#### TranXenoGen, Inc. Final Results for the Year Ended 31 December 2003

TranXenoGen, Inc. ("TranXenoGen" or the "Company"), a developer of new therapeutic production technologies and products, announces operating results for the 12 months ended 31 December 2003.

## 2003 Highlights

- 2003 net loss of \$4.4 million (2002: net loss of \$4.4 million) or \$0.14 loss per share (2002: \$0.14 loss per share).
- Unrestricted cash \$2.2 million at 31 December 2003.
- Intellectual property portfolio enhanced by:
  - Issuance of U.S. Patent 6,686,199, Genetic Manipulation of Spermatogonia, which relates to the Company's proprietary Gene-Testes Transfection Technology for the production of transgenic animals.
  - \_ Notice of Allowance received by Brandeis University from the U.S. Patent and Trademark Office for the patent application Nuclear Reprogramming Using Cytoplasmic Extracts. The patent, which has a priority date of February 1993, covers techniques for the reprogramming of somatic cell nuclei for the generation of cloned and/or transgenic animals and is licensed exclusively to TranXenoGen.
- R&D progress during 2003:
  - Achievement in November 2003 of a key milestone in the ANUP program utilizing two synthetic peptides. In animal model studies, tumor growth was inhibited by up to 70% and blood vessel formation was impacted by inhibiting angiogenesis and infiltration.
  - Achievement of Human Serum Albumin (HSA) expression in chimeric eggs at 6 ng/ml as announced in May 2003.
  - \_ Development of germline transgenic chickens for HSA, Insulin and one partner's monoclonal antibody. Germline transgenic chickens are tested for expression of the protein in order to identify a founder line. If successfully bred, these founder birds could be used initially to generate material for clinical trials and then for commercial production.
  - Continued development of second-generation transgenic technology (Gene-Testes Transfection) with the objective of reducing development time by up to 50% and improving the percentage of transgenic birds produced by the process.
- Implementation of short-term revenue strategies including licensing efforts on recently allowed cloning patents, collaboration efforts to obtain grants and other funding in the area of biodefense/vaccine development and strategic partnering project for Anti-Neoplastic Urinary Protein (ANUP).

## George Uveges, President and Chief Executive Officer, commented:

"2003 was a year of transition and positioning for TranXenoGen. While progress continues on the development of the avian transgenic platform, the Company has increased its focus on several potential short-term revenue opportunities:

- Partnering of its ANUP cancer treatment.
- Licensing its patent portfolio, specifically its cloning patents with a 1993 filing date.
- Seeking funded research programs in biodefense and vaccine development.

In addition, the Company is actively pursuing raising additional capital.

The fund raising and revenue generation efforts are progressing. In order to provide additional time to execute on these initiatives, the Company has implemented the following actions in March to reduce its cash burn rate:

- *The Non-Executive Directors have agreed to defer payment of their director fees for twelve months.*
- Effective as of the end of March, the Chief Executive Officer salary will be reduced to \$60,000 per year reflecting a reduced level of activity.
- Salary reductions for the three senior management personnel.
- *Reduction in workforce by 30%.*
- Spending in other areas will be reduced correspondingly.

Based on these reductions, our cash burn rate as of April 2004 will decrease to approximately \$650,000 per quarter. Our current cash position should fund operations through August 2004 at this reduced burn rate. The achievement of the outlined revenue generation programs should further reduce the cash burn rate and extend the period of operation supported by our current cash balance. As a result of these reductions, the Company will reduce its efforts in non-science areas and activities related to unfunded research.

The Company has made significant progress over the last several years as it has developed its product pipeline. The Company's well-balanced strategy of developing generic products and proprietary novel therapeutic products, licensing of its Intellectual property and contract manufacturing provides a variety of commercialization opportunities. We look forward to updating our shareholders on our fundraising and revenue efforts at the Company's annual general meeting in June."

#### 16 March 2004

**Enquiries:** 

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#### **Risk Warning Notice:**

TranXenoGen, Inc. (symbol TXN.L) is a publicly traded development stage, biotechnology company. Its shares are quoted on the Alternative Investment Market of the London Stock Exchange. The securities of the Company have not been registered under the Securities Act of 1933 and therefore, may not be offered or sold in the United States absent registration or an applicable exemption from the registration requirements under such Act.

The Company is focused on developing new therapeutic production technologies and products. TranXenoGen is a development stage company and, as such, investors should be aware that an investment in the Company involves a substantially high degree of risk.

This press release contains forward-looking statements that can be identified by terminology such as "expects", "potential", "suggests", "may", "will" or similar expressions. Such forward-looking statements regarding our business, which are not historical facts, are "forward-looking statements" that involve risk and uncertainties, which could cause the Company's actual results and financial condition to differ materially from those anticipated by the forward-looking statements. Actual results may differ materially from statements made as a result of various factors, including, but not limited to sufficiency of cash to fund the Company's planned operations, risk associated with inherent uncertainty of product research and development, risk of protecting proprietary rights and competition. Forward-looking statements to reflect the circumstances or events that occur after the date the forward-looking statements are made.

## TranXenoGen, Inc.

## PRESIDENT AND CHIEF EXECUTIVE OFFICER'S STATEMENT

#### **OVERVIEW**

2003 was a year of transition and positioning for TranXenoGen. While progress continues on the development of the Company's avian transgenic platform, as described below, the Company has increased its focus on several short-term revenue generating efforts. The first of these is development of a novel protein, Anti-Neoplastic Urinary Protein ("ANUP") for the treatment of several types of cancer. The Company in-licensed ANUP in 2001 as a 16 kD protein originally isolated from human urine. Over the last two years, the Company has isolated the protein in human blood and developed two synthetic peptides, which were used in animal model studies. The studies showed tumor burden reduction of up to 70% in nude mouse models. The Company is currently seeking a partner to accelerate product development and clinical development including:

- Completion of additional animal model studies to select clinical disease target, formulation and dosing;
- Preclinical studies of ANUP peptide to support IND filing;
- Initiation of Phase I trials; and
- Research to identify mechanism of action and establish a recombinant production system.

The second short-term revenue focus is the marketing of the Company's patent portfolio through license agreements. In 2003, the Company was issued a patent covering the Gene-Testes Technology and in early 2004, the Company received, through its license agreement, a notice of allowance on a cloning patent. The cloning patent covers techniques for the reprogramming of somatic cell nuclei (often referred to as cloning by nuclear transplantation) for the generation of cloned and/or transgenic animals. Because the patent has a filing date of 3 February 1993, the Company believes it has priority over numerous activities currently being undertaken in the industry. The Company has begun to notify potential licensees of its patent position.

The third short-term revenue focus is in the area of biodefense. The Company believes its avian transgenic platform technology has significant application in the areas of biodefense and vaccine production. The Company has submitted several grant proposals in the area and has begun discussion with several potential collaborators who are active in this space.

The Company's primary focus continues to be on developing its avian transgenic platform. While progress has been slower than anticipated, significant progress has been made on both the direct-egg and Gene-Testes Technology. Specifically:

- The achievement of expression levels of 6 ng/ml of Human Serum Albumin (HSA) in chimeric eggs as announced in May 2003.
- Developing germline transgenic chickens for HSA, Insulin and one partner's monoclonal antibody. These transgenic chickens are currently being bred with the objective of producing founder birds for each product. If successfully bred, these founder birds could be used initially to generate material for clinical trials and then for commercial production.

• Developing second-generation transgenic technology with the objective of reducing development time by 50% and improving the percentage of transgenic birds produced.

The Company's focus in 2004 is on:

- Seeking an ANUP strategic funded partnership to accelerate development and support entry into clinical trials as described above.
- Commercialization of the HSA and Insulin products, through geographic and product specific licensing, upon achievement of commercial levels of expression.
- Establishment of collaborations and partnerships for its vaccine projects, including application in the biodefense area.

To achieve the Company's research and commercialization efforts, TranXenoGen needs to obtain additional funding. The Company is seeking funding from three sources:

- The Company, on its own behalf and in collaboration with third parties, is seeking funding through biodefense and other government grant programs;
- Funding from potential partners for the commercialization efforts as outlined above; and
- Capital markets.

# FINANCIAL REVIEW

TranXenoGen finished 2003 with an unrestricted cash position of \$2.2 million. For the year ended 31 December 2003, TranXenoGen reported a net loss of \$4.4 million, or \$0.14 per share, compared to a net loss of \$4.4 million, or \$0.14 per share for 2002. On a cash basis (net loss excluding (i) the non-cash charge related to the issuance of stock options granted to directors and employees prior to the Initial Public Offering in 2000, (ii) depreciation and (iii) amortization), the net cash loss was \$3.4 million in 2003 as compared to \$3.3 million in 2002.

While the cash loss was basically unchanged in 2003 vs. 2002, the components did vary. Research and Development ("R&D") expense declined \$224,000 reflecting a reduction in the Company's animal care cost resulting from the 2002 consolidation of the animal care operation into the Shrewsbury facility, partially offset by higher R&D spending. Offsetting these savings was a \$137,000 increase in Selling, General and Administrative ("SG&A") expense and higher net interest expense. The higher SG&A expense reflects higher professional fees and insurance cost. The higher net interest expense reflects lower interest income due to lower funds invested (as cash was used to fund operations) at lower rates.

The Company had 20 employees as of 31 December 2003 and 2002.

## SCIENCE UPDATE

In 2003, the Company made steady progress in both the development of its avian transgenic technology and its cancer therapeutic known as Anti-Neoplastic Urinary Protein ("ANUP"). Research efforts were focused on demonstrating the effectiveness of ANUP as an antitumor

therapeutic and on the generation of transgenic chickens for key programs to achieve commercial expression levels and the development of a more rapid and efficient transgenic process.

The process for the production of germline transgenic chickens was improved through:

- Improvements made to the direct egg-transfection technology including the pre-selection of eggs and efficiency improvements in the method of gene delivery;
- Streamlining the breeding of chimeric chickens by more stringent transgene analysis of the chimeric chickens; and
- Semen analysis of the roosters.

Germline transgenic chickens have been generated for Insulin, HSA and one monoclonal antibody. As these transgenic chickens mature, the hens will be screened for expression of the protein in their eggs while the roosters will be bred to produce second-generation transgenic hens.

In an effort to reduce the timeframe of the transgenic process and increase the efficiency of generating transgenic chickens, the Company has continued experimentation on both the Primordial Germ Cell ("PGC") and Gene-Testes Transfection technologies. Research on PGC technology has focused mainly on the development of new conditions for maintaining the cells in culture for extended periods of time. The identification of long-term culture conditions would allow for precise genetic manipulation of the cells and more efficient production of transgenic chickens. In the case of the Gene-Testes Technology, the objective has been to shorten the transgenic process timeline by incorporation of the transgene into the sperm of a rooster. Initial experiments have successfully demonstrated the ability to deliver the transgene to the testes of the rooster and identify roosters producing transgenic sperm. The objective of the Gene-Testes Technology research is to demonstrate the production of a transgenic chicken from the breeding of a gene-testes rooster. The Gene-Testes Technology, if successful, has the potential to reduce development times up to 50% since one whole breeding cycle is removed from the process.

Significant progress has been made on the ANUP program with the *in vivo* and *in vitro* testing of two ANUP derived synthetic peptides. Animal model studies, using human cervical cancer, demonstrated the ability of the peptides to reduce tumor burden by up to 70% as compared to control animals. The data confirms previously published results for the ANUP protein in a similar mouse model study and its potential as a cancer therapeutic. Further testing indicated that the ANUP peptides appear to act on blood vessel formation inhibiting both angiogenesis and infiltration. Angiogenesis, the formation of new blood vessels, is a key therapeutic target for the treatment of several diseases such as cancer, diabetic retinopathy and age-related macular degeneration. Additional experimentation in the ANUP program will involve testing of the ANUP peptides against various tumor cell types to identify the best clinical target and identification of the gene for recombinant production of the ANUP protein. One objective of the program is to develop the ability to produce the ANUP product using our transgenic avian platform.

In addition, the Company initiated research to evaluate the potential production of protein-based vaccine candidates using its avian technology for biodefense and infectious diseases, such as influenza. Initial experiments used a yeast-based expression system to determine if difficult to

express viral proteins could be genetically engineered for production and to generate small quantities for collaborators interested in funding the further development. Using three vaccinia viral proteins, which could potentially be candidates for a smallpox vaccine, TranXenoGen researchers were able to successfully produce the recombinant viral proteins in yeast system. This was the first step in a process to demonstrate to potential collaborators the capabilities of producing theses vaccine candidates in the Company's avian transgenic system. Presently, experiments are targeting expression of potentially more serious infectious disease influenza and the production of the viral protein known as hemagglutinin. If successful, the research could lead to a more stable supply of vaccine for administration to at risk populations and the control of infectious disease outbreaks.

# **SUMMARY**

The fund raising and revenue generation efforts are progressing. In order to provide additional time to execute on these initiatives, the Company has implemented the following actions in March to reduce its cash burn rate:

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Based on these reductions, our cash burn rate as of April 2004 will decrease to approximately \$650,000 per quarter. Our current cash position should fund operations through August 2004 at this reduced burn rate. The achievement of the outlined revenue programs should further reduce the cash burn rate and extend the period of operation supported by our current cash balance. As a result of these reductions, the Company will reduce its efforts in non-science areas and activities related to unfunded research.

The Company has made significant progress over the last several years as it has developed its product candidate pipeline. The Company's well-balanced strategy of developing generic products and proprietary novel therapeutic products, licensing of its Intellectual property and contract manufacturing provides a variety of commercialization opportunities. We look forward to updating our shareholders on our fundraising and revenue efforts at the Company's annual general meeting in June.

George Uveges President and Chief Executive Officer

# TranXenoGen, Inc. CONDENSED STATEMENTS OF OPERATIONS

(Amounts in US Dollars)

	Years ended December 31,	
	2003	2002
Revenue:		
Contract revenue	\$ -	\$ 33,333
Expenses:		
Selling, general and administrative	1,633,473	1,496,290
Research and development	1,647,762	1,871,691
Stock-based compensation	414,250	503,875
Depreciation and amortization	562,377	562,579
Total expenses	4,257,862	4,434,435
Operating loss	(4,257,862)	(4,401,102)
Other Income (Expense):		
Interest income	39,838	132,818
Interest expense	(194,709)	(219,296)
Other income, net	62,053	67,511
Loss before provision for income taxes	(4,350,680)	(4,420,069)
Provision for income taxes	<u> </u>	
Net loss	<u>\$(4,350,680)</u>	<u>\$(4,420,069)</u>
Net Loss per Share:		
Basic and diluted	<u>\$ (0.14)</u>	<u>\$ (0.14)</u>
Basic and diluted weighted-average		
common shares outstanding	32,172,904	32,071,329

The accompanying notes are an integral part of these condensed financial statements.

# **TranXenoGen, Inc. CONDENSED BALANCE SHEETS** (Amounts in US Dollars)

	December 31,	
	2003	2002
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 2,186,090	\$ 5,526,361
Other current assets	128,684	95,529
Total current assets	2,314,774	5,621,890
Property and equipment, net	7,545,689	8,065,120
Other Assets:		
Restricted cash	363,785	360,130
Other non-current assets	10,643	30,202
Total other assets	374,428	390,332
Total assets	<u>\$10,234,891</u>	<u>\$14,077,342</u>
LIABILITIES AND STOCKHOLDERS' FOUITY		
Current Liabilities		
Accounts payable	\$ 215.157	\$ 178,484
Accrued expenses and other current liabilities	¢ 213,137 224.367	235.784
Current portion of long-term debt	136,420	109,841
Total current liabilities	575,944	524,109
Long-term deferred lease income	190.583	-
Long-term debt, less current portion	3,548,283	3,698,622
Commitments and contingencies		
Stockholders' Equity:		
Common stock	40,570	40,560
Treasury stock	(195,659)	(195,659)
Additional paid-in capital	22,964,558	22,962,668
Deferred compensation	(98,236)	(512,486)
Accumulated deficit	(16,791,152)	(12,440,472)
Total stockholders' equity	5,920,081	9,854,611
Total liabilities and stockholders' equity	<u>\$10,234,891</u>	<u>\$14,077,342</u>

The accompanying notes are an integral part of these condensed financial statements.

# TranXenoGen, Inc. CONDENSED STATEMENTS OF CASH FLOWS

(Amounts in US Dollars)

	Years ended December 31,	
	2003	2002
Cash Flows from Operating Activities:		
Net loss	\$(4,350,680)	\$(4,420,069)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	562,377	562,579
Compensation expense related to stock options issued	414,250	503,875
Changes in assets and liabilities:		
Other current assets	(33,155)	(6,567)
Accounts payable	36,673	(472,216)
Accrued expenses and other current liabilities	(16,534)	(313,216)
Proceeds from cell tower lease	197,600	
Net cash used in operating activities	(3,189,469)	(4,145,614)
Cash Flows from Investing Activities:		
Additions to property and equipment	(23,387)	(634,325)
Increase in restricted cash	(3,655)	(8,594)
Net cash used in investing activities	(27,042)	(642,919)
Cash Flows from Financing Activities:		
Exercise of stock options	-	6,000
Proceeds from notes payable	-	407,705
Repayment of notes payable	(123,760)	(91,537)
Net cash (used in) provided by financing activities	(123,760)	322,168
Net decrease in cash and cash equivalents	(3,340,271)	(4,466,365)
Cash and cash equivalents, beginning of period	5,526,361	9,992,726
Cash and cash equivalents, end of period	<u>\$ 2,186,090</u>	<u>\$ 5,526,361</u>
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 196,064	\$ 219,602
Fair value of shares of common stock used in connection with milestone	<u> </u>	<u> </u>
payment	<u>\$ 1,900</u>	<u>\$ -</u>

The accompanying notes are an integral part of these condensed financial statements.

#### Notes to the Condensed Financial Statements

#### 1. Basis of Presentation and Management's Plan

The Condensed Financial Statements included in this announcement have been extracted from the audited financial statements of the Company, which have been prepared in conformity with accounting principles generally accepted in the United States. The Condensed Financial Statements should be read in conjunction with the Company's financial statements and notes thereto included in the Company's annual report to shareholders.

The Company has a three-pronged business strategy to pursue the development of a practical, effective manufacturing platform to address the production requirements for high-volume protein based therapeutics as well as to develop novel therapeutic products. The three-pronged business strategy encompasses the following:

- Production of generic biologicals;
- Production of high-volume novel therapeutics such as monoclonal antibodies for strategic partners; and
- Development and manufacture of novel therapeutic protein based products.

The Company is currently targeting its efforts primarily on achieving the production of proteinbased drugs in the egg whites of transgenic chickens. The Company is developing transgenic processes to manufacture therapeutic protein-based drugs, including Insulin, Human Serum Albumin and antibodies for strategic partners.

The Company is subject to a number of risks common to emerging companies in the life sciences industry. Among those risks are the successful development of its transgenic technology, technological innovations, dependence on key individuals, dependence on collaborative arrangements, development of the same or similar technological innovations by the Company's competitors, protection of proprietary technology, compliance with government regulations and approval requirements, including those of the U.S. Food and Drug Administration, uncertainty of market acceptance of products, product liability and the ability to obtain additional financing necessary to fund product development and operations.

The Company's financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As shown in the financial statements, at 31 December 2003, the Company had an unrestricted cash balance of \$2.2 million and liabilities of \$4.1 million. The Company's cash expenses currently exceed its cash receipts, and management expects this trend to continue for the foreseeable future. These factors give rise to substantial doubt about the Company's ability to continue as a going concern.

The Company's continuation as a going concern is dependent upon its ability to continue its development activities, obtain government approvals, including that of the U.S. Food and Drug Administration, to market and/or manufacture its products, generate sales, meet its obligations,

raise additional capital financing and, ultimately, attain profitable operations. Management is actively pursuing financing alternatives and potential collaborative agreements and government sponsored grants so that the Company can meet its obligations and sustain operations. The financial statements do not include any adjustments that might be necessary should the Company be unable to succeed in these efforts.

#### **<u>Risk Warning Notice:</u>**

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