Anno 8 - Numero 284 20/06/2010

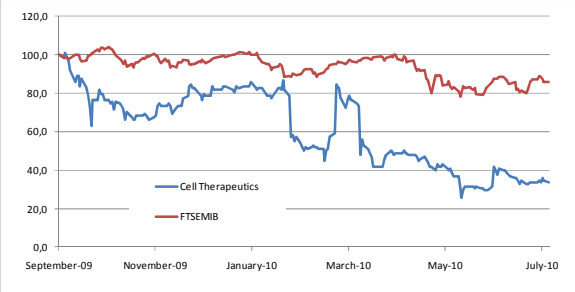
# REPORT RESEARCH Cell Therapeutics

Registrazione al Tribunale di Roma n.521/2002 del 03/09/2002

Direttore: Fabrizio Spagna

## ODAC voted against Pixantrone's approval. CTI is now filing of a Marketing Authorization Application in the European Union

Rating: **HOLD**
(0,5 euro per share)
previous rating (09/11/2009):
(2,5 euro per share, BUY)

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|---|---|
| **Market price (16/07/2010)€** | **0,33** |
| Sector | Pharmaceutical |
| Mibtel Index | 20.118 |
| Market capitalization(Mgl Euro) | 235.448,9 |
| Ordinary shares number(Mgl) | 713.481,5 |
| Free floating | 100,00% |
| Major shareholder: None | 0,00% |
| Min - Max 2010€ 25/05/10 - 14/01/10 | 0,2355 - 0,865 |
| Medium trading volume gg (3 months average) | 10459931,8 |

| Relative Performance | 1M | 3M | 12M |
|---|---|---|---|
| VS FTSEMIB | -13% | -17% | -44% |

*Source: corporate data, Axia's estimates*

- The FDA rejected Cell Therapeutics application regarding the drug Pixantrone. The company stated that it intends to start a new clinical trial to provide further data to demonstrate the drug effectiveness. The new study is going to require years to produce data, therefore Cell Therapeutics would need to raise significant cash to finance its operation. CTI is now focusing on Pixantrone's application in Europe.

- The U.S. Oncologic Drugs Advisory Committee advisory panel has unanimously declared that the data presented by Cell therapeutics regarding Pixantrone were not adequate to support the drug's approval. Cell Therapeutics CEO James Bianco said that the company is "committed to working closely with the FDA to address the committee's comments as quickly as we can".

- Cell Therapeutics announced on May 17 that it has entered into an agreement to exchange with some holders of the company's outstanding convertible notes. According to the agreement CTI may change up to 60 million shares of its stock with up to USD 30 million outstanding notes.

- Cell Therapeutics presented its 2010 first quarter results. The company's net loss amounted to USD 44,2 millions, due to the expenses related to Pixantrone's potential approval. The company reported cash and equivalents for 41,5 millions, an increase on yearly basis.

- Our previous estimate were based on Pixantrone's approval. Since the drug won't enter the market anytime soon after FDA rejection, we reduced our estimates significantly. Our recommendation on the stock is now "HOLD" due to the negative newsflow regarding the drug Pixantrone.

# FDA REJECTS PIXANTRONE

The U.S. Oncologic Drugs Advisory Committee advisory panel met on March 22 to discuss Pixantrone's effectiveness. The panel has unanimously declared (the vote result was 9 – 0) that the data presented by Cell therapeutics regarding Pixantrone were not adequate to support the drug's approval. Specifically, the committee stated that:

1. The trial wasn't well executed and complete (due to the low number of patients involved)
2. The trial result weren't internally consistent since CR/CRus did not occur in the subset of US patients
3. The results were not robust.

The committe believes that Pixantrone needs further evaluation on a larger number of patients and in combination with other agents.
The FDA followed the ODAC suggestions and rejected the drug's application. Cell Therapeutics announced that it intends to start a new trial to provide additional data to support a future approval of the drug.
A new study is going to require years to produce significant data and will require the enrolment of at least 200 patients.

# NOVARTIS – CTI AGREEMENTS

Novartis and CTIC entered into the OPAXIO/Pixantrone agreement on September 15, 2006.
The option cost $ 15 million to NVS, and if exercised grants Novartis an exclusive worldwide license for the development and commercialisation of Opaxio and Pixantrone.

Novartis can exercise its option on Opaxio until 30 days after its approval by either the EMEA in Europe or the FDA in the US. In case it happens, Cell Therapeutics is eligible for up to $ 270 million in milestones, plus royalties.

The rights on Pixantrone can be picked up by Novartis until the later to occur of:

- Three hundred sixty-five days after the database on the Pixantrone extend trial is locked
- Thirty days after the Opaxio participation period expires, which means sixty days after Opaxio approval.

In case Novartis exercises its option for Pixantrone, the license would contemplate that Novartis:

- Reimburses Cell Therapeutics for 50% of the expenses from 9/'06 ($ 25 million circa);
- Pays CTI $ 7,5 million option fee upon license execution;
- Pays $ 10 million FDA approval milestone;
- Pays additional $ 94 million in potential future registration and sales milestones:
- Controls commercialization and development of the product paying 100% future expenses;
- Pays CTI royalties 28,5% to 32,5% on net sales beyond 50 million.

In case Novartis exercises its option for Opaxio, the license would contemplate that Novartis:

- Pays CTI $ 270 million in potential registration and sales milestones;
- Assumes all development and commercial expenses;
- Pays CTI 20%-25% royalties on worldwide sales;
- CTI to field 35 FTE at Novartis expense up to $9 million.

## FIRST QUARTER 2010 RESULTS

Cell Therapeutics presented its 2010 first quarter results, which were influenced by the expenses related to a possible Pixantrone's approval.
The group posted a net loss of US$44,2 million, an increase if compared to the 13,1 millions loss reported on March 31, 2009. The company has US$41,5 million in cash and equivalents and report 5 million of prepaid expenses. Cell Therapeutics has a bash burn rate of 4,4 millions per month, meaning that the company can fund its operation for the following 10 months.

## SHAREHOLDER RIGHTS PLAN

Cell Therapeutics Board of Directors adopted on December 24 a Shareholder rights Plan. The plan's goal is to prevent hostile takeovers, forcing anybody who seeks to acquire control of the company to deal the matter with CTI management rather than just acquiring stocks on the market.
The rights plan aims at granting CTI's shareholder a fair price in case in case of a takeover, it could however discourage potential buyer from seizing control of the company.

# PRODUCTS

The company is focusing on the approval of its two main drugs: Pixantrone and Opaxio.

Pixantrone

Pixantrone is a drug destined to the treatment of non-Hodgkin's lymphoma. Cell Therapeutics was notified in July 2009 by the EMEA that Pixantrone is eligible to be submitted for a Marketing Authorization Application (MAA). In September 2009 Cell Therapeutics submitted a Pediatric Investigation Plan (PIP) to the EMEA as part of the required process for approval of Pixantrone for treating relapsed, aggressive NHL in Europe. The company expects to file a MAA for Pixantrone in September 2010.
Right now Pixantrone is only available on a named-patient program in Europe. Under this type of program investigational drugs like Pixantrone can be administered to patients who are suffering from serious illnesses prior to the drug being approved by the EMEA (European Medicines Evaluation Agency).
The U.S. Oncologic Drugs Advisory Committee advisory panel, however, has unanimously declared on March 22 (the vote result was 9 – 0) that the data presented by Cell therapeutics regarding Pixantrone were not adequate to support the drug's approval. Specifically, the committee stated that:

1. The trial wasn't well executed and complete (due to the low number of patients involved)
2. The trial result weren't internally consistent since CR/CRus did not occur in the subset of US patients
3. The results were not robust.

The committe believes that Pixantrone needs further evaluation on a larger number of patients and in combination with other agents.
The FDA followed the ODAC suggestions and rejected the drug's application. Cell Therapeutics announced that it intends to start a new trial to provide additional data to support a future approval of the drug. However, a new study is going to require years to produce significant data.
Cell Therapeutics met with the experts of the EMEA's Committee for Medicinal Products for Human Use, discussing the preparation of Pixantrone's Marketing Authorization Application in the European Union. CTI expects to submit an updated Pediatric Investigation Plan for pixantrone at the end of the second quarter of 2010.

Opaxio

Cell Therapeutics has withdrawn its European marketing application for Opaxio as a treatment of non-small cell lung cancer. The company will re-focus its efforts toward developing Opaxio as a maintenance treatment for ovarian cancer, a field where there is an unmet medical need and where the potential market could be much greater.
Cell Therapeutics announced on March 4 that it received a statement on March 1 from the Gynecologic Oncology Group (GOG) leadership that the phase III GOG-212 clinical trial of CTI's OPAXIO used as maintenance therapy for ovarian cancer remains a high priority, and enrollment for the study will continue. Based on the study duration, the first data could be available for review in 2011.

## OUR VALUATION

The ODAC advisory panel unanimously agreed that clinical trial data were not adequate to support Pixantrone's approval. The FDA followed the ODAC suggestion stating that further studies are required to show Pixantrone's effectiveness. Cell Therapeutics announced that it intends to conduct an additional trial to demonstrate the drug's effectiveness. Such a trial will however require years to be completed, meaning that Pixantrone won't be approved before a couple of years. The company's next drug on the pipeline is Opaxio, whose study results won't be available before 2011.

Cash becomes a concern for the company. Cell Therapeutics has approximately US$45 million of cash, and a cash burn rate of 4,4 millions per month. CTI has USD 40 millions of debt due in July, but has announced an agreement with some of the convertible notes holders to exchange up to 30 million of notes with the company's common stock. The company is looking for a partner with which to finance a co-dovelopment project to bring its drugs to the market. There is a good market for late stage drugs, so Cell Therapeutics should be able to find a company interested in investing on Pixantrone.

Cell Therapeutics has postponed its shareholders meeting to June 4, this is the second consecutive postponement since April 9.

Due to the negative newsflow regarding the drug Pixantrone and the company's cash situation our recommendation on CTI stock is now HOLD.

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**Report Research**
Newsletter a diffusione elettronica

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