

Edgar Filing: CELL THERAPEUTICS INC - Form 425

CELL THERAPEUTICS INC
Form 425
June 25, 2003

Filed by Cell Therapeutics, Inc.

Pursuant to Rule 425 under the Securities Act of 1933

And deemed filed pursuant to Rule 14a-12

Of the Securities and Exchange Act of 1934

Subject Company: Cell Therapeutics, Inc.

Commission File No: 001-12465

The following is the entire presentation given by Cell Therapeutics, Inc. at its annual meeting of stockholders, held on June 20, 2003.

Welcome

Shareholders & Guests

June 20, 2003

Annual Shareholders Meeting

James A. Bianco

President and CEO

(GRAPHIC)

We're fighting cancer

Business Meeting Agenda

Approve minutes
Elect Directors
Approve 2003 Equity Incentive Plan
Approve an amendment to Employee Stock Purchase Plan
Ratify selection of E&Y as independent auditors

Business Meeting

Call meeting to order
Introduction of officers, directors, accountants, inspector of elections
Record Date: May 7, 2003
Confirmation of quorum established

Business Meeting

Approval of minutes

5

Business Meeting

- Election of class III Directors
- Mary Munding
- Jack Singer
- Marty Sutter
- Election of class I Director
- John Fluke

Business Meeting

Approve 2003 Equity Incentive Plan

7

Business Meeting

Approve amendment to the Company's 1996 Employee Stock Purchase Plan to increase the number of shares by 150,000 to a total of approximately 635,000 shares

Business Meeting

Ratify selection of Ernst & Young as independent auditors
Open the floor to motions

Business Meeting

Voting
Results of voting
Conclusion of the business items

Management Presentation

[GRAPHIC]

Agenda

Oncology Portfolio Strategy *J. Bianco*
Market Dynamics
- Hematology Market
- Solid Tumor Market
CTI-Novuspharma merger
Commercial Development *E. Kenney*
Research and Clinical Development *J. Singer*
Closing Remarks *J. Bianco*

Forward Looking Statement

This presentation contains forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and beliefs and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. The forward-looking statements contained in this presentation include statements about future financial and operating results, the proposed CTI/Novuspharma merger, and risk and uncertainties that could affect CTI's product and products under development. These statements are not guarantees of future performance, involve certain risks, uncertainties and assumptions that are difficult to predict, and are based upon assumptions as to future events that may not prove accurate. Therefore, actual outcomes and results may differ materially from what is expressed herein. For example, if either of the companies do not receive required stockholder approvals or fail to satisfy other conditions to closing, the transaction will not be consummated. In any forward-looking statement in which CTI expresses an expectation or belief as to future results, such expectation or belief is expressed in good faith and believed to have a reasonable basis, but there can be no assurance that the statement or expectation or belief will result or be achieved or accomplished. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: risks associated with preclinical, clinical and sales and marketing developments in the biopharmaceutical industry in general and in particular including, without limitation, the potential failure to meet TRISENOX[®] revenue goals, the potential failure of XYOTAX to prove safe and effective for treatment of non-small cell lung and ovarian cancers, the potential failure of TRISENOX[®] to continue to be safe and effective for cancer patients, determinations by regulatory, patent and administrative governmental authorities, competitive factors, technological developments, costs of developing, producing and selling TRISENOX[®] and CTI's products under development in addition to the risk that the CTI and Novuspharma businesses will not be integrated successfully; costs related to the proposed merger, failure of the CTI or Novuspharma stockholders to approve the proposed merger; and other economic, business, competitive, and/or regulatory factors affecting CTI's and Novuspharma's businesses generally, including those set forth in CTI's filings with the SEC, including its Annual Report on Form 10-K for its most recent fiscal year and its most recent Quarterly Report on Form 10-Q, especially in the Factors Affecting Our Operating Results and Management's Discussion and Analysis of Financial Condition and Results of Operations sections, and its Current Reports on Form 8-K. CTI is under no obligation to (and expressly disclaims any such obligation to) update or alter its forward-looking statements whether as a result of new information, future events, or otherwise.

Where You Can Find

Additional Information

Cell Therapeutics, Inc. (CTI) will file a proxy statement/prospectus and other documents concerning the proposed merger transaction with the Securities and Exchange Commission (SEC). Investors and security holders are urged to read the proxy statement/prospectus when it becomes available and other relevant documents filed with the SEC because they will contain important information. Security holders may obtain a free copy of the proxy statement/prospectus (when it is available) and other documents filed by CTI with the SEC at the SEC's website at <http://www.sec.gov>. The proxy statement/prospectus and these other documents may also be obtained for free from CTI, Investor Relations: 501 Elliott Avenue West, Suite 400 Seattle, WA 98119, www.cticseattle.com.

CTI and Novuspharma S.p.A. and their respective directors and executive officers and other members of their management and their employees may be deemed to be participants in the solicitation of proxies from the shareholders of CTI and Novuspharma with respect to the transactions contemplated by the merger agreement. Information about the directors and officers of CTI is included in CTI's Proxy Statement for its 2003 Annual Meeting of Stockholders filed with the SEC on May 14, 2003.

This document is available free of charge at the SEC's website at <http://www.sec.gov> and from CTI.

Making Cancer More Treatable

*Providing less toxic, more effective
therapies to treat and cure cancer while
permitting patients and their families to
maintain their dignity and quality of life*

New Paradigm in Treating Cancer

Improving treatment outcomes four strategic directions

Improving tolerability of existing chemotherapy agents
Combining therapies to work more effectively without increased side effects
Developing tumor targeted therapies exploiting human genome
Treating cancer as a chronic disease without impacting quality of life

Oncology Strategy

Improve the safety and efficacy of existing agents which provide the cornerstone for standard of care

- Taxanes (>\$2B) XYOTAX
- Camptothecins (>\$1B) CT-2106
- Anthracyclines (>\$500M) Pixantrone

Develop new agents with unique mechanisms of tumor cell killing without more side effects

- TRISENOX®
- LPAAT-β inhibitors

Develop significant sales and marketing presence in cancer market segments where leverage is possible

- Blood-related cancer market

Consider co-marketing relationship where size matters

- Solid tumor indications

Commercial Synergies

Key Products	Hematology	Solid Tumors
TRISENOX®	APL, CML, MDS,	
Pixantrone	Multiple myeloma Aggressive NHL	Breast cancer
XYOTAX	Indolent NHL	Prostate cancer NSC lung cancer
CT-2106		Ovarian cancer Colorectal cancer Small cell lung cancer

Hematology

Commercial opportunity

	<u>2002 Incidence</u>	<u>2002 Prevalence</u>
Total Hematologic	94,850	423,564
TRISENOX®		
APL	1,050	2,535
Myelodysplastic		
Syndromes	15,200	35,562
Multiple Myeloma	14,600	49,542
Pixantrone		
AML	10,600	18,980
Indolent NHL	24,030	142,625
Aggressive NHL	29,370	174,320

Selected Companies

Focused on Hematology Market

Company	Key Products	Market Cap
Genentech	Rituxan [®]	\$ 38 B
Berlex*	Campath [®] , Fludara [®] , Leukine [®]	\$ 10 B
Idec	Zevalin [®] , Rituxan [®]	\$ 6.3 B
Millennium	Velcade	\$ 4.7 B
Celgene	Thalomid [®] , Revimid	\$ 2.7 B
CTI	TRISENOX [®] , Pixantrone	\$ 518 M ¹

* Schering AG

¹ Pro forma market cap

Hematology Market Dynamics

Few big pharma competitors in the space
High incidence diseases with few good treatment options
Concentrated target market
- ~4,500 physicians allows maximum sales and marketing leverage
Many agents used in combination therapy

Oncology

Commercial opportunity

	<u>2002 Incidence</u>	<u>2002 Prevalence</u>
Total Oncologic	516,144	3,132,334
XYOTAX		
Advanced NSC lung	137,600	162,352
Ovarian	25,400	145,831
CT-2106		
Small cell lung	34,380	57,983
Colorectal	147,500	930,083
Pixantrone		
Breast	212,600	1,836,085

Companies Focused on
Oncology-Chemotherapy Market

Company	Key Products	Market Cap
Pfizer	Camptosar [®]	\$ 285 B
GlaxoSmithKline	Hycamtin [®] , Navelbine [®]	\$ 126 B
Novartis	Femara, Aredia [®] , Gleevec, Sandostatin [®] , Zometa	\$ 117 B
Astra-Zeneca	Arimidex [®] , Casodex [®] , Faslodex [®] , IRESSA [®] , Nolvadex [®] , Zoladex [®]	\$ 78 B
Eli Lilly	Gemzar [®]	\$ 78 B
Bristol Myers	Taxol [®] , Ifex [®] , Paraplatin [®]	\$ 56 B
Aventis	Taxotere [®] , Campto [®] , Genasense	\$ 42 B
CTI	XTOTAX, Pixantrone	\$ 518 M ¹

¹ Pro forma market cap

Oncology Market Dynamics

Big pharma significant sales and marketing presence provides barrier to new marketer entry
Novel breakthrough products rapidly adopted and can generate >\$1B in annual sales
Suggests partnership with multi-nationals for blockbuster product may maximize commercial potential

Commercial Strategy

Utilize TRISENOX[®] to establish a commercial organization

Expand TRISENOX[®] indications to capture market share in blood related cancers (MDS, multiple myeloma) making commercial business profitable

Acquire additional products with utility in blood related cancers to expand market share and revenue growth

Grow commercial organization to provide demand generating capacity for launch of XYOTAX

CTI-Novuspharma Merger

Immediate realizable synergies

Pixantrone: commercially attractive phase III product

- May qualify for FDA fast track
- Potential NDA 2005, market launch 2006
- US sales could reach \$150M+

Financially attractive

- \$120M in cash
- \$18-\$20M in cost savings

Significant operating synergies

- Critical mass in global oncology drug development
- Increases commercial capabilities and sales potential in EU for expanded TRISENOX[®] label

Strong Financial Position

- Pro-forma end Q1 cash position \$306 million
- \$111M cash Q1-2003
- \$120M Novuspharma cash Q1-2003
- \$75M convertible offering*
- Exchange offer 12/02 retired \$60M convertible debt
- Merger offers potential for cost synergies
- \$18M to \$20M savings in 2004
- TRISENOX® U.S. business becoming profitable
- Allows ability to grow TRISENOX® sales in EU with new indication (MDS)
- Creates critical mass in cancer drug development and commercialization

* Gross proceeds

Commercial Operations

Edward F. Kenney

Executive Vice President

Chief Operating Officer

[GRAPHIC]

We're fighting cancer

Trisenox

(arsenic trioxide) injection

Indicated for the induction or remission and consolidation for patients with relapsed or refractory acute promyelocytic leukemia (APL)

[GRAPHIC]

TRISENOX®

Product approved US and EU
100% CAGR forecasted through 2003
\$150+ million peak US sales potential
Gaining US market share
EU penetration limited to initial label (APL)
Potential for MDS filing in 2004 allows for re-evaluation of EU commercial potential and strategy

TRISENOX

US Patient Mix

1Q02

APL 15%
Myeloma 43%
MDS 29%
Other 13%

1Q03

APL 10%
Myeloma 43%
MDS 41%
Other 6%

[Graphic]

TRISENOX®

Sales revenues & forecasts

\$Millions				
\$6.0M	\$11.7M	\$24M	\$43.0M	
2001	2002	2003(E)	2004(E)	

Source for 2004 estimate: CIBC World Markets

Solid Tumors

Commercial opportunity

Taxanes

- Taxol[®] (paclitaxel), Taxotere[®] (docetaxel) most widely used cancer drugs
Worldwide sales exceed \$2 billion
Projected number of patients treated monthly
 - Paclitaxel 54,700
 - Docetaxel 26,400
- 70% of taxane use is in 4 tumor types

Worldwide Taxane Sales

2002

Paclitaxel \$857M Sales 60% in ovarian and lung cancers

Docetaxel \$1,192M WW Sales 33% in ovarian and lung cancers

34

US Taxane Sales

2001

“ Paclitaxel “ Docetaxel

NSC Lung Cancer 36,526 pts/yr. (Docetaxel) \$153M 50,134 pts/yr (Paclitaxel) \$280M

Ovarian Cancer 18,002 pts/yr (Paclitaxel) \$195M

Breast Cancer 17,837 pts/yr (Docetaxel) \$244M 15,923 pts/yr (Paclitaxel) \$173M

XYOTAX (polyglutamate paclitaxel)

A safer, potentially more effective taxane

XYOTAX

Target product profile

	<u>XYOTAX</u>	<u>Paclitaxel</u>	<u>Docetaxel</u>
Premedications	No	Yes	Yes
Infusion time	10 mins	3 hrs	1 hr
Special infusion kits	No	Yes	Yes
Hair loss	No	Yes	Yes
Neuropathy	Infrequent	Frequent	Infrequent
Tolerability	Excellent	Fair	Fair
Efficacy	Superior		

Value Drivers

Drivers of market share

- Strength of product attributes
- Efficacy
- Safety
- Convenience
- Reimbursement/third-party provider support
- Price/dosing schedule for XYOTAX

Commercial Growth

[GRAPHIC]

TRISENOX® APL label, > 40 trials, 2003

XYOTAX Phase III trials, 2003

TRISENOX® Potential MDS label, 2004

XYOTAX

Potential NDA, 2004

Pixantrone

Phase III trials, 2004

TRISENOX® Potential myeloma label, 2005

XYOTAX

Potential NSCLC label, 2005

Pixantrone

Potential NDA, 2005

Pixantrone Potential aggressive NHL label, 2006

Research & Clinical Development

Jack W. Singer

Executive Vice President

Research Chair

[GRAPHIC]

We're fighting cancer

Oncology Pipeline

	Preclinical	Phase I	Phase II	Phase III	NDA	Marketed
TRISENOX®	Approved for relapsed or refractory acute promyelocytic leukemia (APL)					
	Multiple myeloma, myelodysplasia, myelogenous leukemia and other cancers					
XYOTAX	Non-small cell lung and ovarian cancers					
Pixantrone	Non-Hodgkin's lymphoma					
CT-2106	Advanced solid tumors					
LPAAT-B inhibitors						

TRISENOX®

Initial label indication: relapsed/refractory APL

Compelling efficacy in other hematologic cancers (multiple myeloma, MDS)

Robust safety data base of over 2,300 patients

- Manageable side effect profile

>40 market expansion investigator sponsored trials targeting larger disease targets

TRISENOX®

Impressive efficacy data in MDS

MDS (145 patients, 81 evaluable)

- 32% objective responses including high risk patients
 - Decreases or eliminates RBC and platelet transfusion dependence
 - 80% of responding pts became transfusion independent lasting up to 2 yrs
 - Well tolerated, no dose reductions required
 - Exploring label expansion in MDS in US and EU in 2004
- Reported at conferences in May, 2003

TRISENOX®

Impressive efficacy data in multiple myeloma

Multiple myeloma (86 patients, 78 evaluable)

- High response rates in combination with dexamethasone, vitamin C, and melphalan
 - ~40% objective responses (\geq PR)
 - ~70% disease control
 - Marked improvement in kidney function
 - Well tolerated; manageable side effects
 - Active in patients who failed Velcade, Thalomid®
 - 2 large combination studies in progress
 - Potential for label expansion
- Reported at conferences in May, 2003

XYOTAX

Safer, potentially more effective taxane

- Links paclitaxel to a digestible polymer
- Accumulates preferentially in tumor tissue
- Allows entry into cancer cells unlike standard paclitaxel
- 10-minute infusion into peripheral vein; no premedications required
- Robust clinical development program
- FDA approved phase III protocols for NSCLC
- Several phase I/II clinical trials ongoing

XYOTAX

Phase I/II clinical trials

- 7 phase I trials
- Single agent
- Combined with platinates
- Every other week dosing
- Combined with radiation
- 4 phase II trials
- High risk NSC lung cancer
- Chemotherapy resistant colorectal cancer
- Chemotherapy resistant ovarian cancer
- Relapsed/refractory breast cancer

XYOTAX

Registration strategy & timeline

- XYOTAX pivotal clinical trials to demonstrate
- Superior survival compared to marketed taxanes in treatment of NSC lung cancer
 - Ease of use
 - Lower overall treatment costs
 - Lower incidence of severe side effects compared to approved agents
- Submit NSC lung cancer NDA in 2H04
Follow-on data in front-line ovarian cancer to supplement market launch

Pixantrone

(from Novuspharma merger)

**New DNA intercalator with improved efficacy and safety
Now in phase III for NHL**

[GRAPHIC]

48

DNA Intercalators

Established efficacy

- Cornerstone of chemotherapy for breast cancer, leukemias, and lymphomas
 - Standard treatment in blood-borne tumors curative
 - Breast cancer highly effective as adjuvant and frontline therapy
 - Only therapy for advanced forms of multiple sclerosis
- However problems with cardiotoxicity
- Irreversible damage to heart muscle
 - Maximum cumulative dose in patient's lifetime
 - Prevents use as repeat therapy

DNA Intercalators

with improved efficacy and safety

Novuspharma's approach

- Alter chemical groups responsible for free-radical production and cardiac toxicity

[GRAPHIC]

Target markets

- Unmet clinical need in second-line therapy (NHL)
- Replace current DNA intercalators as safer treatment in first-line

Pixantrone

	<u>Doxorubicin</u>	<u>Mitoxantrone</u>	<u>Pixantrone</u>
Efficacy in hematology	+++	++	++++
Efficacy in solid tumors	++/+++	++	++
Safety (esp. cardiac)	+	++	++++

Superior anti-tumor activity in P388 and L1210 murine leukemias vs. Dx and Mitox
 Curative in YC-8 murine lymphoma
 Wide therapeutic window effective from 1/3 of MTD
 Synergism with Cisplatin and Rituxan

Effect of pixantrone and mitoxantrone (MITOX) on survival in the YC-8 lymphoma model (iv/iv + 1,5,9)

[Graphic]

Pixantrone *Experimental cardiotoxicity*

[Graphic]

Pixantrone

Target product profile

- Superior safety
 - Cardiac toxicity profile superior to existing agents
 - Not toxic to tissues, eliminates need for central line
 - Less severe nausea and vomiting
- Impressive efficacy
 - Long lasting complete remissions in heavily treated NHL patients
 - As single agent or in combination with chemotherapy
- Potential to be used where other anthracyclines cannot
 - Breast cancer in combination with Herceptin®
 - Breast cancer salvage after prior anthracycline therapy
 - Late-stage lymphomas

Pixantrone

- Extensive clinical trial experience
 - >170 patients
 - 7 phase I, II trials
- Initial market entry into area of high unmet need
 - 3rd-line aggressive NHL
 - Currently no approved therapies
 - Market size ~15,000 patients
- Potential label expansion
 - Relapsed indolent NHL + Rituxan[®] (phase III)
 - 2nd-line combination in high grade NHL (phase II)
 - Salvage breast cancer ± Herceptin[®] (planned)

Pixantrone

Impressive single agent activity (NHL)

- High response rates in relapsed/resistant aggressive NHL
- ORR= >30% (7CRs/5PRs + 5uPRs)
- Durable responses: TTP >8 months for responders
- Well tolerated
- Grade 4 neutropenia 13/33 (40%)
- Grade 4 anemia/thrombocytopenia 0-1/33 (<3%)
- 28/33 (85%) had maximum prior anthracycline exposure
- 14/33 (42%) received >1,000-1500mg/m² Pixantrone
- Encouraging low incidence of cardiac events despite prior anthracycline exposure

Pixantrone

Combination trials

- Highly active in combination regimens for relapsed/refractory NHL replacing doxorubicin
- CHOP n=17
13 patients evaluable; 6CRs/1PR
- ESHAP n=21
19 patients evaluable; 7CRs/4PRs
- Highly active in relapsed/refractory indolent NHL
- FND-R n=9
- 6 patients evaluable; 5CRs/1PR

Preliminary Market Study

% of physicians who would prescribe Pixantrone

by line of therapy

	<u>First Line</u>	<u>Second Line</u>	<u>Third Line</u>
Aggressive	47%	100%	100%
Indolent	27%	67%	67%

- **Almost half of the physicians would try Pixantrone in place of doxorubicin in first line therapy for aggressive patients mostly for patients with cardiovascular risk factors**

CT-2106

Polyglutamate camptothecin

Camptothecins (irinotecan, topotecan) approved for colorectal cancer, small cell lung cancer, and relapsed ovarian cancer

Highly active class of drugs but limited by toxicity

CT-2106 links 20S camptothecin to PG polymer

Excellent activity and safety in animal studies

Preliminary phase I data

- 13 patients treated at doses from 12 to 75 mg/m²
 - MTD not reached
 - Early evidence of activity
 - Presentation on preliminary results targeted for 4Q03
- Plan to initiate phase I/II combination study in colorectal and/or small cell cancer in 1H04

LPAAT-β

Novel cancer target

LPAAT-β cloned and identified as a novel cancer target by CTI scientists
Potential broad utility against many types of common cancers
Preclinical studies of drug-like inhibitors selectively destroy cancerous cells
Plenary presentations at three major cancer meetings in 2002 -2003
Potential clinical candidate in 2004

Closing Remarks

James A. Bianco

President and CEO

We re fighting cancer

[GRAPHIC]

Last 12 Months in Review

Objective

Acquire late stage or commercial product
Reduce burn rate and secure adequate capital to grow commercial operations and see XYOTAX to NDA
Advance discussions toward potential XYOTAX partner
Initiate pivotal XYOTAX phase III trials
TRISENOX® profitable operating business
Highlight clinical data at key scientific meetings

Status

Novuspharma merger
- Pixantrone in phase III
- \$18-\$20m in annual operating synergies
- \$120M balance sheet
\$75M notes offering
Partnership discussions for XYOTAX ongoing
STELLAR-2, -3, -4 trials FDA approved and enrolling
Sales targeted to double to \$24M this year
ASH, AACR, ASCO, MM, MDS

Key Objectives

Next 12-18 Months

Gynecologic Oncology Group to initiate phase III study of XYOTAX in ovarian cancer
Complete enrollment of pivotal trials in non-small cell lung cancer
Successful merger with Novuspharma to maximize cost synergies and efficiencies
Initiate pivotal trial of Pixantrone in aggressive relapsed NHL

Key Objectives

Next 12-18 Months

Explore TRISENOX[®] label expansion in MDS in 2004
Grow TRISENOX[®] sales >\$40M
Submit NDA for XYOTAX
Advance LPAAT inhibitors in development
Secure global commercial partner for XYOTAX

Stock Price Performance

[Graphic]

65

Community Involvement

International Myeloma Foundation Education-Treatment-Research

The Leukemia & Lymphoma Society Fighting Blood-Related Cancers

MMRF Multiple Myeloma Research Foundation

Gilda s Club Worldwide

The Friends of José Carreras International Leukemia Foundation

Lance Armstrong Foundation

Ronald McDonald House - The House that love built. Seattle

Seattle Center Foundation

MS National Multiple Sclerosis Society

Fred Hutchinson Cancer Research Center

United Way of America

[Graphic] cti

Making cancer more treatable

(c) 2003 Cell Therapeutics Inc