

Press release

Innogenetics' outlook for 2003 – enhanced financial prospects and promising new therapeutic developments

Preliminary 2002 results, update on key programs, and outlook for the coming year

Gent, January 15, 2003 – Innogenetics today announced the preliminary indications of its year 2002 financial results, offered an initial outlook for 2003 and provided an update on its therapeutic programs.

Financial highlights

Preliminary indications (unaudited) of 2002 financial results

- Diagnostics Division: profitable
- Product sales: approximate 15% increase
- R&D investments: approximate 20% increase
- Operating expenses: stable
- Cash position: strong - approximately €40 million at year-end
- Audited 2002 financial results will be announced on February 27, 2003

Initial outlook for 2003

- Diagnostics Division: enhanced profitability
- Product sales: 15 to 20% expected increase
- Total revenues: 15 to 20% expected increase
- R&D investments: 10 to 15% expected increase
- Operating expenses: stable
- Operating losses: reduction versus 2002 levels
- Capital expenditures: €7 million, in line with 2002 levels
- Cash burn rate: reduction versus 2002

Philippe Archinard, CEO of Innogenetics, commented: "In 2002, Innogenetics delivered on its promises by achieving profitability in its diagnostic activities and scoring significant successes in its therapeutic programs. As mentioned previously, the need for additional investments in our promising therapeutic pipeline led to a 20% increase in R&D expenditures for 2002, hence impacting our overall operating results."

"Furthermore, we are pleased to report an encouraging outlook for 2003. Revenue growth and enhanced profitability of our Diagnostics Division will continue to support the increased therapeutic R&D commitments: 3 separate Phase II trials including 400 patients with 2 compounds, and a third set to enter clinical evaluation following positive preclinical results."

The strong cash position and a lower cash burn rate in 2003 will ensure the further implementation of the current strategy and projects."



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Hepatitis C therapeutic vaccine – Phase II clinical program

Final results of Phase IIa study extension - confirmation of positive results:

- **vaccine very well tolerated**
- **stable or improved overall liver histology score in 79% of patients**
- **confirmation of therapeutic vaccination approach**

Analysis of the Phase IIa study extension in 34 patients has now been completed. The previously announced positive results were clearly confirmed.

The therapeutic vaccine was very well tolerated, as supported by the low dropout rates over the 17-month study period (34 of 35 patients re-enrolled and completed the study extension).

As reported in October 2002, the overall liver histology score either remained stable or improved in 19 out of 24 patients (79%) as compared to pre-study scores. Liver fibrosis showed improvement in no less than 9 out of 24 patients (38%) and, on average, progression to fibrosis was halted.

Furthermore, the strong immune response to the E1-based therapeutic vaccine was associated with improvements in liver fibrosis and liver enzyme levels (ALT). These results clearly support the scientific rationale for a therapeutic vaccine approach.

It should be stressed that most patients enrolled in this study had failed to respond to interferon-alfa based treatment, the current standard therapy. Such patients would greatly benefit from treatments that slow, halt, or even reverse liver fibrosis, as this process can lead to liver cirrhosis, the predominant cause of severe complications in chronic hepatitis C.

Next steps

1. Extension of initial Phase IIa study

An 18-month, open-label extension of the initial Phase IIa study has started, and will generate relevant clinical data over a 3-year period. Its aim is to explore the long-term disease-modifying effects of therapeutic vaccination in those patients who were enrolled in the two previous studies.

The liver histology results of this extension study are expected by the second quarter of 2004.

2. New 150-patient, international, multicenter, placebo-controlled Phase IIb study

In parallel, a European-wide, multicenter, placebo-controlled Phase IIb clinical trial will start in the first quarter of 2003 with the aim of confirming the positive findings observed to date and demonstrating regression of liver fibrosis of E1-treatment versus placebo.

This new study will enroll 150 patients who are chronically infected with hepatitis C virus (genotype 1). The patients will be non-responders or have contraindications for current standard therapy. Patient recruitment is expected to be finalized in the third quarter of 2003. The study is scheduled to end in the last part of 2004.



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Hepatitis C prophylactic vaccine

Preclinical program ongoing and on track

A prophylactic vaccine aims at preventing the occurrence of a disease, while a therapeutic vaccine treats an existing one.

A pivotal preclinical study for a prophylactic vaccine to prevent hepatitis C infection is currently ongoing. Its aim is to further extend the promising preliminary results obtained to date.

Study results are expected in the first half of 2004.

LyphoDerm

Phase II clinical study for the treatment of hard-to-heal leg ulcers on track

As mentioned in September 2002, XCELLentis started a 180-patient, European-wide, multicenter Phase II study with LyphoDerm in patients with chronic recalcitrant venous leg ulcers. LyphoDerm, XCELLentis' lead development product, combines advances in wound healing with pharmaceutical properties that include ease-of-storage, product availability, long shelf life, and ease-of-application.

This randomized, open-label, parallel-group study will investigate both the safety and efficacy of LyphoDerm during 10 weeks of product application followed by 14 weeks of follow-up. The incidence of "complete wound closure" within 24 weeks is defined as the primary endpoint.

Patient recruitment for the study is on track. The first interim results should be announced towards the end of the third quarter of 2003, with final results expected by the end of 2003.

INNO 201 – Treatment of pulmonary edema associated with cardiac failure

Start of clinical trials in the fourth quarter of 2003

After successfully evaluating its proprietary peptide (INNO 201) in several preclinical models, pulmonary edema associated with cardiac failure has been chosen as the main therapeutic target. The optimal route of administration for this indication is inhalation. The process to produce clinical grade material has been adapted accordingly.

The clinical evaluation program is planned to start in the fourth quarter of 2003.

INNO 202 – Treatment of sepsis

Pivotal preclinical study ongoing

The data available to date from the study in which INNO 202 was administered at the onset of severe sepsis are very promising.

The final outcome of this pivotal preclinical study will be announced by the end of the first quarter of 2003. Evaluation of the development strategy for INNO 202 is currently underway.



About Innogenetics

Innogenetics, a Belgium-based, international biotechnology company, is pursuing a challenging twofold growth strategy, encompassing both diagnostics and therapeutics.

The Company is committed to becoming a worldwide leader in high value-added diagnostics (especially "theranostics") focusing on infectious diseases, neurodegeneration, and genetic testing. With its vertically integrated diagnostics activities, Innogenetics is leveraging its intellectual property, know-how, and product offerings through strategic partnerships with leading in vitro diagnostic players such as Bayer, Roche, and Abbott. By running a profitable diagnostic business, Innogenetics can therefore finance the development of new therapeutics.

At present, the Company's therapeutics portfolio consists of innovative candidates in the fields of hepatitis C, immune disorders, and wound care (the latter through its wholly owned subsidiary XCELLentis). Its clinical development program for a hepatitis C therapeutic vaccine is currently in phase 2. Pre-clinical programs are also underway for the treatment of pulmonary edema and sepsis, as well as for a hepatitis C prophylactic vaccine. Finally, phase 2 clinical trials are ongoing in the field of wound care.

Founded in 1985, Innogenetics has been listed on NASDAQ Europe since November 1996 and on Euronext Brussels since December 2002. The Company has its headquarters in Gent, Belgium, with sales affiliates located in France, Germany, Italy, the Netherlands, Spain, and the USA. It employs 600 people worldwide.

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SPECIAL NOTE REGARDING FORWARD-LOOKING INFORMATION

This press release contains forward-looking statements that involve risks and uncertainties, including but not limited to projections of future revenues, operating income, and other risks. Prospective investors should be aware that these statements are estimates, reflecting only the judgment of our management, and they should not place undue reliance on any forward-looking statements.