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PRESS RELEASE

Regulated Information

Oxurion NV Business Update – FY 2019

Significant Progress with Innovative Pipeline candidates designed to deliver therapies for Diabetic Eye Disease – Beyond VEGF

Positive Results from Phase 1 study evaluating THR-149 (Plasma Kallikrein Inhibitor) for treatment of Diabetic Macular Edema (DME)

Positive Results from Phase 1 study evaluating THR-687 (Integrin Antagonist) for treatment of Diabetic Macular Edema (DME)

Global License Agreement for JETREA®signed with Inceptua Group

Total Cash & Investments at €52.9 million as of December 31, 2019

Highlights

Beyond VEGF Pipeline

- Positive data from Phase 1 study evaluating THR-149 (plasma kallikrein inhibitor) for the treatment of DME announced in July 2019:
  - THR-149 is well-tolerated and safe. No dose-limiting toxicities or drug-related serious adverse events reported
  - Immediate onset of action (Day 1), high efficacy with increasing average improvement in BCVA following a single injection of THR-149
  - Retina expert data presentation delivered at Euretina 2019 and at Retina Society Meeting in London, UK
  - THR-149 is being developed as a potential treatment of choice for DME patients who respond sub-optimally to anti-VEGF therapy
  - Phase 2 study with anti-VEGF poor responding DME patients on track to be initiated by Q2 2020.

- Positive data from Phase 1 study evaluating THR-687 (Pan-RGD integrin antagonist) for the treatment of DME announced in January 2020:
  - THR-687 is well-tolerated and safe. No dose-limiting toxicities or serious adverse events reported
  - Rapid onset of action, high efficacy and prolonged effect on Best Corrected Visual Acuity (BCVA) following a single injection

  - Retina expert data presentation delivered at the Bascom Palmer Eye Institute Angiogenesis, Exudation, and Degeneration 2020 Meeting in Miami, US.
  - THR-687 is being developed as potential treatment of choice for all DME patients
  - Phase 2 study in treatment-naive patients expected to start in Q1 2021.

- Decision to stop investment in all further development THR-317 anti-PIGF antibody program in order to focus resources on THR-149 and THR-687.

Commercial

- As part of the company's strategy to achieve break-even for JETREA, Oxurion has entered into a global commercial license agreement for the distribution of JETREA with the INCEPTUA GROUP, a global pharmaceutical company and service partner.

Financial

- Oxurion had cash, cash equivalents & investments of €52.9 million at the end of December 2019. This compares to €60.5 million at the end of September 2019 and €85.1 million at the end of December 2018.

Leuven, Belgium, March 12, 2020 – 17.45 PM CET – Oxurion NV (Euronext Brussels: OXUR), a biopharmaceutical company developing next generation standard of care therapies, which are designed to better preserve vision in patients with diabetic eye disease, today issues its business and financial update for the twelve month period ending December 31, 2019.

Oxurion has made significant progress with the development of its innovative pipeline of drug candidates for Diabetic Macular Edema (DME).

The Oxurion clinical development pipeline consists of novel products with different, including VEGF independent, modes of action, which together potentially give the Company access to a significant share of the large and fast-growing diabetic eye disease market.

Oxurion's clinical pipeline comprises of

- **THR-149:** a potent plasma kallikrein inhibitor completed a Phase 1 multicenter, dose escalation study for the treatment of DME in July 2019. Positive data showed that THR-149 is well-tolerated and safe with no dose-limiting toxicities or drug-related serious adverse events reported. The data also showed promising efficacy results in relation to BCVA after a single injection.

- **THR-687:** a small molecule pan-RGD integrin antagonist being developed to treat a broad range of patients with diabetic eye disease. Phase 1 study completed in January 2020 and the data showed it is well-tolerated and safe. The data also showed promising efficacy results with rapid onset of action and prolonged effect on BCVA following a single injection.

Patrik De Haes, M.D., CEO of Oxurion, commented:

"The positive Phase 1 results that we have delivered in recent months from both our THR-149 and THR-687 programs have clearly positioned Oxurion as the leader in developing safe and effective next generation therapies for DME and diabetic eye disease more broadly, which go beyond VEGF.

These novel candidates have the potential of being a significant market opportunity, as it is known that 40% of DME patients respond poorly to any anti-VEGF therapy. We believe that those patients will have a better chance of achieving improved visual outcomes when treated with beyond-VEGF therapies such as THR-149 and THR-687.

Our THR-149 program, a potent plasma kallikrein inhibitor which acts via a completely VEGF independent pathway, has reported positive Phase 1 data showing that this compound is well placed to potentially become a treatment of choice for those DME patients who have previously responded sub-optimally to anti-VEGF therapy.

Based on preclinical data and when compared to historical clinical data, THR-687, a small molecule pan-RGD integrin antagonist, has shown the potential to perform as well, if not better, than approved anti-VEGF treatments. This is particularly encouraging given our expectation that THR-687 could have a much broader therapeutic reach than anti-VEGFs.

We are preparing to begin a Phase 2 study with both compounds and expect to start our first trial evaluating multiple doses of THR-149 in Q2 2020. The Phase 2 study with THR-687 is expected to start in Q1 2021.

Our current cash of €52.9 million will allow us to initiate and progress Phase 2 development of these exciting novel compounds as we look to provide both patients and physicians with improved treatment options for the treatment of diabetic eye disease."

Covid-19 Statement

"Oxurion is focused on ensuring the health and safety of its 80 employees and their families wherever they reside in the world. We are continuing to monitor and adapt to this fast-moving situation. We have implemented restricted travel policies and are leveraging modern communication technologies as much as possible. We also have implemented specific in-office sanitary guidelines and are allowing employees to work remotely when needed.

To-date, we have seen little or no impact on our daily operations, including our interactions with investigators, the investor community or other stakeholders.

As a result, we remain on track in all areas, particularly regarding our preclinical and clinical study planning, including our anticipated upcoming Phase 2 studies."

Diabetic Eye Disease – Oxurion's key focus

Diabetic eye disease is a major global healthcare problem and the major cause of blindness in adults of working-age. It is estimated that there are 150 million people with diabetic retinopathy (DR), 50 million of which have vision-threatening disease.

Diabetic eye disease is caused by the high blood glucose levels (hyperglycemia) associated with diabetes. If left unchecked, hyperglycemia causes damage to the capillaries supplying blood, and hence oxygen, to the retina, the structure at the back of the eye responsible for vison.

Diabetic retinopathy (DR) is a serious, sight-threatening disease. DR progresses from mild, non-proliferative to more severe or even proliferative stages (PDR). PDR, the more advanced stage of diabetic eye disease happens when the retina starts growing new fragile blood vessels, which often bleed into the vitreous leading to loss of vision.

Diabetic macular edema (DME) is a severe complication of DR. DME is an accumulation of fluid in the macula – the part of the retina that controls detailed vision - due to leaking blood vessels. DME represents an area of major unmet medical need.

It is estimated that the overall retinal vascular disease therapy market is worth $11 billion per annum of which $4 billion is accounted for by treatments for DR/DME, the vast majority of which relates to anti-VEGF therapies.

In DME, anti-VEGFs, which are the current standard of care, have been shown to deliver sub-optimal results in a significant portion of the patient population. Around 40% of DME patients have an unsatisfactory early visual response with anti-VEGF therapy, and in many cases, anti-VEGFs fail to achieve a clinically meaningful visual improvement.

Oxurion is focused on solving that unmet medical need.

Next generation therapies targeting unmet medical need in DME – Beyond VEGF

Oxurion's R&D activities are focused on using its in-depth understanding of important eye disease mechanisms to generate new therapies that can be game changing in the treatment of several major retinal indications such as diabetic eye disease.

In general, treatment of diabetic eye disease is centered around anti-VEGF therapies, which are used to treat approximately 80% of patients. Despite the significant success of anti-VEGFs, there will always be a need from both physicians and patients for improved therapies that have:

- Faster onset of action
- Better therapeutic effect in terms of visual function (BCVA) and response rate (proportion of patients)
- Longer duration of response allowing extended treatment intervals
- Improved convenience of treatment through a simpler dosing regimen

Those requirements are driving the development of Oxurion's new generation of beyond-VEGF therapies, where Oxurion has focused on market and patient requirements when selecting new drug candidates.

These criteria mean that both THR-149 and THR-687 are being developed to meet specific unmet needs in the market for diabetic eye disease therapies.

THR-149 – a plasma kallikrein inhibitor for treatment of DME

Positive Phase 1 Results with THR-149 for the treatment of DME – Phase 2 program expected to start in Q2 2020

THR-149 is a novel plasma kallikrein inhibitor being developed as a potential new standard of care for the 40% of DME patients who respond sub-optimally to anti-VEGF therapy.

THR-149 acts through inhibition of the Plasma Kallikrein-Kinin (PKaI-Kinin) system, a validated target for DME.

The Phase 1 study for THR-149 showed that it:

- Is well-tolerated and safe. No dose-limiting toxicities nor drug-related serious adverse events were reported at any of the dosages evaluated in the study.

- Delivered promising results in relation to efficacy, in particular changes to the patient's BCVA. A rapid onset of action was observed from Day 1, with an increasing average improvement in BCVA of up to 7.5 letters at Day 14.

  Importantly, this activity was maintained with an average improvement in BCVA of 6.5 letters at Day 90 following a single injection of THR-149.

Data from this positive Phase 1 study with THR-149 were presented at several major retina conferences in Europe and the US in 2019 including:

- 19th Congress of European Society of Retina Specialists (EURETINA) in Paris (5– 8 September),

- Retina Society Annual Meeting in London (11–15 September)

The Company is currently preparing to start a Phase 2 development program, which will evaluate multiple doses of THR-149 in patients with DME. This study is expected to start in Q2 2020.

This novel drug candidate was generated using Bicycle Therapeutics' Bicycles® technology platform.

THR-687 – a pan RGD-integrin antagonist for treatment of DME

Positive Phase 1 Results with THR-687 for the treatment of DME – Phase 2 program expected to start in Q1 2021

Oxurion is developing THR-687, a novel pan-RGD integrin antagonist, to preserve vision in a broad range of patients with diabetic eye disease. This wide-ranging potential is based on the hypothesis that integrin inhibition can address many of the processes that result in the pathological angiogenesis and vascular leakage that cause diabetic eye disease and other retinal diseases.

Topline data from the Phase 1 trial showed that THR-687:

- Is well-tolerated and safe with no dose-limiting toxicities. No serious adverse events were reported at any of the doses evaluated in the study.
- The study also looked at efficacy including changes to the patient's BCVA. Across all doses, a rapid onset of action as measured by mean BCVA change was observed from Day 1 with an increase of 3.1 letters, which further improved to 9.2 letters at Month 1.
- This activity was maintained with a mean BCVA improvement of 8.3 letters at Month 3 following a single injection of THR-687.
- A clear dose response was seen in terms of BCVA with the highest dose of THR-687 delivering a mean BCVA Improvement of 11 letters at Day 14, with a peak improvement of 12.5 letters at Month 3.
- In addition, a peak mean central subfield thickness (CST) decrease of 106 µm was observed at Day 14 with the highest dose of THR-687.

Data from this positive Phase 1 study with THR-687 were presented by Retina expert at the Bascom Palmer Eye Institute Angiogenesis, Exudation, and Degeneration 2020 Meeting in February 2020 in Miami (US).

Oxurion is preparing the complete data analysis from this Phase 1 study with THR-687, ahead of starting a planned Phase 2 study in Q1 2021.

<u>THR-317 – No further investment in clinical development</u>

In August 2019, the Company announced the topline results from an exploratory 70 patient Phase 2a study evaluating the efficacy and safety of intravitreal THR-317, an anti-PIGF antibody, administered in combination with ranibizumab (Lucentis®), a VEGF inhibitor, for the treatment of DME.

The study showed that the combination did not produce an increase in BCVA in the overall population at Month 3.

Certain improvement in mean BCVA at Month 3 could be observed with the combination therapy in 2 pre-specified subgroups of interest:

- poor (or non) responders to prior anti-VEGF, and
- patients with poor vision - baseline BCVA ≤65 letters

Topline data confirmed that THR-317 in combination with ranibizumab is safe and well-tolerated.

Following these mixed results together with the very promising data that have been generated with both THR-687 and THR-149, all investments in further clinical development of THR-317 ceased in December 2019.

Oxurion will follow a publication strategy for any further clinical data related to the above.

Oxurion and Inceptua Group enter global license agreement for the commercialization of JETREA®

Following its earlier decision to stop all of its own JETREA® commercialization activities, and to organise patient and physician access to JETREA® exclusively via a distributor/licensee agreement, Oxurion now announces it has signed a JETREA® global license agreement with Inceptua Group.

With local offices across Europe, USA, and Asia, Inceptua Group is a global pharmaceutical company and service partner spanning the product lifecycle – from clinical trials, through early access programs to licensing and commercialization of products.

As a result of this agreement, it is expected that Oxurion will cease commercialization activities in 2020.

In Europe, the Marketing Authorization (MA) will be transferred from Oxurion NV to the Inceptua Group, which is expected by Summer 2020.

In Switzerland, the hosting agreement will be transferred and in Australia, the distribution agreement will also be transferred to Inceptua.

In the US, current distributors will continue to supply the market until further notice. It is anticipated that the biologics licence application (BLA) in the US will be withdrawn by February 2021 at the latest. After that, access to JETREA® in the US will be decided by Inceptua Group.

JETREA® is a first-in-class pharmacological vitreolysis therapy approved for treatment of symptomatic vitreomacular adhesion or vitreomacular traction. It was launched in early 2013.

Over 35,000 patients have been treated with JETREA® to-date with real world clinical data confirming that the drug is a safe and effective early treatment for a well identified group of patients suffering from symptomatic vitreomacular adhesion or vitreomacular traction.

Patrik De Haes, M.D., CEO of Oxurion NV, said: "*Today's deal with Inceptua is in line with our plan to move the commercialization of JETREA® to a distribution and licensee model. Our worldwide license agreement with INCEPTUA will allow us to fully focus our organization and resources on further progressing our promising clinical pipeline of next generation non-VEGF assets for treatment of diabetic eye disease.*"

Oncurious Update

Increased focus on building portfolio of next generation immuno-oncology therapies

Oncurious' full focus is on the development of next-generation immuno-oncology therapies targeting a broad spectrum of cancers.

Oncurious is identifying a number of multi-specific biologics with distinct modes of action against immunomodulatory targets.

In close collaboration with VIB (Flemish Institute of Biotechnology), the Belgium based world leading life sciences research institute and shareholder of Oncurious (next to Oxurion), these candidates are being evaluated in pre-clinical tumor models, both as monotherapies and in combination with standard of care treatment.

In June 2019, Oncurious received a project grant of close to €1.0 million from Flanders Innovation and Entrepreneurship (VLAIO) to support these developments.

Oncurious is well on track to present a first preclinical proof of concept by mid-2020.

Clinical study TB-403 for treatment of medulloblastoma

Recruitment in US Phase 1/2a study evaluating TB-403, a humanized monoclonal antibody against placental growth factor (PlGF), for treatment of Relapsed or Refractory Medulloblastoma is ongoing, but continues to be very slow.

TB-403 is being developed by Oncurious in conjunction with BioInvent International.

Financial Update

Oxurion generated JETREA® sales of €3.8 million in 2019, compared to €5.2 million in 2018.

Total revenue amounted to €3.9 million in 2019 compared to €5.3 million in 2018.

The Group reported a gross profit of €1.7 million in 2019. This compares to a gross profit of €2.0 million in 2018.

In 2019, Oxurion's R&D expenses were €25.7 million compared to €29.5 million in 2018. On a comparable base (excluding a 2018 milestone payment, excluding increased government grant and recharge income as well as lower Intangible amortization for 2019) the 2019 R&D expenses amount to €24.2 million expenses compared to €25.2 million in 2018. This reflects a further ramping up of preclinical and clinical development programs for our lead assets compensated by reduction in investment on THR-317 towards year-end.

Selling and marketing expenses were €7.0 million in 2019. This compares to €6.2 million in 2018. The increase in these expenses is the reflection of full year commercial activities in 2019 compared to partial year in 2018 as well as finalization of market authorizations and other regulatory transfers from Alcon/Novartis.

General and administrative expenses remained stable at €6.3 million in 2019 compared to €6.3 million in 2018.

The reported net loss for 2019 was €52.1 million. This compares to a net loss of €38.7 million in 2018; the JETREA® intangible write-of at half-year 2019 being the main reason for increase. The JETREA® intangible write-of has no impact on the Oxurion cash position.

The Oxurion cash position (including investments) at the end of 2019 amounted to €52.9 million. This compares to €85.1 million (including investments and restricted cash) at the end of 2018.

2019 Diluted earnings per share are negative €1.36 compared to negative diluted earnings per share of €1.01 in 2018.

END

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About Oxurion

Oxurion (Euronext Brussels: OXUR) is a biopharmaceutical company developing next generation standard ophthalmic therapies, which are designed to better preserve vision in patients with diabetic eye disease, the leading cause of blindness in people of working age worldwide.

Oxurion's clinical pipeline comprises:

- THR-149, a plasma kallikrein inhibitor being developed as a potential new standard of care for DME patients who respond sub-optimally to anti-VEGF therapy.

  THR-149 has shown positive topline Phase 1 results for the treatment of DME. The Company is currently preparing to conduct a Phase 2 clinical program, which is expected to start in Q2 2020. THR-149 was developed in conjunction with Bicycle Therapeutics plc (NASDAQ: BCYC)

- THR-687, is a pan-RGD integrin inhibitor, that is initially being developed as a potential new standard of care for all DME patients

  Positive topline results in a Phase 1 clinical study assessing it as a treatment for DME were announced in January 2020. THR-687 is expected to enter a Phase 2 clinical trial in Q1 2021. THR-687 is an optimized compound derived from a broader library of integrin inhibitors in-licensed from Galapagos nv (Euronext & NASDAQ: GLPG).

Oxurion is headquartered in Leuven, Belgium, and is listed on the Euronext Brussels exchange under the symbol OXUR.

More information is available at www.oxurion.com

Important information about forward-looking statements

Certain statements in this press release may be considered "forward-looking". Such forward-looking statements are based on current expectations, and, accordingly, entail and are influenced by various risks and uncertainties. The Company therefore cannot provide any assurance that such forward-looking statements will materialize and does not assume an obligation to update or revise any forward-looking statement, whether as a result of new information, future events or any other reason. Additional information concerning risks and uncertainties affecting the business and other factors that could cause actual results to differ materially from any forward-looking statement is contained in the Company's Annual Report. This press release does not constitute an offer or invitation for the sale or purchase of securities or assets of Oxurion in any jurisdiction. No securities of Oxurion may be offered or sold within the United States without registration under the U.S. Securities Act of 1933, as amended, or in compliance with an exemption therefrom, and in accordance with any applicable U.S. state securities laws.

Financial information 2019

Consolidated statement of profit and loss

In '000 euro (for the year ended 31 December)	**2019**	**2018**
Income	**3,946**	**5,320**
Sales	3,820	5,221
Income from royalties	126	99
Cost of sales	**-2,259**	**-3,355**
Gross profit	**1,687**	**1,965**
Research and development expenses	-25,709	-29,523
General and administrative expenses	-6,324	-6,349
Selling expenses	-6,955	-6,217
Other operating income	2,022	883
Other operating expense	-4	0
Impairment losses	-16,891	0
Operating result	**-52,174**	**-39,241**
Finance income	495	796
Finance expense	-407	-324
Result before income tax	**-52,086**	**-38,769**
Taxes	-17	-10
Result of the year	**-52,103**	**-38,779**
Attributable to:		
Equity holders of the company	-51,827	-38,474
Non-controlling interest	-276	-305
Result per share		
Basic earnings / loss (-) per share (euro)	-1.36	-1.01
Diluted earnings / loss (-) per share (euro)	-1.36	-1.01

In '000 euro (as at 31 December)	2019	2018
Result of the year	**-52,103**	**-38,779**
Exchange differences on translation of foreign operations	-342	62
Other comprehensive income, net of income tax	**-342**	**62**
Other comprehensive income that will not be reclassified to profit or loss	-342	62
Total comprehensive loss (-) / income for the year	**-52,445**	**-38,717**
Attributable to:		
Equity holders of the company	**-52,169**	**-38,412**
Non-controlling interest	**-276**	**-305**

Consolidated statement of financial position

In '000 euro (as at 31 December)	2019	2018
ASSETS		
Property, plant and equipment	340	614
Right-of-use assets	2,212	0
Intangible assets	1,982	20,450
Other non-current assets	96	127
Non-current tax credit	3,385	2,584
Non-current assets	**8,015**	**23,775**
Inventories	20	1,036
Trade and other receivables	3,592	4,219
Current tax receivables	467	707
Investments	10,444	20,475
Cash and cash equivalents	42,492	64,652
Current assets	**57,015**	**91,089**
Total assets	**65,030**	**114,864**
EQUITY AND LIABILITIES		
Share capital	100,644	137,564
Share premium	0	13
Cumulative translation differences	-615	-273
Other reserves	-12,122	-12,563
Retained earnings	-34,747	-19,853
Equity attributable to equity holders of the company	**53,160**	**104,888**
Non-controlling interest	146	422
Total equity	**53,306**	**105,310**
Lease liabilities	1,335	0
Non-current liabilities	**1,335**	**0**
Trade payables	4,725	5,054
Lease liabilities	898	0
Other short-term liabilities	4,766	4,500
Current liabilities	**10,389**	**9,554**
Total equity and liabilities	**65,030**	**114,864**

Consolidated statement of cash flows

In '000 euro (for the year ended 31 December)	2019	2018
Cash flows from operating activities		
Loss for the period	-52,103	-38,779
Finance expense	407	324
Finance income	-495	-796
Depreciation of property, plant and equipment	1,194	474
Amortization and impairment of intangible assets	18,468	3,153
Equity settled share-based payment transactions	440	592
Decrease in trade and other receivables including tax receivables and inventories	1,082	1,441
Increase / decrease (-) in short-term liabilities	-63	2,474
Net cash flows generated / used (-) in operating activities	***-31,070***	***-31,116***
Cash flows from investing activities		
Disposal of property, plant and equipment (following a sale)	77	98
Decrease / Increase (-) in investments	10,033	29,066
Interest received and similar income	4	141
Purchase of property, plant and equipment	-133	-195
Purchase / divestment (-) of other non-current assets	31	-1
Net cash flows generated / used (-) in investing activities	***10,012***	***29,109***
Cash flows from financing activities		
Principal paid on lease liabilities	-843	0
Interest paid on lease liabilities	-24	0
Proceeds from capital and share premium increases from exercise of warrants	0	92
Paid interests	-10	-8
Net cash flows used (-) / generated in financing activities	**-877**	**84**
Net change in cash and cash equivalents	**-21,935**	**-1,924**
Net cash and cash equivalents at the beginning of the period	64,652	66,175
Effect of exchange rate fluctuations	-225	401
Net cash and cash equivalents at the end of the period	**42,492**	**64,652**

Consolidated statement of changes in equity

	Share capital	Share premium	Cumulative translation differences	Other reserves	Retained earnings	Attributable to equity holders of the company	Non-controlling interest	Total
Balance as at 1 January 2018	**151,991**	**157,661**	**-335**	**-13,141**	**-163,546**	**132,630**	**727**	**133,357**
Result of the year 2018	0	0	0	0	-38,474	-38,474	-305	-38,779
Change to foreign currency translation difference and revaluation reserve	0	0	62	0	0	62	0	62
Net change in fair value of investments	0	0	0	-14	0	-14	0	-14
Issue of ordinary shares	9,875	217	0	0	0	10,092	0	10,092
Capital decrease	-24,302	-157,865	0	0	182,167	0	0	0
Share-based payment transactions	0	0	0	592	0	592	0	592
Balance as at 31 December 2018	**137,564**	**13**	**-273**	**-12,563**	**-19,853**	**104,888**	**422**	**105,310**

Balance as at 1 January 2019	**137,564**	**13**	**-273**	**-12,563**	**-19,853**	**104,888**	**422**	**105,310**
Result of the year 2019	0	0	0	0	-51,827	-51,827	-276	-52,103
Change to foreign currency translation difference and revaluation reserve	0	0	-342	0	0	-342	0	-342
Net change in fair value of investments	0	0	0	1	0	1	0	1
Issue of ordinary shares	0	0	0	0	0	0	0	0
Capital decrease	-36,920	-13	0	0	36,933	0.0356	0	0.0356
Share-based payment transactions	0	0	0	440	0	440	0	440
Balance as at 31 December 2019	**100,644**	**0**	**-615**	**-12,122**	**-34,747**	**53,160**	**146**	**53,306**

The statutory auditor, BDO Bedrijfsrevisoren represented by Gert Claes, has confirmed that the audit procedures, which have been substantially completed, have not revealed any material adjustments which would have to be made to the accounting data included in the Company's annual announcement, and intends to issue an unqualified opinion.