

CELL THERAPEUTICS INC
Form 425
June 17, 2003

Filed by Cell Therapeutics, Inc.
Pursuant to Rule 425 under the Securities Act of 1933
And deemed filed pursuant Rule 14a-12
Of the Securities Exchange Act of 1934
Subject Company: Cell Therapeutics, Inc.
Commission File No.: 001-12465

CTI-Novuspharma Merger

June 17, 2003

CAUTIONARY STATEMENT REGARDING FORWARD LOOKING STATEMENTS

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 and the proposed CTI/Novuspharma merger. 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: 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/prospects (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.

Strategic Rationale

Immediate Realizable Synergies

Greater revenue growth potential

TRISENOX® gaining hematology market share
XYOTAX in pivotal trials for lung cancer
Pixantrone in pivotal trials for NHL
Targeting profitability in 2005

MARKETED
LAUNCH 2005
LAUNCH 2006

Strong combined balance sheet

\$230 million proforma end Q1, 2003

Significant cost savings

\$18-\$20 million annual operating synergies

Strengthened oncology drug development expertise

Global access to patients, physicians and capital markets

Overview of CTI

TRISENOX®: approved in US and EU for APL

100% CAGR expected through 2004

Potential to capture significant share of hematologic malignancy market (MDS, MM)

\$150 million US sales potential

XYOTAX : safer, potentially more effective paclitaxel in pivotal trials for non-small cell lung and ovarian cancers

CT-2106 (PG-CPT): safer, potentially more effective camptothecin in phase I

Balance sheet: ~\$111 million cash as of 3/31/03

Research coverage

CIBC World Markets, Lehman Bros., Piper Jaffray, Wells Fargo, Punk Ziegel, Delafield Hambrecht

Overview of Novuspharma S.p.A.

Pixantrone potential best in class safer, more effective anthracycline in pivotal trials for NHL

Strong balance sheet: ~\$120 million cash as of 3/31/03

Former oncology drug development arm of Boehringer Mannheim, part of Hoffman La Roche

Expertise in pre-development, pharmacology, CMC, Phase I-II

Research coverage: Lehman Bros., SG Cowen, Banca IMI, Caboto

Timing

Unanimous approval of both Boards

Subject to Novuspharma and CTI shareholder approval

Subject to approval of CTI's application to list its shares on the Nuovo Mercato

Merger expected to close Q4

Integration plan & team established

\$18-20 million full year of cost savings expected in 2004

Year end combined cash position forecasted at \$160M

Specifics of Agreement

CTI to issue 16 million shares of CTIC to Novuspharma shareholders

- Fixed exchange ratio 2.45

- Transaction value ~\$235 million

- Dual listing on NASDAQ and Nuovo Mercato

Novuspharma to have two seats on board with a third independent director to be nominated prior to closing

Silvano Spinelli, CEO of Novuspharma to join CTI's management team in following roles

- EVP, Development at CTI

- Managing Director, CTI's European subsidiary in Bresso

Company Profiles

	CTI	Novuspharma
Therapeutic focus	Cancer	Cancer
Key Products		
Marketed	TRISENOX®	--
Phase III	XYOTAX	Pixantrone
Phase I/II	CT-2106 (polyglutamate camptothecin)	MT-201, BBR3576
Core competencies	Sales & Marketing, Phase II/III, Target discovery & validation	Preclinical (in vivo, PK/PD), CMC (analytical), Phase I-II
Head count	288	85
Facilities	170,000 sq ft (Seattle)	75,000 sq ft (Milan)
Balance sheet 3/31/03	\$111 million	\$120 million*

*Converted to US dollars; exchange rate 1.18

Merged Company

Therapeutic focus	Cancer
Key Products	
Marketed	TRISENOX®
Phase III	XYOTAX , Pixantrone
Phase I/II	CT-2106, MT-201, BBR3576
Core competencies	Fully integrated capabilities from target discovery through commercialization
Head count	~320
Facilities	250,000 sq ft (Seattle-Milan)
Balance sheet (3/31/03)	~\$230 million*

*Converted to US dollars; exchange rate 1.18

Operating Synergies

Center of excellence Milan

Medicinal chemistry, lead optimization
Preclinical models, toxicology-ADME, analytical
development, pharmacology
Clinical trials material production
PK/PD testing in Phase I
EU pharmacovigilance, QA/QC
European clinical development

Operating Synergies

Corporate Headquarters Seattle

Target discovery/validation

Clinical Development

Phase I-III

Drug Regulatory Affairs

Drug Safety & Surveillance

Sales & Marketing

Portfolio Synergies

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

Pixantrone

Product Summary

Long lasting complete/partial responses in heavily treated
NHL patients as single agent

Synergistic with combination therapy (Rituxan®)

Cardiac toxicity profile superior to existing agents

Convenience of eliminating central line

Reduces need for expensive anti-emetics

Initial market entry into area of high unmet need

Pixantrone

Clinical Summary

Extensive experience in >170 patients
7 phase I, II trials

Highly active in combination regimens for relapsed/refractory
NHL replacing doxorubicin

CHOP n=17

13 patients evaluable; 6CRs/1PR

ESHAP n=21

19 pts evaluable; 7CRs/4PRs

Highly active in relapsed/refractory indolent NHL

FND-R n=9

6 patients evaluable; 5CRs/1PR

Pixantrone

Impressive Single Agent Activity in Relapsed/Resistant Aggressive NHL

Patient	NHL	Status	Prior Rx mg/m ²	Resistant Prior RX	Response (Pix dose)	Duration (mos)
M-80	DLC	1 st Rel	Dx380	Yes	uPR(650)	NA
F-79	DLC	2 nd Rel	Dx400	Yes	CR(1530)	17
F-65	DLC	2 nd Rel	Dx400	Yes	CR(1530)	4
M-65	DLC	3 rd Rel	Dx250	No	uPR(1190)	NA
M-72	DLC	3 rd Rel	Dx400	No	PR(1530)	6.5
M-66	tFoll	5 th Rel	Dx240/ Mtx50	No	PR(1360)	17+
F-65	Mant	2 nd Rel	Dx300	Yes	CR(1060)	12.5
M-65	DLC	2 nd Rel	Dx300	No	uPR(1020)	NA

Pixantrone

Impressive Single Agent Activity in Relapsed/Resistant Aggressive NHL

Patient	NHL	Status	Prior Rx mg/m ²	Resistant Prior RX	Response (Pix dose)	Duration (mos)
F-72	DLC	4 th Rel	Dx300	Yes	PR(1020)	5
F-41	Mcy	3 rd Rel	Dx300	No	CR(1241)	7
F-60	DLC	3 rd Rel	Dx400	Yes	PR(1020)	NA
M-78	Mant	2 nd Rel	None	Yes	uPR(1020)	NA
F-55	DLC	1 st Rel	Dx300	No	CR(1326)	12
M-66	DLC	2 nd Rel	Dx	Yes	uPR(425)	1

Pixantrone

Impressive Single Agent Activity in Relapsed/Resistant Aggressive NHL

High response rates in relapsed/resistant aggressive NHL
ORR= >30% (7CRs/5PRs + 5uPR s)
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

U.S. Registration Strategy

New strategy for registration in U.S.

Pivotal trial in 3rd line aggressive NHL

- Compelling phase II clinical data

- High unmet need qualifies for fast track

- No approved agents non-randomized single open label trial ~120 pts

- Enrollment completion late 2004

- NDA target Q4 2005

- Potential launch 2006

Phase III in relapsed indolent NHL ± rituximab
to provide market penetration support

Pixantrone

U.S. Market Potential

Anthracyclines

Standard of care

- Front line and relapsed aggressive NHL (CHOP)
- Front line for acute myeloid leukemias
- Front line breast cancer, relapsed HR prostate cancer

\$500+ million in annual sales

Market leaders

- Doxorubicin (US)
- Epirubicin (EU)

Major limitation life time cardiac toxicity threshold

Pixantrone

U.S. Market Potential Survey

If approved in 3rd line aggressive NHL

100% would use it in 2nd & 3rd line

50% would replace doxorubicin in 1st line for aggressive especially high cardiac risk patients

>50% would use it in 2nd and 3rd line indolent

Zevalin and Bexxar® would be used after Pixantrone due to difficulty with nuclear medicine scheduling issues

With supportive data in clinical trials could move into breast and prostate cancers

Base case forecast \$150 million peak U.S. sales

TRISENOX®

Product approved U.S. and EU

100% CAGR forecasted through 2003

\$150+ million peak U.S. sales potential

Compelling efficacy in hematologic cancers (APL, MM, MDS)

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®

Impressive efficacy data in hematologic cancers

Myelodysplasia (120 patients)

Decreases or eliminates RBC and platelet transfusion independence

80% of responding patients became transfusion independent lasting up to 2 yrs

32% objective responses including high risk patients

Well tolerated, no dose reductions required

Projected sNDA and sMAA filing in both EU and US in 2004

Multiple myeloma (86 patients)

High response rates in combination with vitamin C

40% objective responses

100% improvement in kidney function

Well tolerated, manageable side effects

Reported at conferences in May, 2003

TRISENOX®

Sales revenues & forecasts

Source for 2003, 2004 estimates: CIBC World Markets

XYOTAX

Safer, potentially more effective taxane

Novel, patented polyglutamate polymer technology links paclitaxel to a digestible polymer

Polymer bound paclitaxel accumulates preferentially in tumor blood vessels

Allows the chemotherapy to enter cancer cells through a different mechanism than standard paclitaxel

Selectively releases chemotherapy in tumor

A new chemical entity; not a reformulation

Patent protection through 2017

XYOTAX

Target Product Profile

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

XYOTAX

Designated fast track by FDA

PS2 NSC lung cancer is incurable and current treatments offer modest benefit

XYOTAX has the potential to demonstrate improvement over available therapy in these patients based on anti-tumor activity reported in phase I and phase II clinical trials

FDA approved Phase III program in NSC lung cancer to demonstrate superior survival

Front line therapy in PS2

Second line treatment

Gynecologic Oncology Group to run phase III in ovarian cancer

Front line therapy

Phase II XYOTAX

Front Line PS2 NSC Lung Cancer

PS2 accounts for 25% of 170,000 patients with NSC lung cancer (most are elderly)

Current treatments are poorly tolerated (median 2 doses)

Disease progresses rapidly

Median 6 weeks

Median survival poor (2.4 – 3.9 months)*

High unmet need potential accelerated regulatory review

Phase II XYOTAX clinical data supports phase III investigation

Principle investigators on Phase III program are key opinion leaders of major cooperative groups (CALGB, ECOG, SWOG)

*Single agent v. combination therapy respectively

Phase II XYOTAX NSC Lung Cancer

Efficacy (PS2)	Objective Response Rate	Median # of Doses	Time to Progression (months)	Survival (months)
XYOTAX (175 mg/m ²)*	~10%	4	2.6	≥5.4
	Toxicities (Grade 3 / 4) Highest (Grade 4)		10%	
	Neutropenia		4%	
	Neuropathy/Fatigue		7%	
Efficacy (PS2)				
Paclitaxel (225 mg/m ²)**	~10%	2	1.5	2.4
	Toxicities (Grade 3 / 4)***			
	Highest (Grade 4)		53%	
	Neutropenia		63%	
	Neuropathy/Fatigue		>10%	

*ASCO 2003 poster
 ** ASCO 2002 presentation, R.C. Lilenbaum
 *** Paclitaxel/carboplatin regimen, NEJM Vol 346, No. 2, June 10, 2002

XYOTAX Phase III NSC Lung Cancer

STELLAR 2-3-4 trials

STELLAR 2

Second line therapy
XYOTAX v. docetaxel
840 patients
Target enrollment-
end Q2-2004

STELLAR 4

Front line PS2 XYOTAX v.
gemcitabine or vinorelbine
370 patients
Target enrollment-
end Q1-2004

STELLAR 3

Front line PS2
XYOTAX /platinum v.
paclitaxel/platinum
370 patients
Target enrollment-
end Q4-2003

ENDPOINTS on all trials
Superior Survival

XYOTAX for Ovarian Cancer *Phase I-II Summary Efficacy*

XYOTAX (175mg/m²) (n=91, Salvage[^])

Platinum Sensitive

Platinum Resistant

CR/PR	5/18 (28%)	3/20 (15%)
SD	5/18 (28%)	4/20 (20%)

XYOTAX * + cisplatin (75mg/m²) (n=12)

Platinum Sensitive/ Resistant

*175,210,225,250 mg/m²
[^] patients with 2 prior regimens
 Results reported at 2002 EORTC Meeting

PR	5 (42%)
SD	5 (42%)

Phase II XYOTAX Salvage Ovarian Cancer

	XYOTAX ***	Taxol® *	Doxil® **	Topotecan **
Efficacy				
Response rate	28%	15%	28%	28%
Side Effects				
Neutropenia	2%	65%	12%	77%
Neuropathy	10%	21%	N/A	N/A
Skin toxicity	0%	0%	23%	0%
Hair loss	0%	87%	16%	49%
Dose reduction	1%	N/A	57%	78%

* Taxol® package insert, 2nd line data ovarian cancer, 3hr infusion

** J Clin Oncology 2001, Randomized trial Doxil® v. Topotecan in 2nd line ovarian cancer

*** Third-line treatment

XYOTAX Phase III Ovarian Cancer *Gynecologic Oncology Group Trial*

Front Line Ovarian Cancer

XYOTAX /platinum v. paclitaxel/platinum

Conducted by 200+ GOG centers in US

1200 patients (12 months enrollment)

Start late 2004

Endpoint: non inferior PFS, Superior side effect profile

XYOTAX

Why Novuspharma?

Economically superior

- \$120M in cash

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

- Contributes additional phase III \$150M+ product

- Critical mass in global oncology drug development

- Increases commercial capabilities in EU for expanded TRISENOX® label and sales potential

FDA's XYOTAX fast track designation significant validating value driver

Retention of WW (excluding Asia) rights critical among the potential multi-national pharma companies

Allows the Company to re-evaluate prior interest in focusing solely on ex-US partner for XYOTAX and turn attention to more global strategic relationship

Portfolio Synergies

Summary

TRISENOX®

EU sales driven by product label indications

Potential MDS label expansion makes ex-US commercial prospect attractive

Expanded label has attracted interest among several pharma companies for co-promotional relationship

Investment in EU commercial presence would maximize WW revenue potential

XYOTAX

Stronger EU presence to allow more efficient pivotal trial management

35-40% of phase III enrollment in the EU

Transaction allows CTI to retain WW rights and explore growing interest for potential global partnership

Portfolio Synergies

Summary

Pixantrone

Strong US hematology presence will facilitate clinical and regulatory development
Same customer base as TRISENOX® provides sales and marketing efficiencies

CT-2106

Enhances access to clinical sites in EU to expedite phase II trials
Provides cost synergies for required preclinical, manufacturing activities

Preclinical targets

HIF-1a and LPAAT promising novel targets

Remaining product programs with greatest commercial potential will be reviewed and prioritized