FINAL RESULTS

Released : 17 Apr 2018 07:00

RNS Number : 0941L
Amryt Pharma PLC
17 April 2018

17 April 2018
AIM: AMYT
ESM: AYP

AMRYT PHARMA PLC
("Amryt" or the "Company")
The biopharmaceutical company focused on rare and orphan diseases

Final Results
For the 12 months to 31 December 2017

Key Points

CONTINUING STRONG PROGRESS

Financial

- Revenues increased to €12.8m (2016: €1.4m)
  - driven by growth of Lojuxta drug sales
- Cash balances totalled €20.5m at 31 December 2017 (2016: €8.3m), with €10m undrawn from the European Investment Bank facility
- Successful equity placing raised €15m (gross) in October 2017
- Gross profit margin increased to 58% (2016: 57%)

Operational

- Sales of Lojuxta, a drug which treats a rare, life-threatening cholesterol disease, Homozygous Familial Hypercholesterolaemia ("HoFH"), grew strongly
  - first full year's contribution of €11.9m compared to €0.8m for one month in December 2016
  - first distribution agreement signed in November 2017 - covers the Kingdom of Saudi Arabia
  - a further four distribution agreements were signed in Q1 2018
- Pivotal Phase III EASE trial commenced in March 2017 - investigating AP101 as a potential treatment for Epidermolysis bullosa ("EB"), a rare skin disorder that can cause skin to blister and tear at the slightest touch
- In response to physician interest, Amryt is also now evaluating other dermatological indications for AP101, where there is high unmet medical need and which relate to the European Medicine Agency's existing approval for AP101
- Senior Management Team enhanced further by new appointments

Post Period

- Amryt granted access to data from Amicus Therapeutics's landmark EB trial (ESSENCE) - a remarkable sharing of data. As a result, Amryt is now making modest refinements to its

protocol for its Phase III EASE trial, with the aim of increasing the probability of success for the study
  - interim analysis is expected to be completed in Q4 2018, with read out of top-line data expected in Q2 2019

- In-licensing agreement for a gene-therapy platform technology signed with University College Dublin in March 2018
  - technology uses a novel gene delivery mechanism and the focus of potential application is on patients with a sub-type of EB
  - pre-clinical studies are to commence, with initial results planned for Q4 2018

Joe Wiley, CEO of Amryt, said:
"Amryt made very strong progress both financially and operationally in 2017. The dramatic increase in revenues to €12.8m reflected a full year's contribution from sales of Lojuxta, which is used to treat the rare, life-threatening cholesterol disorder, HoFH. We remain in a very good position to expand Lojuxta sales further, having secured a number of distribution agreeements across our licensed territories, including Eastern Europe and the Middle East.

"2017 marked a milestone for our lead development asset, AP101, as we commenced our pivotal Phase III trial, EASE, in March. This study is investigating AP101 as a potential treatment for EB, the rare and distressing genetic skin disorder. We are now refining the study's protocol after being granted remarkable access to Amicus Therapeutics's trial data, which read-out in September 2017. This very generous decision by Amicus Therapeutics allows us the opportunity to increase the chances of our study's success and we now expect interim analysis to be completed in Q4 2018, with read out of top-line data expected in Q2 2019.

"We continue to expand the Company's growth opportunities, and Amryt remains well positioned to continue to make significant progress in 2018."

Enquiries:

Amryt Pharma plc Joe Wiley, CEO Rory Nealon, CFO/COO	+353 (1) 518 0200
Shore Capital *Nomad and Joint Broker* Edward Mansfield, Mark Percy, Daniel Bush	+44 (0) 20 7408 4090
Davy *ESM Adviser and Joint Broker* John Frain, Anthony Farrell	+353 (1) 679 6363
Stifel *Joint Broker* Jonathan Senior, Ben Maddison	+44 (0) 20 7710 7600
WG Partners Nigel Barnes, Nigel Birks, Chris Lee	+44 (0)20 3705 9321
KTZ Communications Katie Tzouliadis, Irene Bermont-Penn, Emma Pearson	+44 (0) 20 3178 6378

About Amryt Pharma plc
(www.amrytpharma.com)

Amryt Pharma is a specialty biopharmaceutical company focused on developing and delivering innovative new treatments to help improve the lives of patients with rare or orphan diseases.

The Company holds an exclusive licence to sell Lojuxta (lomitapide) for adults, across the European Economic Area, Middle East and North Africa, Switzerland, Turkey and Israel. Lojuxta is used to treat a rare life-threatening disease called Homozygous Familial Hypercholesterolaemia ("HoFH"). HoFH impairs the body's ability to remove LDL cholesterol ("bad" cholesterol) from the blood, which typically results in extremely high blood LDL cholesterol levels, leading to aggressive and premature narrowing and blocking of arterial blood vessels. If left untreated, heart attack or sudden death may occur in childhood or early adulthood.

Amryt's lead drug candidate, AP101, is currently in Phase III clinical trials as a potential treatment for Epidermolysis bullosa ("EB"). EB is a rare and distressing genetic skin disorder, which causes exceptionally fragile skin. There is currently no approved treatment and the global market opportunity for EB is estimated to be in excess of EUR 1.3 billion.

Amryt has two earlier stage assets, AP102 and AP103. AP102 is focused on developing novel, next generation somatostatin

analogue ("SSA") peptide medicines for patients with rare neuroendocrine diseases, where there is a high unmet medical need, including acromegaly and Cushing's disease. AP103 is an in-licensed new gene therapy platform, which has potential applicability across a range of genetic disorders, including for patients with a sub-type of EB, Recessive Dystrophic Epidemolysis bullosa.

CHAIRMAN AND CEO'S STATEMENT

Introduction
We are pleased to present the annual report and consolidated financial statements of Amryt Pharma plc for the year ended 31 December 2017.

The financial results for the year ended 31 December 2017 comprise the results of the consolidated Group. By contrast, the financial results for 2016 comprise the results of Amryt Pharmaceuticals DAC ("Amryt DAC") for the period from 1 January 2016 to 18 April 2016 and those of the new consolidated Group from 19 April 2016 to 31 December 2016. This reflects the reverse takeover of Fastnet Equity plc by Amryt DAC on 18 April 2016, the subsequent name change to Amryt Pharma plc and the re-admission of the shares to trading on AIM and ESM.

Following Birken AG's acquisition by the Group in 2016, it was renamed Amryt AG in 2017. All references in the notes to the accounts to Amryt AG relate to the entity that was formerly called Birken AG.

Our Business
Amryt is a commercial stage pharmaceutical company focused on acquiring, developing and delivering innovative new treatments that help improve the lives of patients with rare and orphan diseases. The Group has built a diverse portfolio of assets to treat patients with rare and orphan diseases through the acquisition of its AP101 and AP102 assets in April 2016, the in-licencing of Lojuxta in December 2016 and the in-licencing of a gene therapy platform in March 2018. The Group continues to review new opportunities and the Board is active in seeking to expand the Group's commercial product portfolio.

Performance Highlights
Since the reverse takeover on 18 April 2016, the Group has made excellent progress and 2017 was a very strong year for Amryt which places us in a good position to be able to drive further expansion throughout 2018 and beyond.

Some of the highlights of the Group's performance in 2017 and in 2018 to date are as follows:

- Total revenues for the year increased to €12.8m (2016: €1.4m)
- Revenues from Lojuxta increased to €11.9m in 2017 compared to €0.8m in December 2016
- Gross profit margin increased to 58% in 2017 (2016: 57%)
- Cash balance at 31 December 2017 was €20.5m (2016: €8.3m) with €10m undrawn from the European Investment Bank ("EIB") facility
- Successful equity placing in October 2017 raised gross funds of €15m
- One new distribution agreement signed in 2017 and a further four agreements signed in the current financial year to date
- Lead development asset, AP101, continued to make significant progress
- Additional market opportunities for AP101 in partial thickness wound indications are currently under evaluation
- In-licencing deal signed in March 2018 with University College Dublin for exciting non-viral gene therapy platform technology, which offers potential treatments for patients with Epidermolysis bullosa ("EB") (AP103)
- Expansion of key personnel - Amryt now has in place an exceptionally strong leadership team with the necessary commercial, regulatory and medical infrastructure also in place

Operational Highlights

Lojuxta
LOJUXTA (lomitapide) is a drug used to treat a rare life-threatening disease called Homozygous Familial Hypercholesterolaemia ("HoFH"). HoFH is a life threatening disorder that impairs the body's ability to remove LDL cholesterol ("bad" cholesterol) from the blood. This typically results in extremely high blood LDL cholesterol levels leading to aggressive and premature narrowing and blocking of arterial blood vessels manifesting as cardiovascular disease. If left untreated, heart attack or sudden death may occur in childhood or early adulthood. Lojuxta is approved in Europe to treat adults with HoFH.

With the completion of the Lojuxta in-licencing deal in December 2016, Amryt is now a commercial pharmaceutical company, generating sales across Europe, the Middle East and other licenced territories. Amryt's Lojuxta business has grown significantly in the 13 months since December 2016, with sales for the year growing to €11.9m (2016: €0.8m). This growth was underpinned by strong demand from existing markets within Amryt's licenced territories. In particular, the Group has experienced positive momentum in negotiations regarding the levels of national reimbursement from certain countries and also an increase in individual named patients, who access funding for treatment on a 'named patient' basis in

those countries where there is no national reimbursement agreement.

Future sales growth will be driven by existing markets and from new territories. Since November 2017, Amryt has agreed five new distributor relationships, which together cover seventeen new countries. The Group is actively negotiating the initiation of reimbursement from the UK, France, Spain and Turkey and we are optimistic that some of these discussions will conclude successfully during the course of 2018. If successful, these market-access decisions will allow Amryt to provide access for a cohort of HoFH patients in these territories, which should result in accelerated growth for the business. We have ambitious plans for the remainder of 2018 and we look forward to announcing a series of agreements in the months to come.

Lead development asset - AP101 (Oleogel-S10)

AP101 (Oleogel-S10) is being developed as a prescription medicine for Epidermolysis bullosa ("EB"), for which there are severely limited treatment options. EB is a rare genetic skin disorder that leads to exceptionally fragile skin, and children with the disorder are often referred to as "Butterfly Children". AP101 is currently in an investigational global Phase III clinical trial for this indication; however, it has already been approved in Europe for use in the treatment of partial thickness wounds ("PTW") in adults.

The Group has continued to make strong progress with its lead development asset, AP101, as a new potential treatment for EB. In February 2017, Amryt was granted a patent in Japan for AP101. This followed key patents grants for AP101 in Europe and the US in 2016. In March 2017, Amryt completed discussions with both the Food and Drug Administration ("FDA") and the European Medicines Agency ("EMA") regarding the design of its pivotal Phase III clinical trial for AP101 in EB. Subsequently, on 27 March 2017, we commenced the pivotal Phase III clinical trial, EASE (Efficacy and safety of AP101 in patients with EB), to examine AP101's efficacy for EB patients. The first patient was enrolled to EASE in April 2017.

Amicus Therapeutics granted Amryt detailed access to the data from its landmark ESSENCE trial of SD101 in EB, which read out in September 2017. Based on the insights from these data, Amryt management is now able to refine its protocol for the Group's ongoing global Phase III EASE study of AP101, with the potential to increase the probability of success for the study. The Group is currently in the process of amending the protocol for the EASE study and will discuss any significant changes with the FDA and the EMA. These amendments include a modest increase in the size of the study from 164 to 192 patients and a restriction on certain wound types, the ultimate goal of which is to increase the chances of success in the study. Interim analysis is now expected to be completed in Q4 2018, with read out of top-line data expected in Q2 2019.

Exciting future indications for AP101

AP101 was approved by the EMA in Europe in January 2016 for the treatment of PTW in adults. This followed three positive Phase III studies of 280 patients in grade II burns and split thickness skin graft donor sites. Amryt has recently received interest from physicians to study AP101 in various PTW indications also with high unmet medical need. In response to this interest, the Group is evaluating new life cycle opportunities for AP101.

Dermatological conditions currently under consideration include:

- Toxic Epidermal Necrolysis Syndrome (TENS)(including Stevens-Johnson Syndrome (SJS))
- Bullous Pemphigoid
- Pemphigus Vulgaris
- Grade III/IV radiotherapy and chemotherapy induced dermatitis

The scope of the current EMA approval for AP101 may offer the opportunity to launch AP101 in some of these indications in Europe. Early indications suggest that collectively these indications of TENS/SJS, radiotherapy and chemotherapy induced dermatitis, and bullous pemphigoid and pemphigus vulgaris may have a market potential greater than the EB opportunity that the Group is currently investigating in its EASE Phase III study.

Management intends to file applications for orphan designation for some of these new potential orphan indications in the USA, Europe and Japan and believes that there is significant scope to maximise the value of this existing asset through either a global multi-orphan strategy or via the current EMA marketing approval to secure long term growth.

Strategic Developments since Year End

In March 2018, Amryt reached an exclusive agreement to in-licence a new platform technology for gene therapy with potential applicability across a range of genetic disorders. The technology has been in-licenced from University College Dublin ("UCD") and involves the delivery of gene therapy using Highly Branched Poly (β-Amino Ester) ("HPAE") polymer technology. The initial focus of development efforts to date has been in the area of EB and preliminary data suggests that the treatment could be potentially disease-modifying for patients with Recessive Dystrophic Epidermolysis Bullosa ("RDEB"). Pre-clinical data in a xenograft model has shown significant levels of collagen VII in the skin post therapy. Patients with RDEB have a defect in their gene coding for collagen VII, consequently the replacement of collagen VII could be transformative for these patients.

Potential competitors working in the area of gene therapy in EB are mostly working with viral vectors to deliver collagen VII to the cell. The patented technology which Amryt has exclusively licenced from UCD involves the use of a novel gene delivery mechanism using HPAE polymer technology. If successful, this will eliminate the requirement for viruses as delivery vectors and provides a potential competitive advantage to Amryt.

Amryt intends to conduct various pre-clinical studies in the coming months and intends to report initial results in Q4 2018.

If successful, this platform has the potential to be applicable in other dermatological conditions and possibly beyond.

The name assigned to this development project is 'AP103'.

Corporate and Financial
Revenues for the year to 31 December 2017 totalled €12,778,000 (2016: €1,351,000). Lojuxta generated revenues of €11,924,000. Revenues from Imlan, our derma-cosmetics range of products, amounted to €830,000 and revenues generated from consulting fees amounted to €24,000. In 2016, the Lojuxta revenues are for the period from the completion date of the Licence Agreement with Aegerion Pharmaceuticals Inc ("Aegerion") on 2 December 2016 to 31 December 2016 and totalled €775,000. Imlan revenues for the period from 19 April to 31 December 2016 amounted to €571,000.

The operating loss before finance expense for the year ended 31 December 2017 amounted to €14,207,000, of which research and development expenses amounted to €10,564,000. This included depreciation and amortisation of €257,000 and non-cash share based payments of €565,000. It compares to an operating loss before finance expense for the year ended 31 December 2016 of €7,683,000 which included reverse takeover and acquisition related costs of €1,838,000, depreciation and amortisation of €194,000 and non-cash share based payments of €229,000. Excluding depreciation, amortisation and once off reverse takeover and acquisition costs, the operating loss before finance costs for the year ended 31 December 2017 would have been €13,385,000 (2016: €5,422,000).

The loss on ordinary activities before taxation of €26,136,000 includes €11,104,000 relating to a current non-cash movement on contingent consideration that arose as part of the acquisition of Amryt AG in 2016. The fair value of this contingent consideration was initially determined by discounting the contingent amounts payable to their present value at the date of acquisition. The discount component is being unwound as a current non-cash financing charge in the Statement of Comprehensive Income over the life of the obligation. This current non-cash financing charge of €11,104,000 represents the discount component being unwound to the Statement of Comprehensive Income during 2017.

As at 31 December 2017, the Group had cash on hand of €20.5m. On 2 December 2016, Amryt entered into a five year €20m debt facility agreement with the EIB. The first tranche of €10m was drawn down on 3 April 2017. In October 2017, the Company completed an equity fundraising resulting in gross proceeds of €15m (net proceeds: €14.3m).

Board and Senior Management Changes
Amryt is led by an experienced senior management team which has been enhanced further in 2017 by the appointment of a number of senior managers.

In March 2017, the Group appointed David Allmond as Chief Commercial Officer. David has over 20 years' experience in the pharmaceutical industry in commercial roles. He joined the Company from Aegerion where he was President of EMEA and, in particular, involved in the commercialisation of Lojuxta. Prior to Aegerion, David was Corporate Vice President of Global Marketing for Celgene Corporation where he played a pivotal role in defining strategy for in-line brands, lifecycle/pipeline prioritisation and providing commercial direction for business development. He was previously responsible for EMEA marketing and market access within Celgene. Prior to that, he was Director of Sales and Marketing Effectiveness at Amgen Ltd.

In June 2017, the Group appointed Kieran Rooney, Ph.D., as Vice President of Strategic Alliances and Licencing. Before joining Amryt, he headed a pharmaceutical consulting company, Halo BioConsulting, focusing on business alliances and management consulting. Prior to that, Kieran worked as a consultant for the UK Government and held business development roles at companies including Smith & Nephew, F2G Limited, Pharsight Corporation, and MDS Pharma Services. Kieran is responsible for planning and executing an integrated global business development strategy and has over 25 years of experience in the biopharmaceutical industry, with significant expertise in business development and commercial strategy.

In December 2017, the Group appointed Patrick Jordon as Vice-President of Global Distributor Markets. Patrick has worked in the pharmaceutical industry for the last 18 years, during which time he held senior positions in Pfizer and Merck & Co. ("MSD"). He has significant experience across sales, marketing, business development and general management and has been based in a number of global territories. Latterly, Patrick was the Managing Director of MSD's Saudi operations and before that served as MSD's Regional Managing Director of its Eastern Europe and North Africa business.

Amryt now has in place an exceptionally strong leadership team with the necessary commercial, regulatory and medical infrastructure also in place in Europe. Our strategy is to leverage this capacity to seek to in-license more commercial stage assets, which we are actively pursuing.

Having served on Amryt's Board for approximately a year, Cathal Friel stepped down from the Board of Directors effective from 28 March 2017. Cathal was one of the original founders of Fastnet Equity plc and facilitated the reverse takeover of Fastnet Equity plc and creation of Amryt in April 2016.

Future Developments and Outlook
The Group achieved significant milestones in 2017 and we remain confident of continuing significant progress over 2018.

We are very positive about the growth prospects for our Lojuxta business. Lojuxta revenues in 2017 exceeded management's expectations for the period and we believe that there is a significant opportunity to further grow revenues especially with material, untapped opportunities in our licenced territories. This will be a major focus for us over the

coming quarters.

The Phase III clinical trial, EASE, for our lead asset, AP101, has commenced. The results of our interim analysis on EASE are due in Q4 2018 and will provide an assessment of the progress of our study by an independent data safety monitoring board. We are optimistic in this regard and, should the interim analysis be positive, expect to report top-line data Q2 2019.

We are also very excited about the interest from physicians to study AP101 in various PTW indications with high unmet medical need. The Group will continue to evaluate these opportunities in 2018.

Our new in-licencing agreement is an attractive opportunity for Amryt to be involved in the area of gene therapy, which is one of the most exciting and potentially transformative areas of medicine today. If successful, this platform has the potential to be broadly applicable in other dermatological conditions and possibly beyond.

In the meantime, Amryt will continue to seek to in-license further commercial stage assets to continue to grow our revenues and provide cash resources that will help support these development assets. Amryt has made excellent operational and strategic progress to date and we look forward to reporting on further progress as we continue to develop the business.

Harry Stratford
Non-executive Chairman
16 April 2018

Joe Wiley
CEO
16 April 2018

OPERATIONS REVIEW

Lojuxta
In December 2016, Amryt was delighted to reach an agreement with Aegerion, a NASDAQ-listed biopharmaceutical company, for the exclusive rights to sell Aegerion's drug, Lojuxta in certain territories. These territories comprise the EEA, Middle East and MENA, Switzerland, Turkey and Israel and our exclusive licence became effective on 2 December 2016. As anticipated, the licence agreement has been immediately cash generative for Amryt.

Lojuxta is used to treat a rare life-threatening disease called HoFH and was approved in the EU in late 2013. Current treatment options include statin drugs, PCSK9 inhibitors and apheresis (a blood filtration technique similar to dialysis). However, they are not adequate to control LDL cholesterol levels in some patients, particularly those with the most severe genetic mutations. HoFH was historically estimated to occur in about 1 in 1,000,000 people worldwide although more recent studies suggest it may affect up to 1 in 300,000 people. Amryt believes that there is significant potential for the drug to become a mainstay treatment for patients with HoFH. Lojuxta is currently licenced for use in adults and as part of the post approval commitments with the EMA we will be conducting a paediatric study that if successful could extend the label to children also.

Licence Agreement Terms
Under the terms of our licence agreement, Amryt has the exclusive right to sell Lojuxta across its licenced territories in return for which Amryt will:

- make royalty payments to Aegerion, paid quarterly, based on a percentage of net sales during a calendar year. The royalty percentage is currently 18% of net sales of the product less than US$15,000,000 and 20% of net sales more than US$15,000,000. This royalty may increase to 20% and 22% respectively in the event that the marketing authorisation is formerly transferred to Amryt;

- make once-off commercial milestone payments, subject to achieving certain sales targets. A one-off milestone payment of US$1,000,000 is due the first time that aggregate net sales in a calendar year equals US$20,000,000 with a further one-off US$1,500,000 milestone payment due on reaching US$30,000,000 net sales in a calendar year; and

- take on the ongoing regulatory and post-marketing obligations and commitments in support of Lojuxta as above.

Our licence agreement has an initial term until 1 January 2024 and Amryt may, at its own discretion, extend the licence agreement for a further five years, with the right to extend in further five year periods thereafter.

2017 Revenue and Plans
For the 12 months ended 31 December 2017, Lojuxta generated revenues of €11,924,000 (2016: €775,000 for the month of December 2016). This growth arose from strong demand in existing markets in our territories, in particular, 2017 experienced positive momentum in the reimbursement position in certain countries and also an increase in "named patient" sales.

Future growth will be driven by existing markets and also through expansion into new territories. Since November 2017,

the Group has completed five new distributor relationships, covering 17 countries:

- In November 2017, Amryt signed a distributorship agreement, with Faisal Musaed El Seif Saudi Pharmaceutical Company ("El Seif"), for Amryt's products in the Kingdom of Saudi Arabia ("Saudi Arabia"). El Seif, an affiliate of El Seif Development Company, is a leading distributor of medical devices and pharmaceuticals in Saudi Arabia and has a strong presence in the rare and orphan diseases drug sector. Amryt estimates that there are currently in excess of 150 patients with HoFH in Saudi Arabia. The agreement with El Seif covers AP101 in anticipation of a successful conclusion of the Phase III clinical trials.

- In January 2018 Amryt signed an exclusive distributor agreement for Lojuxta in Switzerland. The agreement is with RCC Pharma AG, a leading Swiss pharmaceutical company with expertise in early access programs in rare and orphan diseases. The Company currently estimates that there are approximately 15 patients with HoFH in Switzerland. It has received requests from clinicians for access to Lojuxta for Swiss patients and this agreement will now enable Amryt to respond more effectively to such requests.

- In January 2018, Amryt also signed an exclusive distribution agreement covering Central and Eastern Europe with GryNumber Health, one of the leading healthcare consultancy and distribution companies in the region. The agreement covers Austria, Croatia, Czech Republic, Estonia, Finland, Hungary, Latvia, Poland, Slovakia, and Slovenia. Amryt estimates that there are approximately 100 patients with HoFH in these countries.

- Amryt signed a further exclusive distribution agreement in January 2018 covering Romania and Bulgaria with Romastru Trading SRL, a Bucharest pharmaceutical services company, part of Pharaon Healthcare Europe, a conglomerate which provides a wide range of services, including medical, market research and distribution.

- In March 2018, Amryt announced that it has further expanded its market coverage for Lojuxta with an exclusive distribution agreement for Lebanon, Jordan and Syria. The agreement is with Pharaon Healthcare-Droguerie Mercury S.A.L., one of the leading full-service distributors in the region. The Group estimates that there are approximately 40 patients with HoFH in the countries covered by this agreement.

The Group has now established the commercial, medical and regulatory infrastructure required to support the commercialisation of Lojuxta across our licenced territories using affiliates, third party consultants and distributors. This infrastructure can also be leveraged to support additional products such as AP101 if approval is received from the regulatory authorities, and other products that may be acquired or in-licenced in the future.

AP101 (Oleogel-S10)
Amryt's lead product, AP101, received marketing approval for the treatment of partial-thickness wounds ("PTW") from the European Commission in January 2016. In Q1 2017, we completed discussions with the FDA and EMA regarding the design of our pivotal Phase III clinical trial for AP101 (Efficacy and Safety of Oleogel-S10 in EB, the "EASE Study") as a potential treatment for EB and on 27 March 2017, commenced a pivotal Phase III trial, EASE, to examine AP101's safety and efficacy.

EB is a chronic and debilitating condition for which there is currently no approved product and significant unmet medical need. All forms of the disorder are considered serious and the most severe are disfiguring and cause intense suffering. The patient advocacy group, Debra International, estimates that there are approximately 500,000 people living with EB worldwide, with some 30,000 in Europe. The Department of Dermatology at Stanford University estimates that there are 25,000 people living with EB in the US. The combined US and European market for the treatment of EB is estimated by management to be in excess of €1.3 billion.

AP101 has already demonstrated encouraging preliminary data in EB in a Phase 2a clinical trial completed in 2011. In addition, three successful Phase III clinical studies in the broad PTW indication have been conducted with AP101. In each of these studies, AP101 successfully demonstrated faster healing in both recent wounds and chronic wounds compared with standard of care therapy. Amryt commenced a single Phase III pivotal study in EB in March 2017 which aims to demonstrate efficacy specifically in EB, a condition that also causes partial thickness wounds.

Clinical trials update
In March 2017, the Group commenced the pivotal Phase III clinical trial, EASE, to examine AP101's efficacy for EB patients. Adult and paediatric patients with EB are being enrolled into a randomised double blind placebo controlled trial. The proportion of patients with completely healed target wounds within 45 days will be evaluated as the primary endpoint. Secondary endpoints include the time to achieve wound healing and changes in pain and pruritus (itch).

In March 2018, Amicus Therapeutics granted Amryt detailed access to the data from its landmark ESSENCE trial of SD101 in EB, which read out in September 2017. Based on insights from these data, Amryt management is now able to refine its protocol for the Group's ongoing global Phase III (EASE) study of AP101, with the potential to increase the probability of success for the study.

The Group is currently in the process of amending the protocol for the EASE study and will discuss any significant changes with the FDA and the EMA. These amendments include a modest increase in the size of the study from 164 to 192 patients and a restriction on certain wound types.

Based on the analysis of the Amicus Therapeutics data, the Group will maintain the current primary endpoint which is the proportion of patients with first complete closure of the target EB wound treated with AP101 versus placebo within 45 days of treatment. The exclusion of EB Simplex patients for the EASE study will help to ensure that patients with likely faster spontaneous healing rates will not be included in the study and is expected to increase the likelihood of demonstrating a statistically significant treatment effect.

These changes will result in a slight delay of the interim analysis which the Company expects will be complete in early Q4 2018. Assuming a positive interim analysis, the Group expects read out of top-line data from our AP101 Phase III study in Q2 2019. The incremental cost of these changes is expected to be approximately €1m. The unblinded interim analysis will be conducted by an independent data-safety-monitoring-board and will result in three possible outcomes:

- continue the study with no change to sample size, which would reflect conditional statistical power of at least 80% or better;
- increase the number of patients in the study to maintain an 80% conditional statistical power;
- or discontinue the study for futility.

The unblinded interim analysis read out potentially represents a significant milestone for the Group.
In 2017, the Group agreed with the regulatory authorities to conduct some further non-clinical studies in parallel with this Phase III study. In 2018, various non-clinical studies, requested by the FDA as part of an investigational new drug ("IND") filing to open clinical trial sites in the USA, have recently been successfully completed. No safety signals or concerns were noted from the preliminary data and the Company is now hopeful that the combination of these studies, and safety data from patients enrolled to date in non-US EASE study sites, will enable it to request an IND to open trial sites in the USA, which it anticipates will be in Q3 2018.

Extended patents and regulatory approvals
In January 2016, we secured approval from the EMA for the use of AP101 in the European Union for the treatment of all PTWs. We subsequently secured a European method of use patent for the treatment of PTW in March 2016 and obtained a US method of use patent for the treatment of EB in September 2016. In February 2017, Amryt was granted a patent in Japan by the Japanese Patent Office for AP101 for the treatment of EB. All these patents expire in 2030.

Future indications for AP101 asset
Amryt has recently received interest from physicians to study AP101 in various PTW indications also with high unmet medical need. In response to this interest, the Group is evaluating new life cycle opportunities for AP101. Dermatological conditions under consideration include:

- Toxic Epidermal Necrolysis Syndrome (TENS)(including Stevens-Johnson Syndrome (SJS))
- Bullous Pemphigoid
- Pemphigus Vulgaris
- Grade III/IV radiotherapy and chemotherapy induced dermatitis

Toxic Epidermal Necrolysis Syndrome (TENS) (including Stevens-Johnson Syndrome (SJS)) is a rare, acute, serious and potentially fatal skin reaction in which there is sheet-like skin and mucosal loss. Amryt has recently agreed to facilitate a compassionate use protocol in this area, which may generate valuable data in the coming quarters. One of the most common effects of radiation or chemotherapy is acute skin reaction that ranges from a mild rash to severe ulceration. Approximately 10% of patients treated with radiation therapy will experience severe skin reaction resulting in grade III/IV wounds.

The scope of the current EMA approval for AP101 may offer the opportunity to launch AP101 in some of these indications in Europe. Early indications suggest that collectively these indications of TEN/SJS, radiotherapy and chemotherapy induced dermatitis, and bullous pemphigoid and pemphigus vulgaris may have a market potential greater than the EB opportunity which the Group is currently investigating in its EASE Phase III study.

AP102
AP102 is an early stage drug asset, which may represent a novel, next generation somatostatin analogue ("SSA") peptide medicine for patients with rare neuroendocrine diseases, where there is a high unmet medical need, including acromegaly. Acromegaly is a rare endocrine disorder in which the body produces excessive growth hormone, leading to abnormal growth throughout the body over time.

In November 2016, we secured orphan drug designation for AP102 from the FDA. The FDA's Orphan Drug Designation program provides orphan status to drugs and biologics that are being developed to address rare diseases or disorders that

affect fewer than 200,000 people in the United States. With orphan designation, AP102 qualifies for various incentives, including tax credits for qualified clinical trials and market exclusivity upon regulatory approval.

In February 2017, we received positive results from a pre-clinical study that compared AP102 with pasireotide, an approved product for treating patients with resistant acromegaly. Significantly, AP102 did not demonstrate the potential to cause diabetes, an observation which, if replicated in clinical studies, could be clinically beneficial in treating acromegaly. Amryt's study used a well-established diabetic rat model to examine whether or not AP102 has an effect on glucose levels or on food/water intake compared with controls. The study results showed that AP102 had no effect on either in diabetic rats compared with controls. This indicates no impairment in glucose control in these diabetic animals when treated with AP102. Throughout 2017, the Group initiated and conducted various other pre-clinical studies. These studies are ongoing and the Group expects to complete these pre-clinical studies in 2018.

AP103 (Gene therapy platform)
In March 2018, Amryt completed a new exclusive in-licencing of a new platform technology for gene therapy with potential applicability across a range of genetic disorders. This technology has been exclusively in-licenced from University College Dublin ("UCD") and involves the delivery of gene therapy using HPAE polymer technology. The initial focus of development efforts to date has been in the area of EB and preliminary data suggests that the treatment could be potentially disease-modifying for patients with Recessive Dystrophic Epidermolysis bullosa ("RDEB"). Pre-clinical data in a xenograft model has shown significant levels of collagen VII in the skin post therapy. Patients with RDEB have a defect in their gene coding for collagen VII, consequently the replacement of collagen VII could be transformative for these patients.

Potential competitors are working in the area of gene therapy in EB are mostly working with viral vectors to deliver collagen VII to the cell. The patented technology which Amryt has exclusively licenced from UCD involves the use of a novel gene delivery mechanism using HPAE polymer technology. If successful, this could eliminate the requirement for viruses as delivery vectors and provides a potential competitive advantage to Amryt. Amryt intends to conduct various pre-clinical studies in the coming months and will report initial results in Q4 2018.

Imlan
Amryt has a range of dermo cosmetic products that we acquired with the Amryt AG transaction, which are sold under the Imlan brand. Completely free of emulsifiers, preservatives, colorants and fragrances and other additives or irritants, Imlan is marketed as a treatment for sensitive, allergy-prone and dry skin. It is also recommended for the basic care of eczema or psoriasis.

Revenues for the year ended 31 December 2017 amounted to €830,000 compared to revenues of €571,000 in the period from the acquisition of Amryt AG in April 2016 to 31 December 2016.

Concert Party
The Company has a concert party, the Amryt Concert Party, that came into effect on admission of the Company's shares to trading on AIM on 19 April 2016 ("Admission") . Details of the members of the Amryt Concert Party can be found in part VIII of the Company's AIM Admission document which is available on the Company's website: https://www.amrytpharma.com/investors/circulars-and-admission-document/

The members of the Amryt Concert Party at the time of Admission are still considered by the Panel to be acting in concert save that Mr. Cathal Friel is no longer considered a constituent member of the Amryt Concert Party.

Consolidated Statement of Comprehensive Income
For the year ended 31 December 2017

	Note	31 December 2017 €'000	31 December 2016 €'000
Revenue		**12,778**	1,351
Cost of sales		**(5,373)**	(586)
Gross profit		**7,405**	765
Administrative, selling and marketing expenses		**(10,483)**	(4,037)
Share based payment expenses		**(565)**	(229)
Reverse takeover and acquisition related costs		**-**	(867)
Non-cash deemed cost of reverse takeover		**-**	(971)
Total administrative, selling and marketing expenses		**(11,048)**	(6,104)
Research and development expenses		**(10,564)**	(2,344)
Operating loss before finance expense		**(14,207)**	(7,683)
Non-cash change in fair value of contingent consideration		**(11,104)**	-
Finance expense		**(825)**	(121)
Loss on ordinary activities before taxation		**(26,136)**	(7,804)
Tax on loss on ordinary activities		**-**	-

Loss for the year attributable to the equity holders of the Company		**(26,136)**	(7,804)
Exchange translation differences which may be reclassified through the profit or loss		**22**	(5)
Total other comprehensive loss		**22**	(5)
Total comprehensive loss for the year attributable to the equity holders of the Company		**(26,114)**	(7,809)
Loss per share:			
Loss per share - basic and diluted, attributable to ordinary equity holders of the parent (cent)	3	**(11.72)**	(4.78)

Consolidated Statement of Financial Position
For the year ended 31 December 2017

	31 December 2017 €'000	31 December 2016 €'000
Assets		
Non-current assets		
Intangible assets	**52,606**	52,521
Property, plant and equipment	**1,160**	1,183
Total non-current assets	**53,766**	53,704
Current assets		
Trade and other receivables	**4,729**	2,540
Inventories	**1,083**	770
Cash and cash equivalents	**20,512**	8,271
Total current assets	**26,324**	11,581
Total assets	**80,090**	65,285
Equity and liabilities		
Equity attributable to owners of the parent		
Share capital	**21,173**	20,419
Share premium	**57,334**	43,695
Other reserves	**(21,512)**	(22,079)
Accumulated deficit	**(35,109)**	(8,998)
Total equity	**21,886**	33,037
Non-current liabilities		
Contingent consideration	**32,418**	23,314
Deferred tax liability	**5,384**	5,384
Long term loan	**10,603**	-
Total non-current liabilities	**48,405**	28,698
Current liabilities		
Trade and other payables	**9,799**	3,550
Total current liabilities	**9,799**	3,550
Total liabilities	**58,204**	32,248
Total equity and liabilities	**80,090**	65,285

Consolidated Statement of Cash Flows
For the year ended 31 December 2017

	31 December 2017 €'000	31 December 2016 €'000
Cash flows from operating activities		
Loss on ordinary activities before taxation	**(26,136)**	(7,804)
Finance expense	**825**	121
Depreciation and amortisation	**259**	194
Share based payment expense	**565**	229

Non-cash change in fair value of contingent consideration	**11,104**	-
Non-cash deemed cost of reverse takeover	**-**	971
Movements in working capital and other adjustments:		
Change in trade and other receivables	**(2,189)**	(1,975)
Change in trade and other payables	**6,022**	2,236
Change in contingent consideration	**(2,000)**	-
Change in inventories	**(313)**	(83)
Net cash flow used in operating activities	**(11,863)**	(6,111)
Cash flow from investing activities		
Cash consideration on acquisition of Amryt AG	**-**	(10,150)
Cash consideration on acquisition of SOM	**-**	(89)
Cash inflow on acquisition of Amryt AG	**-**	705
Cash inflow on reverse takeover of Fastnet Equity plc	**-**	11,993
Payments for property, plant and equipment	**(243)**	(12)
Payments for intangible assets	**(87)**	-
Cash inflow on sale of property, plant and equipment	**9**	10
Deposit interest received	**5**	1
Net cash flow (used in)/from investing activities	**(316)**	2,458
Cash flow from financing activities		
Proceeds from issue of equity instruments - net of expenses	**14,393**	11,251
Issue of convertible debenture securities	**-**	545
Increase in long term debt	**10,000**	-
Repayment of short term loans	**(47)**	(47)
Net cash flow from financing activities	**24,346**	11,749
Exchange and other movements	**74**	4
Net change in cash and cash equivalents	**12,241**	8,100
Cash and cash equivalents at beginning of year	**8,271**	171
Restricted cash at end of year	**537**	-
Cash at bank available on demand at end of year	**19,975**	8,271
Total cash and cash equivalents at end of year	**20,512**	8,271

Consolidated Statement of Changes in Equity
For the year ended 31 December 2017

	Share capital	Share premium	Share based payment reserve	Merger reserve	Reverse acquisition reserve	Exchange translation reserve	Accumulated deficit	Total
	€'000	€'000	€'000	€'000	€'000	€'000	€'000	€'000
Balance at 1 January 2016	1	-	-	-	-	-	(1,194)	**(1,193)**
Loss for the year	-	-	-	-	-	-	(7,804)	**(7,804)**
Foreign exchange translation reserve	-	-	-	-	-	(5)	-	**(5)**
Total comprehensive income	-	-	-	-	-	(5)	(7,804)	**(7,809)**
Issue of shares by Amryt DAC on acquisition of Amryt AG	-	11,179	-	-	-	-	-	**11,179**
Issue of shares by Amryt DAC on acquisition of SOM	-	3,715	-	-	-	-	-	**3,715**
Issue of shares by Amryt DAC on conversion of convertible debenture securities	-	2,600	-	-	-	-	-	**2,600**
Issue of shares on acquisition of Amryt DAC	1,557	-	-	35,818	-	-	-	**37,375**
Issue of placing shares - net of costs	526	10,725	-	-	-	-	-	**11,251**
Issue of placing warrants	-	(2,251)	2,251	-	-	-	-	-
Share based payments	-	-	229	-	-	-	-	**229**
Reverse acquisition adjustment	18,335	17,727	1,735	-	(62,107)	-	-	**(24,310)**
Balance at 31 December 2016	20,419	43,695	4,215	35,818	(62,107)	(5)	(8,998)	**33,037**

Balance at 1 January 2017	20,419	43,695	4,215	35,818	(62,107)	(5)	(8,998)	**33,037**
Loss for the year	-	-	-	-	-	-	(26,136)	**(26,136)**
Foreign exchange translation reserve	-	-	-	-	-	27	-	**27**
Total comprehensive income	-	-	-	-	-	27	(26,136)	**(26,109)**
Issue of placing shares - gross of costs	754	14,329	-	-	-	-	-	**15,083**
Issue of placing shares - costs	-	(690)	-	-	-	-	-	**(690)**
Share based payments	-	-	565	-	-	-	-	**565**
Share based payments - lapsed	-	-	(25)	-	-	-	25	-
Balance at 31 December 2017	**21,173**	**57,334**	**4,755**	**35,818**	**(62,107)**	**22**	**(35,109)**	**21,886**

Notes

1 General information

Amryt Pharma plc (the "Company") is a company incorporated in England and Wales. Details of the registered office, the officers and advisers to the Company are presented on the Company Information page at the end of this report. The Company is listed on the AIM market of the London Stock Exchange (ticker: AMYT.L) and the Enterprise Securities Market of the Irish Stock Exchange (ticker: AYP). Amryt is a development and commercial stage pharmaceutical Company focused on acquiring, developing and delivering innovative new treatments to help improve the lives of patients with rare and orphan diseases.

2 Basis of preparation

The consolidated Financial Statements consolidate those of the Company and its subsidiaries (together the "Group"). The consolidated Financial Statements of the Group and the individual Financial Statements of the Company have been prepared in accordance with International Financial Reporting Standards ("IFRS") as adopted by the EU and with those parts of the Companies Act 2006 applicable to companies reporting under IFRS.

The financial information for the year ended 31 December 2017 does not constitute statutory accounts as defined by section 435 of the Companies Act 2006 but is extracted from the audited accounts for the year. The 31 December 2016 accounts, which relate to Amryt Pharmaceuticals DAC, have been delivered to the Companies Registration Office in Ireland. The 31 December 2017 accounts will be delivered to Companies House within the statutory filing deadline. The auditors have reported on those accounts. Their report was unqualified and did not contain statements under Section 498 (2) of (3) of the Companies Act 2006.

Summary of Significant Accounting policies

Research and development expenses

Development costs are capitalised as an intangible asset if all of the following criteria are met:

1. The technical feasibility of completing the asset so that it will be available for use or sale;
2. The intention to complete the asset and use or sell it;
3. The ability to use or sell the asset;
4. The asset will generate probable future economic benefits and demonstrate the existence of a market or the usefulness of the asset if it is to be used internally;
5. The availability of adequate technical, financial and other resources to complete the development and to use or sell it; and
6. The ability to measure reliably the expenditure attributable to the intangible asset.

In process R&D acquired as part of a business combination is capitalised at the date of acquisition. Research costs are expensed when they are incurred.

The assessment whether development costs can be capitalized requires management to make significant judgements. Management has reviewed the facts and circumstances of each project in relation to the above criteria and in management's opinion, the criteria prescribed for capitalising development costs as assets have not yet been met by the Group in relation to AP101 or AP102. Accordingly, all of the Group's costs related to research and development projects are recognised as expenses in the Consolidated Statement of Comprehensive Income in the period in which they are incurred. Management expects that the above criteria will be met on filing of a submission to the regulatory authority for final drug approval or potentially in advance of that on the receipt of information that strongly indicates that the development will be successful.

Revenue recognition

Revenue from the sale of goods is recognised in the Consolidated Statement of Comprehensive Income when the significant risks and rewards of ownership have been transferred to the buyer. Imlan revenue is generally recorded as of the date of shipment, consistent with typical ex-works shipment terms. For Lojuxta revenues, the Group sells direct to customers and also uses third parties in the distribution of the product to customers. Where the shipment terms do not

permit revenue to be recognised as of the date of shipment, revenue is recognised when the Group has satisfied all of its obligations to the customer in accordance with the shipping terms. Revenue, including any amounts invoiced for shipping and handling costs and excluding sales taxes, represents the value of the goods supplied to external customers. Revenue is recognised to the extent that it is probable that economic benefit will flow to the Group, that risks and rewards of ownership have passed to the buyer and the revenue can be reliably measured. No revenue is recognised if there is uncertainty regarding recovery of the consideration due at the outset of the transaction or the possible return of goods.

Contingent consideration
Contingent consideration arising as a result of business combinations is initially recognised at fair value using a probability adjusted present value model. The fair value of the contingent consideration is updated at each reporting date. The key judgements and estimates applied by management in the determination of the fair value of the contingent consideration relate to the determination of an appropriate discount rate, the assessment of market size and opportunity and probability assessments based on market data for the chance of success of the commercialisation of an orphan drug.

Acquired intangible assets
Acquired intangible assets outside business combinations are stated at the lower of cost less provision for amortisation and impairment or the recoverable amount. Acquired intangibles assets are amortised over their expected useful economic life on a straight line basis. In determining the useful economic life each acquisition is reviewed separately and consideration given to the period over which the Group expects to derive economic benefit.

Intangibles assets acquired in 2016 as part of the acquisitions of Amryt AG and SomPharmaceuticals are currently not being amortised as the assets are still under development.

3 Loss per share - basic and diluted
In the current year, the weighted average number of shares in the loss per share ("LPS") calculation, reflects the weighted average total actual shares of Amryt Pharma plc in issue at 31 December 2017.

In 2016, the weighted average number of shares in the LPS calculation, reflects the legal subsidiary's, Amryt Pharmaceuticals DAC ("Amryt DAC"), weighted average pre-combination ordinary shares multiplied by the exchange ratio established in the acquisition, and the weighted average total actual shares of the legal parent, Amryt Pharma plc ("Amryt"), in issue after the date of acquisition.

Issued share capital - ordinary shares of £0.01 each

	Number of shares	Weighted average shares
1 January 2016	**58,075,221**	**55,638,866**
18 April 2016 - Issue of shares by Amryt DAC on acquisition of Amryt	37,048,622	
18 April 2016 - Issue of shares by Amryt DAC on acquisition of SOM	12,277,102	
18 April 2016 - Issue of shares by Amryt DAC on conversion of convertible debentures securities	8,590,365	
19 April 2016 - Issue of shares by Amryt Pharma plc - share for share exchange on acquisition of Amryt DAC B ordinary shares [1]	7,503,786	
19 April 2016 - Issue of shares by Amryt Pharma plc - share consolidation	43,171,134	
19 April 2016 - Issue of shares by Amryt Pharma plc - share placing	41,673,402	
31 December 2016	**208,339,632**	**163,336,437**
11 October 2017 - Issue of shares by Amryt Pharma plc - share placing	66,477,651	
31 December 2017	**274,817,283**	**223,075,123**

[1] As part of the 24 August 2015 share placing, Amryt DAC issued B ordinary shares. These shares have not been included in the pre-acquisition weighted average number of shares as they did not carry rights to dividends or repayment of capital on the winding up of Amryt DAC.

The calculation of loss per share is based on the following:

	31 December 2017	31 December 2016
Loss after tax attributable to equity holders of the Company (€'000)	**(26,136)**	(7,804)
Weighted average number of ordinary shares in issue	**223,075,123**	163,336,437
Fully diluted average number of ordinary shares in issue	**223,075,123**	163,336,437
Basic and diluted loss per share (cent)	**(11.72)**	(4.78)

Where a loss has occurred, basic and diluted LPS are the same because the outstanding share options and warrants are anti-dilutive. Accordingly, diluted LPS equals the basic LPS. The share options and warrants outstanding as at 31 December 2017 totalled 42,842,882 (31 December 2016: 39,102,583) and are potentially dilutive.

4 Business Combinations and Asset Acquisitions
Reverse Acquisition of Fastnet Equity Group plc by Amryt Pharmaceuticals DAC
On 16 October 2015, Fastnet Equity plc ("Fastnet") signed non-binding heads of terms with Amryt Pharmaceuticals DAC ("Amryt DAC"), for the acquisition of Amryt DAC's entire issued and to be issued share capital. The acquisition was completed on 18 April 2016 and on the same date Amryt DAC completed the acquisitions of Amryt AG and SomPharmaceuticals ("SOM"), for consideration satisfied by the issue of new ordinary shares in Amryt DAC. To complete the acquisition of Amryt DAC a total of 123,495,095 new ordinary shares of 1p in Fastnet were issued at an issue price of 24p per share ("Consideration Shares").

The acquisition by Fastnet of Amryt DAC has been treated for accounting purposes as a reverse acquisition by Amryt DAC of Fastnet. In a reverse acquisition, the cost of the business combination is deemed to have been incurred by the legal subsidiary (Amryt DAC) in the form of notional equity instruments issued to the owners of the legal parent. The value of the notional shares is calculated by reference to the proportion of shares that would be needed to be issued by Amryt DAC to Fastnet if the old shareholder base of Fastnet was to acquire the same percentage holding in Amryt DAC as it received in the combined Group.

Acquisition of Amryt AG (previously "Birken")

Amryt DAC signed a conditional share purchase agreement to acquire Amryt AG on 16 October 2015 ("Amryt AG SPA"). The Amryt AG SPA was completed on 18 April 2016 with Amryt DAC acquiring the entire issued share capital of Amryt AG. The consideration comprises:

- Initial cash consideration of €1,000,000 (paid by Amryt DAC prior to its acquisition by the Company);
- Milestone payments of:
  - €10,000,000 on receipt of first marketing approval by the EMA of Episalvan, paid on the completion date (18 April 2016);
  - Either (1) €5,000,000 once net ex-factory sales of Episalvan have been at least €100,000 or (ii) if no commercial sales are made within 24 months of EMA first marketing approval (being 14 January 2016), €2,000,000 24 months after receipt of such approval which was paid in January 2018 and €3,000,000 following the first commercial sale;
  - €10,000,000 on receipt of marketing approval by the EMA or FDA of a pharmaceutical product containing Betulin as its API for the treatment of Epidermolysis Bullosa;
  - €10,000,000 once net ex-factory sales/net revenue in any calendar year exceed €50,000,000;
  - €15,000,000 once net ex-factory sales/ net revenue in any calendar year exceed €100,000,000;
- Cash consideration of €150,000, due and paid on the completion date (18 April 2016);
- Royalties of 9% on sales of Episalvan products for 10 years from first commercial sale; and
- Shares in Amryt DAC that equated to a 30% equity shareholding prior to the acquisition of Amryt DAC by the Company. The Amryt AG sellers received 37,048,622 in Consideration Shares (valued at €11.2 million) for their shareholding in Amryt DAC.

Fair Value Measurement of Contingent Consideration

Contingent consideration comprises the milestone payments and sales royalties detailed above. As at the acquisition date, the fair value of the contingent consideration was estimated to be €23,314,000. The fair value of the royalty payments was determined using probability weighted revenue forecasts and the fair value of the milestones payments was determined using probability adjusted present values. The probability adjusted present values took into account published orphan drug research data and statistics which were adjusted by management to reflect the specific circumstances applicable to the drugs acquired in the Amryt AG transaction. A discount rate of 28.5% was used in the calculation of the fair value of the contingent consideration and this was sense checked by management against the implied rate of return ("IRR") on the project. As noted earlier in the report the size of the market for the products under development provides a real opportunity to the Group to meet its forecast revenue targets and therefore the milestone targets which underpin the contingent consideration payments. At that time management anticipated that AP101 for EB would be ready to launch in 2019. However, management noted that due to issues outside their control (i.e. regulatory requirements and the commercial success of the product) the timing of when such revenue targets may occur may change. Such changes may have a material impact on the assessment of the fair value of the contingent consideration.

It is necessary to review the contingent consideration on a regular basis as the probability adjusted fair values are being unwound as financing expenses in the Statement of Comprehensive Income over the life of the obligation. Contingent consideration is reviewed on a bi-annual basis and is disclosed in the published interim results for the 6 month period to 30 June and the year end results to 31 December.

The total non-cash finance charge recognised in the Statement of Comprehensive Income Statement for the year ended 31 December 2017 is €11,104,000. The Group is currently in the process of amending the protocol for the EASE study and will discuss any significant changes with the FDA and the EMA. These amendments include a modest increase in the size of the study from 164 to 192 patients and a restriction on certain wound types, the ultimate goal of which is to increase the chances of success of the study. These changes will result in a slight delay of the interim analysis which the Group expects will be complete in Q4 2018, with read out of top-line data from the AP101 Phase III study expected in Q2 2019. Consequently, the launch date for EB and PTW has now been delayed to 1 July 2020. Coupled with this, management has completed its annual forecast and revenues have been amended to reflect current expectations. Both these factors have resulted in a change to the probability weighted revenue forecasts and the probability of the adjusted present values which are used in the calculation of the contingent consideration balance and impact the amount being unwound to the Consolidated Statement of Comprehensive Income.

One milestone payment consisted of (i) €5,000,000 once net ex-factory sales of Episalvan have been at least €100,000 or (ii) if no commercial sales are made within 24 months of EMA first marketing approval, €2,000,000 24 months after receipt of such approval and €3,000,000 following the first commercial sale. No commercial sales of Episalvan have been made since EMA first marketing approval. However, if no commercial sales occur, €2,000,000 is due for payment 24 months after the EMA first marketing approval. The Group made this payment of €2,000,000 in January 2018 and does not consider it to be contingent consideration at year end. Consequently, at 31 December 2017 €2,000,000 is included in accruals, thereby reducing the contingent consideration balance at 31 December 2017 from €34,418,000 to €32,418,000.

Assets acquired and liabilities acquired:

	FV of assets acquired

	€'000
Assets	
Intangible assets, in process R&D	48,461
Property, plant and equipment	1,373
Cash and cash equivalents	705
Inventories	687
Trade and other receivables	133
Total assets	**51,359**
Liabilities	
Accounts payable and accrued liabilities	332
Deferred tax liability	5,384
Total liabilities	**5,716**
Total net assets	**45,643**
Consideration	
Issue of fully paid ordinary shares	11,179
Cash consideration	11,150
Contingent consideration	23,314
Total consideration	**45,643**

5 Annual Report and Annual General Meeting ("AGM")

The Annual Report for the year ended 31 December 2017 will be posted to shareholders on 4 May 2018 and will be available to download from the Company's website at www.amrytpharma.com on 4 May 2018.

Notice of the AGM will be posted to shareholders on 4 May 2018.

END

FR EAXLKFDAPEFF