Bresso, Italy, 13 November 2002 – Novuspharma SpA (Nuovo Mercato: NOV.MI), a biopharmaceutical company focused on cancer, today announces financial results for the nine months ended 30 September 2002 and an update on R&D in the third quarter.

Highlights:

- ~ Pivotal phase III study underway for pixantrone (BBR 2778) in indolent non-Hodgkin's Lymphoma (NHL) in combination with Rituxan (rituximab), with 100 centres involved worldwide.

- ~ Encouraging preliminary results seen in dose ranging trials for pixantrone (BBR 2778) in combination with other cytotoxic therapies, with a high proportion of complete responses (CRs) seen among currently evaluable patients.

- ~ Agreement signed with Micromet AG to co-develop MT201, a fully human antibody targeting the Ep-CAM molecule. Preparations underway for a broad phase II development programme in 2003.

- ~ Encouraging preliminary results seen with BBR 3576 in phase II trials in hormone refractory prostate cancer (HRPC), with 8 responses out of 42 currently evaluable patients. Preparations underway for pivotal trials in this indication next year, including an expansion of the phase II programme.

- ~ Further development of BBR 3438 will be discontinued, along with BBR 3576 in gastric cancer.

- ~ HIF-1 research programme expanded though a three year collaboration with the US National Cancer Institute (NCI).

- ~ Optimisation of Cephalon's lead proteasome inhibitors underway.

- ~ Cash balance at 30 September of €115.3 million (31 December 2001: €141.8 million).

Dr Silvano Spinelli, Chief Executive Officer, said:
"We are extremely pleased with progress across all fronts of the business during the third quarter. Our most advanced programmes with DNA intercalators pixantrone (BBR 2778) and BBR 3576 are yielding encouraging results, and our collaborative approach is bearing fruit through the diversification of the product pipeline with innovative therapies. All this has been achieved within budget. We look forward to an even more productive year ahead. "

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CHIEF EXECUTIVE OFFICER'S REVIEW
FINANCIAL REVIEW

Revenues for the nine months ended 30 September 2002 were €2.8 million compared to €0.1 million in 2001. Revenues in the period were mainly due to public grants supporting Novuspharma's research programmes.

Net loss for the period was €24.5 million compared with €11.0 million in 2001. This increase was in-line with the company's expectations and reflects the advanced stage of the products in clinical development, particularly the large-scale studies with pixantrone (BBR 2778) for NHL.

The company's cash balance as of 30 September 2002 was €115.3 million (31 December 2001: €141.8 million). We expect the company's cash position at the end of 2002 to be around €110.0 million, in-line with current market estimates and leaving Novuspharma well financed to achieve its goals in 2003 and beyond.

CLINICAL PROGRAMMES

Pixantrone (BBR 2778)

- ~ Recruitment for the phase III study in relapsed indolent NHL is underway with 100 centres being opened worldwide. This study is comparing single agent rituximab, the current standard treatment, with a pixantrone (BBR 2778)/rituximab combination. This trial is expected to recruit around 800 patients in the US and Europe and its primary efficacy endpoint is time to disease progression.
- ~ Encouraging preliminary results have been obtained in the dose ranging trials for pixantrone (BBR 2778) in combination with other cytotoxic therapies. Recruitment is almost complete in the ESHAP variant trial, in aggressive NHL, where pixantrone (BBR 2778) is being combined with cisplatin and high doses of ara-c (the so called BSHAP combination regimen). A very high number of complete responses have been seen among the first 10 evaluable patients.
- ~ The first patients treated with the variant FND-R combination have responded well, with most showing complete remission. In this trial, pixantrone (BBR 2778) replaces the DNA intercalator mitoxantrone in the FND-R combination, where it is being administered in combination with fludarabine, steroid and rituximab.

BBR 3576/BBR 3438

- ~ Encouraging preliminary results have been obtained for BBR 3576 in phase II trials in hormone refractory prostate cancer (HRPC): In 42 patients, at least 8 have shown a significant response as assessed by a decrease in PSA, a serum marker.
- ~ Based on these encouraging results, BBR 3576 has been selected for full development in this indication. Preparations are underway to start phase III trials next year, including an expansion of the phase II programme to include an additional treatment schedule and a combination study with other chemotherapy agents. Novuspharma expects to start discussions with the FDA regarding the registration strategy in Q1 2003.
- ~ Further development of BBR 3438 will be discontinued, along with BBR 3576 in gastric cancer.

Pixantrone (BBR 2778), BBR 3576 and BBR 3438 belong to a family of molecules know as DNA intercalators with improved efficacy and safety (see the editorial notes for a full explanation).

MT201

- ~ In September, Novuspharma entered into an agreement with Micromet AG to co-develop MT201, a fully human antibody targeting the Ep-CAM molecule, which has potential in a wide range of solid tumours.
- ~ Preliminary results from the phase I study in hormone-refractory prostate cancer (HRPC) have shown that MT201 is well tolerated, with full results expected in the next few months.
- ~ Preparations are underway to start a broad phase II programme next year, including up to 1,000 patients in a range of solid tumour indications, including lung, breast and ovarian cancer.

RESEARCH PROGRAMMES

Proteasome Inhibitors

- ~ The collaboration with Cephalon, signed in May this year, is progressing well. Following technology transfer from Cephalon to Novuspharma's laboratories, a programme of lead optimisation is underway, with around 50 new inhibitors prepared and undergoing testing, with promising results to date.

Expansion of HIF-1 project

- ~ In September, Novuspharma expanded its research focused HIF-1 inhibitors, through a Cooperative Research and Development Agreement (CRADA) with the US National Cancer Institute (NCI). HIF-1 is a transcription factor known to play a role in regulating tumour cell survival, proliferation and angiogenesis (growth of new blood vessels into tumours).
- ~ Novuspharma has identified a number of lead HIF-1 inhibitors that are currently undergoing optimisation. Under the terms of the CRADA, the NCI will conduct a series of tests to validate mechanism of action, while the NCI's Open Chemical Repository will be used to identify completely new leads.

Progress in other research projects

- ~ A number of inhibitors of the c-kit and Ret oncogenes with anti-tumour activity have been identified. Lead optimisation is currently ongoing.
- ~ A number of novel targets potentially involved in lung and colon metastasis have been identified in pre-clinical models. Validation of corresponding human genes ongoing.
- ~ The platinum-based compounds BBR 3464 and BBR 3610 are currently undergoing formulation studies, with the aim of improving efficacy before possible clinical studies.

Notes to Editors

Novuspharma SpA, based in Bresso, Milan, is a biopharmaceutical company focused on the discovery and development of innovative anti-cancer therapies. It has three products in clinical development and a dynamic research programme. Novuspharma was created in 1998 as a spin-off from Boehringer Mannheim and Hoffmann-La Roche, and has a proven track record in product development. Novuspharma makes use of a complete range of discovery and development platforms and focuses its specific expertise on the most critical part of the development process from the initial identification of leads to late clinical development stages as far as New Drug Application.

DNA intercalators with improved efficacy and safety. The most advanced products which Novuspharma has in clinical development belong to the DNA intercalator family of molecules. The currently marketed drugs from this class form one of the keystones of modern chemotherapy but suffer from the major drawback that they cause irreversible damage to heart muscle, which limits their use to a maximum cumulative dose within a patient's life-time. Novuspharma has used its expertise in medical chemistry to alter the structure of currently marketed DNA intercalators, in order to improve their safety and efficacy and specifically to reduce their cardiotoxicity.

Pixantrone (BBR 2778) and non-Hodgkin's lymphoma. Pixantrone (BBR 2778) is a DNA intercalator with improved efficacy and safety which Novuspharma is developing for non-Hodgkin's lymphoma (NHL). NHL is caused by the abnormal proliferation of lymphocytes (immune system cells) and 160,000 patients are estimated to be suffering from the disease in the US alone, projected to grow to 250,000 by 2007. Pixantrone (BBR 2778) has produced encouraging results to date, both from preclinical studies and from clinical trials. In particular, in phase II trials in patients with advanced aggressive NHL, pixantrone (BBR 2778) achieved 5 complete responses (CRs) and 4 partial responses (PRs) out of 33 patients. Currently Novuspharma is conducting a pivotal phase III trial in relapsed indolent NHL. This trial is expected to recruit around 800 patients in the US and Europe and will compare the efficacy and safety of pixantrone (BBR 2778), in combination with rituximab (Rituxan®) to rituximab alone, with time to disease progression as the primary efficacy endpoint.

BBR 3576 is a DNA intercalator with improved efficacy and safety which has shown its highest activity in solid tumours. BBR 3576 has produced encouraging results to date, both from preclinical studies and from clinical trials. In particular, preliminary phase II results in hormone refractory prostate cancer (HRPC) have shown a promising number of complete and partial responses. The phase II programme for BBR 3576 in HRPC is currently being expanded and preparations are underway for a phase III trial to start in 2003.

MT201 is a fully human antibody targeting the Ep-CAM antigen that Novuspharma is developing in collaboration with Micromet AG. The Ep-CAM antigen is a well validated clinical target which is present on the surface of the majority of carcinoma cells and therefore MT201 has the potential to be used in a wide range of solid tumours. In addition, the human nature of MT201 gives it low immunogenity and should allow it to induce efficient elimination of tumour cells by interacting with the patient's immune system. Preliminary data from an ongoing phase I study in HRPC suggests MT201 is well tolerated and preparations are underway for phase II trials in a number of solid tumours in 2003.

For further information, please visit the Company's website at www.novuspharma.com.

Profit and Loss highlights

Amounts in €uro/000	Three month period 1/7-30/9		Nine month period 1/1-30/9	
	2002	2001	2002	2001
Revenues	**126**	**1**	**2,800**	**45**
R&D costs	- 5,480	- 3,058	- 17,196	- 9,203
Other operating costs	- 1,420	- 1,122	- 4,996	- 3,662
EBITDA	**- 6,774**	**- 4,179**	**- 19,392**	**- 12,820**
Depreciation, amortisation and write-downs	- 5,341	- 1,120	- 7,665	- 3,320
EBIT	**- 12,115**	**- 5,299**	**- 27,057**	**- 16,140**
Net financial income	665	1,565	2,517	5,176
Result for the period	**- 11,450**	**- 3,734**	**- 24,540**	**- 10,964**

Balance sheet highlights

Amounts in €uro/000	30/09/2002	30/06/2002	31/12/2001
Net financial position	115,347	127,460	141,837
Net working capital	1,836	259	-
Net intangible and tangible fixed assets	8,855	9,715	10,382
Total	**126,038**	**137,434**	**152,219**
Net working capital	-	-	1,767
Long-term obligations	950	897	825
Net equity	125,088	136,537	149,627
Total	**126,038**	**137,434**	**152,219**