November 14, 2014, 8.00am

OZEQUITIES NEWSLETTER

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FEATURE

Week's Special

CIR: COMPREHENSIVE PORTFOLIO OF VEGF-C/-D AND VEGFR-3 PATENTS - FOCUS IS OPT-302 FOR THE TREATMENT OF WET AMD, THE LEADING CAUSE OF BLINDNESS IN THE WESTERN WORLD - RECENT $17.4M RAISING BY THE COMPANY - WITH A MARKET CAP OF ~$8.5M - BEARS TESTIMONY TO ITS PROSPECTIVITY

By Jenny Prabhu and Gerald Stanley

Circadian Technologies Ltd, the first company to list on the then Australian Second Board in March 1985, today owns a comprehensive intellectual property estate covering the key angiogenesis targets VEGF-C, VEGF-D and VEGFR-3. The IP asset was originally acquired in a joint venture with the Ludwig Institute for Cancer Research and Licentia (the commercial arm of the University of Helsinki), the original owners of the IP. By 2008, Circadian had moved to full ownership of the IP asset, with the Ludwig Institute and Licentia remaining as substantial shareholders.

Circadian is a well-managed, highly-credentialed major Australian biotech, and is recognised as such by its prestigious shareholders - although in the broad Australian market that seems to reward only dividend yield it trades under the radar. The fact that a company with an $8.5 million capitalisation has been able to raise $17.4 million ($12.8 million still being subject to AGM approval on 18 November 2014) in this market, is testimony to the importance of its portfolio.

The initial "hard yards" since Circadian was transformed by the acquisition of its VEGF portfolio back in 2006 have been done. The company has completed a Phase 1a/1b clinical trial for its oncology asset VGX-100 at US clinical sites and that asset is now well positioned for licensing and partnership opportunities. The completion of this trial positions the company to focus on the significant opportunity represented by the OPT-302 (soluble VEGFR-3) program for the treatment of eye diseases, including wet age-related macular degeneration. The recent capital raising will be used to progress OPT-302 through Phase 1 and 2A clinical trials in patients with wet AMD.

The strong support from specialist healthcare investors in the US, Europe and Australia and from existing knowledgeable shareholders validates the Company's technology and strategy to focus on the ophthalmology program whilst also pursuing opportunities for its non-core assets. The non-core assets include a collaboration with Healthscope, the Peter MacCallum Cancer Centre and scientists at National ICT Australia to develop a diagnostic test for Cancers of Unknown Primaries (CUP), and a test for the differential diagnosis of the lung disease lymphangiogleiomyomatosis (LAM). In addition, Eli Lilly has an exclusive, royalty-bearing license under the Company's IP asset to develop VEGFR-3 antibodies for cancer therapy. Eli Lilly is currently completing a Phase 1 clinical trial with its VEGFR-3 antibody in solid tumours.

Circadian is advancing its lead OPT-302 program through its 100% owned subsidiary Opthea as a treatment in combination with the blockbuster drug Lucentis to treat wet age-related macular degeneration in patients. The annual global market for drugs like Lucentis and Eylea that target VEGF-A in wet AMD is in excess of $US5 billion.
In animal studies Circadian has found that OPT-302 is as effective as Eylea in reducing wet AMD lesion size and results in improved efficacy when used in combination with Eylea.

Wet age-related macular degeneration is an incurable eye disease and the lead cause for blindness in people 55+

The eye works in a very similar fashion to a camera. The lens at the front of the eye focuses the image onto the retina which lines the back of the eye and the retina acts like the film in the camera. The image is sent from the retina through

the optic nerve and interpreted by the brain.

The macula is at the very centre of the retina. It is responsible for central, detailed vision and for the ability to read, distinguish faces, drive a car and any other activities which require fine vision. The peripheral retina gives the ability to see general shapes and gives the 'get-about' or peripheral vision.

Wet AMD is caused by abnormal growth and leakage of blood vessels. Both wet and dry forms of macular degeneration (MD) begin in the Retinal Pigment Epithelium, or RPE, a layer of cells underneath the retina. The RPE is responsible for passing oxygen, sugar and other essentials up to the retina and moving waste products down to the blood vessels underneath (these vessels are called 'the choroid'). MD occurs when this "garbage collection" breaks down and waste products from the retina build up underneath the RPE. These deposits, known as 'drusen', are easily seen by an eye care professional as yellow spots. As MD progresses, vision loss occurs because the RPE cells die or because the RPE cells fail to prevent blood vessels from the choroid from growing into the retina. Wet AMD is characterized by this abnormal growth of vessels.

In the early stages of MD, when drusen first appear, a sufferer may not realise there is anything wrong and vision may still be normal. This is, however, the best time to detect the disease and begin treatment. The earlier the disease is detected and treated, the more vision is likely to be retained. Although there is currently no cure for MD, there are treatment options that can slow down its progression in some patients, depending on the stage and type of the disease (wet, dry, and other forms).

Members of the VEGF (vascular endothelial growth factor) family of proteins, which includes VEGF-A, VEGF-C and VEGF-D, stimulate blood vessel growth and vessel leakage by binding to VEGF receptors on vessels. Existing therapies on the market for treatment of wet AMD all target VEGF-A. Despite the availability of these therapies, only one third of patients recover driving vision and at least 50% of patients do not achieve a significant gain in vision. There is also a proportion of patients that continue to progress to registered blindness despite receiving Lucentis, Eylea or Avastin, which also works via the same mechanism.

In spite of VEGF-C and VEGF-D playing important roles in blood vessel growth and vessel leakage, there are no therapies on the market targeting these molecules. Circadian's approach is to more completely block a validated pathway that has been shown to be important for wet AMD progression, by using OPT-302 (which inhibits both VEGF-C and VEGF-D) as a combination therapy with a VEGF-A inhibitor (Lucentis, Eylea or Avastin).

Current treatments for wet age-related macular degeneration (wet AMD)- various sources

There are currently no treatments for the dry form of MD, however taking specific high dose formula of vitamins and mineral supplements can reduce the risk of progressing from intermediate dry macular degeneration to advanced or wet macular degeneration.

Current treatments for wet AMD include angiogenesis inhibitors that block the activity of VEGF-A, a protein that stimulates blood vessels to grow and leak. These inhibitors include:

EYLEA, marketed by Regeneron/Bayer. Eylea is also known as VEGF Trap-eye and was approved by the FDA in late 2011;

Lucentis, (ranibizumab injection) (Genentech/Roche/Novartis) was approved by the FDA in 2006. Lucentis is an antibody fragment that also binds to and inhibits the activity of human VEGF-A.

Both Eylea and Lucentis are administered via injection into the vitreous portion of the eye after it has been numbed. The frequency and actual number of injections needed are often determined on a case by case basis. An injection every four or eight weeks may be optimal for Lucentis and Eylea respectively.

Avastin, also made by Genentech/Roche, is a VEGF-A inhibitor approved as a cancer therapy but is also widely used for the treatment of wet AMD. Avastin has been found in clinical trials to have similar activity to Lucentis.

Macugen (pegaptanib sodium injection) was approved by the FDA in 2004. Macugen blocks only one form of VEGF-A and consequently is not as clinically effective as the other drugs on the market. It is still available for treatment of wet AMD but is not used as often as the other treatments.
Fovista, in development by Ophthotech, is an inhibitor of PDGF-BB. Ophthotech announced results of a Phase IIb clinical trial in October this year. Data from this trial demonstrated that combination Fovista + Lucentis therapy was clinically more effective at improving vision in patients than Lucentis alone.

Patients receiving the combination therapy were able to see, on average, 4.1 more letters on a Standard eye chart than those patients who only received Lucentis. This improvement in vision is almost equivalent to being able to see an additional line (which is 5 letters) on a eye chart.

Ophthotech listed on the NASDAQ in September 2013 and currently has a market capitalization in Excess of $US1.3 bln. Ophthotech is currently testing Fovista in a combination therapy with Lucentis in several Phase 3 clinical studies.

A number of other therapies, such as photodynamic therapy and laser photocoagulation have now been superseded by the targeted therapies and their clinical use is very limited. While laser photocoagulation surgery was the first treatment used for wet AMD, approved by the FDA in 1991, it cannot be used to treat those with "subfoveal" age related macular degeneration in which the abnormal blood vessels are located under the fovea, in the centre of the macula. Since almost 90% of wet AMD is subfoveal, only a small percentage of patients are candidates for laser coagulation treatment.

There are also a number of other potential treatments for macular degeneration being investigated in laboratories and tested in human clinical trials. Many of these are exploring sustained release or alternative delivery strategies for the existing therapies on the market, so as to reduce the need to administer therapies via ocular injection on a monthly or once every 2 months basis. Circadian's OPT-302 is a novel and promising approach for the treatment of wet AMD. Used in combination with existing therapies, improved clinical efficacy may also reduce the required dosing frequency.

CIRCADIAN TECHNOLOGIES LTD - A SNAPSHOT

Circadian Technologies Ltd (then Circadian Pharmaceuticals Ltd) headed by Sir Peter Derham and founding managing director Leon Serry was the first second board company to list in Australia - in March 1985 after raising $1 million. Its focus at the time of listing was on a melatonin analog that used the circadian rhythms to combat jetlag (a joint venture was later signed with Eli Lilly). After listing, Circadian funded a 25 pct stake in Axon Instruments, an Australian company domiciled in the US that manufactured precision instruments used in neuroscience (taken over by Molecular Devices of the US in 2004).

Circadian today owns a comprehensive intellectual property estate covering the key angiogenesis targets VEGF-C, VEGF-D and VEGFR-3 that regulate blood and lymphatic vessel growth and vessel leakage. The applications of the technology are substantial and broad. Circadian's internal product development programs are primarily focused on developing OPT-302, a soluble form of VEGFR-3, for the treatment of wet AMD. The program is on-track to initiate a Phase 1 clinical study in wet AMD patients in 2Q 2015. Circadian also has a Phase 2 ready oncology asset (VGX-100) that represents a licensing or partnership opportunity, as well as licensing Eli Lilly/Imclone to develop an antibody to VEGFR-3 as a cancer treatment.

Circadian is also listed on the OTC market in the US (OTCQX:CKDXY).

Progressing OPT-302 - Circadian's lead molecule - now fully funded

**On Jan 14*: Circadian Technologies Ltd through its 100%-owned subsidiary Opthea Pty Ltd in Melbourne announced it has signed a commercial license agreement with Selexis SA in Geneva covering the use of the CHO-M Cell Line and related technologies for the production of Opthea's lead molecule OPT-302.

**On May 12* the FDA endorsed Opthea's proposed clinical indication and preclinical program for OPT-302 as a drug for the treatment of wet AMD, estimated to be a $5 billion per year market in the US alone.
CEO Megan Baldwin said in the report "We are pleased to complete this key milestone which is a major step forward towards filing the IND for OPT-302. Clarity has been provided on our strategy to bring this novel therapy to patients

suffering from wet AMD and we aim to submit an IND and initiate a Phase 1/2a clinical trial in the first half of 2015".

**On October 6* a capital raising of $17.4 million was announced, fully funding the program through to the end of Phase 1 and 2A clinical studies for the treatment of wet AMD. The Phase 1 clinical trial is expected to commence in the second quarter 2015, with results expected in first quarter 2016. Results from Phase 2a clinical trial are expected in the 2nd quarter 2017.

The pipeline

Circadian's pipeline comprises:

- **OPT-302**: a soluble form of VEGFR-3 (Fc-fusion protein or 'Trap' to block both VEGF-C and VEGF-D) for the treatment of wet AMD, currently on-track to initiate a Phase I clinical trial in wet AMD patients under an IND in 2Q'15.

- **VGX-100**: a neutralizing monoclonal antibody for VEGF-C which has completed enrollment in a Ph1a/1b clinical trial in advanced cancer patients as a single-agent and in combination with the VEGF-A inhibitor (bevacizumab, Avastin®). Data from the clinical trial was presented at the Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago (USA) in May 2014. The trial, run under and IND with the US FDA, enrolled 43 patients and was conducted in the USA at the University of Texas MD Anderson Cancer Center (Houston) and UCLA Hematology-Oncology (Santa Monica). The trial demonstrated an encouraging clinical profile for VGX-100 and that VGX-100 is well tolerated when administered on its own or in combination with Avastin®. This Phase II-ready asset is well-positioned for alternative commercialization opportunities including out-licensing or acquisition.

- **IMC-3C5**: a neutralizing monoclonal antibody for VEGFR-3 in development by ImClone, an Eli Lilly Company. ImClone has exclusive rights from Circadian to develop the VEGFR-3 antibody in return for annual license fees, which covers to royalty payments if the product is marketed. ImClone is expecting to complete a Phase I clinical study in cancer patients in H1 2015.

- Circadian also has a partnership with Healthscope Limited who is clinically validating, at Healthscope's expense, CUPGUIDE, a diagnostic test for Cancers of Unknown Primary (CUP). In addition, Circadian has non-exclusive licenses in place with a number of research reagent suppliers. Circadian receives royalties on sale of these reagents under these licenses.

CIRCADIAN TECHNOLOGIES LTD FINANCIALS

Code:	CIR
Last Traded price	16c.
Shares Issued	148.1m.
Market Cap	$23.7m.

Year ended June 30, Values in $m's

INCOME	**2014**	**2013**
Operating Revenue	-	-
Operating (loss)	(6.85)	(6.56)
Net (Loss)	(3.99)	(5.00)
(Loss)PS (Cents)	(8.22)	(9.79)

BALANCE SHEET	**2014 Proforma**	**2014**	**2013**
Current Assets	26.18	9.98	13.47
Non Current Assets..	2.48	2.48	2.94
Current Liabilities	1.76	1.76	1.91
Non Current Liabilities	0.22	0.22	0.14
Net Assets & Shareholders' Funds	26.68	10.48	14.36
Intangibles	-	-	0.50
Net Tangible Assets	26.68	10.48	13.86

Gearing (Net of Cash) %	.nil	.nil	.nil
NTA per share (cents)	18	22	29
Shares Issued (m's)	148.09	48.63	48.63
Options Issued (m's) *	9.7		

* Exercisable at 27 cents by November 25, 2018

Cash Flows:	**2014 Proforma**	**2014**	**2013**
Cash on hand (at open)	7.16	11.00	16.44
Operating Activities	-	(4.17)	(5.61)
Investing	-	0.34	0.23
Financing Activities	16.20	-	-
Exchange Impact	-	-0.01	(0.06)
Cash on hand at Year end	**23.36**	**7.16**	**11.00**

1/On October 6 Circadian announced a capital raising of $17.4 million by way of a placement to raise $14 million at 17.5c per share, a 10% discount to the last closing and a proposed $3.4 million fully underwritten 2 for 5 rights issue at the same 17.5c price to be offered to existing eligible shareholders with 1 for 2 free attaching options exercisable at 27c before November 25 2018.
Bell Potter Securities acted as Lead Manager on the placement and is the underwriter to the proposed rights issue.

2/Circadian also owns c. 9% of Antisense Therapeutics, the only Australian listed company with two Phase II trials under way - for MS and Acromegaly.
Also c. 5% of Optiscan, whose endomicroscopy platform is used in conjunction with the Olympus endoscope.
(Both were part of the original Circadian stable of venture capital funded biotech).

Directors:

Ms Dominique Fisher**,** BA (Hons), non-executive chairman
Dominique Fisher was appointed a non-executive director of Circadian in September 2005. She became Chairman of the Board in the subsequent month and is a member of the Company's Audit and Risk Committee. She has extensive business experience in the corporate area, including the commercialisation of new technologies. Ms Fisher is Principal and Executive Director of EC Strategies Pty Ltd, which advises local and offshore companies on technology strategies and major commercial transactions. She is Managing Director of Helix Digital Pty Ltd and is the Executive Chairman of CareerLounge Pty Ltd. Her past appointments have included a non-executive director of Pacific Brands Limited and membership of its Audit and Risk Committee, Chairman of Sky Technologies Pty Ltd, Councillor of the Australia Council of the Arts, and Chairman of its Dance Board, Insurance Australia Group Limited (IAG), member of the Prostate Cancer Foundation Victoria, NRMA, the Malthouse Theatre, Sydney Opera House and member of the ICT Advisory Board, advising the Federal Government on key issues affecting the development of the information technology and communications sector.

Dr Megan Baldwin, MD and CEO
Dr Megan Baldwin was appointed CEO and Managing Director effective February 24 2014. Dr Baldwin brings over 18 years of experience focussing on angiogenesis and therapeutic strategies for cancer and ophthalmic indications. Dr Baldwin joined Circadian in 2008 and since then has held various positions, including Head of Preclinical R&D and Chief Executive Officer of Opthea Pty Ltd, the 100% owned subsidiary of Circadian, developing OPT-302 (formerly VGX-300) for the treatment of wet age-related macular degeneration. Prior to joining Circadian, she was employed at Genentech (now Roche), the world leader in the field of angiogenesis-based therapies for cancer and other diseases. Her experience included several years as a researcher in the group of leading angiogenesis expert Napoleone Ferrara, before moving to Genentech's commercial division and having responsibility for corporate competitive intelligence activities. In these roles, she developed extensive commercial and scientific knowledge in the field of anti-angiogenic and oncology drug development. Megan has a scientific background of more than 15 years, focused on angiogenesis and therapeutic strategies for cancer and ophthalmological indications. She holds a PhD in Medicine from the University of Melbourne, having conducted her doctoral studies at the Ludwig Institute for Cancer Research.

Tina McMeckan, BLibArts&Sc, MBA, FAICD, non exec director
Tina McMeckan was appointed a non-executive director of Circadian in January 2008 and is Chairman of the Audit and Risk Committee. Her specific skills are in the commercialisation of science and technology and the energy sector. Ms McMeckan is presently Chairman of the Centre for Eye Research Australia and a Director of CRC for Spatial Information, SP AusNet Limited, Global Carbon Capture and Storage Institute and was a director of Metlink Pty Ltd until April 2012. She is a past member of the Funds Management Committee of the AusIndustry Research and Development Board and has held senior investment management positions with the Australian Industry Development Corporation and Amrad Corporation Ltd (acquired by CSL Limited), focusing on capital raisings for innovation-based ventures. She also has extensive board expertise in public and private utility infrastructure, including power production, networks and retailing business in the gas and electricity industries. She was formerly the Chairman of NanoVentures Australia Ltd and a member of the National Board of Norton Rose law firm. Her other appointments as a director have included United Energy, Snowy Hydro Trading, the Westar and Kinetik Energy Group, Victorian Power Exchange, Vision Cooperative Research Centre, Solaris Power and the formerly listed company Alinta Limited (October 2003 to August 2007).

Dr Russell Howard, non exec director
Russell Howard has dedicated his career to life sciences and biotechnology to generate valuable products that provide solutions to problems in medicine, agriculture, and the chemicals manufacturing business.
Russell is the Founder and CEO of Oakbio, a biotechnology company based in California, developing breakthrough sustainable microbe-based technologies that convert CO2 in waste gas into valuable chemical products. As well as providing a new and cost-competitive solution to the challenge of making chemicals without disruption to precious resources of land, food, water, and agriculture, this technology has potential impact for the critical challenge of climate change.
Very recently, upon return to Australia, Russell became Executive Chairman at Neuclone, a Sydney company developing biosimilar monoclonal antibody drugs. Neuclone's proprietary manufacturing technology generates products differentiated by low production cost. Price-competitive biosimilar drugs can share in multi-billion dollar emerging markets while simultaneously providing cost-affordable treatments to millions more people.
Before Oakbio, Russell was Founder and CEO of Maxygen, a biotechnology company creating over 30 breakthrough products by gene shuffling of DNA. Russell led Maxygen from inception through IPO and 10's of corporate deals plus spin-out of companies in Agriculture (Verdia, sold to Dupont), chemicals manufacture (Codexis) and protein pharmaceuticals (Perseid, sold to Astellas). Prior to Maxygen, Russell was President & Scientific Director at Affymax, pursuing combinatorial small molecule drug discovery.
Russell also spent over 20 years studying infectious diseases, primarily the molecular basis for the pathology of malaria and immune evasion by antigenic variation. He served on WHO and USAID advisory panels for malaria vaccine development. At the National Institutes of Health in MD, USA, Russell was responsible for invention of a rapid, inexpensive, human malaria diagnostic test marketed worldwide for over 15 years.

Senior management:

Mike Tonroe,BSc(Hons), ACA, MAICD
Chief Financial Officer
Mike Tonroe is a Chartered Accountant and was appointed Chief Financial Officer and Company Secretary in May 2014. Prior to joining Circadian, Mike was the Chief Financial Officer and Company Secretary at the Australian Synchrotron in Melbourne. Mike has over 20 years' experience of financial management in board-level positions for private and listed companies in Australia, UK, the US and Canada. Mike holds a Graduate Degree in Business Studies from Buckingham University and is a Member of the Australian Institute of Company Directors. Mike is also the Company Secretary for all of the Group's subsidiaries, including Syngene Limited and Vegenics Pty Ltd, and all other Circadian subsidiary companies.

Mike Gerometta, PhD
Head of CMC Development
Mike Gerometta has been with Circadian since December 2008 and is principally responsible for the outsourcing of Circadian's research and cGMP manufacturing activities. Mike has over 20 years'experience in the Australian biotechnology industry, most recently as Chief Operating Officer of Q-Gen, QIMR's translational research, manufacturing arm. He has also spent 19 years at Agen Biomedical, occupying a variety of positions and roles, most recently as Research and Product Development Director. In this role he was responsible for the chemistry,

manufacturing and controls (CMC), pre-clinical program and patent management for Agen's ThromboViewR project, a blood clot imaging agent. Previously, he has worked at Biotech Australia, Sydney, and together with earlier positions at Agen, developed numerous successful immunodiagnostic assays for the medical, veterinary and food industries across various diagnostic platforms for the laboratory and point-of-care. He was awarded his PhD in biotechnology from the Queensland University of Technology and has a degree in chemistry from the University of Technology in Sydney.

Ian Leitch, PhD
Director – Clinical Research
Ian Leitch has been Director of Clinical Research of Circadian Technologies Ltd since September 2011. He has over 15 years of research and management experience from drug discovery through clinical development in biotechnology/pharmaceutical companies. For the five years prior to joining Circadian, he was a member of the Medical Sciences group at Amgen Inc in Thousand Oaks, California, involved in the development of novel therapeutics in Amgen's oncology pipeline. In his role as Senior Manager in the Early Development Oncology Therapeutic Area, he had responsibility for the oversight, design, management and execution of Phase I–II clinical studies in oncology. Prior to joining Amgen, he spent eight years at Miravant Medical Technologies in Santa Barbara, California. He held positions of increasing responsibility, including Senior Program Manager for Cardiovascular Research and Clinical Study Director for Ophthalmology. At Miravant, he managed pre-clinical efficacy studies, developed relationships with Key Opinion Leaders and designed Phase I–II clinical studies in a collaboration with the cardiovascular device company Guidant Inc. He previously held the position of NHMRC Senior Research Officer at the University of Newcastle, and was based at the John Hunter Hospital in Australia. He received his PhD from the Department of Pharmacology, Faculty of Medicine, at Monash University in 1993 and completed part of the degree at the University of California, Santa Barbara, as part of an Education Abroad Program Scholarship.

Richard Chadwick, PhD
Head of Intellectual Property
Richard Chadwick, who joined Circadian in February 2008, is qualified as both a European and Australian patent attorney. Richard joined Circadian from FB Rice & Co, where he had been working for five years in the Biotechnology Group. Prior to that, Richard had 10 years' experience in intellectual property in the UK. This included working as an in-house attorney at Dow Corning Limited and five years working as an in-house attorney at Unilever.

Angus Tester, PhD
Senior Research Scientist
Angus Tester has held the position of senior research scientist at Circadian since February 2009. He is responsible for conducting pre-clinical research undertaken at the Circadian research laboratory, and for providing scientific support to the oncology and ophthalmology research and development programs. Angus completed his PhD in Biochemistry at Monash University and has over 15 years of experience working in the fields of cancer and biological research within laboratories located both in Australia and North America. He has gained extensive skills and experience in the development and optimisation of assays for screening and testing the Circadian compounds for their clinical utility and for the PK, PD and biomarker programs.

Major shareholders:

The following holdings are post tranche 1 of the placement and the rights issue announced on 6 October 2014. Subject to shareholder approval at the 2014 AGM on 18 November 2014, the holdings listed are subject to change following the issue of tranche 2 shares under the placement.

BNP Paribas nominees 18%
Deutsche Bank AG and related bodies corporate 9.15%
Licentia Ltd, the investment arm of the Helsinki University, 4.2% (former co-owner of VEGF in j/v with Ludwig Institute).
Ludwig Institute 4.17% (former co-owner of VEGF in j/v with Licentia)
Baker Brothers Life Sciences 2.8%
Leon Serry 4.19%