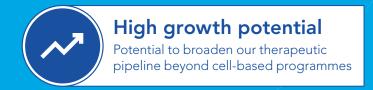


# ReNeuron

# Our vision is to deliver life changing therapies to patients

- A leader in the cell therapy field
- Novel cell-based therapies targeting unmet needs
  - At the forefront in our selected indications
    - Secure intellectual property
      - Manufacturing capability



# Highlights



# CTX cells for stroke disability

- Positive Phase II efficacy data in PISCES II clinical trial
- Phase I clinical trial data from PISCES I study published in The Lancet
- Pivotal Phase III clinical trial planned to commence in US in early 2018, following positive feedback from the FDA



### hRPCs for retinal diseases

- Phase I/II clinical trial in retinitis pigmentosa ongoing in US with Phase I data expected later in 2017 and data from enlarged Phase II study expected in H2 2018
- Cryopreserved formulation of hRPC approved by FDA for use in clinical trials
- Phase II clinical trial application planned later in 2017 in cone-rod dystrophy



### CTX cells for critical limb ischaemia

 Phase I clinical trial completed with no significant adverse safety events reported



### **CTX-derived exosomes**

- Positive pre-clinical data with ExoPr0 exosome therapy candidate presented at leading scientific conferences
- Data indicates that ExoPrO can cross the blood-brain barrier and has potential to target multiple diseases
- Initial clinical trial application expected in late 2018 in cancer
- Loss for the period of £15.6 million (2016: £11.4 million); cash outflow from operating activities of £12.6 million (2016: £11.9 million)
- Cash, cash equivalents and bank deposits at 31 March 2017 of £53.1 million (2016: £65.7 million)

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# Find out more at www.reneuron.com



# ReNeuron at a glance

# Products to improve patients' lives

# Our products

We have therapeutic candidates in clinical development for motor disability as a result of stroke, for critical limb ischaemia and for retinal diseases including the blindness-causing disease retinitis pigmentosa.

Our proprietary exosome technology platform has a potential as a new nanomedicine targeting cancer and as a potential delivery system for drugs.



### CTX cells for stroke disability

Our lead therapeutic candidate is our CTX stem cell therapy for the treatment of patients left disabled by the effects of a stroke.

The only current treatment option is available within four hours of stroke onset. Our treatment targets patients months after their stroke.

After positive Phase I and Phase II studies and positive feedback from the FDA, we are planning to commence a Phase III pivotal study.

# up to \$3.9 billion

Assumed peak sales to 2026\*

Read more on page 11  $\rightarrow$ 



# hRPCs for retinitis pigmentosa

Our lead therapeutic hRPC candidate is for the treatment of retinitis pigmentosa (RP), a blindness-causing disease of the retina. This treatment is in mid-stage clinical development.

There is no approved drug treatment for RP and our hRPC-based therapy has been granted Orphan Drug Designation in the EU and US.

# up to \$1.8 billion

Assumed peak sales to 2026\*

Read more on page 12  $\rightarrow$ 



### hRPCs for cone-rod dystrophy

We have selected cone-rod dystrophy (CRD) as our second indication as part of our strategy to evaluate the efficiency of our hRPC therapeutic candidate across a range of genetic diseases of the eye. CRD is an inherited eye disorder characterised by the deterioration of the cone and rod cells in the retina of the eye leading to a loss of vision.

1 in 40,000

people affected by cone-rod dystrophy in the US

Read more on page 13  $\rightarrow$ 



### **CTX-derived exosomes**

Exosomes are nanoparticles released by cells containing a number of active proteins and microRNAs. Our exosomes nanomedicine platform is generating promising early pre-clinical data in cancer.

Data shows that our exosomes can cross the blood-brain barrier and has potential to target multiple diseases.

# £2.1 million

Innovate UK grant awarded to pursue clinical development

Read more on page 14  $\rightarrow$ 

<sup>\*</sup> According to analysts' estimates.

# What sets us apart

# Our strengths



# Our Company pipeline breadth

We have two stem cell therapy candidates in mid to late stage clinical development and our proprietary exosome technology platform is in pre-clinical development.



# Our platform technologies

Our unique cell expansion technologies enable us to manufacture our products at scale. Our stem cell therapy candidates are allogeneic and are delivered in cryopreserved form enabling "off-the-shelf" delivery to the patient.



### Our well backed and funded business

We have a robust balance sheet and are backed by major generalist and specialist life science institutional investors, including Woodford Investment Management (35%), Wales Life Science Fund (9.5%), Invesco (9.3%) and Aviva (5.7%).



# Focus on high value indications

We focus on indications where we can have a large impact on patients due to an unmet or poorly met medical need and where there is high commercial potential.



# Highly experienced Board and management team

Our Board and leadership team comprise individuals with many combined years of experience in successful biotechnology and pharmaceutical companies.

# Our strategy

1

Develop best-in-class cell-based therapies for life-changing high value products.

2

Gain clinical validation for our therapeutic programmes, via robust clinical trials in well regulated territories.

3

Realise value for our technologies and therapeutic programmes, via direct sales or substantial licence deals.

# Chairman and Chief Executive Officer's joint statement



#### Overview

Our therapeutic development programmes have continued to progress well during the period, the highlight being positive Phase II data from the PISCES II clinical trial of our CTX cell therapy candidate for stroke disability. We are encouraged by the subsequent feedback we have received from the FDA regarding our planned US pivotal Phase III clinical trial with CTX for stroke disability. The unmet medical need in chronic stroke disability is enormous and a great strain on carers and patient-support organisations. We are pleased to have moved ever closer to potentially offering a new therapeutic option to these patients.

We have made significant advances with our hRPC cell therapy candidate, both in terms of progressing the ongoing US Phase I/II clinical trial in retinitis pigmentosa and obtaining FDA approval for the cryopreserved formulation of this therapeutic candidate, enabling us to expand our ophthalmology programmes into new indications. We have also generated and presented further encouraging pre-clinical data with our ExoPr0 exosome therapy candidate targeting cancer.

"Our therapeutic development programmes have continued to progress well during the period, the highlight being positive Phase II data from the PISCES II clinical trial of our CTX cell therapy candidate for stroke disability."

### Review of programmes CTX for stroke disability

During the period, we completed dosing and announced positive data in the Phase II clinical trial (PISCES II) of our CTX cell therapy candidate for stroke disability. PISCES II is a single-arm, open-label study in patients living with disability resulting from ischaemic stroke. At the time of announcement of the initial data, all 21 patients in the study had completed three month follow-up, with ten patients followed for six months and three for twelve months.

The study's primary endpoint was for two patients to reach a minimum two point improvement in the grasping and lifting test, sub-test number 2, of the Action Research Arm Test (ARAT) at three months post-treatment. Three of the 21 patients achieved this at three, six and twelve months respectively after treatment and were within a group of four responders who also showed clinically relevant improvements on the total ARAT score of arm motor performance. Although the ARAT sub-test number 2 study endpoint was not met (as some responses came later than the three month target), we believe the result is nonetheless highly encouraging.

Strongly positive results were also seen in the other endpoints of the study, with seven patients (33%) showing a clinically relevant improvement on the modified Rankin Scale (mRS) (a measure of disability and dependence) and eight patients (38%) showing a clinically relevant improvement on the Barthel Index (a measure of performance in activities of daily living). In total, 15 out of 21 patients had a clinically significant response on at least one efficacy measure. Improvements in the ARAT scores, modified Rankin Scale and Barthel Index were all sustained throughout the follow-up period.



# Chairman and Chief Executive Officer's joint statement continued

### **Review of programmes** continued

### CTX for stroke disability continued

The study also demonstrated that the CTX treatment was well tolerated, with no cell-related adverse events. Longer-term safety and efficacy data from the study will be presented at forthcoming stroke and rehabilitation medical conferences. The PISCES II study was part-funded by a regenerative medicine and cell therapy development grant from Innovate UK.

The above PISCES II data was generated after the publication of long-term follow-up data from our PISCES I stroke clinical trial in The Lancet. The PISCES I study was the first clinical trial of our CTX cell therapy candidate for stroke disability. The Lancet paper describes two year follow-up clinical data relating to the eleven stroke patients treated in the study. Improvements in neurological status and limb function compared with pre-treatment baseline performance were observed in this study within three months of treatment and maintained throughout long-term follow-up. The CTX treatment was also well tolerated by the patients in the PISCES I study, with no cell-related or immunological adverse events reported across the four ascending dose levels.

As a result of the positive data reported from both the PISCES I and PISCES II studies, we have consulted the FDA regarding our plans to conduct a randomised, placebo-controlled, pivotal Phase III clinical trial with CTX in the US, in patients with disability post-stroke. As we reported recently, the FDA has responded positively to our proposals regarding the design and conduct of the proposed Phase III clinical trial and, significantly, specifically recommended that we apply for a Special Protocol Assessment (SPA) for the Phase III study. The SPA process is exclusively reserved for studies considered potentially pivotal in support of product marketing label claims.

Based on the FDA's recommendation, we plan to apply for an SPA for our proposed Phase III clinical trial with CTX for stroke disability. As part of our US regulatory strategy, we also plan to apply for Regenerative Medicine Advanced Therapy (RMAT) designation for our CTX cell therapy candidate for stroke disability. The benefits of RMAT designation are similar to those of Breakthrough Therapy designation, including increased interactions with the FDA during development and eligibility for priority review and accelerated marketing approval.

"The FDA has responded positively to our proposals regarding the design and conduct of the proposed Phase III clinical trial in stroke disability." 15 out of 21 15 out of 21 patients in our PISCES II stroke study had a clinically significant response on at least one efficacy measure.

We are now working to finalise the relevant data packages to enable us to submit both the SPA and RMAT designation applications within the broader IND application to commence a Phase III clinical trial with CTX for stroke disability in the US. We expect to make this combined submission in the final quarter of this year, with the study now expected to commence in early 2018, subject to the requisite regulatory approvals. Data from the study are expected about two years later, in early 2020.

Separately, we have consulted with the European Medicines Agency on our plans for the Phase III clinical trial and we have taken the advice received into account when developing our protocol for the study. In this regard, we intend to file a clinical trial application to regulatory authorities in Europe, shortly after the corresponding US submission. Meetings with the Japanese regulatory agency (PMDA) are also ongoing in order to advance our CTX cell therapy candidate for stroke disability in Japan under regulations that offer the potential for conditional marketing approval for cell therapies at an earlier stage of clinical development.

### hRPC for retinitis pigmentosa

During the period under review, we completed dosing of the second dose cohort of three patients in the Phase I element of the Phase I/II clinical trial of our human retinal progenitor cell (hRPC) cell therapy candidate for the blindness-causing disease retinitis pigmentosa (RP). This US study, which is being conducted at Massachusetts Eye and Ear Infirmary in Boston, is an open-label, dose escalation study to evaluate the safety, tolerability and preliminary efficacy of our hRPC stem cell therapy candidate in 15 patients with advanced RP.

During the period, we also successfully developed a cryopreserved formulation of the hRPC therapeutic candidate. The FDA has recently approved this formulation and we have now started treating patients with it in the ongoing US Phase I/II study clinical trial in RP patients. The ability to cryopreserve our retinal cell therapy candidate at drug product level represents a major step forward for our retinal disease programme and mirrors the earlier breakthrough we achieved with the cryopreservation of our CTX cell therapy candidate. The new proprietary formulation enables the hRPCs to be frozen for shipping and storage and easily thawed at the point of clinical use. This freeze-thaw modality provides a greatly enhanced shelf life for the product, lower prospective cost of goods and the capability to ship the cells for clinical and commercial application anywhere in the world.

The new hRPC cryopreserved formulation has also allowed an expansion of ReNeuron's clinical programmes in ophthalmology. Firstly, we will shortly file an application with the FDA to expand the Phase II element of the ongoing US Phase I/II clinical trial in RP from six to 20 patients. The expanded study is designed to provide the depth and quality of data that, if positive, will allow subsequent progression to a Phase II/III pivotal study in this indication. In order to maintain the pace of patient recruitment and reduce reliance on a single clinical site, we also intend to open up further US clinical sites for this study. As a consequence of these changes, we expect safety and tolerability data from the Phase I part of the RP study in the first nine patients later this year, with longer-term safety data as well as efficacy read-outs from the enlarged Phase II part of the study in the second half of 2018.

Secondly, we intend to expand our hRPC retinal disease programmes into a further disease indication, cone-rod dystrophy (CRD). In contrast to RP, where the initial impact is a loss of rods leading to a deterioration in peripheral vision and night vision, CRD is a group of rare eye disorders associated with a loss of cone cells in the retina that initially results in deterioration of central visual acuity and colour vision. CRD frequently affects patients in childhood and has no cure. It is an inherited orphan disease that affects roughly one in 40,000 people.



The expansion of our ophthalmology programmes into CRD is part of a broader strategy to evaluate the efficacy of our hRPC therapeutic candidate across a range of genetic diseases of the eye. We intend to file an application to commence a Phase II clinical trial later this year in patients with CRD, to be run alongside the Phase II part of the ongoing RP clinical trial. Data from the CRD study are expected in mid 2019.

"Cone-rod dystrophy frequently affects patients in childhood and has no cure. It is an inherited orphan disease that affects roughly one in 40,000 people."

### CTX for critical limb ischaemia

In order to focus on the significant opportunity presented by our stroke disability programme, our expanded retinal disease programmes and our emerging exosome platform, we have decided to put our programme for critical limb ischaemia on hold for the time being. Patient dosing was recently completed in a Phase I safety study in this indication, with no significant adverse safety events reported postadministration of the CTX cells via intramuscular injection.

### **Exosome nanomedicine platform**

During the period, and subsequently, we have continued to generate and present pre-clinical data relating to our exosome development programme. Exosomes are nanoparticles secreted from all cells including ReNeuron's proprietary CTX stem cell line. They play a key role in cell-to-cell signalling and early research with ExoPr0, our first CTX-derived exosome therapeutic candidate, has demonstrated that it may have a significant effect in regulating cell growth and apoptosis in cancer.

In conjunction with our academic collaborators at the Department of Biochemical Engineering, University College London (UCL), we have presented data relating to the upstream cell culture processes needed to generate our exosomes and the downstream purification methods that can be applied to remove protein and DNA-based impurities from the exosomes at commercially relevant scale. These new methods were shown to yield a threefold increase in particle protein purity and a more than fivefold increase in particle DNA purity compared with previous purification processes.

In conjunction with the UK's Cell and Gene Therapy Catapult, we have also presented data relating to the characterisation of our exosomes to ensure consistency and control during manufacture. The data demonstrated a robust approach to optimising and qualifying assays for microRNA components found in the exosomes. The application of robust characterisation and purification methods to our exosome populations will support their future development across multiple potential disease indications.

# Chairman and Chief Executive Officer's joint statement continued

### Review of programmes continued

Exosome nanomedicine platform continued

Finally, we recently presented data relating to the in vivo biodistribution of ExoPrO, using the most common and disease applicable routes of administration to deliver the exosomes. The studies showed that ExoPrO can be targeted to specific organs and tissues by either local or systemic administration and, most importantly, can penetrate the blood-brain barrier. These findings, together with earlier research results, suggest that there is significant potential to develop ExoPrO for the treatment of multiple diseases, both as a novel therapeutic candidate and as a drug delivery vehicle.

On the basis of the above progress and subject to continued success with ongoing pre-clinical development work, we expect to be able to reach the clinic with ExoPr0 in late 2018, targeting cancer.

### Other activities

Subsequent to the period end, we were awarded a £1.8 million grant from Innovate UK to further advance our next generation commercial cell therapy manufacturing capabilities. The grant will fund key process development activities relating to upscaled commercial manufacture of our cell therapy candidates, including the development of robust manufacturing processes utilising next generation technology and techniques that will enable the production of our therapeutic candidates at a commercial scale. The work will be undertaken by ReNeuron, as lead participant, and our collaborators on the grant, the Cell and Gene Therapy Catapult.

We are also pleased to be an industry participant in the recently launched Future Targeted Healthcare Manufacturing Hub. The Hub, led by UCL and funded by the Engineering and Physical Sciences Research Council, is an industry-academia consortium established to address the manufacturing, business and regulatory challenges to ensure that new targeted biological medicines can be developed quickly and manufactured at a cost affordable to society.

"With our stroke programme moving into Phase III clinical development over the coming months and our retinal disease programmes moving into Phase II clinical development later this year, we expect to achieve significant clinical milestones during each of the next three years."

### Summary and outlook

Our therapeutic development programmes have continued to progress well during the period, the highlight being positive Phase II data from the PISCES II clinical trial of our CTX cell therapy candidate for stroke disability. We are encouraged by the subsequent feedback we have received from the FDA regarding our planned US pivotal Phase III clinical trial with CTX for stroke disability. The unmet medical need in chronic stroke disability is enormous and we are ever closer to being able to offer an effective therapy to these patients.

We have made significant advances with our hRPC cell therapy candidate, both in terms of progressing the ongoing US Phase I/II clinical trial in retinitis pigmentosa and obtaining approval for the cryopreserved formulation of this therapeutic candidate, enabling us to expand our ophthalmology programmes into new indications. We have also generated and presented further encouraging pre-clinical data with our ExoPr0 exosome therapy candidate targeting cancer.

With our stroke programme moving into Phase III clinical development over the coming months and our retinal disease programmes moving into Phase II clinical development later this year, we expect to achieve significant clinical milestones during each of the next three years.

On page 60 of this report is the Notice of the 2017 Annual General Meeting (AGM) to be held at 10 a.m. on 6 September 2017. A short explanation of the resolutions to be proposed at the AGM is set out on page 62. The Directors recommend that you vote in favour of the resolutions to be proposed at the AGM, as they intend to do in respect of their own beneficial holdings of Ordinary shares.

Olav Hellebø

**Chief Executive Officer** 

John Berriman

Arll 16

Non-executive Chairman

18 July 2017

# Delivering unique stem cell technologies

Using our unique and scalable stem cell technologies, we have created a pipeline of commercially focused cell-based therapeutic candidates addressing significant areas of unmet or poorly met medical need. These therapeutic candidates are based around our CTX neural cell line, our human retinal progenitor cells (hRPCs) and our CTX-derived exosome nanomedicine platform.

Product indication	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Market approval
CTX Stroke disability						
CTX Critical limb ischaemia						
hRPC Retinitis pigmentosa	<u>o</u>					
hRPC Cone-rod dystrophy						
Exosomes (CTX-derived) Cancer	3					

### **Business review**

# Our products and technologies

ReNeuron has used its unique stem cell technologies to develop cell-based therapies for significant disease conditions where the cells can be readily administered "off the shelf" to any eligible patient without the need for additional drug treatments.

Both ReNeuron's stem cell products are allogeneic and cryopreserved, enabling the treatment of many patients from the same cell bank. The products can be shipped to clinical sites and stored there in their cryopreserved form and then thawed and administered to the patient in an "off-the-shelf" manner.

This provides us with major commercial and competitive advantages in terms of the availability of a genuine off-the-shelf, low-cost-of-goods cell-based treatment with a shelf life enabling shipping to, and storage at, clinical sites on a global basis.

### **CTX**

CTX is an immortalised neural cell line which has been generated using our proprietary cell expansion and cell selection technology and then taken through a full manufacturing scale-up and quality-testing process. As CTX is derived from a single donor, there should be complete consistency between cell banks and no risk of the variability which can arise when multiple donors are needed for cell supply.

All cells used in CTX-based treatments can simply be expanded from the existing tested banks. There will therefore be no need to re-derive and test new CTX cell lines for subsequent clinical trials or for the market.

### Human retinal progenitor cells (hRPCs)

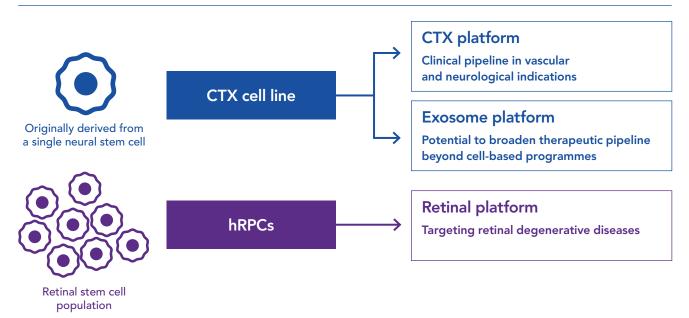
hRPCs are cells that differentiate into components of the retina. These cells are grown using a patented low-oxygen

cell expansion technology licensed from the Schepens Eye Research Institute at Harvard Medical School. Through our collaboration with Schepens we have developed the ability to scale hRPCs using this technology and we have established GMP-compliant hRPC cell banks to provide future drug product.

### CTX-derived exosomes

Cells often communicate via exosomes, nanosized packages of information released by the cell for absorption by other cells. These packages of information contain a variety of proteins, genetic material and other cargo which have the ability to induce functional changes in recipient cells. Under certain conditions, exosomes produced by stem cells initiate repair and regeneration. However, depending on the state of the cell and its environmental stimuli, stem cells have the ability to communicate different information and induce different functional changes.

We have developed a technology by which our CTX stem cell line, already in clinical trials as a cell therapy candidate, can be cultured under different environments to produce therapy-specific agents and can be harvested at a commercially relevant scale. The ability to produce a commercially valuable therapeutic product from stem cell-derived exosomes demands a standardised stem cell producer line appropriately sourced and isolated, manufactured to GMP, grown in serum-free conditions and (ideally) already having demonstrated patient safety. In the stem cell field, our CTX cell line uniquely meets all these conditions.



ReNeuron Group plc



# CTX cells for Stroke disability

### Indication: stroke disability

Stroke is the single largest cause of adult disability in the developed world. Over 150,000 people suffer a stroke each year in the UK, and circa 800,000 people in the US. Approximately 80% of these strokes are ischaemic in nature. According to the World Health Organization, each year, approximately 15 million people worldwide suffer their first ischaemic stroke.

### The market

Between 2012 and 2030, total stroke-related costs in the US are projected to triple, from \$71.6 billion to \$184.1 billion. Treatments for stroke are currently limited to the acute phase, three to four hours after a stroke event. Our CTX stem cell therapy candidate for stroke (CTX) is aimed at the post-stroke rehabilitation period for which there are currently no therapies available, with the target of improving recovery and functional abilities such that patients can lead a more productive life.

Market potential has been estimated by analysts at peak sales of up to £3.9 billion.

### Our product

Our CTX stem cell therapy candidate, comprising cells derived from our CTX neural stem cell line, has been shown to reverse the functional deficits associated with stroke disability when administered several weeks after the stroke event in relevant pre-clinical models.

The treatment involves a single injection of CTX cells into the brain, adjacent to the area damaged by the stroke.

### **Progress to date**

The PISCES Phase I trial in stroke patients demonstrated a good safety profile and sustained reductions in neurological impairment and spasticity lasting out to two years post-treatment.

Positive data have been reported from the PISCES Phase II clinical trial in stroke patients, with 15 out of the 21 patients treated showing a clinically significant response on at least one efficacy measure.

The PISCES Phase II study also demonstrated that the CTX treatment was well tolerated, with the only adverse effects being attributed to the underlying condition or minor adverse effects from the surgical procedure.

Following a successful meeting with the FDA, we are working to finalise the relevant data packages to enable us to submit a Special Protocol Assessment (SPA) and Regenerative Medicine Advanced Therapy (RMAT) designation applications within the broader IND application to commence a Phase III clinical trial with CTX for stroke disability in the US. Subject to regulatory approval, we plan to treat the first patient in the controlled Phase III study in early 2018.

# Over 150,000

Over 150,000 people suffer a stroke each year in the UK, and circa 800,000 people in the US.

15 million

Each year approximately 15 million people worldwide suffer their first ischaemic stroke.

Sources: Stroke Association (UK), American Stroke Association

# \$184.1 billion

Between 2012 and 2030, total stroke-related costs in the US are projected to triple, from \$71.6 billior to \$184.1 billion.







# CTX cells for critical limb ischaemia

# Indication: critical limb ischaemia (CLI)

Peripheral arterial disease (PAD) is one of the most common vascular diseases, affecting one in three people over the age of 70. Critical limb ischaemia is the severe "end stage" manifestation of PAD and is caused by chronic lack of blood supply to the lower leg.

### The market

There are estimated to be over 1 million people in the US with CLI.

It is a common side effect of diabetes, as well as strokes and obesity. For approximately 25% of CLI patients the primary treatment is amputation, with an estimated 160,000 legs amputated per annum due to CLI in the US alone.

### Our product

Our CTX stem cell therapy candidate for CLI comprises cells derived from our CTX neural stem cell line. Our CTX stem cells are administered via straightforward intramuscular injection.

### **Progress to date**

In order to focus on the significant opportunities on our stroke disability and retinal disease programmes, we have decided to pause the CLI programme. Patient dosing in a Phase I safety study recently completed with no significant adverse safety events reported post administration of the CTX cells.

Source: www.vasculardiseasesmanagement.com

# Business review - our products and technologies continued



# hRPCs for retinitis pigmentosa

# Indication: retinitis pigmentosa (RP)

Retinitis pigmentosa is an inherited, degenerative eye disease which causes severe vision impairment and often blindness due to loss of the photoreceptor cells found in the retina. It is the most common inherited cause of blindness in people between the ages of 20 and 60. RP is typically diagnosed in adolescents and young adults and most sufferers will be legally blind by the age of 40. The incidence of RP is 1:4,000 in the US with an estimated treatment population of 200,000 in the US and the EU.

#### The market

There are no treatments currently available for RP, and two of the few approaches in development only target a small subpopulation of the RP patient population with specific genetic mutations. Our human retinal progenitor cell (hRPC) programme is expected to be applicable to the broad, heterogeneous RP patient population.

Our hRPC-based therapy for RP has been granted Orphan Drug designation in both the EU and the US, providing the potential for ten and seven year market exclusivity post-approval of the therapy in these territories, respectively.

The FDA has also awarded Fast Track designation to the programme. This designation is intended to expedite the development and review of new drugs or biological products targeting unmet medical need where the diseases concerned are serious or life threatening.

Market potential has been estimated by analysts at peak sales of up to 1.8 billion.

### Our product

Pre-clinical studies have demonstrated that, when transplanted into the retina, our hRPCs have the potential to preserve pre-existing photoreceptors, potentially reducing or halting further deterioration of vision. In addition, some of the hRPCs had both matured into apparently functional photoreceptors and engrafted into the photoreceptor layer, raising the possibility of a degree of reversal of the decline in vision associated with RP.

### **Progress to date**

In April 2015 the Company filed an Investigational New Drug (IND) application with the US FDA to commence a Phase I/II clinical trial with hRPCs in patients with RP. The IND was approved in May 2015 and the first patient was treated in the clinical trial in March 2016. The trial is being conducted at Massachusetts Eye and Ear Infirmary in Boston.

Massachusetts Eye and Ear Infirmary is a world-renowned clinical centre for the treatment of retinal diseases and the Phase I/II clinical study is being conducted with leading retinal clinicians Dr Eric Pierce, PI, and Dr Dean Elliot, surgeon.

The ongoing Phase I/II clinical trial is evaluating the safety, tolerability and preliminary efficacy of our hRPC cell therapy candidate. We are currently treating patients in the Phase I part of the study. Our recently approved cryopreserved product has enabled us to expand the Phase II part of the study from six patients to 20 patients. This expanded study is designed to provide the depth and quality of data that, if positive, will allow subsequent progression to a Phase II/III pivotal study in the indication.

# 200,000

The incidence of RP is 1:4,000 in the US with an estimated treatment population of 200,000 in the US and the EU.

Source: National Eye Institute

# 1.5 million patients

Retinitis pigmentosa affects approximately 1 in 3,000 to 4,000 people, with an estimated 1.5 million patients worldwide.



# hRPCs for cone-rod dystrophy

### Indication: cone-rod dystrophy

We are expanding our hRPC retinal cell disease programme into a further indication, cone-rod dystrophy (CRD). In contrast to RP, where the initial impact is a loss of rods, CRD is associated with a loss of both cone and rod cells in the retina. This disorder initially results in deterioration of central visual acuity and colour vision.

### The market

CRD is an inherited disease that affects patients in childhood and is present in one in 40,000 people. As with RP, there is in no cure for this condition.

### Our product

This product uses the same recently approved cryopreserved hRPC formulation as used to treat retinitis pigmentosa. Our hRPC technology is aimed to provide protection to photoreceptors (cone and rod cells) when transplanted into the affected area and may also replace damaged cells.

STRATEGIC REPORT

### **Progress to date**

The safety of this product is being demonstrated in the ongoing Phase I RP clinical trial; therefore we intend to file an application to start a new US Phase II clinical trial in patients with CRD later in 2017, to be conducted alongside the Phase II part of the RP clinical trial.

CRD is a rare and inherited disease, with no cure, that affects patients in childhood

# Business review – our products and technologies continued



# CTX-derived exosomes

# Indication: multiple potential disease indications

Early research with ExoPr0, our first CTX-derived exosome therapeutic candidate, has demonstrated that it may have a significant effect in regulating cell growth and apoptosis in cancer.

Recent data have identified that ExoPr0 can be targeted to specific tissues and organs and, most importantly, can penetrate the blood-brain barrier, suggesting that there is significant potential to develop ExoPr0 for the treatment of multiple diseases, both as a novel therapeutic candidate and as a drug delivery vehicle.

### Our product

Exosomes are nanoparticles secreted from all cells including ReNeuron's proprietary CTX stem cell line, which has demonstrated to be a potent producer of exosomes. We have therefore generated a strong intellectual property portfolio relating

to this process. Based upon promising pre-clinical studies, we are pursuing pre-clinical development of our selected exosome nanomedicine candidate, designated ExoPr0.

Exosome-based therapies also offer a number of advantages over cell-based therapies for some indications. They are easier to manufacture and less immunogenic and can be standardised and tested in terms of dose and biological activity in a similar manner to conventional biopharmacological products.

### **Progress to date**

We have continued our collaboration with the Cell and Gene Therapy Catapult and the Department of Biochemical Engineering at University College London supported by the £2.1 million grant received from Innovate UK. This has enabled good progress to be made on the development of robust manufacturing systems to enable the production of ExoPr0

at a commercial scale, as well as product characterisation work and pre-clinical efficacy and toxicity testing of the ExoPr0 candidate.

We continue to generate and present pre-clinical data relating to the exosome development programme. These pre-clinical data have demonstrated that ExoPr0:

- inhibits glioblastoma cell migration;
- reduces tumour volume in a cell-line derived xenograft mouse model of glioblastoma;
- has identified micro-RNAs contained in ExoPr0 responsible for cell growth and apoptosis in cancer; and
- crosses the blood-brain barrier.

Assuming continued success with ongoing pre-clinical development work, we expect to be able to file an application to commence the first human clinical trial with ExoPr0 in 2018, targeting cancer.

# Awarded a £2.1 million grant



# Our manufacturing capability

# Investing in commercial potential

ReNeuron has invested heavily in its cell manufacturing process and technologies, converting exciting stem cell science into cell-based therapy candidates with real commercial potential.

Our cell-based therapy candidates are manufactured in accordance with stringent quality standards. We work to good manufacturing practice (GMP) standards and strive for continuous improvement in order to maintain our quality standards at the highest level.

We have established world-class CMC (chemistry, manufacturing and control) and quality teams at our new facility in Pencoed. The team has industry-leading experience in the development of cell therapy products as well as decades of experience in the commercialisation of complex biologics.

### **CTX**

Each patient treatment will require one vial of CTX drug product and each vial will contain many millions of identical living cells from our conditionally immortalised neural stem cell line. The process for production of these cells is well established and has already been successfully transferred to a number of contract manufacturers as part of the overall strategy to have security of future commercial supply.

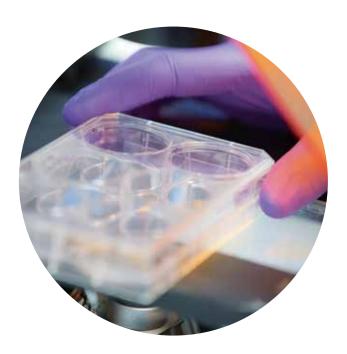
CTX cells are cryopreserved and are supported by a logistics system that can be easily applied to commercial scale allogeneic products, which gives flexibility in terms of scheduling patient treatment without further manipulation.

CTX cells are administered using ReNeuron proprietary cell injection systems in conjunction with industry-standard devices for stereotactic surgery.

### **hRPC**

Each patient treatment of the hRPC drug product contains millions of living human retinal progenitor cells in a parenteral presentation. These cells are expanded in number during the production process using our technology for growth and expansion in a low-oxygen environment, this being more

"We have industry-leading experience in the development of cell therapy products, as well as decades of experience in the commercialisation of complex biologics."



typical of the conditions that these cells would experience in the retina.

As with our CTX cells, we have recently developed and obtained FDA approval for a cryopreserved hRPC formulation as a parenteral presentation, which is supported by a logistics system that can be easily applied to commercial scale allogeneic products. It allows flexibility in terms of scheduling patient treatment without further manipulation.

### **Exosomes**

The CTX cell line is a constitutive producer of large numbers of extracellular microvesicles called exosomes. These exosomes contain miRNA and proteins in a lipid membrane, and they have been well characterised by us. The fact that we have the ability to manufacture CTX cells at a commercial scale provides an excellent upstream platform for the manufacture of exosomes. The exosomes can be easily and consistently purified from the CTX supernatant using well established industry-standard technologies such as tangential flow filtration and chromatography.

The exosomes drug product will be presented as a parenteral in an industry-standard vial which is therefore simple and easy to use in a clinical setting.

# Our manufacturing capability continued

# Bringing together ReNeuron's world-class R&D activities and GMP manufacturing capability

In February 2016, the Company relocated its operations to a new purpose-built 25,000 sq ft facility at Pencoed, South Wales. Work continues towards the completion and licensing of the manufacturing areas of the facility.

When fully licensed, we believe the building will house one of the world's most advanced commercial cell therapy manufacturing facilities, providing us with vertically integrated capability from research to commercial supply. We continue to work with the Welsh Government on the completion

of this important project, which will enable the manufacture of all pipeline products at this site.

To support this project, we have also been awarded a £1.8 million grant from Innovate UK to further advance our next generation commercial cell therapy manufacturing processes. The Pencoed site will utilise this next generation process technology.

The grant, entitled "Cell2Sell – commercial scale next generation platform for allogeneic stem cell production", has been awarded under Innovate UK's Cell & Gene Therapies

Industrial Manufacture grant scheme and will fund a collaborative programme of work to be undertaken by us, as lead participant, and key collaborators on the grant, including the Cell and Gene Therapy Catapult.

In addition, as part of our overall manufacturing strategy we have signed long-term contracts with reputable contract manufacturers in the US and the EU to cover our immediate cell manufacturing needs. This dual sourcing approach will be further enhanced when the Pencoed manufacturing suites come online.







### Risks and uncertainties

# How we manage risk

A number of specific Committees exist in the Group which meet regularly to review progress and agree actions encompassing research activities, development programmes and wider business and commercial issues. Through these Committees, and through formal Board meetings, the Directors are able to continuously monitor, evaluate and mitigate the potential impact of the principal risks facing the Group as it develops.

## Clinical and regulatory risk

There are significant inherent risks in developing stem cell therapies for commercialisation due to the long and complex development process. Any therapy which we wish to offer commercially to the public must be put through extensive research, pre-clinical and clinical development, all of which takes several years and is extremely costly. We may fail to develop a drug candidate successfully because we cannot demonstrate in clinical trials that it is safe and efficacious.

In addition, the complexity and multijurisdictional nature of the regulatory processes could result in either delays in achieving regulatory approval or non-approval. If a product is approved, the regulators may impose additional requirements, for example, restrictions on the therapy's indicated uses or the levels of reimbursement receivable, which could impact on its commercial viability. Once approved, the product and its manufacture will continue to be reviewed by the regulators and may be withdrawn or restricted.

### Intellectual property

Intellectual property protection remains fundamental to our strategy of developing novel drug candidates. Our ability to stop others making a drug, using it or selling the invention or proprietary rights by obtaining and maintaining protection is critical to our success. We manage a portfolio of patents and patent applications which underpin our research and development programmes. We invest significantly in

maintaining and protecting this intellectual property to reduce the risks over the validity and enforceability of our patents. However, the patent position is always uncertain and often involves complex legal issues. Therefore, there is a risk that intellectual property may become invalid or expire before, or soon after, commercialisation of a drug product and we may be blocked by other companies' patents and intellectual property.

## Manufacturing risk

Our ability to successfully scale-up production processes to viable clinical trial or commercial levels is vital to the commercial viability of any product. Availability of raw materials is extremely important to ensure that manufacturing campaigns are performed on schedule and therefore dual sourcing is used where possible. Product manufacture is subject to continual

regulatory control and products must be manufactured in accordance with good manufacturing practice. Any changes to the approved process may require further regulatory approval which may incur substantial cost and delays. These potential issues could adversely impact on the results from operations and our cash liquidity.

### Financial risk

The financial risks faced by the Group include foreign currency risk, liquidity risk and risk associated with cash held on deposit with financial institutions. The Board reviews and agrees policies for managing each of these risks. The Group's main objectives in using financial instruments are the maximisation

of returns from funds held on deposit, balanced with the need to safeguard the assets of the business.

The Group does not enter into forward currency contracts. The Group holds currency in US Dollars and Euros to cover short and medium-term expenses in those currencies.

In addition, and in common with other small biotechnology companies, the Group is subject to a number of other risks and uncertainties, which include:

- the early stage of development of the business;
- availability and terms of capital needed to sustain operations, and failure to secure partnerships that will fund late stage trials and commercial exploitation;
- competition from other companies and market acceptance of its products;
- its reliance on consultants, contractors and personnel at third party research institutions; and
- the ability to attract and retain qualified personnel.

### Financial review

# A robust balance sheet



### **Revenues**

Revenues in the year amounted to £46k (2016: £29k), being royalties from non-therapeutic licensing activities. Grant income of £0.85 million (2016: £0.53 million) was also recognised in other income.

### **Operating expenses**

Research and development costs increased to £16.65 million (2016: £10.27 million) and accounted for 80% of net operating expenses (2016: 72%). This increase is primarily due to the increased level of clinical trial activity and associated cell manufacturing and process development costs across the Group's therapeutic programmes. Pre-clinical research costs also increased in the period, reflecting the further progression of the Company's exosome programme.

General and administrative expenses increased slightly to £4.14 million (2016: £4.02 million).

### Finance income

Finance income, which represents income received from the Group's cash and investments and gains from foreign exchange, was £1.72 million in the period (2016: £0.88 million). The increase in finance income reflects the increase in average cash and investment balances compared to the equivalent prior period, as well as a favourable movement in exchange rates during the period on cash and investments held in foreign currency.

#### **Taxation**

The total tax credit for the period was £2.59 million, relating to an accrual for a research and development tax credit for the period (2016: £1.49 million). The increase on the previous year reflects the increase in applicable costs.

### Result for the year

As a result of the above, the total comprehensive loss for the year increased to £15.57 million (2016: £11.35 million).

### Cash flow

Cash outflow from operating activities was £12.64 million (2016: £11.92 million), largely reflecting the operating costs incurred during the period. Capital expenditure was £0.53 million (2016: £0.29 million). The Group had cash, cash equivalents and bank deposits totalling £53.06 million at the year end (2016: £65.71 million).

In August 2015, the Company raised £68.4 million, before expenses, by means of a placing to shareholders. The Directors expect that the Group's current financial resources will be sufficient to support operations for at least the next twelve months. Consequently, the going concern basis has been adopted in the preparation of these financial statements.

Michael Hunt

**Chief Financial Officer** 

18 July 2017



### **Board of Directors**



### John Berriman Non-executive Chairman

John Berriman was appointed to the Board in July 2011 and became Chairman in March 2015. He is currently also chairman of Confo Therapeutics NV, Autifony Therapeutics Ltd and Depixus SAS, and a nonexecutive director of Autolus Ltd. He is past chairman of Heptares Therapeutics Ltd (sold to Sosei in February 2015) and Algeta ASA (sold to Bayer AG in 2014) and was a director of Micromet Inc. until its sale to Amgen in 2012. Previously he was a director of Abingworth Management, an international healthcare venture capital firm.









### Olav Hellebø Chief Executive Officer

Olav Hellebø was appointed to the Board in September 2014. Prior to ReNeuron, he held the role of CEO at Clavis Pharma ASA, a Norwegian, oncologyfocused, listed biotechnology company. At Clavis, he built a multi-national leadership team, taking the company's lead programme through Phase III clinical development as well as completing substantial fundraising and out-licensing transactions for the business. Prior to Clavis, he headed up the global biologics franchise at UCB Pharma and was head of the UK commercial operations of Novartis.



### Michael Hunt ACA **Chief Financial Officer**

Michael Hunt joined ReNeuron in 2001. Between 2005 and 2014 he served as CEO, leading the business through its early development to its current position as one of the global, clinical stage leaders in the regenerative medicine field. He was appointed as Chief Financial Officer in 2014. Prior to ReNeuron, he spent six years at Biocompatibles International plc (sold to BTG plc), where he held a number of senior financial and general management positions. His early industrial career was spent at Bunzl plc.



### Simon Cartmell OBE Non-executive Director

Simon Cartmell OBE was appointed to the Board in July 2011. He is an experienced Non-executive Director currently chairing three early stage medical device businesses, largely in his role as operating partner for Touchstone Innovations plc, an established UK Venture Capital firm. As chief executive officer of ApaTech Ltd, he built a world leader in orthobiologics and led its sale to Baxter International Inc in March 2010. Prior to ApaTech he was chief executive officer of Celltech Pharmaceuticals and a director of Celltech Group plc before which he was chief operating officer of Vanguard Medica plc. His early career was spent at Glaxo plc in multiple senior UK and global commercial strategy, product development, supply chain, marketing, sales and business development roles.







### **Key to Committees**

Nominations and Corporate Governance

Remuneration

Audit

Committee Chair



### Dr Tim Corn Non-executive Director

Dr Tim Corn was appointed to the Board in June 2012. He serves as chair of the board of trustees of the Neuro Foundation and non-executive director on the board of HRA Pharma. and previously non-executive director on the board of Circassia Pharmaceuticals. He was formerly chief medical officer at EUSA Pharma International, a division of Jazz Pharmaceuticals, at EUSA Pharma Inc, and at Zeneus Pharma. He has held senior clinical and regulatory positions at GlaxoWellcome, MSD Research Laboratories. Athena Neuroscience and Elan as well as in the UK regulatory agency. He has played a key role in more than 20 regulatory approvals in the US and the EU for products in the fields of neurology and oncology. He was elected fellow of the faculty of pharmaceutical medicine in 1996 and of the Royal College of Psychiatrists in 1998.





### Professor Sir Chris Evans OBE Non-executive Director

Professor Sir Chris Evans OBE was appointed to the Board in August 2013. As founder and chairman of Excalibur Group and Arthurian Life Sciences, he is a highly successful scientist and entrepreneur with numerous prestigious awards and medals for his work. He has built over 50 medical companies from scratch, many from his own ideas and inventions, and floated 20 new medical businesses on stock markets in six different countries. He has created companies worth over \$7 billion employing over 4,000 scientists, built hundreds of complex medical laboratories and facilities around the world and positively impacted many millions of lives with his work. He has also raised \$2 billion for cancer research projects. He is also the founder of Chiroscience, Celsis, Biovex, Merlin, Vectura and Piramed. Arix Bioscience was founded in January 2016 by Sir Chris. Arix is an international company and will back opportunities across the spectrum of medical sciences and healthcare.



### Dr Paul Harper Non-executive Director

Dr Paul Harper was appointed to the Board in July 2005. He initially pursued a career in drug discovery and development with Glaxo Group Research as head of antimicrobial chemotherapy, with Johnson & Johnson Limited as director of research and development and with Unipath plc. This was followed by work in a number of start-up companies and SMEs as chief executive officer or adviser. These included, as chief executive officer, preparing Cambridge Antibody Technology Ltd for flotation on the London Stock Exchange and founding Provensis Limited to develop a drug device product.







### Dr Mike Owen Non-executive Director

Dr Mike Owen was appointed to the Board in December 2015. His career in biotech. the pharmaceutical industry and academia spans almost 40 years. He was formerly senior vice president for biopharmaceuticals research at GlaxoSmithKline and was also a founder and chief scientific officer of Kymab Ltd, an antibody-based biotech company, and for many years held a research position at the Imperial Cancer Research Fund (now CR-UK). He currently serves as a director of Zealand Pharma, Ossianix Inc, BliNK Biomedical SAS, Avacta plc, GammaDelta Therapeutics and Glythera Ltd and is a member of the scientific advisory boards of Avacta and the CRT Pioneer Fund LP. He is a fellow of the Academy of Medical Sciences and a member of the European Molecular Biology Organisation.

# Senior management



Dr Randolph Corteling Head of Research

Dr Randolph Corteling was appointed Head of Research in April 2015. He received his first degree (BSc Pharmacology (Hons)) from the University of East London in 1997, followed by three years at Novartis as a Research Associate, before undertaking a PhD in Medical and Surgical Sciences under the supervision of Professor Ian Hall at The University of Nottingham. He then subsequently spent three years as a Heart and Stroke Foundation postdoctoral fellow at the University of Calgary, Canada, before joining ReNeuron as a senior member of the research team in 2007.



Sharon Grimster VP Development & General Manager, Wales

Sharon Grimster joined ReNeuron in 2013 and was appointed as VP Development & General Manager, Wales in April 2015. She has significant experience in pharmaceutical development and she has a particular expertise in biologics manufacturing. Prior to working at ReNeuron, she held senior team roles at F-star and Antisoma, where she was responsible for a range of development functions, including project management, regulatory affairs, manufacturing, quality and business operations. She started her pharmaceutical career at Celltech, where she led teams in project management, manufacturing and research.



Dr Julian Howell Chief Medical Officer

Dr Julian Howell has held a number of leadership roles in clinical development during the last 15 years, bringing small molecules and biological products through all phases of clinical development in Europe and the US. He joined ReNeuron from Shield Therapeutics, where he held the role of group medical director. Prior to that, he led the clinical team at ProStrakan, contributing to multiple US and EU new product approvals in oncology supportive care, GI and pain treatments. He gained medical and surgical qualifications in the UK and worked in the UK health service before completing an MBA at Cranfield University and joining the pharmaceutical industry, initially at SmithKlineBeecham and subsequently in senior clinical and medical affairs roles at Roche, Chiron and Pharmion.



Dr John Sinden Chief Scientific Officer

Dr John Sinden is a scientific co-founder of ReNeuron and from 1998 to 2015 was an Executive Director of the ReNeuron companies. Prior to founding ReNeuron and becoming its first employee, he was reader in neurobiology of behaviour at the Institute of Psychiatry at King's College London. He graduated in Psychology from the University of Sydney and completed a PhD in Neuroscience from the University of Paris at the Collège de France. He subsequently held postdoctoral appointments at Oxford University and the Institute of Psychiatry prior to joining the permanent staff of the Institute in 1987. He is an honorary professor in the Faculty of Medical Sciences at University College London and has over 140 scientific publications and book chapters. He holds fellowships of the Royal Society of Medicine and the Royal Society of Biology and is a member of the International Society for Stem Cell Research and the Expert Working Group on Cell and Gene Therapies for the Bioindustry Organization BioSafe Committee.



**Shaun Stapleton Head of Regulatory Affairs** 

Shaun Stapleton joined ReNeuron from RRG (a Voisin Consulting Life Sciences company), where he was a director and vice president of regulatory science. He supported clients on a number of global development and registration projects, including advanced therapies and orphan drugs. Having graduated in Biochemistry from Imperial College London, he began his career in research with the Imperial Cancer Research Fund, before moving into the pharmaceutical industry. He held positions of increasing responsibility in regulatory affairs at Sterling Winthrop, Eli Lilly and Boehringer Ingelheim before becoming senior director of regulatory affairs at Ipsen, where he managed regulatory input into development programmes globally, securing new product approvals in the US, the EU and internationally in the neurology, endocrinology and oncology therapeutic areas.



Olav Hellebø Chief Executive Officer See page 20 for biography.



Michael Hunt ACA Chief Financial Officer See page 20 for biography.

### **Advisers**

# Company Secretary and registered office Michael Hunt

Pencoed Business Park

Pencoed

Bridgend CF35 5HY

Principal banker Barclays Bank plc

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**Patent agents** 

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Buchanan

107 Cheapside London

EC2V 6DN

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Computershare Services plc

The Pavilions

Bridgwater Road

Bristol BS13 8AE

**Solicitors** 

Covington & Burling LLP

265 Strand London

WC2R 1BH

**Independent auditors** 

PricewaterhouseCoopers LLP

**Chartered Accountants and Statutory Auditors** 

One Kingsway

Cardiff

CF10 3PW

# Directors' report

for the year ended 31 March 2017

The Directors present their report and the audited consolidated financial statements of the Company for the year ended 31 March 2017.

### Presentation of financial statements

The Group accounts include the financial statements of the Company and its subsidiary undertakings made up to 31 March 2017.

#### **Business review**

A review of the Group's trading during the year and its position at the year end is provided in the Financial Review section of the Strategic Report. The review includes the key performance indicators of the Group. The principal risks and uncertainties facing the Group are set out on page 17 of the Strategic Report. The future outlook for the Group is set out in the Chairman and Chief Executive Officer's Joint Statement on page 8.

### Results and dividends

The results for the year are given in the Group Statement of Comprehensive Income set out on page 38. The Directors do not recommend the payment of a dividend (2016: fnil).

### Research and development

During the year the Group incurred research and development costs of £16,648,000 (2016: £10,272,000), all charged to the Group Statement of Comprehensive Income.

#### **Directors**

The Directors who held office during the year and up to the signing of the financial statements, unless otherwise stated, are listed below:

John Berriman, Non-executive Chairman
Olav Hellebø, Chief Executive Officer
Michael Hunt ACA, Chief Financial Officer
Simon Cartmell OBE, Non-executive Director
Dr Tim Corn, Non-executive Director
Professor Sir Chris Evans OBE, Non-executive Director
Dr Paul Harper, Non-executive Director
Dr Mike Owen, Non-executive Director

### Qualifying third party indemnity

Certain Directors benefited from qualifying third party indemnity provisions in place during the year and at the date of this report.

### Policy and practice on payment of creditors

It is the Group's policy to agree payment terms with all suppliers in advance of the supply of goods and services and to adhere to those payment terms. Trade payables of the Group at the year end as a proportion of amounts invoiced by suppliers during the year represent 87 days (2016: 91 days).

The Company had no trade payables at the year end (2016: fnil).

### Directors' responsibilities statement

The Directors are responsible for preparing the Annual Report and the financial statements in accordance with applicable law and regulations.

Company law requires the Directors to prepare financial statements for each financial year. Under that law the Directors have prepared the Group and Parent Company financial statements in accordance with International Financial Reporting Standards (IFRSs) as adopted by the European Union. Under

company law the Directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the state of affairs of the Group and the Company and of the profit or loss of the Group for that period. In preparing these financial statements, the Directors are required to:

- select suitable accounting policies and then apply them consistently;
- make judgements and accounting estimates that are reasonable and prudent;
- state whether applicable IFRSs as adopted by the European Union have been followed, subject to any material departures disclosed and explained in the financial statements; and
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the Company will continue in business.

The Directors are responsible for keeping adequate accounting records that are sufficient to show and explain the Company's transactions and disclose with reasonable accuracy at any time the financial position of the Company and the Group and enable them to ensure that the financial statements comply with the Companies Act 2006. They are also responsible for safeguarding the assets of the Company and the Group and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities. The Directors are responsible for the maintenance and integrity of the Company website, www.reneuron.com. Legislation in the United Kingdom governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.

# Directors' statement on disclosure of information to auditors

In accordance with Section 418 of the Companies Act, in the case of each of the persons who are Directors at the time when the report is approved, the following applies:

- so far as each Director is aware, there is no relevant audit information of which the Company's auditors are unaware; and
- each Director has taken all the steps that he ought to have taken as a Director in order to make himself aware of any audit information and to establish that the Company's auditors are aware of that information.

### Independent auditors

The auditors, PricewaterhouseCoopers LLP, have indicated their willingness to continue in office and a resolution concerning their reappointment will be proposed at the Annual General Meeting.

### Annual General Meeting

The Annual General Meeting of the Company will be held at the offices of Covington & Burling LLP, 265 Strand, London WC2R 1BH on 6 September 2017 at 10 a.m. The Notice of the Annual General Meeting is enclosed on page 60 of this document.

By order of the Board

Michael Hunt Director

18 July 2017

## Corporate governance report

for the year ended 31 March 2017

This report provides general information on the Group's adoption of corporate governance principles. As an AIM-listed company, ReNeuron is not required to comply with the UK Corporate Governance Code, the set of recommended corporate governance principles for UK public companies issued by the Financial Reporting Council. However, the Directors support high standards of corporate governance and have established a set of corporate governance principles which they regard as appropriate for the stage of development of the Group. These principles are revised from time to time as necessary to ensure that they comply with best corporate governance practice as far as practicable given the Company's size and nature of its business.

### The Board

As at 31 March 2017, the Board comprised six Non-executive Directors and two Executive Directors. There were no changes to the members of the Board during the year.

Directors' biographies are set out on pages 20 and 21.

The Board is responsible to the shareholders for the proper management of the Group and meets at least six times a year to set the overall direction and strategy of the Group, to review scientific, operational and financial performance and to advise on management appointments. All key operational and investment decisions are subject to Board approval. The Company Secretary is responsible for ensuring that Board procedures are followed and applicable rules and regulations are complied with.

There is a clear separation of the roles of Chief Executive Officer and Non-executive Chairman. The Chairman is responsible for overseeing the running of the Board, ensuring that no individual or group dominates the Board's decision making and ensuring the Non-executive Directors are properly briefed on matters. The Chief Executive Officer has the responsibility for implementing the strategy of the Board and managing the day-to-day business activities of the Group.

The Board considers there to be sufficient independence on the Board and that all of the Non-executive Directors are of sufficient competence and calibre to add strength and objectivity to the Board and bring considerable experience in scientific, operational and financial development of biopharmaceutical products and companies.

All of the Directors are subject to election by shareholders at the first Annual General Meeting after their appointment to the Board and will continue to seek re-election at least once every three years.

The Board has a process for evaluation of its own performance and that of its Committees and individual Directors, including the Chairman.

### **Board Committees**

The Board has established an Audit Committee, Remuneration Committee and Nominations and Corporate Governance Committee with formally delegated duties and responsibilities. Dr Paul Harper chairs the Audit Committee, Simon Cartmell OBE chairs the Remuneration Committee and John Berriman chairs the Nominations and Corporate Governance Committee.

Dr Harper is not regarded as independent due to his length of tenure as a Director of the Parent Company. However, the Board believes Dr Harper's specific skills and experience make him the best choice for the role of Audit Committee Chairman.

The Audit Committee normally meets twice a year and has responsibility for, amongst other things, planning and reviewing the Annual Report and Accounts and interim statements involving, where appropriate, the external auditors. The Committee also approves external auditors' fees and ensures the auditors' independence as well as focusing on compliance with legal requirements and accounting standards. It is also responsible for ensuring that an effective system of internal control is maintained. The ultimate responsibility for reviewing and approving the annual financial statements and interim statements remains with the Board.

The Remuneration Committee, which meets as required, but at least once a year, has responsibility for making recommendations to the Board on the compensation of senior executives and determining, within agreed terms of reference, the specific remuneration packages for each of the Executive Directors. It also supervises the Company's Share Option Schemes and sets performance conditions for options granted under the Schemes.

The Nominations and Corporate Governance Committee, which meets as required, but at least once a year, has responsibility for reviewing the size and composition of the Board, the appointment of replacement or additional Directors, the monitoring of compliance with applicable laws, regulations and corporate governance guidance and making appropriate recommendations to the Board.

## Corporate governance report continued

for the year ended 31 March 2017

### Risk management and internal control

The Board is responsible for the systems of internal control and for reviewing their effectiveness. The internal controls are designed to manage rather than eliminate risk and provide reasonable but not absolute assurance against material misstatement or loss. Through the activities of the Audit Committee, the effectiveness of these internal controls is reviewed annually.

A comprehensive budgeting process is completed once a year and is reviewed and approved by the Board. The Group's results, compared with the budget, are reported to the Board on a bi-monthly basis.

The Group maintains appropriate insurance cover in respect of actions taken against the Directors because of their roles, as well as against material loss or claims against the Group. The insured values and type of cover are comprehensively reviewed on a periodic basis.

### Corporate social responsibility

The Group is aware of its corporate responsibilities concerning the impact of its activities on the environment, and seeks to minimise this impact wherever possible. Through the various procedures and systems it operates, the Group ensures full compliance with health and safety and environmental legislation relevant to its activities.

The Group is committed to providing a safe environment for its staff and all other parties for which the Group has a legal or moral responsibility in this area. The Group operates a Health and Safety Committee which meets monthly to monitor, review and make decisions concerning health and safety matters. The Group's health and safety policies and procedures are enshrined in the Group's documented quality systems, which encompass all aspects of the Group's day-to-day operations.

#### Communications

The Group places a high priority on regular communications with its various stakeholder groups and aims to ensure that all communications concerning the Group's activities are clear, fair and accurate. The Group maintains a regularly updated website at www.reneuron.com. Users can register to be alerted when announcements or details of presentations and events are posted on the website.

Beyond the Annual General Meeting, the Chief Executive Officer, the Chief Financial Officer and, where appropriate, other members of the senior management team meet regularly with investors and analysts to provide them with updates on the Group's business and to obtain feedback regarding the market's expectations of the Group.

## Directors' remuneration report

for the year ended 31 March 2017

This report sets out the remuneration policy operated by the Company in respect of the Executive and Non-executive Directors, as of the date of this report. No Director is involved in discussions relating to their own remuneration.

### Remuneration policy for Executive Directors

The Remuneration Committee sets the remuneration policy that aims to align Executive Director remuneration with shareholders' interests and to attract and retain the best talent for the benefit of the Group. The Committee has sought independent advice when setting the remuneration policy. Executive Directors are appointed under service contracts with notice periods not exceeding twelve months. Remuneration for Executive Directors is composed of the following elements:

### **Basic salary**

Basic salaries are reviewed annually and revised salaries take effect from the start of the financial year. The review process is managed by the Remuneration Committee with reference to market salary data and the Executive's performance during the year.

#### **Bonuses**

Annual bonuses are based on achievement of Group strategic and operational objectives, and personal performance objectives. The maximum annual bonus that may be payable in cash is set at 50% of base salary for the Executive Directors. Up to a further 50% of base salary may be awarded (subject to the achievement of further stretching strategic corporate objectives) in nominal price share options under the Company's Deferred Share-based Bonus Plan.

### Longer-term incentives

In order to further incentivise Executive Directors and align their interests with shareholders, the Company operates a Long Term Incentive Plan under which nominal price share options may be granted from time to time. The quantum of these awards will relate to the Executive Director's base salary and will vest subject to the performance conditions detailed in the notes to the tables on pages 32 to 34 of this report.

Executive Directors are expected to build a direct stake in the Company's shares over time, either through the purchase of shares in the market from time to time and/or through the future exercise of share options.

The Company has the ability to grant share options under its Share Option Schemes subject to a cap, as previously agreed with shareholders, of up to 10% of total issued share capital in any ten year period.

#### Pension

The Group operates a defined contribution pension scheme which is available to all employees. The Company contribution in respect of Executive Directors is currently set at 10% of base salary. The Executive Director may choose to take some or all of this benefit as a cash alternative, subject to the Company remaining cash neutral after relevant payroll taxes.

### Other benefits

Other benefits provided are life assurance, private medical insurance and professional subscriptions where relevant to the duties of the Executive Director. The Company also pays a car allowance of £10,000 per annum to each Executive Director (disclosed as part of salaries and fees in the remuneration table overleaf).

### Non-executive Directors' remuneration

The remuneration of the Non-executive Directors is determined by the Remuneration Committee with regard to market comparatives. In setting the remuneration policy for Non-executive Directors, the Committee has sought independent advice and, where appropriate, has consulted with certain of its shareholders. Non-executive Directors are appointed for an initial three year term via an appointment letter from the Company, with a three month notice period. The appointment term is renewable for further three year terms after the initial term has expired.

Non-executive Directors receive their fees in the form of a basic cash fee and an equity-based fee which takes the form of nominal price share options under the Company's Non-executive Share Option Scheme. To avoid any incentive effect that may influence the Non-executive Director's independence, these share options will vest over three years on a straight-line basis and are not subject to performance conditions.

Non-executive Directors do not receive any pension, bonus or other benefits from the Company. The remuneration of the Non-executive Directors is reviewed by the Board annually.

# Directors' remuneration report continued

for the year ended 31 March 2017

### Directors' emoluments

The Directors received the following remuneration during the year:

Audited	Salaries and fees £'000	Bonuses £'000	Benefits in kind £'000	2017 Total £'000	2017 Pension contributions £'000	2016 Total £'000	2016 Pension contributions £′000
John Berriman	52	_	-	52	-	43	_
Olav Hellebø	296	103	2	401	29	407	28
Michael Hunt	209	70	2	281	20	289	19
Simon Cartmell OBE	38	_	_	38	_	35	_
Dr Tim Corn	30	_	-	30	-	29	_
Professor Sir Chris Evans OBE	26	_	_	26	_	25	_
Dr Paul Harper	34	_	_	34	_	32	_
Dr Mike Owen	26	_	_	26	_	8	_
Total	711	173	4	888	49	868	47

Bonuses disclosed above represent a cash element paid as a percentage of base salary ranging from 35% to 36% based on achievement of corporate and personal performance objectives in the financial year ended 31 March 2017. In addition, the Executive Directors received non-cash bonuses in the form of nominally priced share options awarded under the Group's Deferred Share-based Bonus Plan in respect of corporate objectives achieved in the financial year ended 31 March 2016. The estimated gain on these options at the time of grant was £50,000 (2016: £nil) to Olav Hellebø and £25,000 (2016: £nil) to Michael Hunt.

The Executive Directors elected to take some of their pension benefit as a cash alternative.

The Non-executive Directors also received an equity-based fee in the year which took the form of nominal price share options under the Company's Non-executive Share Option Scheme. The estimated gain on these options at the time of grant was £6,000 (2016: £nil) to each of the Non-executive Directors.

Directors' emoluments include amounts payable to third parties in respect of fees as described in note 29 of the financial statements.

The Directors who held office at the end of the year held the following interests in the Ordinary shares of the Company:

	Ordinary shar	es of 1p each
	2017 Number	2016 Number
John Berriman	1,043,476	1,043,476
Olav Hellebø	669,422	322,778
Michael Hunt	2,008,471	1,758,471
Simon Cartmell OBE	787,500	787,500
Dr Tim Corn	200,000	200,000
Professor Sir Chris Evans OBE	24,010,525	24,010,525
Dr Paul Harper	451,709	451,709
Dr Mike Owen	-	_

### **Directors' emoluments** continued

The Directors who held office at the end of the year held the following interests in options over shares of the Company:

### John Berriman

	Note	At 1 April 2016 Number	Lapsed during the year Number	Granted during the year Number	At 31 March 2017 Number	Exercise price	Exercise period*
Options – unapproved	6	480,073	_	_	480,073	3.75p	September 2014–September 2021
Options – unapproved	8	575,249	_	_	575,249	2.87p	September 2015–September 2022
Options – unapproved	10	600,000	_	_	600,000	3.6p	September 2016–September 2023
Options – unapproved	12	600,000	_	_	600,000	3.45p	September 2017–September 2024
Options – unapproved	17	_	_	300,000	300,000	1.0p	August 2016–July 2026
		2,255,322	_	300,000	2,555,322		

### Olav Hellebø

	Note	At 1 April 2016 Number	Lapsed during the year Number	Granted during the year Number	At 31 March 2017 Number	Exercise price	Exercise period*
Options – approved	13	7,246,376	_	_	7,246,376	1.0p	September 2017–September 2024
Options – unapproved	13	8,309,180	_	_	8,309,180	1.0p	September 2017–September 2024
Options – unapproved	14	18,123,636	_	_	18,123,636	1.0p	October 2018–October 2025
Options – unapproved	15	_	_	19,066,667	19,066,667	1.0p	July 2019–July 2026
Options – unapproved	16	_	-	2,500,000	2,500,000	1.0p	July 2018–July 2026
		33,679,192	_	21,566,667	55,245,859		

<sup>\*</sup> The exercise period indicates the earliest dates for which the options are exercisable subject to meeting the performance conditions disclosed below.

# Directors' remuneration report continued for the year ended 31 March 2017

### Directors' emoluments continued Michael Hunt

	Note	At 1 April 2016 Number	Lapsed during the year Number	Granted during the year Number	At 31 March 2017 Number	Exercise price	Exercise period*
Options – unapproved	1	567,586	(567,586)	-	-	4.4p	August 2009–August 2016
Options – unapproved	1	567,586	(567,586)	_	_	6.61p	August 2010–August 2016
Options – unapproved	2	989,806	_	_	989,806	10.61p	August 2010–August 2017
Options – unapproved	2	989,806	_	_	989,806	18.94p	August 2010–August 2017
Options – approved	4	347,808	_	_	347,808	1.0p	August 2011–August 2019
Options – unapproved	5	1,035,533	_	_	1,035,533	1.0p	August 2013–August 2020
Options – unapproved	7	1,458,334	_	_	1,458,334	1.0p	September 2014–September 2021
Options – approved	9	3,181,818	_	_	3,181,818	1.0p	September 2015–September 2022
Options – approved	11	694,500	_	_	694,500	1.0p	September 2016–September 2023
Options – unapproved	11	3,263,833		_	3,263,833	1.0p	September 2016–September 2023
Options – approved	13	1,715,333	_	_	1,715,333	1.0p	September 2017–September 2024
Options – unapproved	13	2,347,167	_	_	2,347,167	1.0p	September 2017–September 2024
Options – unapproved	14	7,090,909	_	_	7,090,909	1.0p	October 2018–October 2025
Options – unapproved	15	_	_	8,291,667	8,291,667	1.0p	July 2019–July 2026
Options – unapproved	16	_	_	1,250,000	1,250,000	1.0p	July 2018–July 2026
		24,250,019	(1,135,172)	9,541,667	32,656,514		
Simon Cartmell OBE	:						
Jimon Garanien Obl		A 1 Apr 201 lote Numbe	il during 6 the year	Granted during the year Number	At 31 March 2017 Number	Exercise price	Exercise period*
Options – unapproved		6 480,073	3 –	_	480,073	3.75p	September 2014–September 2021
Options – unapproved		8 575,249	9 –	-	575,249	2.87p	September 2015–September 2022
Options – unapproved		10 600,000	) –	_	600,000	3.6p	September 2016–September 2023
Options – unapproved		12 600,000	) –	_	600,000	3.45p	September 2017–September 2024
Options – unapproved		17 -		300,000	300,000	1.0p	August 2016–July 2026

<sup>\*</sup> The exercise period indicates the earliest dates for which the options are exercisable subject to meeting the performance conditions disclosed below.

300,000

2,555,322

2,255,322

### **Directors' emoluments** continued

### Dr Tim Corn

							Dr 11m Corn
Exercise perio	Exercise price	At 31 March 2017 Number	Granted during the year Number	Lapsed during the year Number	At 1 April 2016 Number	Note	
September 2015–September 202	2.87p	575,249	-	_	575,249	8	Options – unapproved
September 2016–September 202	3.6p	500,000	_	-	500,000	10	Options – unapproved
September 2017–September 202	3.45p	500,000	_	_	500,000	12	Options – unapproved
August 2016–July 202	1.0p	300,000	300,000	_	-	17	Options – unapproved
		1,875,249	300,000	-	1,575,249		
					=	-vans OBI	Professor Sir Chris I
Exercise perio	Exercise price	At 31 March 2017 Number	Granted during the year Number	Lapsed during the year Number	At 1 April 2016 Number	Note	
September 2016–September 202	3.6p	500,000	_	_	500,000	10	Options – unapproved
September 2017–September 202	3.45p	500,000	_	_	500,000	12	Options – unapproved
August 2016–July 202	1.0p	300,000	300,000	_	_	17	Options – unapproved
<u> </u>		1,300,000	300,000	_	1,000,000		
Exercise perio	Exercise price	At 31 March 2017 Number	Granted during the year Number	Lapsed during the year Number	At 1 April 2016 Number	Note	Dr Paul Harper
Exercise perio August 2009–August 201		31 March 2017	during the year	during the year	1 April 2016 Number	Note 1	Dr Paul Harper  Options – unapproved
· .	price	31 March 2017	during the year Number	during the year Number	1 April 2016 Number		
August 2009–August 201	price 4.4p	31 March 2017 Number	during the year Number	during the year Number	1 April 2016 Number 113,517	1	Options – unapproved
August 2009–August 201 August 2010–August 201	4.4p 10.61p	31 March 2017 Number - 296,942	during the year Number —	during the year Number (113,517)	1 April 2016 Number 113,517 296,942	1 2	Options – unapproved Options – unapproved
August 2009–August 201 August 2010–August 201 August 2012–August 201	4.4p 10.61p 4.22p	31 March 2017 Number - 296,942 260,797	during the year Number — —	during the year Number (113,517)	1 April 2016 Number 113,517 296,942 260,797	1 2 3	Options – unapproved Options – unapproved Options – unapproved
August 2009–August 201 August 2010–August 201 August 2012–August 201 August 2013–August 202	4.4p 10.61p 4.22p 3.85p	31 March 2017 Number - 296,942 260,797 319,605	during the year Number — — —	during the year Number (113,517)	1 April 2016 Number 113,517 296,942 260,797 319,605	1 2 3 3	Options – unapproved Options – unapproved Options – unapproved Options – unapproved
August 2009–August 201 August 2010–August 201 August 2012–August 201 August 2013–August 202 September 2014–September 202	4.4p 10.61p 4.22p 3.85p 3.75p	31 March 2017 Number – 296,942 260,797 319,605 480,073	during the year Number	during the year Number (113,517)	1 April 2016 Number 113,517 296,942 260,797 319,605 480,073	1 2 3 3 6	Options – unapproved
August 2009–August 201 August 2010–August 201 August 2012–August 201 August 2013–August 202 September 2014–September 202 September 2015–September 202	4.4p 10.61p 4.22p 3.85p 3.75p 2.87p	31 March 2017 Number — 296,942 260,797 319,605 480,073 575,249	during the year Number	during the year Number (113,517)	1 April 2016 Number  113,517 296,942 260,797 319,605 480,073 575,249	1 2 3 3 6 8	Options – unapproved
August 2009–August 201 August 2010–August 201 August 2012–August 201 August 2013–August 202 September 2014–September 202 September 2015–September 202 September 2016–September 202	4.4p 10.61p 4.22p 3.85p 3.75p 2.87p 3.6p	31 March 2017 Number  - 296,942 260,797 319,605 480,073 575,249 500,000	during the year Number	during the year Number (113,517)	1 April 2016 Number  113,517 296,942 260,797 319,605 480,073 575,249 500,000	1 2 3 3 6 8 10	Options – unapproved
August 2009–August 201 August 2010–August 201 August 2012–August 201 August 2013–August 202 September 2014–September 202 September 2015–September 202 September 2016–September 202 September 2017–September 202	4.4p 10.61p 4.22p 3.85p 3.75p 2.87p 3.6p 3.45p	31 March 2017 Number  - 296,942 260,797 319,605 480,073 575,249 500,000 500,000	during the year Number	during the year Number  (113,517)	1 April 2016 Number  113,517 296,942 260,797 319,605 480,073 575,249 500,000	1 2 3 3 6 8 10	Options – unapproved
August 2009–August 201 August 2010–August 201 August 2012–August 201 August 2013–August 202 September 2014–September 202 September 2015–September 202 September 2016–September 202 September 2017–September 202	4.4p 10.61p 4.22p 3.85p 3.75p 2.87p 3.6p 3.45p	31 March 2017 Number  - 296,942 260,797 319,605 480,073 575,249 500,000 500,000 300,000	during the year Number	during the year Number  (113,517)	1 April 2016 Number  113,517 296,942 260,797 319,605 480,073 575,249 500,000 500,000	1 2 3 3 6 8 10	Options – unapproved
August 2009–August 201 August 2010–August 201 August 2012–August 201 August 2013–August 202 September 2014–September 202 September 2015–September 202 September 2016–September 202 September 2017–September 202	4.4p 10.61p 4.22p 3.85p 3.75p 2.87p 3.6p 3.45p	31 March 2017 Number  - 296,942 260,797 319,605 480,073 575,249 500,000 500,000 300,000	during the year Number	during the year Number  (113,517)	1 April 2016 Number  113,517 296,942 260,797 319,605 480,073 575,249 500,000 500,000	1 2 3 3 6 8 10	Options – unapproved
August 2009–August 201 August 2010–August 201 August 2012–August 201 August 2013–August 202 September 2014–September 202 September 2015–September 202 September 2016–September 202 September 2017–September 202 August 2016–July 202	4.4p 10.61p 4.22p 3.85p 3.75p 2.87p 3.6p 3.45p 1.0p	31 March 2017 Number  - 296,942 260,797 319,605 480,073 575,249 500,000 300,000 3,232,666	during the year Number	during the year Number (113,517)	1 April 2016 Number 2016 Numbe	1 2 3 3 6 8 10 12 17	Options – unapproved

 $<sup>\</sup>star$  The exercise period indicates the earliest dates for which the options are exercisable subject to meeting the performance conditions disclosed below.

# Directors' remuneration report continued

for the year ended 31 March 2017

### **Directors' emoluments** continued

#### Note 1:

These options were issued subject to a performance condition, being the first patient administered with a ReNeuron cell therapy in Phase I/II trials; these options expired in August 2016.

### Note 2:

These options were issued subject to a performance condition, being the successful completion of an initial clinical trial of a ReNeuron cell therapy; at 31 March 2017 these options were exercisable.

### Note 3:

These options were issued subject to a performance condition, being the first patient administered with a ReNeuron cell therapy in a second clinical trial; at 31 March 2017 these options were exercisable.

#### Note 4:

These options have been issued in accordance with the Group's Deferred Share-based Bonus Plan in respect of corporate and personal objectives achieved in the financial year ending 31 March 2009 and carry no further performance conditions; at 31 March 2017 these options were exercisable.

#### Note 5

These options were issued subject to the amended performance conditions below. If all the performance conditions bar performance condition (ii) are met then 50% of the options become exercisable; at 31 March 2017 50% of these options were exercisable.

- (i) The first patient is administered with a ReNeuron cell therapy in a second clinical trial.
- (ii) The total shareholder return (TSR) of the Company meets or exceeds that of the AIM Healthcare Index in any three year period from date of grant of the option.
- (iii) The business must have operated within its internal financial budgets throughout the period to vesting.
- (iv) The business must be a going concern (under the accepted accounting definition) at the time of any exercise of an option.

### Note 6

These options were issued subject to a performance condition, being the first patient administered with a ReNeuron cell therapy in a third clinical trial; at 31 March 2017 these options were exercisable.

### Note 7:

These options were awarded in accordance with the Group's Long Term Incentive Plan and are subject to the amended performance conditions set out below. If all the performance conditions bar performance condition (ii) are met then 50% of the options become exercisable; at 31 March 2017 50% of these options were exercisable.

- (i) The first patient is administered with a ReNeuron cell therapy in a third clinical trial.
- (ii) The total shareholder return (TSR) of the Company meets or exceeds that of the AIM Healthcare Index in any three year period from date of grant of the option.
- (iii) The business must have operated within its internal financial budgets throughout the period to vesting.
- (iv) The business must be a going concern (under the accepted accounting definition) at the time of any exercise of an option.

### Note 8:

These options were issued subject to a performance condition, being the first patient administered with a ReNeuron cell therapy in a fourth clinical trial; at 31 March 2017 these options were exercisable.

### Directors' emoluments continued

#### Note 9:

These options were awarded in accordance with the Group's Long Term Incentive Plan and are subject to the amended performance conditions set out below. If all the performance conditions bar performance condition (ii) are met then 50% of the options become exercisable; at 31 March 2017 50% of these options were exercisable.

- (i) The first patient is administered with a ReNeuron cell therapy in a fourth clinical trial.
- (ii) The total shareholder return (TSR) of the Company meets or exceeds that of the AIM Healthcare Index in any three year period from date of grant of the option.
- (iii) The business must have operated within its internal financial budgets throughout the period to vesting.
- (iv) The business must be a going concern (under the accepted accounting definition) at the time of any exercise of an option.

### Note 10:

These options were issued subject to a performance condition, being the first patient administered with a ReNeuron cell therapy in a fifth clinical trial; at 31 March 2017 these options were not exercisable.

### Note 11:

These options were awarded in accordance with the Group's Long Term Incentive Plan and are subject to the amended performance conditions set out below. If all the performance conditions bar performance condition (ii) are met then 50% of the options become exercisable; at 31 March 2017 50% of these options were not exercisable.

- (i) The first patient is administered with a ReNeuron cell therapy in a fifth clinical trial.
- (ii) The total shareholder return (TSR) of the Company meets or exceeds that of the AIM Healthcare Index in any three year period from date of grant of the option.
- (iii) The business must have operated within its internal financial budgets throughout the period to vesting.
- (iv) The business must be a going concern (under the accepted accounting definition) at the time of any exercise of an option.

### Note 12:

These options were issued subject to a performance condition, being the first patient administered with a ReNeuron cell therapy in a sixth clinical trial; at 31 March 2017 these options were not exercisable.

### Note 13:

These options were awarded in accordance with the Group's Long Term Incentive Plan and are subject to the amended performance conditions set out below. If all the performance conditions bar performance condition (ii) are met then 50% of the options become exercisable; at 31 March 2017 50% of these options were not exercisable.

- (i) The first patient is administered with a ReNeuron cell therapy in a sixth clinical trial.
- (ii) The total shareholder return (TSR) of the Company meets or exceeds that of the AIM Healthcare Index in any three year period from date of grant of the option.
- (iii) The business must have operated within its internal financial budgets throughout the period to vesting.
- (iv) The business must be a going concern (under the accepted accounting definition) at the time of any exercise of an option.

### Note 14:

These options were awarded in accordance with the Group's Long Term Incentive Plan and are subject to the performance conditions set out below; at 31 March 2017 these options were not exercisable.

- (i) 33.3% vest when the first patient is administered with a ReNeuron cell therapy in a sixth clinical trial.
- (ii) 33.3% vest on completion of the fourth clinical trial of a ReNeuron cell therapy.
- (iii) 33.4% vest if the total shareholder return (TSR) of the Company meets or exceeds that of the AIM Healthcare Index in any three year period from date of grant of the option.

#### GOVERNANCE

# Directors' remuneration report continued

for the year ended 31 March 2017

### Directors' emoluments continued

### Note 15:

These options were awarded in accordance with the Group's Long Term Incentive Plan and are subject to the performance conditions set out below; at 31 March 2017 these options were not exercisable.

- (i) 33.3% vest when the first patient is administered with a ReNeuron cell therapy in a seventh clinical trial.
- (ii) 33.3% vest on completion of the fifth clinical trial of a ReNeuron cell therapy.
- (iii) 33.4% vest if the total shareholder return (TSR) of the Company meets or exceeds that of the AIM Healthcare Index in any three year period from date of grant of the option.

### Note 16:

These options have been issued in accordance with the Group's Deferred Share-based Bonus Plan in respect of corporate and personal objectives achieved in the financial year ended 31 March 2016 and carry no further performance conditions; at 31 March 2017 these options were not exercisable.

### **Note 17:**

These options have been issued in accordance with the Non-executive Share Option Scheme. These share options vest over three years on a straight-line basis and are not subject to performance conditions; at 31 March 2017 22.22% of these options were exercisable.

By order of the Board

Simon Cartmell OBE Non-executive Director

18 July 2017

# **Financial statements**



# Independent auditors' report

to the members of ReNeuron Group plc

# Report on the financial statements

## Our opinion

In our opinion:

- ReNeuron Group plc's Group financial statements and Company financial statements (the "financial statements") give a true
  and fair view of the state of the Group's and of the Company's affairs as at 31 March 2017 and of the Group's loss and the
  Group's and the Company's cash flows for the year then ended;
- the Group financial statements have been properly prepared in accordance with International Financial Reporting Standards (IFRSs) as adopted by the European Union;
- the Company financial statements have been properly prepared in accordance with IFRSs as adopted by the European Union and as applied in accordance with the provisions of the Companies Act 2006; and
- the financial statements have been prepared in accordance with the requirements of the Companies Act 2006.

#### What we have audited

The financial statements, included within the Annual Report and Accounts (the "Annual Report"), comprise:

- the Group and Parent Company statements of financial position as at 31 March 2017;
- the Group statement of comprehensive income for the year then ended;
- the Group and Parent Company statements of cash flows for the year then ended;
- · the Group and Parent Company statements of changes in equity for the year then ended; and
- the Notes to the financial statements, which include a summary of significant accounting policies and other explanatory information.

Certain required disclosures have been presented elsewhere in the Annual Report, rather than in the notes to the financial statements. These are cross-referenced from the financial statements and are identified as audited.

The financial reporting framework that has been applied in the preparation of the financial statements is IFRSs as adopted by the European Union, and applicable law and, as regards the Company financial statements, as applied in accordance with the provisions of the Companies Act 2006.

In applying the financial reporting framework, the Directors have made a number of subjective judgements, for example in respect of significant accounting estimates. In making such estimates, they have made assumptions and considered future events.

# Opinion on other matters prescribed by the Companies Act 2006

In our opinion, based on the work undertaken in the course of the audit:

- the information given in the Strategic Report and the Directors' Report for the financial year for which the financial statements are prepared is consistent with the financial statements; and
- the Strategic Report and the Directors' Report have been prepared in accordance with applicable legal requirements.

In addition, in light of the knowledge and understanding of the Group, the Company and their environment obtained in the course of the audit, we are required to report if we have identified any material misstatements in the Strategic Report and the Directors' Report. We have nothing to report in this respect.

# Other matters on which we are required to report by exception

# Adequacy of accounting records and information and explanations received

Under the Companies Act 2006 we are required to report to you if, in our opinion:

- we have not received all the information and explanations we require for our audit; or
- adequate accounting records have not been kept by the Company, or returns adequate for our audit have not been received from branches not visited by us; or
- the Company financial statements are not in agreement with the accounting records and returns.

We have no exceptions to report arising from this responsibility.

# Directors' remuneration

Under the Companies Act 2006 we are required to report to you if, in our opinion, certain disclosures of Directors' remuneration specified by law are not made. We have no exceptions to report arising from this responsibility.

# Responsibilities for the financial statements and the audit

## Our responsibilities and those of the Directors

As explained more fully in the Directors' Responsibilities Statement, the Directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view.

Our responsibility is to audit and express an opinion on the financial statements in accordance with applicable law and International Standards on Auditing (UK and Ireland) (ISAs (UK & Ireland)). Those standards require us to comply with the Auditing Practices Board's Ethical Standards for Auditors.

This report, including the opinions, has been prepared for and only for the Company's members as a body in accordance with Chapter 3 of Part 16 of the Companies Act 2006 and for no other purpose. We do not, in giving these opinions, accept or assume responsibility for any other purpose or to any other person to whom this report is shown or into whose hands it may come save where expressly agreed by our prior consent in writing.

# What an audit of financial statements involves

We conducted our audit in accordance with ISAs (UK & Ireland). An audit involves obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. This includes an assessment of:

- whether the accounting policies are appropriate to the Group's and the Company's circumstances and have been consistently applied and adequately disclosed;
- the reasonableness of significant accounting estimates made by the Directors; and
- the overall presentation of the financial statements.

We primarily focus our work in these areas by assessing the Directors' judgements against available evidence, forming our own judgements, and evaluating the disclosures in the financial statements.

We test and examine information, using sampling and other auditing techniques, to the extent we consider necessary to provide a reasonable basis for us to draw conclusions. We obtain audit evidence through testing the effectiveness of controls, substantive procedures or a combination of both.

In addition, we read all the financial and non-financial information in the Annual Report to identify material inconsistencies with the audited financial statements and to identify any information that is apparently materially incorrect based on, or materially inconsistent with, the knowledge acquired by us in the course of performing the audit. If we become aware of any apparent material misstatements or inconsistencies we consider the implications for our report. With respect to the Strategic Report and Directors' Report, we consider whether those reports include the disclosures required by applicable legal requirements.

Jason Clarke BSc ACA (Senior Statutory Auditor)

for and on behalf of PricewaterhouseCoopers LLP Chartered Accountants and Statutory Auditors Cardiff

18 July 2017

# FINANCIAL STATEMENTS

# Group statement of comprehensive income for the year ended 31 March 2017

	Note	2017 £'000	2016 £'000
Revenue: royalty income	5	46	29
Other income: grants		854	534
Research and development costs	6	(16,648)	(10,272)
General and administrative costs	6	(4,139)	(4,015)
Operating loss		(19,887)	(13,724)
Finance income	7	1,722	878
Loss before income tax		(18,165)	(12,846)
Income tax credit	10	2,592	1,492
Loss and total comprehensive loss for the year		(15,573)	(11,354)
Loss and total comprehensive loss attributable to equity owners of the Company		(15,573)	(11,354)
Basic and diluted loss per Ordinary share	12	(0.5p)	(0.4p)

# Group and Parent Company statements of financial position $_{\rm as\ at\ 31\ March\ 2017}$

	Group		Compa	any	
Note	2017 £'000	2016 £'000	2017 £'000	2016 £'000	
Assets					
Non-current assets					
Property, plant and equipment 13	724	361	-	_	
Intangible assets 14	-	1,591	-	_	
Investment in subsidiaries 15	-	_	91,337	76,743	
Investments – bank deposits 17	-	5,000	-	5,000	
Trade and other receivables 16	-	11	-	_	
	724	6,963	91,337	81,743	
Current assets					
Trade and other receivables	1,060	1,421	133	236	
Income tax receivable	4,015	2,764	-	_	
Investments – bank deposits 17	24,936	43,283	24,936	43,283	
Cash and cash equivalents	28,125	17,426	23,219	13,454	
	58,136	64,894	48,288	56,973	
Total assets	58,860	71,857	139,625	138,716	
Equity					
Equity attributable to owners of the Company					
Share capital 23	31,646	31,646	31,646	31,646	
Share premium account	97,704	97,704	97,704	97,704	
Capital redemption reserve	8,964	8,964	8,964	8,964	
Merger reserve	2,223	2,223	1,858	1,858	
Accumulated losses					
At 1 April	(72,879)	(62,206)	(6,899)	(7,096)	
Loss for the year attributable to the owners	(15,573)	(11,354)	(210)	(484)	
Other changes in retained earnings	1,072	681	1,072	681	
	(87,380)	(72,879)	(6,037)	(6,899)	
Total equity	53,157	67,658	134,135	133,273	
Liabilities					
Current liabilities					
Trade and other payables 19	5,703	3,700	5,490	5,443	
Provisions 20	-	498	-	_	
Financial liabilities: finance leases 21	-	1	-		
	5,703	4,199	5,490	5,443	
Total liabilities	5,703	4,199	5,490	5,443	
Total equity and liabilities	58,860	71,857	139,625	138,716	

The financial statements on pages 38 to 59 were approved by the Board of Directors on 18 July 2017 and were signed on its

Michael Hunt Director

Company registered number: 05474163

# FINANCIAL STATEMENTS

# Group and Parent Company statements of changes in equity for the year ended 31 March 2017

Group	Share capital £'000	Share premium account £'000	Capital redemption reserve £'000	Merger reserve £'000	Accumulated losses £'000	Total equity £'000
As at 1 April 2015	17,888	46,267	8,964	2,223	(62,206)	13,136
Issue of Ordinary shares	13,758	54,696	_	_	_	68,454
Costs of share issue	_	(3,259)	_	_	_	(3,259)
Credit on share-based payment	_	_	_	_	681	681
Loss and total comprehensive loss for the year	_	_	_	_	(11,354)	(11,354)
As at 31 March 2016	31,646	97,704	8,964	2,223	(72,879)	67,658
Credit on share-based payment	-	_	_	_	1,072	1,072
Loss and total comprehensive loss for the year	_	_	-	-	(15,573)	(15,573)
As at 31 March 2017	31,646	97,704	8,964	2,223	(87,380)	53,157
Company	Share capital £'000	Share premium account £'000	Capital redemption reserve £'000	Merger reserve £'000	Accumulated losses £'000	Total equity £'000
As at 1 April 2015	17,888	46,267	8,964	1,858	(7,096)	67,881
Issue of Ordinary shares	13,758	54,696	_	_	_	68,454
Costs of share issue	_	(3,259)	_	_	_	(3,259)
Credit on share-based payment	-	_	_	_	681	681
Loss and total comprehensive loss for the year	-	_	=	_	(484)	(484)
As at 31 March 2016	31,646	97,704	8,964	1,858	(6,899)	133,273
Credit on share-based payment	_	_	-	_	1,072	1,072
Loss and total comprehensive loss for the year	_	_	_	_	(210)	(210)
As at 31 March 2017	31,646	97,704	8,964	1,858	(6,037)	134,135

# Group and Parent Company statements of cash flows for the year ended 31 March 2017

		Group		Comp	oany
	Note	2017 £′000	2016 £'000	2017 £′000	2016 £'000
Cash flows from operating activities					
Cash (used in)/generated from operations	26	(13,976)	(11,920)	255	(853)
Income tax credit received		1,340	_	-	_
Net cash (used in)/generated from operating activities		(12,636)	(11,920)	255	(853)
Cash flows from investing activities					
Capital expenditure		(532)	(293)	-	_
Loans provided to subsidiaries		-	_	(14,348)	(7,892)
Interest received		520	345	511	331
Net cash (used in)/generated from investing activities		(12)	52	(13,837)	(7,561)
Cash flows from financing activities					
Proceeds from issuance of Ordinary shares		-	68,454	-	68,454
Costs of share issue		-	(3,259)	-	(3,259)
Bank deposit matured/(placed)		23,347	(48,283)	23,347	(48,283)
Net cash generated from financing activities		23,347	16,912	23,347	16,912
Net increase in cash and cash equivalents		10,699	5,044	9,765	8,498
Cash and cash equivalents at the start of the year		17,426	12,382	13,454	4,956
Cash and cash equivalents at the end of the year		28,125	17,426	23,219	13,454

# Notes to the financial statements

#### 1. General information

ReNeuron Group plc (the "Company") and its subsidiaries (together, the "Group") research and develop therapies using stem cells. The Company is a public limited company incorporated and domiciled in the United Kingdom. The address of its registered office is Pencoed Business Park, Pencoed, Bridgend CF35 5HY. Its shares are listed on the Alternative Investment Market (AIM) of the London Stock Exchange.

# 2. Accounting policies and basis of preparation

The principal accounting policies adopted in the preparation of these financial statements are set out below. These policies have been consistently applied to all of the financial years presented for both the Group and the Company. The accounting policies relate to the Group unless otherwise stated.

# Basis of preparation

These financial statements have been prepared in accordance with International Financial Reporting Standards (IFRSs) as adopted by the European Union, the interpretations of the International Financial Reporting Interpretations Committee (IFRIC) and the Companies Act 2006 applicable to companies reporting under IFRS.

These financial statements have been prepared on a historical cost basis, as modified by the valuation of certain assets and liabilities at fair value through profit or loss.

#### Basis of consolidation

The consolidated financial statements include the financial statements of the Company and its subsidiary undertakings made up to 31 March 2017.

The purchase method of accounting is used to account for the acquisition of subsidiaries by the Group. The cost of an acquisition is measured as the fair value of the assets given, equity instruments issued and liabilities incurred or assumed at the date of exchange, plus costs directly attributable to the acquisition. Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are measured initially at their fair values at the acquisition date, irrespective of the extent of any minority interest. The excess of the cost of acquisition over the fair value of the Group's share of the identifiable net assets acquired is recorded as goodwill. If the cost of acquisition is less than the fair value of the net assets of the subsidiary acquired, the difference is recognised directly in the Group Statement of Comprehensive Income.

Intercompany transactions and balances and unrealised gains on transactions between Group companies are eliminated. Unrealised losses are also eliminated but considered an impairment indicator of the asset transferred. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group.

The Group elected not to apply IFRS 3 "Business Combinations" retrospectively to business combinations which took place prior to 1 April 2006 that have been accounted for by the merger accounting method.

# Significant accounting judgements, estimates and assumptions

The key area that requires management to make difficult, subjective or complex judgements about matters that are inherently uncertain is:

## Impairment of non-financial assets

The Group assesses whether there are any indicators of impairment for all non-financial assets at each reporting date. Other non-financial assets are tested for impairment when there are indicators that the carrying amounts may not be recoverable. These indicators include the progress towards and outcome of clinical trials and the Group's funding position.

# Foreign currency translation

The consolidated financial statements are presented in Pounds Sterling (£), which is the Company's functional and presentational currency. Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognised in the Group Statement of Comprehensive Income in the year in which they occur.

# Revenue

Revenue represents income received from royalties arising from collaborations with third parties and is recognised when they fall due to the Group.

#### Research and development expenditure

Capitalisation of expenditure on product development commences from the point at which technical feasibility and commercial viability of the product can be demonstrated and the Group is satisfied that it is probable that future economic benefits will result from the product once completed. No such costs have been capitalised to date, given the early stage of the Group's intellectual property.

Expenditure on research and development activities that do not meet the above criteria, including ongoing costs associated with acquired intellectual property rights and intellectual property rights generated internally by the Group, is charged to the Group Statement of Comprehensive Income as incurred.

# 2. Accounting policies and basis of preparation continued

#### **Pension benefits**

The Group operates a defined contribution pension scheme. Contributions payable for the year are charged to the Group Statement of Comprehensive Income. Differences between contributions payable in the year and contributions actually paid are shown as either accruals or prepayments in the Group and Parent Company Statements of Financial Position. The Group has no further payment obligations once the contributions have been paid.

#### Leases

Leasing arrangements which transfer to the Group substantially all the benefits and risks of ownership of assets are treated as finance leases, as if the asset had been purchased outright. The assets are included within the relevant category of property, plant and equipment and the capital elements of the leasing commitments are shown as obligations under finance leases. Assets held under finance leases are depreciated over the lower of their useful life and the terms of the lease. The interest element of the lease rental is included in the Group Statement of Comprehensive Income.

All other leases are considered operating leases, the costs of which are charged to the Group Statement of Comprehensive Income on a straight-line basis over the lease term. Benefits such as rent-free periods, and amounts received or receivable as incentives to take on operating leases, are spread on a straight-line basis over the lease term.

#### Government and other grants

Revenue grants are credited to other operating income within the Group Statement of Comprehensive Income, assessed by the level of expenditure incurred on the specific grant project, when it is reasonably certain that amounts will not need to be repaid.

# **Share-based payments**

The Group operates a number of equity-settled, share-based compensation plans. The fair value of share-based payments under such schemes is expensed on a straight-line basis over the vesting period, based on the Group's estimate of shares that will eventually vest and adjusted for the effect of market-based vesting conditions. Vesting periods are estimated to be two years for options issued under the deferred bonus and four years for other schemes.

The fair value calculation of share-based payments requires several assumptions and estimates as disclosed in note 25. The calculation uses the Black-Scholes model. At each balance sheet date, the Group reviews its estimate of the number of options that are expected to vest and recognises any revision to original estimates in the Group Statement of Comprehensive Income, with a corresponding adjustment to equity.

For equity-settled share-based payments where employees of subsidiary undertakings are rewarded with shares issued by the Parent Company, a capital contribution is recorded in the subsidiary, with a corresponding increase in the investment in the Parent Company.

#### Warrants

Where warrants have been issued together with Ordinary shares, the proportion of the proceeds received that relates to the warrants is credited to reserves.

Where warrants have been issued as recompense for services supplied, the fair value of warrants is charged to the Group Statement of Comprehensive Income over the period the services are received and a corresponding credit is made to reserves.

# Intangible assets

Intangible assets relating to intellectual property rights acquired through licensing or assigning patents and know-how are carried at historical cost less accumulated amortisation and any provision for impairment. Milestone payments associated with these rights are capitalised when incurred. Where a finite useful life of the acquired intangible asset cannot be determined, the asset is not subject to amortisation but is tested for impairment annually or more frequently whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. No amortisation other than historical impairment has been charged to date as the products underpinned by the intellectual property rights are not yet available for commercial use.

## Property, plant and equipment

Property, plant and equipment are stated at cost, net of depreciation and any provision for impairment. Cost includes the original purchase price of the asset and the costs attributable to bringing the asset to its working condition for its intended use. Depreciation is calculated so as to write off the cost less their estimated residual values, on a straight-line basis over the expected useful economic lives of the assets concerned. The principal annual periods used for this purpose are:

Plant and equipment 3-8 years

Computer equipment 3-5 years

# 2. Accounting policies and basis of preparation continued

#### Investments in subsidiaries

Investments in subsidiaries are shown at cost less any provision for impairment. Any monies paid to subsidiaries are deemed to be a capital contribution.

#### Current income tax

The credit for current income tax is based on the results for the year, adjusted for items which are non-assessable or disallowed. It is calculated using tax rates that have been enacted or substantively enacted at the financial year end.

#### Deferred tax

Deferred tax is provided in full, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. However, deferred tax is not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss. Deferred tax is determined using tax rates and laws that have been enacted or substantively enacted by the balance sheet date and are expected to apply when the related deferred tax asset is realised or the deferred tax liability is settled.

Deferred tax assets are recognised to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilised.

## Bank deposits, cash and cash equivalents

Cash and cash equivalents in the Group and Parent Company Statements of Cash Flows and the Group and Parent Company Statements of Financial Position include cash in hand and deposits held on call with banks with original maturities of three months or less. Bank deposits with original maturities in excess of three months are classed as investments and measured at amortised cost using the effective interest rate method. Bank deposits with maturities between four and twelve months are disclosed within current assets and those with maturities greater than twelve months are disclosed within non-current assets.

#### Trade payables

Trade payables are recorded at fair value when goods or services have been received from a supplier.

#### Capital redemption reserve

Section 733 of the Companies Act 2006 provides that where shares of a company are redeemed or purchased wholly out of the Company's profits, or by a fresh issue, the amount by which the Company's issued share capital is diminished on cancellation of the shares shall be transferred to a reserve called the "capital redemption reserve". It also provides that the reduction of the Company's share capital shall be treated as if the capital redemption reserve were paid-up capital of the Company.

#### **Provisions**

Provisions are recognised when the Group has an obligation as a result of past events, for which it is probable that an outflow of resources will be required to settle the obligation and the amount can be reliably estimated.

# Contractual milestone payments

The Group is expected to incur future contractual milestone payments linked to the future development of its therapeutic programmes. These costs will be recognised as and when a contractual milestone is expected to be achieved.

# Accounting developments

The following new standards, new interpretations and amendments to standards and interpretations are applicable for the first time for the financial year ended 31 March 2017. None of them have any impact on the financial statements of the Group:

- Amendment to IFRS 11 "Joint Arrangements" on acquisition of an interest in a joint operation (effective annual periods beginning on or after 1 January 2016);
- Annual improvements 2014 (effective annual periods beginning on or after 1 January 2016);
- Amendments to IAS 16 "Property, Plant and Equipment" and IAS 41 "Agriculture" regarding bearer plant (effective annual periods beginning on or after 1 January 2016);
- Amendments to IAS 16 "Property, Plant and Equipment" and IAS 38 "Intangible Assets" on depreciation and amortisation (effective annual periods beginning on or after 1 January 2016);
- Amendments to IAS 27 "Separate Financial Statements" on the equity method (effective annual periods beginning on or after 1 January 2016); and
- Amendment to IAS 1 "Presentation of Financial Statements" on the disclosure initiative (effective annual periods beginning on or after 1 January 2016).

# 2. Accounting policies and basis of preparation continued

# Accounting developments continued

There are a number of new standards, interpretations and amendments to existing standards that are not yet effective and have not been adopted early by the Group. The future introduction of these standards is not expected to have a material impact on the financial statements of the Group.

- Annual improvements 2014–2016 cycle;
- Amendment to IFRS 2 "Share-based Payments" classification and measurement of share-based payment transactions;
- Amendment to IFRS 7 "Statement of Cash Flows" on disclosure initiative:
- Amendment to IAS 12 "Income Taxes" on recognition of deferred tax assets for unrealised losses;
- Amendment to IFRS 10 and IAS 28 on sale of contribution of assets (postponed);
- IFRS 9 "Financial Instruments" (effective for annual periods beginning on or after 1 January 2018);
- IFRS 15 "Revenue from Contracts with Customers" (effective for annual periods beginning on or after 1 January 2018); and
- IFRS 16 "Leases".

#### 3. Going concern

The Group is expected to incur significant further costs as it continues to develop its therapies and technologies through clinical development and as it further establishes its cell manufacturing and development facility in South Wales.

In August 2015, the Company raised £68.4 million, before expenses, by means of a placing to shareholders. The Directors expect that the Group's financial resources will be sufficient to support operations for at least the next twelve months from the date these financial statements are approved by the Board of Directors. Consequently, the going concern basis has been adopted in the preparation of these financial statements.

## 4. Segment analysis

The Group has identified the Chief Executive Officer as the chief operating decision maker (CODM). The CODM manages the business as one segment, the development of cell-based therapies, and all activities and assets are based in the UK. Since this is the only reporting segment, no further information is included. The information used internally by the CODM is the same as that disclosed in the financial statements.

#### 5. Revenue

Revenue represents income received from royalties arising from collaborations with third parties. The Group's revenue derives wholly from assets in the UK. All revenue is derived from customers in the US.

# 6. Operating expenses

	2017 £′000	2016 £'000
Loss before income tax is stated after charging:		
Research and development costs:		
Employee benefits (note 9)	4,194	3,205
Depreciation of property, plant and equipment (note 13)	96	40
Impairment of intangible assets	1,591	_
Other expenses	10,767	7,027
Total research and development costs	16,648	10,272
General and administrative costs:		
Employee benefits (note 9)	1,975	1,543
Legal and professional fees	556	586
Depreciation of property, plant and equipment (note 13)	73	52
Operating lease charges:		
- land and buildings	178	309
Dilapidations provision (note 20)	_	5
Other expenses	1,357	1,520
Total general and administrative costs	4,139	4,015
Total research and development costs and general and administrative costs	20,787	14,287

# 6. Operating expenses continued

During the year the Group obtained services from the Group's auditors and its associates as detailed below:

Services provided by the Group's auditors	2017 £'000	2016 £'000
Fees payable to the Group's auditors:		
– for the audit of the Parent Company and consolidated financial statements	20	19
– for the audit of the Company's subsidiaries pursuant to legislation	22	22
– other audit work	3	_
Total	45	41
7. Finance income		
	2017 £'000	2016 £'000
Interest receivable on short-term and investment bank deposits	520	345

1,202

1,722

533

878

#### 8. Directors' emoluments

Foreign exchange gains

**Total** 

The Directors of the Company have authority and responsibility for planning, directing and controlling the activities of the Group and they therefore comprise key management personnel as defined by IAS 24 "Related Party Disclosures".

	2017 £'000	2016 £'000
Aggregate emoluments of Directors:		
Salaries and other short-term employee benefits	888	972
Pension contributions	49	55
	937	1,027
Share-based payments	557	372
Directors' emoluments including share-based payments	1,494	1,399

Two Directors (2016: two) had retirement benefits accruing to them under defined contribution pension schemes in respect of qualifying services.

None of the Directors exercised share options during the year (2016: 5,361,673 options were exercised at a gain of £81,000).

For detailed disclosure of Directors' emoluments, including highest paid Director, please refer to the Directors' Remuneration Report on pages 27 to 34.

Directors' emoluments include amounts payable to third parties as described in note 29.

# 9. Employee information

The monthly average number of persons (including executive Directors) employed by the Group during the year was:

	2017 Number	2016 Number
By activity:		
Research and development	45	37
Administration	8	7
	53	44

# 9. Employee information continued

Group	2017 £'000	2016 £'000
Staff costs:		
Wages and salaries	4,423	3,465
Social security costs	503	429
Share-based payment charge	1,072	681
Other pension costs	171	173
	6,169	4,748

The Company holds the employment contracts for the two Executive Directors (2016: two) but all employee costs relating to these individuals are incurred by ReNeuron Limited.

The Group operates defined contribution pension schemes for UK employees and Directors. The assets of the schemes are held in separate funds and are administered independently of the Group. The total pension cost during the year was £171,000 (2016: £173,000). There were no prepaid or accrued contributions to the scheme at the year end (2016: £nil).

# 10. Income tax credit

	2017 £'000	2016 £'000
UK research and development tax credit at 14.5% (2016: 14.5%)	2,592	1,492

No corporation tax liability arises on the results for the year due to the loss incurred.

As a loss-making small and medium-sized enterprise, the Group is entitled to research and development tax credits at 14.5% (2016: 14.5%) on 230% of qualifying expenditure for the year to 31 March 2017.

The tax credit compares with the loss for the year as follows:

	2017 £'000	2016 £'000
Loss before income tax	18,165	12,846
Loss before income tax multiplied by the main rate of corporation tax of 20% (2016: 20%)	3,633	2,569
Effects of:		
- difference between depreciation and capital allowances	100	33
– other short-term timing differences	100	21
– expenses not deductible for tax purposes	(207)	(137)
– losses not recognised	(1,432)	(994)
– adjustments in respect of prior year	398	_
Tax credit	2,592	1,492

No deferred tax asset has been recognised by the Group or Company as there are currently no foreseeable trading profits.

The potential deferred tax assets/(liabilities) of the Group are as follows:

	Amount not recognised 2017 £'000	Amount not recognised 2016 £'000
Tax effect of timing differences because of:		
Accelerated capital allowances	30	(159)
Short-term timing differences not recognised	_	100
Losses carried forward	12,677	13,183
	12,647	13,124

#### 10. Income tax credit continued

The potential deferred tax assets of the Company are as follows:

	Amount not recognised 2017 £'000	Amount not recognised 2016 £′000
Tax effect of timing differences because of:		
Losses carried forward	521	736

# 11. Loss for the financial year

As permitted by Section 408 of the Companies Act 2006 the Parent Company's Statement of Comprehensive Income for the current year has not been presented in these financial statements. The Parent Company's loss and total comprehensive loss for the financial year was £210,000 (2016: £484,000).

# 12. Basic and diluted loss per Ordinary share

The basic and diluted loss per share is calculated by dividing the loss for the financial year of £15,573,000 (2016: £11,354,000) by 3,164,618,541 shares (2016: 2,609,315,899 shares), being the weighted average number of 1 pence Ordinary shares in issue during the year. Potential Ordinary shares are not treated as dilutive as the entity is loss making.

# 13. Property, plant and equipment

13. I Toperty, plant and equipment	Leasehold	Plant and		
Group	improvements £'000	equipment f'000	Computer equipment £'000	Total £′000
Cost	1 000	1 000	1 000	1 000
At 1 April 2015	1,635	742	113	2,490
Additions		200	92	292
Disposals	(1,635)	(435)	(11)	(2,081)
At 31 March 2016		507	194	701
Accumulated depreciation				
At 1 April 2015	1,635	595	99	2,329
Charge for the year	_	57	35	92
Disposals	(1,635)	(435)	(11)	(2,081)
At 31 March 2016	-	217	123	340
Net book amount				
At 31 March 2016	-	290	71	361
Cost				
At 1 April 2016	_	507	194	701
Additions	_	470	62	532
Disposals	_	(22)	(6)	(28)
At 31 March 2017	-	955	250	1,205
Accumulated depreciation				
At 1 April 2016	-	217	123	340
Charge for the year	_	114	55	169
Disposals	-	(22)	(6)	(28)
At 31 March 2017	-	309	172	481
Net book amount				
At 31 March 2017	-	646	78	724

The figures stated above include plant and equipment held under finance leases at cost of £3,000 (2016: £3,000), depreciation of £2,000 (2016: £2,000) and net book value of £1,000 (2016: £1,000).

The Company had no property, plant or equipment at 31 March 2017 (2016: £nil).

# 14. Intangible assets

	Licence fees £'000	Intellectual property rights not amortised £'000	Total £′000
At 1 April 2016			
Cost	1,884	6,143	8,027
Accumulated amortisation and impairment	(1,884)	(4,552)	(6,436)
Net book amount at 1 April 2016	_	1,591	1,591
Impairment charge	_	(1,591)	(1,591)
Net book amount at 31 March 2017	-	-	-

Following an impairment review of intangible assets, the Directors consider it appropriate to write off in full previously capitalised intangible assets relating to in-licensed intellectual property no longer relevant to the ongoing operations of the Group. This impairment review has resulted in a non-cash charge of £1,591,000 within research and development costs in the Group's Statement of Comprehensive Income.

The Company holds no intangible assets (2016: nil).

#### 15. Investment in subsidiaries

## Company

Net book amount	2017 £'000	2016 £'000
At the start of the year	76,743	68,415
Investment in subsidiary	14,348	7,892
Capital contribution arising from share-based payments	246	436
Net book amount at 31 March	91,337	76,743

The Company has invested in ReNeuron Limited to allow it to carry on the trade of the Group. A capital contribution arises where share-based payments are provided to employees of subsidiary undertakings settled with equity to be issued by the Company.

Taking into account the market capitalisation of the Group, the prospect of its therapies and the investor appetite for this sector, there has been no impairment to investments in subsidiaries in the year.

The Company's investments comprise interests in Group undertakings, details of which are shown below:

Name of undertaking	ReNeuron Holdings Limited	ReNeuro	on Limited	ReNeuron (UK) Limited	ReNeuron, Inc.
Country of incorporation	England and Wales		gland Wales	England and Wales	Delaware, USA
Description of shares held	£0.10	£0.001	£0.10	£0.10	\$0.001
	Ordinary shares	Ordinary shares	Ordinary shares	Ordinary shares	Common stock
Proportion of nominal value of shares held by the Company	100%	100%	100%	100%	100%

ReNeuron Limited is the principal trading company in the Group. The other subsidiaries are dormant.

ReNeuron Limited, ReNeuron Holdings Limited and ReNeuron, Inc. are held directly by ReNeuron Group plc. ReNeuron (UK) Limited is held directly by ReNeuron Holdings Limited. The registered office address for all the subsidiaries is Pencoed Business Park, Pencoed, Bridgend CF35 5HY, with the exception of ReNeuron, Inc. whose registered office address is P.O. Box 1480, Redondo Beach, CA 90278.

# 16. Trade and other receivables

	Group		Company	
	2017 £'000	2016 £'000	2017 £'000	2016 £'000
Current				
Other receivables	603	913	133	236
Prepayments and accrued income	457	508	-	_
	1,060	1,421	133	236
Non-current				
Other receivables	-	11	-	_
	-	11	-	_
Total trade and other receivables	1,060	1,432	133	236

The classes within trade and other receivables do not include impaired assets.

# 17. Investments – bank deposits

	Group		Company	
Bank deposits maturing:	2017 £'000	2016 £'000	2017 £'000	2016 £'000
Four to twelve months: current asset investments	24,936	43,283	24,936	43,283
After more than twelve months: fixed asset investments	_	5,000	-	5,000

# 18. Cash and cash equivalents

	Group		Company	
	2017 £'000	2016 £'000	2017 £'000	2016 £'000
d	28,125	17,426	23,219	13,454

# 19. Trade and other payables

	Group		Company	
	2017 £'000	2016 £'000	2017 £'000	2016 £'000
Trade payables	1,817	1,502	3	3
Taxation and social security	137	110	-	_
Accruals	3,749	2,088	-	-
Amounts owed to Group undertakings	_	-	5,487	5,440
Total payables falling due within one year	5,703	3,700	5,490	5,443

Amounts owed by the Company to Group undertakings are not interest bearing and have no fixed repayment date.

#### 20. Provisions

	Group	
	2017 £'000	2016 £'000
Balance as at 1 April	498	605
Amount utilised	(498)	(112)
Amount charged to the Group Statement of Comprehensive Income	-	5
Balance as at 31 March	-	498
Building dilapidations	-	355
Restructuring	-	143
	-	498
Due within one year	-	498
Due after more than one year	-	_
	-	498

The provision in respect of building dilapidations due on exit of the premises in Guildford was utilised in the year.

The Group relocated its business from Guildford to Pencoed, South Wales, in February 2016. Existing employees of the business were offered terms to incentivise their relocation with the business. However, some employees left when the Guildford office closed. The financial statements include a provision of fnil (2016: £143,000) being the estimated further cost of restructuring payments to be made to those staff employed by the Company at 31 March 2017.

The Company had no provisions at 31 March 2017 (2016: nil).

#### 21. Finance leases

Future minimum payments under finance leases:

	Group	
	2017 £'000	2016 £'000
Within one year	-	1
Total gross payments	-	1
Less finance charges included above	-	_
Present value of payments	-	1

# 22. Financial risk management

# Capital management

The Group's key objective in managing its capital is to safeguard its ability to continue as a going concern. In particular it has sought and obtained equity funding alongside non-dilutive grant support and collaborations to pursue its programmes. The Group strives to optimise the balance of cash spend between research and development and general and administrative expenses and, in so doing, maximise progress for all pipeline products.

#### Risk

The financial risks faced by the Group include liquidity and credit risk, interest rate risk and foreign currency risk.

# 22. Financial risk management continued

#### Risk continued

Liquidity and credit risk

The Group seeks to maximise the returns from funds held on deposit balanced with the need to safeguard the assets of the business.

The agreed policy is to invest surplus cash in interest-bearing current/liquidity accounts and term deposits and to spread the credit risk across a number of counterparties, the selection criteria being as follows:

- UK-based banks;
- minimum credit rating with Fitch and/or Moody's (long term A-/A3; short term F1/P-1); and
- familiar and respected names.

At 31 March 2017 and 31 March 2016 no current asset receivables were aged over three months. No receivables were impaired or discounted.

#### Interest rate risk

A portion of the Group's cash resources are placed on fixed deposit, with a maximum original term of 24 months, to secure fixed and higher interest rates. The Directors do not currently consider it necessary to use derivative financial instruments to hedge the Group's exposure to fluctuations in interest rates.

#### Foreign currency risk

The Group holds part of its cash resources in US Dollars and Euros to cover payments committed in the immediate future. At 31 March 2017 cash and bank deposits of £15,077,000 (2016: £7,803,000) were held in these currencies. Creditors of the Group include £644,000 denominated in US Dollars and £496,000 denominated in Euros. All of the Group's receivables are denominated in Pounds Sterling.

At 31 March 2017, if Pounds Sterling had weakened/strengthened by 5% against the US Dollar with all other variables held constant, the recalculated post-tax loss for the year would have been £560,000 (2016: £250,000) higher/lower.

At 31 March 2017, if Pounds Sterling had weakened/strengthened by 5% against the Euro with all other variables held constant, the recalculated post-tax loss for the year would have been £120,000 (2016: £110,000) higher/lower.

The Group has not entered into forward currency contracts.

# Ageing profile of the Group's financial liabilities

The Group's financial liabilities consist of:

	Group	
	2017 £'000	2016 £'000
Finance leases – due in more than one year	1	_
Finance leases – due in one year or less	1	1
Trade and other payables	5,564	3,590
	5,566	3,591

# Currency profile of the Group's cash and cash equivalents

_		oup
Currency	2017 £'000	2016 £'000
Pounds Sterling	20,484	14,906
US Dollars	4,670	1,292
Euros	2,971	1,228
	28,125	17,426

# 22. Financial risk management continued

# Currency profile of the Group's bank deposit investments

	Gr	Group		
Currency	2017 £′000	2016 £'000		
Pounds Sterling	17,500	43,000		
US Dollars	7,436	4,173		
Euros	-	1,110		
	24,936	48,283		

# Fair values of financial assets and financial liabilities

The following table provides a comparison by category of the carrying amounts and the fair value of the Group's financial assets and liabilities at 31 March. Fair value is the amount at which a financial instrument could be exchanged in an arm's length transaction between informed and willing parties, other than a forced or liquidation sale and excludes accrued interest.

	201	2017		
	Book value £'000	Fair value £'000	Book value £'000	Fair value £'000
Investments – bank deposits	24,936	24,936	48,283	48,283
Cash at bank and in hand	28,125	28,125	17,426	17,426
Receivables: non-current	-	_	11	11
Receivables: current	1,060	1,060	1,421	1,421
Trade and other payables	(5,566)	(5,566)	(3,590)	(3,590)

# 23. Share capital

	2017 £'000	£′000
Authorised	Unlimited	Unlimited
Issued and fully paid		
3,164,618,541 Ordinary shares of 1.0 pence each (2016: 3,164,618,541 of 1.0 pence each)	31,646	31,646

On 24 August 2015 the Company issued 40,000,000 Ordinary shares at 5.0 pence per share and on 25 August 2015 the Company issued 1,327,411,939 Ordinary shares at 5.0 pence per share.

During the year to 31 March 2017, no Ordinary shares were issued as a result of the exercise of options awarded under the Group's share option schemes (2016: 8,378,902).

# 24. Warrants

# Warrant instrument with Novavest Growth Fund Limited

Novavest Growth Fund Limited has the right to subscribe for 58,239 ReNeuron Limited Ordinary shares at a price of £17.16 per Ordinary share. Pursuant to a put/call agreement dated 6 November 2000, on exercise of such warrant, shares acquired by Novavest in ReNeuron Limited will be exchanged for 582,390 Ordinary shares of ReNeuron (UK) Limited. The Company intends in due course to enter into an agreement with Novavest whereby if the warrant is exercised, the ReNeuron Limited shares acquired by Novavest are exchanged directly for 582,390 Ordinary shares of the Company.

# 25. Share options

The Group operates share option schemes for Directors and employees of Group companies and specific consultants. Options have been issued through a combination of an Inland Revenue-approved Enterprise Management Incentive (EMI) scheme and unapproved schemes.

The awards of share options to Executive Directors and employees of the Group are made in accordance with the Group's Deferred Share-based Bonus Plan and Long Term Incentive Plan.

Total options existing over 1.0 pence Ordinary shares in companies in the Group as at 31 March 2017 are summarised below. At 31 March 2017, the total outstanding options represented 6.3% of the total shares in issue.

Date of grant	Number of options at 1 April 2016	Granted during the year	Lapsed during the year	As at 31 March 2017	Note	Exercise price	Date from which exercisable*	Date of expiry**
August 2006	2,122,772	_	(2,122,772)	-	1	4.41p	August 2009	August 2016
August 2006	1,135,172	_	(1,135,172)	_	1	6.61p	August 2009	August 2016
August 2007	4,038,407	_	(534,494)	3,503,913	2	10.6p	August 2010	August 2017
August 2007	1,979,612	_	-	1,979,612	2	18.94p	August 2010	August 2017
August 2009	2,164,614	_	(567,233)	1,597,381	3	4.22p	August 2012	August 2019
August 2009	347,809	_	_	347,809	4	1.0p	August 2011	August 2019
August 2009	1,713,637	_	_	1,713,637	5	1.0p	August 2012	August 2019
August 2010	2,013,509	_	(767,051)	1,246,458	4	3.85p	August 2013	August 2020
August 2010	3,954,315	_	-	3,954,315	6	1.0p	August 2013	August 2020
September 2011	3,600,547	_	(960,146)	2,640,401	7	3.75p	September 2014	September 2021
September 2011	4,765,833	_	-	4,765,833	8	1.0p	September 2014	September 2021
September 2012	4,515,706	_	(1,282,806)	3,232,900	9	2.87p	September 2015	September 2022
September 2012	6,776,212	_	-	6,776,212	10	1.0p	September 2015	September 2022
September 2013	4,970,000	_	(1,325,000)	3,645,000	11	3.6p	September 2016	September 2023
September 2013	7,947,917	_	_	7,947,917	12	1.0p	September 2016	September 2023
September 2014	8,375,000	_	(2,025,000)	6,350,000	13	3.45p	September 2017	September 2024
September 2014	25,134,723	_	_	25,134,723	14	1.0p	September 2017	September 2024
October 2015	6,350,000	_	(1,225,000)	5,125,000	15	1.0p	October 2018	October 2025
October 2015	51,232,727	_	-	51,232,727	16	1.0p	October 2018	October 2025
July 2016	_	54,916,668	-	54,916,668	17	1.0p	July 2019	July 2026
July 2016	_	4,250,000	_	4,250,000	18	1.0p	July 2018	July 2026
July 2016	-	1,800,000	-	1,800,000	19	1.0p	August 2016	July 2026
July 2016	_	8,500,000	(250,000)	8,250,000	20	1.0p	July 2019	July 2026
Total	143,138,512	69,466,668	(12,194,674)	200,410,506				

<sup>\*</sup> The exercise periods indicate the earliest dates for which the options are exercisable subject to meeting the performance conditions disclosed overleaf.

 $<sup>^{\</sup>star\star}$  All options lapse in full if they are not exercised by the date of expiry.

# 25. Share options continued

#### Note 1:

These options were issued subject to a performance condition, being the first patient administered with a ReNeuron cell therapy in Phase I/II trials; these options expired in August 2016.

#### Note 2:

These options were issued subject to a performance condition, being the successful completion of an initial clinical trial of a ReNeuron cell therapy; at 31 March 2017 these options were exercisable.

#### Note 3:

These options were issued subject to a performance condition, being the first patient administered with a ReNeuron cell therapy in a second clinical trial; at 31 March 2017 these options were exercisable.

#### Note 4:

These options have been issued in accordance with the Group's Deferred Share-based Bonus Plan in respect of corporate and personal objectives achieved in the financial year ending 31 March 2009 and carry no further performance conditions; at 31 March 2017 these options were exercisable.

#### Note 5:

These options were awarded in accordance with the Group's Long Term Incentive Plan and are subject to the performance conditions below; at 31 March 2017 these options were exercisable.

- (i) The first patient is administered with a ReNeuron cell therapy in a second clinical trial.
- (ii) The total shareholder return (TSR) of the Company must exceed that of the FTSE All-Share Pharmaceutical and Biotechnology Index in any given three year period from date of grant. Where the TSR ranks between median and upper quartile of the Index over the three year period, the options will vest pro-rata between 25% and 100%. Where the TSR ranks below the median in the performance period, no options will vest.
- (iii) The business must have operated within its internal financial budgets throughout the period to vesting.
- (iv) The business must be a going concern (under the accepted accounting definition) at the time of any exercise of an option.

#### Note 6:

These options were issued subject to the amended performance conditions below. If all the performance conditions bar performance condition (ii) are met then 50% of the options become exercisable; at 31 March 2017 50% of these options were exercisable.

- (i) The first patient is administered with a ReNeuron cell therapy in a second clinical trial.
- (ii) The total shareholder return (TSR) of the Company meets or exceeds that of the AIM Healthcare Index in any three year period from date of grant of the option.
- (iii) The business must have operated within its internal financial budgets throughout the period to vesting.
- (iv) The business must be a going concern (under the accepted accounting definition) at the time of any exercise of an option.

#### Note 7:

These options were issued subject to a performance condition, being the first patient administered with a ReNeuron cell therapy in a third clinical trial; at 31 March 2017 these options were exercisable.

#### Note 8:

These options were awarded in accordance with the Group's Long Term Incentive Plan and are subject to the amended performance conditions set out below. If all the performance conditions bar performance condition (ii) are met then 50% of the options become exercisable; at 31 March 2017 50% of these options were exercisable.

- (i) The first patient is administered with a ReNeuron cell therapy in a third clinical trial.
- (ii) The total shareholder return (TSR) of the Company meets or exceeds that of the AIM Healthcare Index in any three year period from date of grant of the option.
- (iii) The business must have operated within its internal financial budgets throughout the period to vesting.
- (iv) The business must be a going concern (under the accepted accounting definition) at the time of any exercise of an option.

# 25. Share options continued

#### Note 9:

These options were issued subject to a performance condition, being the first patient administered with a ReNeuron cell therapy in a fourth clinical trial; at 31 March 2017 these options were exercisable.

#### Note 10:

These options were awarded in accordance with the Group's Long Term Incentive Plan and are subject to the amended performance conditions set out below. If all the performance conditions bar performance condition (ii) are met then 50% of the options become exercisable; at 31 March 2017 50% of these options were exercisable.

- (i) The first patient is administered with a ReNeuron cell therapy in a fourth clinical trial.
- (ii) The total shareholder return (TSR) of the Company meets or exceeds that of the AIM Healthcare Index in any three year period from date of grant of the option.
- (iii) The business must have operated within its internal financial budgets throughout the period to vesting.
- (iv) The business must be a going concern (under the accepted accounting definition) at the time of any exercise of an option.

#### **Note 11:**

These options were issued subject to a performance condition, being the first patient administered with a ReNeuron cell therapy in a fifth clinical trial; at 31 March 2017 these options were not exercisable.

#### Note 12:

These options were awarded in accordance with the Group's Long Term Incentive Plan and are subject to the amended performance conditions set out below. If all the performance conditions bar performance condition (ii) are met then 50% of the options become exercisable; at 31 March 2017 these options were not exercisable.

- (i) The first patient is administered with a ReNeuron cell therapy in a fifth clinical trial.
- (ii) The total shareholder return (TSR) of the Company meets or exceeds that of the AIM Healthcare Index in any three year period from date of grant of the option.
- (iii) The business must have operated within its internal financial budgets throughout the period to vesting.
- (iv) The business must be a going concern (under the accepted accounting definition) at the time of any exercise of an option.

### Note 13:

These options were issued subject to a performance condition, being the first patient administered with a ReNeuron cell therapy in a sixth clinical trial; at 31 March 2017 these options were not exercisable.

#### Note 14:

These options were awarded in accordance with the Group's Long Term Incentive Plan and are subject to the amended performance conditions set out below. If all the performance conditions bar performance condition (ii) are met then 50% of the options become exercisable; at 31 March 2017 these options were not exercisable.

- (i) The first patient is administered with a ReNeuron cell therapy in a sixth clinical trial.
- (ii) The total shareholder return (TSR) of the Company meets or exceeds that of the AIM Healthcare Index in any three year period from date of grant of the option.
- (iii) The business must have operated within its internal financial budgets throughout the period to vesting.
- (iv) The business must be a going concern (under the accepted accounting definition) at the time of any exercise of an option.

#### Note 15:

These options were issued subject to the performance conditions set out below; at 31 March 2017 these options were not exercisable.

- (i) 50% vest when the first patient is administered with a ReNeuron cell therapy in a sixth clinical trial.
- (ii) 50% vest on completion of the fourth clinical trial of a ReNeuron cell therapy.

## 25. Share options continued

#### Note 16:

These options were awarded in accordance with the Group's Long Term Incentive Plan and are subject to the performance conditions set out below; at 31 March 2017 these options were not exercisable.

- (i) 33.3% vest when the first patient is administered with a ReNeuron cell therapy in a sixth clinical trial.
- (ii) 33.3% vest on completion of the fourth clinical trial of a ReNeuron cell therapy.
- (iii) 33.4% vest if the total shareholder return (TSR) of the Company meets or exceeds that of the AIM Healthcare Index in any three year period from date of grant of the option.

### **Note 17:**

These options were awarded in accordance with the Group's Long Term Incentive Plan and are subject to the performance conditions set out below; at 31 March 2017 these options were not exercisable.

- (i) 33.3% vest when the first patient is administered with a ReNeuron cell therapy in a seventh clinical trial.
- (ii) 33.3% vest on completion of the fifth clinical trial of a ReNeuron cell therapy.
- (iii) 33.4% vest if the total shareholder return (TSR) of the Company meets or exceeds that of the AIM Healthcare Index in any three year period from date of grant of the option.

#### Note 18:

These options have been issued in accordance with the Group's Deferred Share-based Bonus Plan in respect of corporate and personal objectives achieved in the financial year ended 31 March 2016 and carry no further performance conditions; at 31 March 2017 these options were not exercisable.

#### Note 19:

These options have been issued in accordance with the Non-executive Share Option Scheme. These share options vest over three years on a straight-line basis and are not subject to performance conditions; at 31 March 2017 22.22% of these options were exercisable.

#### Note 20:

These options were issued subject to the performance conditions set out below; at 31 March 2017 these options were not exercisable.

- (i) 50% vest when the first patient is administered with a ReNeuron cell therapy in a seventh clinical trial.
- (ii) 50% vest on completion of the fifth clinical trial of a ReNeuron cell therapy.

#### Fair value charge

Fair value charges for share options have been prepared based on a Black-Scholes model with the following key assumptions:

Date of grant	Exercise price Pence	Share price at date of grant Pence	Risk-free rate %	Assumed time to exercise Years	Assumed volatility %	Fair value per option Pence
September 2013	3.60	3.60	2.94	5	83.8	2.42
September 2013	1.00	3.60	2.94	5	83.8	3.05
September 2014	3.45	3.45	2.54	5	61.3	1.85
September 2014	1.00	3.60	2.54	5	61.3	2.74
October 2015	1.00	4.125	1.74	5	58.3	3.37
July 2016	1.00	3.00	0.80	5	58.4	2.25

The risk-free rate is taken from the average yields on government gilt edged stock. No dividends are assumed. The assumed vesting period is four years. No lapses are assumed until they take place. Assumed volatility is based on historical experience up to the date of the grant.

# 25. Share options continued

# Fair value charge continued

The weighted average exercise prices for options were as follows:

	2017		201	6
	Number of options ′000	Weighted average exercise price Pence	Number of options '000	Weighted average exercise price Pence
Outstanding at 1 April	143,139	2.06	108,359	3.13
Granted	69,467	1.00	57,733	1.00
Lapsed	(12,195)	3.97	(14,574)	6.41
Exercised	-	-	(8,379)	1.00
Outstanding at 31 March	200,411	1.58	143,139	2.06
Exercisable at 31 March	24,410	4.73	31,380	4.79

The share price on 31 March 2017 was 2.3 pence (2016: 3.4 pence).

The pattern of exercise price and life is shown below:

		201	7			201	2016	
	Weighted average Weighted remaining life (year:			Weighted	Number -	Weighted a remaining li		
Range of exercise prices	average exercise price	Number — of options	Expected	Contractual	average exercise price	of options	Expected	Contractual
1.0p	1.0p	176,214,841	2.91	8.21	1.0p	108,223,173	2.29	8.45
Up to 10p	3.5p	18,712,140	2.78	5.82	3.7p	28,897,320	1.52	6.05
10p to 20p	13.6p	5,483,525	0.42	0.42	13.3p	6,018,019	1.42	1.42
Total		200,410,506				143,138,512		

# 26. Cash (used in)/generated from operations

	Gro	up	Company	
	Year ended 31 March 2017 £'000	Year ended 31 March 2016 £'000	Year ended 31 March 2017 £'000	Year ended 31 March 2016 £'000
Loss before income tax	(18,165)	(12,846)	(210)	(484)
Adjustments for:				
Interest received	(520)	(345)	(511)	(331)
Depreciation of property, plant and equipment	169	92	_	-
Impairment of intangible assets	1,591	_	-	_
Provisions movement	(498)	(107)	-	_
Share-based payment charges	1,072	681	826	245
Changes in working capital:				
Receivables	372	(751)	103	(236)
Payables	2,003	1,356	47	(47)
Cash (used in)/generated from operations	(13,976)	(11,920)	255	(853)

#### 27. Financial commitments

The future aggregate minimum lease payments under non-cancellable operating leases are as follows:

	Gro	oup
	2017 £'000	2016 £'000
Not later than one year	13	13
Later than one year and no later than five years	506	355
Later than five years	656	820
Total lease commitments	1,175	1,188

The operating lease commitment is in respect of the lease of offices and laboratories in Pencoed. The ten year lease was signed by the Company with the Welsh Ministers on 11 February 2016 for the offices and laboratory space in new premises in Pencoed, South Wales, with the initial rent being reduced over the first three years.

An agreement for lease entered into on 31 March 2014 remains in force but has subsequently been varied in supplemental agreements. Pursuant to this agreement and supplemental agreements, on satisfactory completion of a GMP production facility, a new lease will be entered into over c.25,700 sq ft for offices, laboratories and the GMP production facility at the premises in Pencoed.

The Company had no other financial commitments at 31 March 2017 (2016: £nil).

The Group is expected to incur future contractual milestone payments linked to the future development of its therapeutic programmes. These costs will be recognised when each contractual milestone has been achieved.

#### 28. Contingent liabilities

The Group had no contingent liabilities as at 31 March 2017 (2016: fnil).

## 29. Related party disclosures

The following transactions were carried out with some of the Directors of the Company who are key management personnel as defined by IAS 24 "Related Party Disclosures".

Aesclepius Consulting Limited charged fees of £19,000 (2016: £19,000) in respect of services provided as a Non-executive Director by Dr Tim Corn.

Arthurian Life Sciences Limited charged fees of £nil in the current year (2016: £150,000 in relation to the August 2015 placing) and £2,083 (2016: £25,000) in respect of services provided as a Non-executive Director by Professor Sir Chris Evans OBE.

Biomedicon Limited charged fees of £21,500 (2016: £20,135) in respect of services provided as a Non-executive Director by Dr Paul Harper.

# Parent Company and subsidiaries

The Parent Company is responsible for financing and setting Group strategy. ReNeuron Limited carries out the Group strategy, employs all staff excluding the Directors and owns and manages all of the Group's intellectual property. The proceeds of the issue of shares by the Parent Company are passed when required to ReNeuron Limited as a loan. ReNeuron Limited makes payments including the expenses of the Parent Company.

Company: transactions with subsidiaries	2017 £'000	2016 £'000
Purchases and staff:		
Parent Company expenses paid by subsidiary	1,055	1,082
Transactions involving Parent Company shares:		
Share options	246	436
Cash management:		
Loans to subsidiary	14,348	7,892
Company	2017 £'000	2016 £'000
Year-end balance of loan to subsidiary	82,321	67,973

# Notice of annual general meeting

NOTICE IS HEREBY GIVEN that the annual general meeting of ReNeuron Group plc (incorporated and registered in England and Wales with registered no. 5474163) (the "Company") will be held at the offices of Covington & Burling LLP, 265 Strand, London WC2R 1BH on 6 September 2017 at 10 a.m. to consider and, if thought fit, pass the following resolutions, of which Resolutions 1 to 4 will be proposed as ordinary resolutions and Resolution 5 will be proposed as a special resolution.

#### **ORDINARY BUSINESS**

- 1. To receive and adopt the Company's Annual Report and Accounts for the financial year ended 31 March 2017 and the Directors' Report, and the Independent Auditors' Report on those accounts.
- 2. To reappoint as a Director John Berriman, who is retiring by rotation in accordance with Article 122 of the Company's Articles of Association and who, being eligible, is offering himself for reappointment.
- 3. To reappoint PricewaterhouseCoopers LLP as auditors of the Company from the conclusion of this annual general meeting until the conclusion of the next annual general meeting of the Company at which accounts are laid and to authorise the Directors to determine the remuneration of the auditors.

#### **SPECIAL BUSINESS**

- 4. That the Directors of the Company be and are hereby generally and unconditionally authorised, pursuant to Section 551 of the Companies Act 2006 (the "2006 Act") to:
  - (a) allot Ordinary shares and to grant rights to subscribe for or to convert any security into Ordinary shares in the Company (all of which shares and rights are hereafter referred to as "Relevant Securities") representing up to £10,548,725 in nominal value in aggregate of shares; and
  - (b) allot Relevant Securities (other than pursuant to paragraph (a) above) representing up to £10,548,725 in nominal value in aggregate of shares in connection with a rights issue, open offer, scrip dividend, scheme or other pre-emptive offer to holders of Ordinary shares where such issue, offer, dividend, scheme or other allotment is proportionate (as nearly as may be) to the respective number of Ordinary shares held by them on a fixed record date (but subject to such exclusions or other arrangements as the Directors may deem necessary or expedient to deal with legal or practical problems under the laws of any overseas territory, the requirements of any regulatory body or any stock exchange in any territory, in relation to fractional entitlements, or any other matter which the Directors consider merits any such exclusion or other arrangements),

provided that in each case such authority shall expire (unless previously renewed, varied or revoked by the Company in general meeting) 15 months after the date of the passing of this resolution or at the conclusion of the next annual general meeting of the Company following the passing of this resolution, whichever occurs first, save that the Company may before such expiry, variation or revocation make an offer or agreement which would or might require such relevant securities to be allotted after such expiry, variation or revocation and the Directors may allot relevant securities pursuant to such an offer or agreement as if the authority conferred hereby had not expired or been varied or revoked.

- 5. That the Directors are hereby empowered pursuant to Section 570 of the 2006 Act:
  - (a) subject to and conditionally upon the passing of Resolution 4 to allot equity securities (as defined by Section 560 of the 2006 Act) for cash pursuant to the authority conferred by Resolution 4 as if Section 561 of the 2006 Act did not apply to such allotment; and
  - (b) to sell Ordinary shares if, immediately before such sale, such shares are held as treasury shares (within the meaning of Section 724 of the 2006 Act) as if Section 561 of the 2006 Act did not apply to such sale,

provided that such powers:

- (1) shall be limited to:
  - (i) the allotment of equity securities (or sale of Ordinary shares) representing up to £10,548,725 in nominal value in aggregate of shares pursuant to the authority conferred by paragraph (b) of Resolution 4; and
  - (ii) the allotment of equity securities (or sale of Ordinary shares), otherwise than pursuant to sub-paragraph (i) above, representing up to £3,164,615 in nominal value in aggregate of shares (and including, for the avoidance of doubt, in connection with the grant of options (or other rights to acquire Ordinary shares) in accordance with the rules of the Company's share option schemes (as varied from time to time) or otherwise to employees, consultants and/or Directors of the Company and/or any of its subsidiaries); and

#### **SPECIAL BUSINESS** continued

(2) shall expire 15 months after the passing of this resolution or at the conclusion of the next annual general meeting of the Company following the passing of this resolution, whichever occurs first, but so that the Company may before such expiry, revocation or variation make an offer or agreement which would or might require equity securities to be allotted (or Ordinary shares to be sold) after such expiry, revocation or variation and the Directors may allot equity securities (or sell Ordinary shares) in pursuance of such offer or agreement as if such powers had not expired or been revoked or varied.

18 July 2017

By order of the Board

Michael Hunt Company Secretary Registered office Pencoed Business Park Pencoed Bridgend CF35 5HY United Kingdom

#### **NOTES**

- (1) In this Notice "Ordinary shares" shall mean Ordinary shares in the capital of the Company, having a nominal value of 1.0 pence per share.
- (2) A shareholder entitled to attend and vote at the meeting is also entitled to appoint one or more proxies to attend, speak and vote on a show of hands and on a poll instead of him or her. A proxy need not be a member of the Company. Where a shareholder appoints more than one proxy, each proxy must be appointed in respect of different shares comprised in his or her shareholding which must be identified on the Form of Proxy. Each such proxy will have the right to vote on a poll in respect of the number of votes attaching to the number of shares in respect of which the proxy has been appointed. Where more than one joint shareholder purports to appoint a proxy in respect of the same shares, only the appointment by the most senior shareholder will be accepted as determined by the order in which their names appear in the Company's register of members. If you wish your proxy to speak at the meeting, you should appoint a proxy other than the Chairman of the meeting and give your instructions to that proxy.
- (3) A corporation which is a shareholder may appoint one or more corporate representatives who have one vote each on a show of hands and otherwise may exercise on behalf of the shareholder all of its powers as a shareholder provided that they do not do so in different ways in respect of the same shares.
- (4) To be effective, an instrument appointing a proxy and any authority under which it is executed (or a notarially certified copy of such authority) must be deposited at the offices of Computershare Investor Services PLC, The Pavilions, Bridgwater Road, Bristol BS99 6ZY, by no later than 10 a.m. on 4 September 2017 except that should the meeting be adjourned, such deposit may be made not later than 48 hours before the time of the adjourned meeting, provided that the Directors may in their discretion determine that in calculating any such period no account shall be taken of any day that is not a working day. A Form of Proxy is enclosed with this Notice. Shareholders who intend to appoint more than one proxy may photocopy the Form of Proxy prior to completion. Alternatively, additional Forms of Proxy may be obtained by contacting Computershare Investor Services PLC on 0370 707 1272. The Forms of Proxy should be returned in the same envelope and each should indicate that it is one of more than one appointments being made. Completion and return of the Form of Proxy will not preclude shareholders from attending and voting in person at the meeting.
- (5) A "Vote withheld" option has been included on the Form of Proxy. The legal effect of choosing the "Vote withheld" option on any resolution is that the shareholder concerned will be treated as not having voted on the relevant resolution. The number of votes in respect of which there are abstentions will, however, be counted and recorded, but disregarded in calculating the number of votes for or against each resolution.
- (6) In accordance with Regulation 41 of the Uncertificated Securities Regulations 2001, the Company specifies that only those shareholders registered in the register of members of the Company as at the close of business on the day which is two working days before the day of the meeting shall be entitled to attend or vote (whether in person or by proxy) at the meeting in respect of the number of shares registered in their names at the relevant time. Changes after the relevant time will be disregarded in determining the rights of any person to attend or vote at the meeting.

# Explanatory notes to the business of the annual general meeting

#### **Resolution 1**

The Company's Annual Report and Accounts for the financial year ended on 31 March 2017 and the Directors' Report and the Independent Auditors' Report on those accounts will be presented to shareholders for approval.

#### **Resolution 2**

Article 122 of the Company's Articles of Association requires that at every annual general meeting of the Company at least one third of the Directors for the time being (or, if their number is not a multiple of three, the number nearest to but not greater than one third) shall retire from office by rotation and that all Directors holding office at the start of business on the date of this Notice of annual general meeting, and who also held office at the time of both of the two immediately preceding annual general meetings and did not retire at either such meeting, shall retire from office and shall be counted in the number required to retire at the annual general meeting. Having so retired by rotation in accordance with Article 122, the following Director is standing for reappointment by the shareholders at the annual general meeting:

• John Berriman, who is a Non-executive Director of the Company.

It is noted that Dr Paul Harper has confirmed to the Company that he wishes to retire at the meeting and not offer himself for re-election and this retirement which shall take effect from the conclusion of the meeting has been included for the purposes of calculating the number of the Directors who are to retire by rotation in accordance with Article 123 of the Company's Articles of Association.

#### **Resolution 3**

At every annual general meeting at which accounts are presented to shareholders, the Company is required to appoint auditors to serve until the next such annual general meeting. PricewaterhouseCoopers LLP have confirmed that they are willing to continue as the Company's auditors for the next financial year. The Company's shareholders are asked to reappoint them and to authorise the Directors to determine their remuneration, which will, in accordance with the Company's practice concerning good corporate governance, be subject to the recommendation of the Audit Committee.

#### **Resolution 4**

This resolution seeks to authorise the Directors to allot shares, subject to the normal pre-emption rights reserved to shareholders contained in the 2006 Act. The Investment Association (IA) regards as routine a request by a company seeking an annual authority to allot new shares in an amount of up to a third of the existing issued share capital. In addition, the IA will also regard as routine a request for authority to allot up to a further third of the existing issued share capital provided such additional third is reserved for fully pre-emptive rights issues. Resolution 4 seeks to reflect the spirit of the IA's recommendations, though sub-paragraph (b) of Resolution 4 covers a broader range of offers, issues and allotments. The limits imposed under sub-paragraphs (a) and (b) of Resolution 4 each represent one third of the existing issued share capital of the Company.

# **Resolution 5**

Pursuant to Section 561 of the 2006 Act existing shareholders of the Company have a right of pre-emption in relation to future issues of shares. Sub-paragraph (1)(i) of Resolution 5 allows the disapplication of pre-emption rights to allow the issue of shares to existing shareholders, for example, by way of a rights issue or open offer. The limit imposed in respect of the general disapplication pursuant to sub-paragraph 1(ii) of Resolution 5 represents 10% of the existing issued share capital of the Company. The Directors consider it important that they have the authority set out in sub-paragraph (1)(ii), which would allow them to issue shares in connection with the grant of options (or other rights to acquire Ordinary shares) in accordance with the rules of the Company's share option schemes and more generally for other purposes.

# Glossary of scientific terms

#### **Allogeneic**

Where a tissue donor and recipient of the cells are different individuals.

## **Cell Banking**

A process for the controlled preparation of a cell therapy product of a uniform composition stored under defined conditions, resulting in a large number of vials of frozen cells.

#### **Cell Line**

A well characterised cell culture that has been demonstrated to be consistent. Cell lines may comprise a family of cells isolated from a single tissue or organ, or may be clonally derived from a single ancestor cell.

# **Cell therapy**

A process by which healthy cells are introduced into a tissue or an organ to reconstruct or promote regeneration in order to treat disease.

# Cone-rod dystrophy

A group of inherited eye disorders with degeneration of cone cells in the retina resulting in loss of central acuity and colour vision that is progressive over time.

#### Critical limb ischaemia

Critical limb ischaemia is the end stage of peripheral arterial disease, where a progressive decrease in blood flow to limbs can lead to gangrene and amputation.

## Cryopreservation

Maintenance of the viability of cells using agents to protect them from damage that can occur during cooling and storage at very low temperatures.

#### **Diabetes**

A disease characterised by absolute or relative insulin insufficiency and high blood sugar.

## Differentiation

Development of a stem cell into a more specialized type.

#### Exosomes

Cell-derived vesicles (typically between 30-100nm in diameter) that contain a number of active proteins and/or microRNAs.

#### Glioblastoma multiforme (GBM)

A highly malignant, rapidly growing type of brain tumour that arises from glial (supportive) cells in the brain. GBM is also known as glioblastoma and grade IV astrocytoma.

# **Good Manufacturing Practice (GMP)**

Regulations, codes and guidelines to ensure that products are consistently produced and controlled according to quality standards appropriate to their intended use and as required by the product specification.

#### Immortalised cell line

A population of cells from a multicellular organism which would normally not proliferate indefinitely but, due to mutation, have evaded normal cellular senescence and instead can keep undergoing division. The cells can therefore be grown for prolonged periods in vitro.

#### Indication

The use for which a drug or therapy is intended.

#### Ischaemic stroke

The most common type of stroke (over 80% of cases), which happens when a clot blocks an artery that carries blood to the brain.

#### **MicroRNAs**

Small non-coding RNA molecules (21-25 nucleotides in length), which function in RNA silencing and post-transcriptional regulation of gene expression.

#### **Nanoparticles**

Particles between 1-100nm in size, a particle being a small object that behaves like a whole unit with respect to its transport and properties.

# Neural stem cells

Cells within the brain which can both make more of themselves and also mature into neurons, oligodendrocytes and glia (supporting cells).

# **Neurodegenerative**

A varied assortment of CNS disorders characterised by gradual and progressive loss of neural tissue.

## **Neurons**

A nervous system cell able to conduct electrical impulses.

# Glossary of scientific terms continued

#### **Parenteral**

Taken into the body or administered in a manner other than through the digestive tract, particularly by intravenous or intramuscular injection.

# Peripheral arterial disease

A condition in which reduced blood supply to the limbs causes cramping, chronic pain and, in extreme cases, loss of limb.

#### Phase I clinical trial

The assessment of the safety of a biologically active substance in patients or healthy volunteers.

#### Phase II clinical trial

A clinical trial designed to evaluate the efficacy and safety of a treatment or drug for the condition it is intended to treat.

## Phase III clinical trial

A large scale clinical trial of a treatment or drug that in Phase I and Phase II has been shown to be both efficacious and safe.

# **Photoreceptors**

Cells in the retina (rod cells and cone cells) that convert light into electrical impulses.

# Regenerative medicine

The process of replacing or regenerating cells, tissues or organs to restore or establish normal function.

#### **Retinal disease**

Conditions that lead to damage of the layer of tissue in the back of the eye that senses light and sends images to the brain.

# Retinitis pigmentosa

A group of inherited diseases of the retina that cause damage to the rods leading to a loss of peripheral vision that is progressive over time.

#### Stem cell

A cell that is both able to reproduce itself and, depending on its stage of development, to generate all or certain other cell types within the body or within the organ from which it is derived.

#### **Stroke**

Damage to a group of nerve cells in the brain due to interrupted blood flow, caused by a blood clot or blood vessel bursting. Depending on the area of the brain that is damaged, a stroke can cause coma, paralysis, speech problems and dementia.

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