, 2009

#### EXHIBIT INDEX

#### Number Description

- 1.1 Underwriting Agreement. (4)
- 4.1 Registrant s Amended and Restated Articles of Incorporation, as amended. (1)
- 4.2 Registrant s Amended and Restated Bylaws. (2)
- 4.3 Specimen Common Stock Certificate. (3)
- 4.4 Form of Common Stock Warrant. (4)
- 5.1 Opinion of O Melveny & Myers LLP.
- 23.1 Consent of Stonefield Josephson, Inc., Independent Registered Public Accounting Firm.
- 23.2 Consent of O Melveny & Myers LLP (included in Exhibit 5.1).
- 24.1 Power of Attorney (included on signature page of the Registration Statement hereto).

- (1) Incorporated by reference to Exhibit 4.1 to the Registrant s Registration Statement on Form S-3 (File No. 333-153358), Exhibit 3.1 to the Registrant s Current Report on Form 8-K, filed on February 9, 2009, Exhibit 3.1 to the Registrant s Current Report on Form 8-K, filed on March 27, 2009, and Exhibit 3.1 to the Registrant s Current Report on Form 8-K, filed on April 13, 2009.
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