

## Cytos Biotechnology Announces Full Year 2009 Financial Results and Major Developments in 2009

Schlieren (Zurich), Switzerland, February 3, 2010 – Cytos Biotechnology Ltd (SIX:CYTN) today presented its full year 2009 financial results and annual major developments. Furthermore Cytos Biotechnology informed that the chairman of the Board of Directors, Dr. F. L'Eplattenier (70), does not stand for re-election due to age at the next shareholders' meeting.

### Financial Results 2009 (consolidated):

- Cash, cash equivalents, financial assets and trade receivables from collaboration partners were at CHF 60.5 million at year end 2009.
- According to present financial plans, Cytos Biotechnology is thus financed into the year 2012.
- Revenues of CHF 9.1 million in 2009, net loss of CHF 24.8 million.
- Cash used in operations was CHF 2.5 million/month in 2009, well below last year.

### Major Developments in 2009:

#### **Immunodrug™ agreements with Pfizer in human health**

- Signing of an exclusive global research, option and license agreement for novel vaccines for a defined number of human diseases worth up to CHF 150 million plus royalties in August 2008.
- Announcement of execution by Pfizer of its options under this agreement and taking commercial licenses for the specified vaccines in January 2009.
- During 2009, Pfizer and Cytos successfully completed technology transfer of the GMP pilot scale process for Qb manufacturing and Cytos Biotechnology received a manufacturing technology transfer fee under the commercial license agreements.

#### **Clinical Immunodrug™ development**

##### ***CYT003-QbG10 for allergic rhinoconjunctivitis***

- CYT003-QbG10 monotherapy for the treatment of allergic rhinoconjunctivitis was safe and efficacious in a phase IIb study with 299 allergic patients
- The study met its primary and both secondary endpoints
- Primary efficacy was assessed by recording rhinoconjunctivitis symptom and medication scores in patient diaries over a 14 day period.
- Secondary efficacy parameters were quality of life with rhinoconjunctivitis assessed by a validated questionnaire, and change in allergen tolerance determined by a standard conjunctival provocation test.

##### ***CYT003-QbG10 for allergic asthma bronchiale***

- Start of a phase IIa study with CYT003-QbG10 in patients with allergic asthma bronchiale.
- Target enrollment of 60 patients was reached in January 2010.
- Results are expected by Q2 in 2010.

### ***NIC002 for smoking cessation (partnered with Novartis)***

- Cytos Biotechnology was informed by Novartis that an interim analysis of a phase II study with the nicotine vaccine NIC002 for smoking cessation showed that the primary endpoint was not achieved.
- In this study, which is still ongoing at the end of 2009, the treatment was safe and well tolerated but failed to induce sufficiently high antibody titers, which may have led to the negative outcome.
- Partner Novartis will decide on the next steps once the scheduled 12 month duration of the clinical trial is completed and when all data have been analyzed.

### ***CYT006-AngQb for hypertension***

- Results from two phase II studies (study 02 and study 03) showed that the vaccine was safe and well tolerated but failed to induce a significant reduction of the ambulatory blood pressure, contrary to the first study (study 01).
- The conclusions drawn from the results of the three studies are that the altered treatment regimen of studies 02 and 03 reproducibly leads to qualitatively different antibody responses with a significantly lower affinity than the conventional treatment regimen of study 01.
- The antibody affinity, which is of critical importance in cases where small target molecules like angiotensin II (8 aminoacids) are to be neutralized, can potentially be controlled by adjusting treatment parameters like the timing of booster injections.
- Cytos Biotechnology has therefore decided to continue its research with CYT006-AngQb in hypertension.

### ***CYT013-IL1bQb for type II diabetes mellitus***

- Start of a phase I/IIa study with CYT013-IL1bQb in patients with type II diabetes mellitus.
- The phase I stage with up to 32 patients will evaluate ascending dose regimens of CYT013-IL1bQb.
- Cohorts 1 and 2 (16 patients) were fully enrolled by year end 2009.

### ***CAD106 for Alzheimer's disease (partnered with Novartis)***

- Advancement of CAD106 in clinical development by Novartis triggered a compensation of CHF 2.5 million to Cytos Biotechnology in January 2009. A second payment in the amount of CHF 2.5 million is due early 2010.
- The treatment regimen with active A $\beta$  immunotherapy CAD106 in Alzheimer patients is being optimized.

### **Restructuring of Cytos Biotechnology to focus on key development programs**

- In order to align its financial resources on the key development programs and its collaborations with Novartis and Pfizer, Cytos Biotechnology reduced its workforce of 135 full time employees to 85.
- Restructuring lowered gross cash used in operations from CHF 3.0 million in the first half year to CHF 2.0 million in the second half year of 2009.

Wolfgang Renner, PhD, CEO of Cytos Biotechnology commented: "Two highlights of the year 2009 were the announcement of execution by Pfizer of its options under our agreement as well as the successful completion of our phase IIb study with CYT003-QbG10 for the treatment of allergic diseases. With QbG10 we are working on a completely novel approach for the causal treatment of this common chronic disease. QbG10 is designed to deliver a potentially missing stimulus to the patient's immune system, a stimulus which has most likely been eliminated in the past century with the

development of modern standards of hygiene. Our innovative research with QbG10 in this indication has in the past years been repeatedly rewarded with positive results.

Due to the fact that we are exploring unknown territory with our novel therapeutic vaccines, the outcome of our research and development cannot always be predicted and an element of trial and error remains. We experienced this side of the coin in our hypertension and smoking cessation projects (the latter being partnered with Novartis) where changes in the treatment parameters, which were aimed at improving efficacy did not show the desired effect. When we analyzed the data in detail, we identified potential reasons which could explain the observed result and which give us a deeper understanding into the natural processes which are modulated with our vaccine candidates.

This growing body of knowledge has already been applied to our second generation vaccines targeting full length proteins, e.g. CYT013-QbIL1b for the treatment of type II diabetes, which make good progress and where we expect first clinical results during the year 2010. In order to focus our available resources on these key development programs we acted immediately upon the setback in spring 2009 and reduced our gross cash burn from CHF 3.0 million per month in the first half of 2009 to 2.0 million in the second half.

As a result of this restructuring, the company now focuses on its partnerships with Novartis and Pfizer, on two clinical programs, CYT003-QbG10 and CYT013-IL1bQb, on two preclinical programs in inflammation and further research with the hypertension vaccine CYT006-AngQb. Certain non-core assets like the technology for the discovery of human monoclonal antibodies (i.e. the business conducted through our wholly owned subsidiary Cytos Biotherapeutics Ltd) are available for sale. With these measures we are confident that we can overcome the technical difficulties that we have experienced during the year 2009 and move one step closer to our goal, the development and commercialization of a new treatment modality for common chronic diseases."

## Full year consolidated financial figures 2009:

### **Balance Sheet**

Funds available for financing the operations amounted to CHF 60.5 million at December 31, 2009, and include cash, cash equivalents, financial assets and trade receivables from collaboration partners. They were thus CHF 37.5 million lower than end of December 2008. This net change resulted from payments from collaboration partners, financing of the ongoing operations, and financing activities including the repurchase of 18.4% of the outstanding convertible bonds which are due for repayment in February 2012.

### **Revenues**

Revenues decreased from CHF 19.7 million in 2008 to CHF 9.1 million in 2009. The revenues in 2009 resulted mainly from deferred income in conjunction with the execution of commercial license agreements end of December 2008 by Pfizer and the subsequent transfer of manufacturing technology as well as license income from a development collaboration.

### **Cash burn and Liquidity**

The gross cash burn for operating activities decreased from CHF 3.3 million per month in 2008 to CHF 2.5 million per month in 2009. Based on our present financial plans, Cytos Biotechnology is financed until the beginning of 2012 but will need to raise further financing through new licensing deals, sale of assets or the issuance of new shares or other securities in order to be able to repay the outstanding convertible bonds due in February 2012.

### Financial summary (consolidated)

(in CHF million)	Results 2009	Results 2008
Research and collaboration revenues	9.1	19.7
Net operating costs	(36.3)	(43.6)
Operating loss	(27.2)	(23.9)
Net loss	(24.8)	(26.0)
Net loss per share (in CHF)	(4.71)	(4.94)

(in CHF million)	December 31, 2009	December 31, 2008
Cash, cash equivalents, financial assets & trade receivables	60.5	98.0
Convertible bonds (outstanding nominal value)	57.1	70.0
Full-time employees (number)	85	132

The full financial statements can be found on [www.cytos.com](http://www.cytos.com).

### Full year statutory financial figures 2009:

#### Financial summary (statutory)

(in CHF million)	Results 2009	Results 2008
Research and collaboration revenues	1.2	27.7
Total operating expenses	(40.0)	(40.2)
Operating loss	(38.8)	(12.4)
Other income	17.9	41.5
Net profit/(loss)	(15.4)	28.9

(in CHF million)	December 31, 2009	December 31, 2008
Total assets	121.9	151.1
Total liabilities	74.5	88.3
Shareholder's equity	47.4	62.8

The full financial statements can be found on [www.cytos.com](http://www.cytos.com).

### Retirement of Dr. F. L'Eplattenier due to age

Dr. F. L'Eplattenier (70), Chairman of the Board of Directors, informed Cytos Biotechnology that he does not stand for re-election for another term due to age.

Cytos Biotechnology will initiate the process to search a new chairman and inform further when inviting to the ordinary shareholders' meeting.

#### For further information please contact:

Wolfgang A. Renner, PhD  
Chief Executive Officer  
Cytos Biotechnology Ltd  
Phone: +41 44 733 47 03  
Fax: +41 44 733 47 04  
e-Mail: [wolfgang.renner@cytos.com](mailto:wolfgang.renner@cytos.com)  
Website: [www.cytos.com](http://www.cytos.com)

## **About Cytos Biotechnology**

*Cytos Biotechnology Ltd is a public Swiss biotechnology company that specializes in the discovery, development and commercialization of a new class of biopharmaceutical products – the Immunodrugs™. Immunodrugs™ are intended for use in the treatment and prevention of common chronic diseases, which afflict millions of people worldwide. Immunodrugs™ are designed to instruct the patient's immune system to produce desired therapeutic antibody or T cell responses that modulate chronic disease processes. Taking advantage of the high flexibility of its Immunodrug™ platform, Cytos Biotechnology has built a diversified pipeline of Immunodrug™ candidates in various disease areas, of which six are currently in clinical development. The Immunodrug™ candidates are developed both in-house and together with Novartis, Pfizer and Pfizer Animal Health. Founded in 1995 as a spinoff from the Swiss Federal Institute of Technology (ETH) in Zurich, the Company is located in Schlieren (Zurich). Currently, the Company has 84 full-time employees. Cytos Biotechnology Ltd is listed on the SIX Swiss Exchange (SIX:CYTN).*

## **Glossary**

**Affinity:** a measure which describes how strong an antibody binds to its target molecule.

**Allergen:** a normally harmless substance that elicits a misdirected immune response.

**Ambulatory blood pressure:** blood pressure measured by numerous readings over a 24-hour period or longer. Provides accurate and reliable information about a person's blood pressure.

**Angiotensin II:** a small peptide that is part of the renin-angiotensin system (RAS). Induces narrowing of blood vessels and other effects to raise blood pressure.

**Antibody:** class of blood proteins generated by the immune system to neutralize foreign material such as bacteria, viruses or toxins (i.e. antigens).

**Average combined symptom and medication score:** symptoms and concomitant medication use are recorded during the study on individual diary cards during a defined period of time. As a clinical outcome measure, the World Allergy Organization (WAO) recommends to utilize the average of the scores achieved for total allergy symptoms and medication use.

**Beta-amyloid:** substance that is deposited in plaques found in the brains of Alzheimer's disease patients.

**Biopharmaceutical:** drug created by means of biotechnology, especially genetic engineering.

**Immunotherapy / immunotherapeutic:** a therapy / a medication aimed at activation of the immune system to modulate a certain disease process.

**Monotherapy:** treatment with one drug as opposed to combination therapy. Here the term refers to treatment with QbG10 alone (i.e. CYT003-QbG10) in contrast to a regimen where QbG10 was combined to allergen extract (i.e. CYT005-AllQbG10 combination therapy).

**Phase IIa/II/IIb:** clinical trial that examines a new drug candidate's safety, tolerability and exploratory efficacy. Phase IIa studies usually include a small number of patients, whereas phase IIb studies are designed as larger and often multicenter trials to examine the new drug in a relevant number of patients.

**Placebo:** dummy medical treatment.

**Preclinical:** phase of activities where a new drug candidate is tested in animal models.

**QbG10:** Cytos Biotechnology's Immunodrug™ Qb filled with the immunostimulatory DNA sequence G10.

**Regimen:** describes the schedule and composition according to which a drug is administered.

**Rhinoconjunctivitis:** combination of rhinitis (inflammation of the nasal mucosa) and conjunctivitis (inflammation of the mucous membrane of the eye).

**T cell:** immune cell playing an important role in cell-mediated immunity. One differentiates various subgroups such as cytotoxic (killer) T cells, T helper (Th) cells and regulatory T cells.

**Typ II Diabetes:** most common form of diabetes.

This foregoing press release may contain forward-looking statements that include words or phrases such as "expect", "will", "potential", "designed", "believe", "intend" or other similar expressions. These forward-looking statements are subject to a variety of significant uncertainties, including scientific, business, economic and financial factors, and therefore actual results may differ significantly from those presented. There can be no assurance that any further therapeutic entities will enter clinical trials, that clinical trial results will be predictive for future results, that therapeutic entities will be the subject of filings for regulatory approval, that any drug candidates will receive marketing approval from the U.S. Food and Drug Administration or equivalent regulatory authorities, or that drugs will be marketed successfully. Against the background of these uncertainties readers should not rely on forward-looking statements. The company assumes no responsibility to update forward-looking statements or adapt them to future events or developments. This document does not constitute an offer or invitation to subscribe or purchase any securities of Cytos Biotechnology Ltd.