

Edgar Filing: CELL THERAPEUTICS INC - Form 425

CELL THERAPEUTICS INC  
Form 425  
June 26, 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 presentation is being used by Dr. James Bianco of Cell Therapeutics, Inc. ( CTI ) at presentations involving the proposed business combination between CTI and Novuspharma S.p.A. ( Novuspharma ).

**[GRAPHIC]**

cti

Making cancer more treatable

**CELL THERAPEUTICS, INC. *NASDAQ: CTIC***

## 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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](http://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.

## Highlights

**XYOTAX in phase III trials**

- Fast track status in NSCLC
- GOG ovarian cancer trial

**TRISENOX 100% compounded annual growth rate**

- Profitable business unit in 2003

**Pixantrone best in class**

- Potential accelerated registration aggressive NHL

**Strong financial position**

## Oncology Pipeline

	<u>Preclinical</u>	<u>Phase I</u>	<u>Phase II</u>	<u>Phase III</u>	<u>NDA</u>	<u>Marketed</u>
<b>TRISENOX®</b>						Approved for relapsed or refractory acute promyelocytic leukemia (APL)
						Multiple myeloma, myelodysplasia, myelogenous leukemia and other cancers
<b>XYOTAX</b>						Non-small cell lung and ovarian cancers
<b>Pixantrone</b>						Non-Hodgkin's lymphoma
<b>CT-2106</b>						Colorectal cancer
						Small cell Lung
<b>LPAAT-B inhibitors</b>						

# **XYOTAX**

*(polyglutamate paclitaxel)*

*A safer, potentially  
more effective taxane*

## **XYOTAX Accumulates in the Tumor**

[GRAPHIC]

**XYOTAX Enters Cancer Cells Through  
Different Mechanism than Taxol<sup>®</sup>**

[GRAPHIC]



# **XYOTAX Tumor Selective Release of Chemotherapy**

[GRAPHIC]

## 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		

**[GRAPHIC]**

cti

## **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

### **Robust pivotal trial program in over 1,500 patients**

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

- Front line therapy in PS2
- Second line treatment

### **NDA in NSC lung cancer targeted for Q4-2004**

### **Gynecologic Oncology Group to run phase III in ovarian cancer**

- Front line therapy

## **NSC Lung Cancer**

## **Phase II XYOTAX**

### *Front Line PS2 NSC Lung Cancer*

**PS2 accounts for 20-30% of 136,000 patients with NSC lung cancer**

**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 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

## **XYOTAX Phase II High Risk**

### **NSC Lung Cancer**

#### *Patient Characteristics*

**XYOTAX 175 mg/m<sup>2</sup> every 3 weeks**  
**n = 28 patients treated**  
**Median age 76 (range 49-88)**

**Performance status**

---

**PS0 6 (21%)**  
**PS1 14 (50%)**  
**PS2 8 (29%)**

**Disease stage**

---

**IIIB 8 (29%)**  
**IV 20 (71%)**

\*Data presented at ASCO 2003

## **XYOTAX Phase II High Risk NSC Lung Cancer**

### **Number of Treatment Cycles Received**

---

<b>14 patients (64%)</b>	<b>≥ 4 cycles of treatment</b>
<b>6 patients (27%)</b>	<b>6 cycles of treatment</b>
<b>2 patients (9%)</b>	<b>8 cycles of treatment</b>

\*Data presented at ASCO 2003

**XYOTAX Phase II High Risk****NSC Lung Cancer***Adverse Events (n = 28)*

	<u>Grade III</u>	<u>Grade IV</u>
<b>Neuropathy</b>	<b>5</b>	<b>0</b>
<b>Neutropenia</b>	<b>2</b>	<b>1</b>
<b>Febrile neutropenia</b>	<b>1</b>	<b>0</b>
<b>Anemia</b>	<b>1</b>	<b>0</b>
<b>Hair loss</b>	<b>0</b>	<b>0</b>
<b>Hypersensitivity</b>	<b>0</b>	<b>0</b>

\*Generalized weakness, fatigue and neuropathy were seen mostly in patients with concomitant progressive disease and significant disease related comorbid conditions



## Phase II XYOTAX NSC Lung Cancer

<u>Efficacy (PS2)</u>	<u>Objective Response Rate</u>	<u>Median # of Doses</u>	<u>Time to Progression (months)</u>	<u>Survival (months)</u>
XYOTAX (175 mg/m2)* Efficacy (PS2)	~10%	4	2.6	≥5.4
Paclitaxel (225 mg/m2)**	~10%	2	1.5	2.4

\* ASCO 2003 poster

\*\* ASCO 2002 presentation, R.C. Lilenbaum

**XYOTAX***Phase III NSC Lung Cancer Studies*

<u>Trial</u>	<u>Design</u>	<b>XYOTAX</b>		<u>Primary Endpoint</u>	<u># of pts</u>	<u>Data Release</u>
		<u>Comparator dose (mg/m2)</u>	<u>dose (mg/m2)</u>			
STELLAR 2 <b>2nd Line</b> <b>NSC Lung</b>	Superiority Open-label Randomized	Docetaxel 75  Q3 weeks	210  Q3 wks	Survival	840	2H04
STELLAR 3 <b>1st Line</b> <b>NSC Lung</b> <b>PS2</b>	Superiority Open-label Randomized	Paclitaxel 225 +  carbo AUC 6 Q3  weeks	210 +  carbo AUC 6  Q3 wks	Survival	370	2H04
STELLAR 4 <b>1st Line</b> <b>NSC Lung</b> <b>PS 2</b>	Superiority Open-label Randomized	Gemcitabine 1000  d1, 8, 15 or Navelbine 20 d1, 8,  15	235  Q3 wks	Survival	370	2H04

## **Ovarian Cancer**

## **XYOTAX Phase II Ovarian**

### *Patient Characteristics (n=99)*

#### Age

---

<b>Median</b> (range)	<b>57</b> (29-89)
-----------------------	-------------------

#### Number Prior Regimens

---

<b>2</b>	<b>39 pts*</b>
<b>3 or 4</b>	<b>29 pts</b>
<b>5 or 6</b>	<b>18 pts</b>
<b>7-12</b>	<b>13 pts</b>

\*1 patient had 1 prior regimen

**XYOTAX Phase II Ovarian***Adverse Events (n=99)*

	<u>Grade III</u>	<u>Grade IV</u>
Hematologic		
<b>Hematologic</b>	<b>18(18%)</b>	<b>4(4%)</b>
<b>Neutropenia</b>	<b>15(15%)</b>	<b>8(8%)</b>
<b>Anemia</b>	<b>6(6%)</b>	<b>0</b>
<b>Thrombocytopenia</b>	<b>1(1%)</b>	<b>0</b>
Non-hematologic		
<b>Hepatic</b>	<b>0</b>	<b>0</b>
<b>Renal</b>	<b>0</b>	<b>0</b>
<b>Gastrointestinal</b>	<b>2(2%)</b>	<b>0</b>
<b>Infection</b>	<b>0</b>	<b>0</b>
<b>Musculoskeletal</b>	<b>1(1%)</b>	<b>0</b>
<b>Constitutional (fatigue)</b>	<b>5(5%)</b>	<b>0</b>
<b>Neuropathy</b>	<b>14(14%)</b>	<b>0</b>
<b>Allergy (hypersensitivity)</b>	<b>1(1%)</b>	<b>0</b>

## XYOTAX Phase II Ovarian

### Tumor Response

#### Platinum Sensitive

#### # Prior Regimens

2

(n=18\*)

≥3

(n=24)

<b>PR</b>	<b>8(33%)</b>	<b>1(4%)</b>
<b>SD</b>	<b>2(11%)</b>	<b>11(46%)</b>

#### Platinum Resistant

#### # Prior Regimens

1 or 2

(n=21)

≥3

(n=36)

<b>3(14%)</b>	<b>3(8%)</b>
<b>3(14%)</b>	<b>11(31%)</b>

Presented at the ONS Meeting 2003

\*1 patient had 1 prior regimen

/

## XYOTAX Phase III Ovarian Cancer

### *Gynecologic Oncology Group Trial*

Trial	Design	Comparator dose (mg/m2)	XYOTAX dose (mg/m2)	Primary Endpoint	# of pts	Data Release
1st Line Ovarian	Non-Inferiority Open-label Randomized	Paclitaxel 175 + carbo AUC 6 Q3 weeks  Paclitaxel 175 Q4 weeks x 12 for CRs	210 + Carbo  AUC 6  Q3 wks  210  Q4 Wks x  12 for CRs	PFS Toxicities	~1200	2006

# XYOTAX

## *Estimated US Regulatory Timelines*

	<u>1H</u> <u>04</u>	<u>2H</u> <u>04</u>	<u>1H 05</u>	<u>2H 05</u>	<u>1H 06</u>	<u>2H 06</u>
<b>First line</b> <b>NSC Lung</b> (STELLAR 3)	NDA Submission		Approval			
<b>First line</b> <b>NSC Lung</b> (STELLAR 4)	NDA Submission		Approval			
<b>Second line</b> <b>NSC Lung</b> (STELLAR 2)	NDA Submission		Approval			
<b>First line Ovarian</b>	NDA Submission		Approval			



**TRISENOX**

*(arsenic trioxide) injection*

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

## **TRISENOX**

### **Commercial Opportunity**

**Product marketed in US, and EU**

**100% CAGR forecasted in 2003**

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

**>40 market expansion clinical trials ongoing**  
**Gaining share in U.S. blood related cancer market**

- EU penetration limited to initial label (APL)

**Potential label extension in 2004 for MDS indication could contribute significantly to both US and EU sales**

## TRISENOX

### *US Patient Mix*

	1Q02	1Q03
<b>APL</b>	15%	10%
<b>Myeloma</b>	43%	43%
<b>MDS</b>	29%	41%
<b>Other</b>	13%	6%

## TRISENOX

*Profitable Commercial Effort in 2003*

<b>Sales</b>	<b>\$ Millions</b>
<b>2001</b>	\$6.0M
<b>2002</b>	\$ 11.7M
<b>2003 (E)</b>	\$ 24.0M
<b>2004 (E)</b>	\$ 43.0M

Source for 2004 estimate: CIBC World Markets

## **TRISENOX<sup>®</sup>**

*Impressive efficacy data in MDS*

**MDS (145 patients, 81 evaluable)**

**32% objective responses in both low and high risk**

**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**

**Potential 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)
- Marked improvement in kidney function

**Well tolerated; manageable side effects**

**Active in patients who failed Velcade<sup>®</sup>, Thalomid<sup>®</sup>**

**2 large combination studies in progress**

**Potential for label expansion in 2005**

Reported at conferences in May, 2003

## Commercial Synergies

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

## Commercial Operations

### *Drivers for Expansion*

[GRAPH]

2003	2004	2005	2006
<b>TRISENOX</b>	<b>TRISENOX</b>	<b>TRISENOX</b>	
APL label,	MDS label	Myeloma label	
> 40 clinical trials			
<b>XYOTAX</b>	<b>XYOTAX</b>	<b>XYOTAX</b>	
Phase III trials	NDA	NSCLC label	
<b>Pixantrone</b>	<b>Pixantrone</b>	<b>Pixantrone</b>	<b>Pixantrone</b>
Phase III trials	Phase III trials	NDA	Aggressive NHL label



## **Pixantrone**

[GRAPHIC]

## **Pixantrone**

*(from Novuspharma merger)*

**New potential best-in-class DNA intercalator with improved efficacy and safety**

**Phase III in aggressive NHL targeted Q1 04**

**Should qualify for accelerated regulatory review**

**Potential NDA in 2005**

**Initial indication could generate \$150+ million annual sales**

## DNA Intercalators

### **Established efficacy**

- Cornerstone of chemotherapy for breast cancer, leukemias, and lymphomas
- Standard treatment in blood-born 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)**

**[GRAPH]**

## **Pixantrone**

*Experimental cardiotoxicity*

[GRAPHIC APPEARS HERE]

## 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**

### ***Clinical Summary***

#### **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<sup>®</sup> (phase III)
- 2nd-line combination in high grade NHL (phase II)
- Salvage breast cancer ± Herceptin<sup>®</sup> (planned)

## Pixantrone

Impressive Single Agent Activity in  
Relapsed/Resistant Aggressive NHL

<u>Patient</u>	<u>NHL</u>	<u>Status</u>	<u>Prior Rx mg/m<sup>2</sup></u>	<u>Resistant Prior Rx</u>	<u>Response (Pix dose)</u>	<u>Duration (mos)</u>
M-80	DLC	1 <sup>st</sup> Rel	Dx380	Yes	uPR(650)	NA
F-79	DLC	2 <sup>nd</sup> Rel	Dx400	Yes	CR(1530)	17
F-65	DLC	2 <sup>nd</sup> Rel	Dx400	Yes	CR(1530)	4
M-65	DLC	3 <sup>rd</sup> Rel	Dx250	No	uPR(1190)	NA
M-72	DLC	3 <sup>rd</sup> Rel	Dx400	No	PR(1530)	6.5
M-66	tFoll	5 <sup>th</sup> Rel	Dx240/Mt x50	No	PR(1360)	17+
F-65	Mant	2 <sup>nd</sup> Rel	Dx300	Yes	CR(1060)	12.5
M-65	DLC	2 <sup>nd</sup> Rel	Dx300	No	uPR(1020)	NA

## Pixantrone

Impressive Single Agent Activity in

Relapsed/Resistant Aggressive NHL

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

**Encouraging low incidence of cardiac events despite prior anthracycline or anthracenedione exposure**

## **Pixantrone**

### *U.S. Registration Strategy*

#### **Pivotal trial in 3rd line aggressive NHL**

- Compelling phase II clinical data
- High unmet need - qualifies for accelerated review
- 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**

## Preliminary Market Study

*% of physicians who would prescribe Pixantrone  
by line of therapy*

---

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

---

- 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

## Pixantrone U.S. Market Potential

*NHL indication only*

<b>Aggressive NHL incidence(55%)</b>	<b>151,877</b>
- Stage III/IV (80%)	121,502
- Chemotherapy (front line-CHOP)	72,901
- Salvage chemotherapy	54,169
<b>Indolent NHL incidence (45%)</b>	<b>124,263</b>
- Stage III/IV	68,345
- Chemotherapy (+/-Rituxan)	44,735
- Salvage chemotherapy	18,905

## **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**

**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**



## **Novuspharma**

**[GRAPHIC]**

cti

## Strategic Rationale

### *Immediate Realizable Synergies*

#### **Greater revenue growth potential**

- TRISENOX gaining hematology market share    **MARKETED**
- XYOTAX in pivotal trials for lung cancer    **LAUNCH 2005**
- Pixantrone in pivotal trials for NHL    **LAUNCH 2006**
- Targeting profitability in 2005

#### **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 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

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

\*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**



**[GRAPHIC]**

cti

Making cancer more treatable

**CELL THERAPEUTICS, INC. NASDAQ: CTIC**

The following sidebars are also being used by Dr. James Bianco of CTI at presentations involving the proposed business combination between CTI and Novuspharma.

## Last 12 Months in Review

<u>Objective</u>	<u>Status</u>
<b>Acquire late stage or commercial product</b>	<b>Novuspharma merger</b>
	- Pixantrone in phase III
	- \$18-\$20m in annual operating synergies
	- \$120M balance sheet
<b>Reduce burn rate and secure adequate capital to grow commercial operations and see XYOTAX to NDA</b>	<b>\$75M notes offering</b>
<b>Advance discussions toward potential XYOTAX partner</b>	<b>Partnership discussions for XYOTAX ongoing</b>
<b>Initiate pivotal XYOTAX phase III trials</b>	<b>STELLAR-2, -3, -4 trials FDA approved and enrolling</b>
<b>TRISENOX profitable operating business</b>	<b>Sales targeted to double to \$24M this year</b>
<b>Highlight clinical data at key scientific meetings</b>	<b>ASH, AACR, ASCO, MM, MDS</b>

## 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- 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

## Hematology

### *Commercial opportunity*

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

## Oncology

### *Commercial opportunity*

	2002 Incidence	2002 Prevalence
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

## Market Dynamics

### Hematology

**Few Big pharma competitors**  
- Berlex, Genentech, Idec, Millenium, Celgene  
**Low S&M barriers to entry**

**High incidence diseases with few treatment options**

**Concentrated market ~4,500 allows maximum S&M leverage with modest size field force**

### Oncology

**Big pharma dominates solid tumor space**  
- Pfizer, Novartis, Glaxo, BMS, AstraZeneca, Lilly  
**Considerable sales and marketing barriers to entry**  
**Novel break through products can generate >\$1B in annual sales**  
**Co-promotional relationship may be necessary to maximize commercial potential**