



Amryt Pharma plc

Interim Report June 2018
(Unaudited)

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Chairman & CEO's Statement

Introduction

We are pleased to report on the progress of Amryt Pharma plc and present the unaudited interim financial results for the six-month period ended 30 June 2018. As used herein, references to “we”, “us”, “Amryt” or the “Group” in this unaudited interim report shall mean Amryt Pharma plc and its world-wide subsidiaries, collectively. References to the “Company” in this interim report shall mean Amryt Pharma plc.

Overview

Amryt is a revenue generating pharmaceutical company focused on acquiring, developing and commercialising innovative new treatments for patients affected by rare or orphan diseases where there is high unmet medical need. The Group has built a diverse portfolio of commercial and development stage assets and the Company's ambition is to become a world leader in rare and orphan diseases. Our strategy is focused on three pillars:

- Lojuxta – driving further revenue growth of our lead commercial asset in existing and new territories
- In-licence Opportunities – actively seeking to expand the Group's commercial product portfolio by acquiring further commercial or near commercial assets to leverage our successful Lojuxta business
- Epidermolysis Bullosa (“EB”) Pipeline – developing our lead development asset, AP101, which is in Phase III as a potential treatment for EB as well as progressing our gene therapy technology (AP103) into the clinic

H1 2018 Highlights

2017 was a very strong year for Amryt, marked by excellent financial, operational and strategic progress with our lead commercial product, Lojuxta, and our lead development asset, AP101. The Group has continued to achieve significant milestones in the first half of 2018. Some highlights of the Group's performance over the period are as follows:

- Lojuxta revenues for H1 amounted to €6.6 million, which represents a 14.6% increase on the same period in 2017. The Group saw a 13.6% increase in total revenues to €7.0 million for H1 2018 as compared to €6.2 million for H1 2017
- Significant expansion of the Lojuxta licence territories to include Russia and the Commonwealth of Independent States (“CIS”)
- Eight new Lojuxta distribution agreements signed in H1 2018 (nine signed since November 2017), which together cover 23 countries
- Continued progress of our lead development asset, AP101, currently in a Phase III clinical trial (EASE) which is the largest ever global Phase III study in EB
- New gene therapy platform for EB (AP103) acquired in March 2018 with pre-clinical efficacy data expected in Q4 2018
- Cash at 30 June 2018 was €12.2 million with a €10.0 million undrawn balance on our European Investment Bank (“EIB”) facility as of June 2018. €5.0 million of this undrawn balance was subsequently drawn down in September 2018.

Post Period-End Events & Outlook

- A Paediatric Rare Disease designation was granted by the FDA which means if a New Drug Application ("NDA") for AP101 is approved, Amryt will be eligible to receive a priority review voucher that can be used, sold or transferred. Disclosed sale prices for vouchers have ranged from \$67.5m to \$350m
- An Investigational New Drug ("IND") approval, recently obtained from the FDA, permits the Group to open EASE clinical trial sites in the US which should accelerate enrolment into EASE
- The EASE study is progressing well and we expect the final patient required for the unblinded interim efficacy analysis to be enrolled by the end of September. Accordingly, the unblinded interim efficacy analysis is on track and expected to be completed in late Q4 2018 as planned
- AP103 pre-clinical studies to be concluded in the coming months with initial results expected Q4 2018
- The significant momentum built in Lojuxta revenues in H1 has continued into H2, underpinned by the recent NHS England reimbursement approval and the first orders already being received for patients in the UK & Saudi Arabia, and anticipated growth in distributor markets which will also provide opportunities for continued growth in 2018 and beyond. Forecasted full year revenues are anticipated to be in line with expectations

Operational Update

Lead Commercial Asset - Lojuxta ▼

Lojuxta (lomitapide) is an approved treatment for adult patients with the rare cholesterol disorder - Homozygous Familial Hypercholesterolaemia ("HoFH"). This disorder impairs the body's ability to remove low density lipoprotein ("LDL") cholesterol ("bad" cholesterol) from the blood, typically leading to abnormally high blood LDL cholesterol levels in the body from before birth - often ten times more than people without HoFH - and subsequent aggressive and premature narrowing and blocking of blood vessels, heart attacks and strokes, even at a very young age if not properly diagnosed or receiving adequate treatment. Lojuxta is indicated as an adjunct to a low-fat diet and other lipid-lowering medicinal products with or without LDL apheresis in adult patients with HoFH.

Following the completion of the Lojuxta in-licensing deal in December 2016, Amryt became a commercial pharmaceutical company, generating sales across Europe, the Middle East and other licenced territories. Amryt's Lojuxta business has grown significantly since the product was in-licenced in December 2016. Amryt has been growing its distribution network with eight new distribution agreements in H1 2018.

In May 2018, Amryt signed a licence extension with Novelson to expand significantly its exclusive licence agreement for Lojuxta into Russia and CIS, as well as the non-EU Balkan states and is actively seeking distribution partners in these territories. As part of this agreement Amryt, has formally become the Marketing Authorisation holder for Lojuxta in Europe which has marginally increased the level of royalties payable to Novelson. Amryt estimates there may be up to 450 additional patients who could benefit from treatment with Lojuxta across the countries covered by the extended agreement, representing an increase of approximately 25% in the total number of addressable patients in the Amryt territories. The Company believes the total addressable market opportunity for Lojuxta in its territories to be in excess of €125 million.

Patent extensions for Lojuxta have recently been granted in multiple markets within our territories including France, Germany, Italy and Spain. The Company expects that these extensions will prolong our product patent in these territories through 2028. The Company has also recently received enquiries from physicians to study Lojuxta in an orphan indication called Familial Chylomicronaemia.

Chairman & CEO's Statement

Amryt has agreed to provide the product for an investigator led study which, if successful, would provide important proof of concept data in this indication and may support further studies.

Lojuxta revenues for the six months to 30 June 2018 amounted to €6.6 million which represents a 14.6% increase on the same period in 2017. Our focus on adoption of, and access to, Lojuxta in new and existing territories is already delivering significant returns and we are confident that this positive momentum will continue to grow revenues for the balance of 2018 and beyond. This anticipated full year growth is underpinned by:

- (i) The recent reimbursement decision by NHS England for Lojuxta which has already resulted in the first orders being received; and
- (ii) Amryt's strategy to appoint local distribution partners for new territories which is already resulting in new prescriptions as evidenced by the recent order being received for patients in Saudi Arabia.

Since November 2017, Amryt has agreed nine new distributor relationships, which together cover 23 countries. In November 2017, Amryt signed a distribution agreement with El Seif for the key territory of Saudi Arabia and since then has identified over 100 of the estimated 150 patients eligible to be treated. Recently, the first orders for patients in Saudi Arabia have been received and Amryt expects this significant market to help drive growth in H2 2018 and beyond. In May 2018, Amryt signed distribution agreements with Al Hafez Trading Establishment, which operates in Kuwait, Ebn Sina Medical, the leading medical organisation in Qatar, Muscat Pharmacy and Stores in Oman, and Goro Healthcare of the UAE and Bahrain. In addition, Amryt's distributor for Central and Eastern Europe is seeing good revenue momentum in Austria and Lithuania where the first patients have been initiated.

Future sales growth will be driven by existing markets and from new territories. The Group is actively negotiating the initiation of reimbursement in a number of markets and we are optimistic that some of these discussions will conclude successfully during the course of the second half of 2018. In particular, the Group is expecting a decision from France in the coming weeks. 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 updating the market in due course.

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 (the "EASE" study); 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 January 2016, we received marketing approval for AP101 for the treatment of Partial Thickness Wounds ("PTW") in adults from the European Commission.

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 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.

Chairman & CEO's Statement

Clinical Trials Update

Adult and paediatric patients with EB are currently 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).

Amryt expects the final patient required for the unblinded interim efficacy analysis to be enrolled by the end of September. Accordingly, the unblinded interim efficacy analysis is on track and expected to be completed in late Q4 2018. The unblinded interim efficacy 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 due to futility

Assuming a positive unblinded interim efficacy analysis and no additional patients are added to the study, the Group expects read out of top-line data from the EASE Phase III study in Q2 2019.

The Board believes that the unblinded interim efficacy analysis read out represents a significant milestone for Amryt in EB.

During H1 2018, various non-clinical studies, requested by the FDA as part of an IND filing to open clinical trial sites in the US, have been successfully completed. No safety signals or concerns were noted from the preliminary data and IND approval has recently been received from the FDA. This will enable us to open clinical trial sites in the US, thereby accelerating enrolment of patients into the EASE study. Amryt recently received Paediatric Rare Disease designation from the FDA for AP101, which, pending successful approval of AP101 in EB, will allow the Group apply for a priority review voucher that can be used, sold or transferred. The Board also intends to apply for breakthrough designation following the opening of the IND in the USA. Breakthrough designation would expedite the review by the FDA of AP101 upon completion of the Phase III clinical trial.

Potential Future Indications for AP101

In January 2016, Amryt received marketing approval for AP101 for the treatment of PTW in adults from the European Commission. This followed three positive Phase III studies of 280 patients in Grade II burns and split thickness skin graft donor sites. To date, the Group has not launched in PTW. This approval gives Amryt the option to target PTW indications where there is a high unmet medical need.

Amryt has recently received enquiries from physicians to study AP101 in various PTW indications also with high unmet medical need. In response to this interest from physicians, the Group is evaluating some exciting new life cycle opportunities for AP101.

Dermatological conditions currently under consideration include:

- Severe burns
- Toxic Epidermal Necrolysis Syndrome (TENS)(including Stevens-Johnson Syndrome (SJS))
- Bullous Pemphigoid

Chairman & CEO's Statement

- Pemphigus Vulgaris
- Grade III/IV radiotherapy and chemotherapy induced dermatitis

In addition to the indications studied in the PTW Phase III studies (burns and split thickness skin grafts), the scope of the current European Commission approval for AP101 may offer the opportunity to also launch AP101 in some of these indications in Europe.

In order to maximise the value of this asset and following the EASE trial for AP101 in EB, the Group further intends to file applications for orphan designation for some of these new potential orphan indications in the US, Europe and Japan and believes there is significant scope to maximise the value of the AP101 asset through either a global multi-orphan strategy or via the current EMA marketing approval to secure long-term growth.

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 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. Throughout 2017 and the first half of 2018, the Group initiated various additional pre-clinical studies which are ongoing. However, the Board has decided to focus the Group's resources and is currently prioritising its EB franchise and the growth of our commercial business. The Board may seek to find a partner for AP102 in due course.

AP103 (Gene Therapy in EB)

In March 2018, Amryt concluded an exclusive in-licencing of a novel non-viral platform technology for gene therapy in EB with potential applicability across a range of other genetic disorders. This technology has been exclusively in-licenced from University College Dublin ("UCD") and involves the delivery of gene therapy using High 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 a potentially disease-modifying therapy for patients with Recessive Dystrophic Epidermolysis bullosa ("RDEB"). Patients with RDEB lack collagen VII and pre-clinical data in a xenograft model has shown significant levels of collagen VII in the skin post-therapy. Patients with RDEB lack collagen VII due to a defect in their gene coding for collagen VII. Consequently, the replacement of the collagen VII gene 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 non-viral 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 conclude various confirmatory pre-clinical studies in the coming months and will report the initial results of the studies in Q4 2018.

Imlan

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

Financial Performance

The unaudited results for the current period are those of the Company and its subsidiaries for the six months to 30 June 2018.

Total revenues for the six-month period to 30 June 2018 amounted to €7,020,000, which represents a 13.6% increase on total revenues for the same period in 2017. Lojuxta generated revenues of €6,591,000 and revenues from Imlan, the Group's derma-cosmetics range of products, amounted to €429,000. This compares to total revenues for the 6-month period 30 June 2017 of €6,180,000, with Lojuxta generating revenues of €5,751,000 and Imlan generating revenues of €429,000. Total revenues for the year ended 31 December 2017 amounted to €12,778,000.

Gross margin for the six months to 30 June 2018 was 61.4% compared to 59.3% for the six-month period ended 30 June 2017.

The operating loss before finance expense for the period amounted to €6,497,000 which includes non-cash depreciation and amortisation of €158,000 and non-cash share-based payments of €382,000. This compares to an operating loss before finance expense for the period ended 30 June 2016 of €5,789,000, which includes non-cash depreciation and amortisation of €131,000 and non-cash share-based payment expenses of €312,000. Excluding depreciation, amortisation and share based payment expenses, the operating loss before finance costs for the six-month period to 30 June 2018 would have been €5,957,000 (2017: €5,346,000).

The non-cash change in fair value of contingent consideration which arose as part of the acquisition of Amryt AG in 2016 amounted to €4,154,000 during the period. 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 non-cash financing charge in the statement of comprehensive income over the life of the obligation. This current non-cash financing charge of €4,154,000 reflects the impact of the discount component being unwound to the statement of comprehensive income in H1 2018.

The loss on ordinary activities after the non-cash fair value of contingent consideration amounted to €11,384,000 (2017: €13,826,000).

As of 30 June 2018, the Group had cash on hand of €12.2 million (30 June 2017: €10.9 million). On 2 December 2016, Amryt entered into a five year €20 million debt facility agreement with the EIB. The first tranche of €10 million was drawn down in April 2017. The second tranche of €5 million was drawn down post-period end in September 2018.

The AIM rules on how companies communicate their governance practices have changed and the board recently elected to adopt the ten principles as set out in the Quoted Companies Alliance

Chairman & CEO's Statement

("QCA"). These principles will serve as a framework for communicating our governance practices to shareholders and the wider market. Our website and annual report for the year ended 2018 will set out how we currently comply with the principles of the QCA code.

Outlook

The Board is optimistic about the growth prospects for the Group across all three pillars of our strategy. Lojuxta revenues for the first six months were in line with the Board's expectations for the period and we are very encouraged with the momentum created in the first half of 2018, which continues into the second half. We believe there is a significant opportunity to further grow revenues, particularly given the latent and significant opportunities that exist in the territories we currently cover. This will remain a core focus for us over the coming quarters and beyond.

Our active pipeline, including the Phase III clinical trial EASE for our lead development asset AP101, is progressing well. We expect the final patient required for the unblinded interim efficacy analysis to be enrolled by the end of September. Accordingly, the unblinded interim efficacy analysis is on track and expected to be completed in late Q4 2018 as planned. It is estimated that the addressable market for AP101 is more than €1 billion. In addition, AP103 pre-clinical studies are expected to be concluded in the coming months with initial results anticipated in Q4 2018.

Amryt is actively seeking to expand the Group's commercial product portfolio by in-licensing or acquiring further commercial or near commercial assets to leverage on our successful Lojuxta business, grow our revenues and provide further cashflow to support continued growth.

Forecasted full-year revenues are anticipated to be in line with expectations.

Harry Stratford

Non-executive Chairman

26 September 2018

Joe Wiley

CEO

26 September 2018

Consolidated Statement of Comprehensive Income

For the six months ended 30 June 2018

	Note	Unaudited 6 months to 30 June 2018 €'000	Unaudited 6 months to 30 June 2017 €'000	Audited 12 months to 31 December 2017 €'000
Revenue		7,020	6,180	12,778
Cost of sales		(2,711)	(2,515)	(5,373)
Gross profit		4,309	3,665	7,405
Research and development expenses		(4,240)	(5,359)	(10,564)
Administrative, selling and marketing expenses		(6,184)	(3,783)	(10,483)
Share based payment expenses	3	(382)	(312)	(565)
Operating loss before finance expense		(6,497)	(5,789)	(14,207)
Non-cash change in fair value of contingent consideration	4	(4,154)	(7,706)	(11,104)
Net finance expense		(733)	(331)	(825)
Loss on ordinary activities before taxation		(11,384)	(13,826)	(26,136)
Tax on loss on ordinary activities		—	—	—
Loss for the period attributable to the equity holders of the Company		(11,384)	(13,826)	(26,136)
Exchange translation differences which may be reclassified through the profit and loss		(10)	(5)	22
Total other comprehensive (loss)/ profit		(10)	(5)	22
Total comprehensive loss for the period attributable to the equity holders of the Company		(11,394)	(13,831)	(26,114)
Loss per share:				
Loss per share – basic and diluted, attributable to ordinary equity holders of the parent (cent)	5	(4.14)	(6.64)	(11.72)

Consolidated Statement of Financial Position

As at 30 June 2018

	Note	Unaudited 30 June 2018 €'000	Audited 31 December 2017 €'000
Assets			
Non-current assets			
Intangible assets	6	52,679	52,606
Property, plant and equipment	7	1,055	1,160
Total non-current assets		53,734	53,766
Current assets			
Trade and other receivables		4,539	4,729
Inventories		1,360	1,083
Cash and cash equivalents		12,209	20,512
Total current assets		18,108	26,324
Total assets		71,842	80,090
Equity and liabilities			
Equity attributable to owners of the parent			
Share capital	8	21,173	21,173
Share premium	8	57,334	57,334
Other reserves		(21,162)	(21,512)
Accumulated deficit		(46,493)	(35,109)
Total equity		10,852	21,886
Non-current liabilities			
Contingent consideration	4	36,572	32,418
Long term loan	9	11,045	10,603
Deferred tax liability		5,384	5,384
Total non-current liabilities		53,001	48,405
Current liabilities			
Trade and other payables		7,989	9,799
Total current liabilities		7,989	9,799
Total liabilities		60,990	58,204
Total equity and liabilities		71,842	80,090

Consolidated Statement of Cash Flows
For the six months ended 30 June 2018

		Unaudited	Unaudited	Audited
		6 months to 30 June 2018	6 months to 30 June 2017	12 months to 31 December 2017
	Note	€'000	€'000	€'000
Cash flows from operating activities				
Loss on ordinary activities before taxation		(11,384)	(13,826)	(26,136)
Finance expense		733	331	825
Depreciation and amortisation		158	131	259
Share based payment expense	3	382	312	565
Non-cash change in fair value of contingent consideration	4	4,154	7,706	11,104
Movements in working capital and other adjustments:				
Change in trade and other receivables		190	(1,331)	(2,189)
Change in trade and other payables		116	(380)	6,022
Change in contingent consideration		—	—	(2,000)
Change in inventories		(277)	(215)	(313)
Net cash flow used in operating activities		(5,928)	(7,272)	(11,863)
Cash flow from investing activities				
Payments for property, plant and equipment	7	(34)	(8)	(243)
Payments for intangible assets	6	(91)	—	(87)
Cash inflow on sale of property, plant and equipment		—	5	9
Deposit interest received		5	—	5
Bank charges and interest paid		(300)	—	—
Net cash flow used in investing activities		(420)	(3)	(316)
Cash flow from financing activities				
Acquisition of Amryt AG - milestone payment	4	(2,000)	—	—
Proceeds from issue of equity instruments - net of expenses		—	—	14,393
Long term loan received	9	—	10,000	10,000
Repayment of short-term loan		—	(47)	(47)
Net cash flow from financing activities		(2,000)	9,953	23,346
Exchange and other movements		45	(8)	74
Net change in cash and cash equivalents		(8,303)	2,670	12,241
Cash and cash equivalents at beginning of period		20,512	8,271	8,271
Restricted cash at end of period		—	—	537
Cash at bank available on demand at end of period		12,209	10,941	19,975
Total cash and cash equivalents at end of period		12,209	10,941	20,512

Consolidated Statement of Changes in Equity

For the six months ended 30 June 2018

	Note	Share capital €'000	Share premium €'000	Share based payment reserve €'000	Merger reserve €'000	Reverse acquisition €'000	Exchange translation reserve €'000	Accumulated deficit €'000	Total €'000
Balance at 1 January 2017 (Audited)		20,419	43,695	4,215	35,818	(62,107)	(5)	(8,998)	33,037
Loss for the year		—	—	—	—	—	—	(26,136)	(26,136)
Translation reserve		—	—	—	—	—	27	—	27
Total comprehensive (loss)/ 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 payment expenses		—	—	565	—	—	—	—	565
Share based payment expenses – lapsed		—	—	(25)	—	—	—	25	—
Balance at 31 December 2017 (Audited)		21,173	57,334	4,755	35,818	(62,107)	22	(35,109)	21,886
Balance at 1 January 2018		21,173	57,334	4,755	35,818	(62,107)	22	(35,109)	21,886
Loss for the period		—	—	—	—	—	—	(11,384)	(11,384)
Translation reserve		—	—	—	—	—	(32)	—	(32)
Total comprehensive loss		—	—	—	—	—	(32)	(11,384)	(11,416)
Share based payment expenses	3	—	—	382	—	—	—	—	382
Balance at 30 June 2018 (Unaudited)		21,173	57,334	5,137	35,818	(62,107)	(10)	(46,493)	10,852

Share capital represents the cumulative par value arising upon issue of ordinary shares of 1p each and deferred shares of 29.4p each.

Share premium represents the consideration that has been received in excess of the nominal value on issue of share capital.

Share based payment reserve relates to the charge for share based payments in accordance with International Financial Reporting Standard 2.

The reverse acquisition reserve arose during the period ended 31 December 2016 in respect of the reverse acquisition of Amryt Pharma plc by Amryt Pharmaceuticals DAC (“Amryt DAC”). Since the shareholders of Amryt DAC became the majority shareholders of the enlarged group the acquisition is accounted for as though there is a continuation of Amryt DAC’s Financial Statements. The reverse acquisition reserve is created to maintain the equity structure of Amryt Pharma plc in compliance with UK company law.

The merger reserve was created on the acquisition of Amryt DAC. Consideration on the acquisition included the issuance of shares. Under section 612 of the Companies Act 2006, the premium on these shares has been included in a merger reserve.

The exchange translation reserve was created on the retranslation of non-Euro denominated foreign subsidiaries.

Accumulated deficit represents losses accumulated in previous years and the current period.

Notes to the Interim Results

1. General Information

Amryt Pharma plc 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). As used herein, references to “we”, “us”, “Amryt” or the “Group” in this unaudited interim report shall mean Amryt Pharma plc and its world-wide subsidiaries, collectively. References to the “Company” in this interim report shall mean Amryt Pharma plc.

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.

Following on from its acquisition by the Group in 2016, Birken AG 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.

The unaudited interim results for the six-month period ended 30 June 2018 comprise the Company and its subsidiaries (together the “Group”). The information for the year ended 31 December 2017 contained within the condensed financial statements does not constitute statutory accounts as defined in Section 435 of the Companies Act 2006. The financial statements for the year ended 31 December 2017 have been delivered to the Registrar of Companies and the auditor’s report on those financial statements was unqualified, did not include an emphasis of matter, and did not contain a statement made under Section 498 of the Companies Act 2006.

2. Accounting Policies

Basis of preparation

The interim results have been prepared on the basis of the recognition and measurement requirements of International Financial Reporting Standards (“IFRS”) as adopted by the European Union (“EU”), and their interpretations adopted by the International Accounting Standards Board (“IASB”) as adopted by the EU and with those parts of the Companies Act 2006 applicable to companies reporting under IFRS. As is permitted by the AIM rules the Directors have not adopted the requirements of IAS 34 “Interim Financial Reporting” in preparing the financial statements. Accordingly, the financial statements are not in full compliance with IFRS and have not been audited or reviewed pursuant to guidance issued by the Auditing Practices Board. The accounting policies used in the preparation of the interim financial information are the same as those used in the Group’s audited financial statements for the year ended 31 December 2017 and those which are expected to be used in the financial statements for the year ended 31 December 2018.

The Directors consider that the financial information presented in this Interim Report represents fairly the financial position, operations and cash flows for the period, in conformity with IFRS.

Consolidation

The consolidated financial statements comprise the financial statements of the Company and its subsidiaries. Subsidiaries are entities controlled by the Group. Where the Group has control over an investee, it is classified as a subsidiary. The Group controls an investee if all three of the following elements are present: power over an investee, exposure to variable returns from the investee, and

Notes to the Interim Results

the ability of the investor to use its power to affect those variable returns. Control is reassessed whenever facts and circumstances indicate that there may be a change in any of these elements of control. Subsidiaries are fully consolidated from the date that control commences until the date that control ceases. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group. Intergroup balances and any unrealised gains or losses or income or expenses arising from intergroup transactions are eliminated in preparing the consolidated Financial Statements.

Presentation of Balances

The Financial Statements are presented in Euro ('€') which is the functional and presentational currency of the Group. Balances in the Financial Statements are rounded to the nearest thousand (€'000) except where otherwise indicated.

The following table discloses the major exchange rates of those currencies utilised by the Group:

Foreign currency units to 1 €	US\$	£	CHF	SEK	NOK	DKK
Average period to 30 June 2018	1.2113	0.8809	1.1672	10.1422	9.6526	7.4459
At 30 June 2018	1.1675	0.8769	1.1529	10.2943	9.5437	7.4429
Average year to 31 December 2017	1.1259	0.8715	1.1082	9.6085	9.2979	7.4411
At 31 December 2017	1.1901	0.8813	1.1678	9.8719	9.9537	7.4412
Average period to 30 June 2016	1.1101	0.7698	1.0967	—	—	—
At 30 June 2016	1.1143	0.7626	1.1053	—	—	—

(US\$ = US Dollars; £ = Pounds Sterling, CHF = Swiss Franc, SEK = Swedish Kroner, NOK = Norwegian Kroner, DKK = Danish Kroner)

Critical accounting judgements and key sources of estimation uncertainty

The preparation of financial statements in conformity with IFRS requires management to make judgements, estimates and assumptions that affect the application of policies and amounts reported in the Financial Statements and accompanying notes. The estimates and associated assumptions are based on historical experience and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis of making the judgements about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognised in the period in which the estimate is revised if the revision affects only that period or in the period of the revision and future periods if the revision affects both current and future periods.

Summary of principal accounting policies

The principal accounting policies are summarised below. They have been consistently applied throughout the period covered by the Financial Statements.

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

Notes to the Interim Results

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 from services rendered in the consolidated statement of comprehensive income is recognised in proportion to the stage of completion of the transaction at the reporting date.

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.

Research and Development Expenses

The costs relating to the development of products are accounted for in accordance with IAS 38 "Intangible Assets", where they meet the criteria for capitalization. Research costs are expensed when they are incurred.

The assessment whether development costs can be capitalized requires management to make significant judgements. In management's opinion, the criteria prescribed under IAS 38.57 "Intangible Assets" for capitalising development costs as assets have not yet been met by the Group. Accordingly, all of the Group's costs related to research and development projects are recognised as expenses in the income statement in the period in which they are incurred. Management expects that criteria prescribed under IAS 38.57 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.

Business Combinations

Business combinations are accounted for using the acquisition method. The cost of an acquisition is measured as the aggregate of the consideration transferred, measured at acquisition date fair value and the amount of any non-controlling interest in the acquiree. Fair values are attributed to the identifiable assets and liabilities unless the fair value cannot be measured reliably, in which case the value is subsumed into goodwill. In the consolidated Financial Statements, acquisition costs incurred are expensed and included in general and administrative expenses.

To the extent that settlement of all or any part of the consideration for a business combination is deferred, the fair value of the deferred component is determined through discounting the amounts payable to their present value at the date of the exchange. The discount component is unwound as an interest charge in the consolidated statement of comprehensive income over the life of the obligation. Any contingent consideration is recognised at fair value at the acquisition date and included in the cost of the acquisition. The fair value of contingent consideration at acquisition date is arrived at through discounting the expected payment (based on scenario modelling) to present value. In general, in order for contingent consideration to become payable, pre-defined revenues and/or milestones dates must be exceeded. Subsequent changes to the fair value of the contingent consideration will be recognised in profit or loss unless the contingent consideration is classified as equity, in which case it is not re-measured and settlement is accounted for within equity.

Frequently, the acquisition of pharmaceutical patents and licences is effected through a non-operating corporate structure. As these structures do not represent a business, it is considered that the transactions do not meet the definition of a business combination. Accordingly, the transactions are accounted for as the acquisition of an asset. The net assets acquired are recognised at cost.

Notes to the Interim Results

Acquired Intangibles 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.

Share based payments

The Company issues share options as an incentive to certain senior management and staff. The fair value of options granted is recognised as an expense with a corresponding credit to the share-based payment reserve. The fair value is measured at grant date and spread over the period during which the awards vest.

For equity-settled share-based payment transactions, the goods or services received and the corresponding increase in equity are measured directly at the fair value of the goods or services received, unless that fair value cannot be estimated reliably. If it is not possible to estimate reliably the fair value of the goods or services received, the fair value of the equity instruments granted as calculated using the Black-Scholes model is used as a proxy.

The Company may issue warrants to key consultants, advisers and suppliers in payment or part payment for services or supplies provided to the company. In addition, the Company may grant warrants to subscribers as part of the issue of new ordinary shares in the Company. The fair value of warrants granted is recognised as an expense unless the grant relates to the issue of new ordinary shares in the Company in which case the fair value is recognised in share premium. The corresponding credits are charged to the share-based payment reserve. The fair value is measured at grant date and spread over the period during which the warrants vest. The fair value is measured using the Black-Scholes model if the fair value of the services received cannot be measured reliably.

3. Share-based payments

The Company has issued share options as an incentive to certain senior management and staff. In addition, the Company has issued warrants to equity investors and to key consultants and advisers in payment or part payment for services or supplies provided to the Group.

Each share option and warrant convert into one Ordinary Share of Amryt Pharma plc on exercise and are accounted for as equity-settled share-based payments. The options and warrants may be exercised at any time from the date of vesting to the date of their expiry. The equity instruments granted carry neither rights to dividends nor voting rights.

No share options or warrants were granted in the 6-month period to 30 June 2018. All share options granted in 2016 and 2017 were granted under the terms of the Amryt Share Option Plan and are subject to vesting conditions. No warrants were granted in 2017 and all warrants granted in 2016 were granted under individual agreements as part of the April 2016 share placing. In addition to the share options and warrants granted during 2016 and 2017, a total of 537,280 share options and warrants were in existence at 30 June 2018 that relate to the old oil and gas business.

Notes to the Interim Results

Share options and warrants in issue:

	Share Options		Warrants	
	Units	Weighted average exercise price	Units	Weighted average exercise price
Balance at 1 January 2017	15,795,314	19.8p	23,307,269	25.4p
Granted during the period	3,265,867	18.97p	—	—
Lapsed during the period	(4,993,188)	22.98p	(203,788)	88.0p
Balance at 30 June 2017	14,067,993	18.45p	23,103,481	24.74p
Exercisable at 30 June 2017	2,781,961	21.08p	23,103,481	24.74p
Balance at 1 July 2017	14,067,993	18.45p	23,103,481	24.74p
Granted during the period	5,628,593	20.95p	—	—
Lapsed during the period	—	—	—	—
Balance at 31 December 2017	19,696,586	19.16p	23,103,481	24.74p
Exercisable at 31 December 2017	3,281,961	20.61p	23,103,481	24.74p
Balance at 1 January 2018	19,696,586	19.16p	23,103,481	24.74p
Granted during the period	—	—	—	—
Lapsed during the period	—	—	—	—
Balance at 30 June 2018	19,696,586	19.16p	23,103,481	24.74p
Exercisable at 30 June 2018	6,115,854	19.07p	23,103,481	24.74p

The fair value is estimated at the date of grant using the Black-Scholes pricing model, taking into account the terms and conditions attached to the grant. There were no new share options or warrants granted in the 6 month period to 30 June 2018. The following are the inputs to the model for the equity instruments granted in 2017:

	2018 Options Inputs	2018 Warrant Inputs	2017 Options Inputs	2017 Warrant Inputs
Days to Expiry	—	—	2,555	—
Volatility	—	—	44%-48%	—
Risk free interest rate	—	—	0.42%-0.77%	—
Share price at grant	—	—	18.18p-25.88p	—

The share options outstanding as at 30 June 2018 have a weighted remaining contractual life of 5.44 years with exercise prices ranging from £0.155 to £0.48.

The warrants outstanding as at 30 June 2018 have a weighted remaining contractual life of 0.71 years with exercise prices ranging from £0.24 to £1.12.

The value of share options and warrants charged to the Statement of Comprehensive Income during the period is as follows:

	6 months to 30 June 2018 €'000	6 months to 30 June 2017 €'000	12 months to 31 December 2017 €'000
Share options	382	312	565
Total	382	312	565

4. Business Combinations and Asset Acquisitions

Acquisition of Amryt AG (“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);
- Cash consideration of €150,000, due and paid on the completion date (18 April 2016);
- 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 (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 (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 (EB);
 - €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;
- 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 the date of acquisition 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. 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

Notes to the Interim Results

to 31 December. The total non-cash finance charge recognised in the statement of comprehensive income statement for the period ended 30 June 2018 is €4,154,000.

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. The contingent consideration balance at 30 June 2018 is €36,571,000 (31 December 2017: €32,418,000).

5. Loss per Share – Basic and Diluted

The weighted average number of shares in the loss per share (“LPS”) calculation reflects the weighted average total actual number of shares in issue.

Issued share capital – Ordinary Shares of £0.01 each

	Number of shares	Weighted average shares
1 January 2017	208,339,632	163,336,437
30 June 2017	208,339,632	208,339,632
11 October 2017 - Issue of share by Amryt Pharma plc – share placing	66,477,651	
31 December 2017	274,817,283	223,075,123
30 June 2018	274,817,283	274,817,283

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

	6 months to 30 June 2018	6 months to 30 June 2017	12 months to 31 December 2017
Loss after tax attributable to equity holders of the Company (€'000)	(11,384)	(13,826)	(26,136)
Weighted average number of Ordinary Shares in issue	274,817,283	208,339,632	223,075,123
Fully diluted average number of Ordinary Shares in issue	274,817,283	208,339,632	223,075,123
Basic and diluted loss per share (cent)	(4.14)	(6.64)	(11.72)

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 30 June 2018 totalled 42,800,067 (30 June 2017: 37,430,035) (31 December 2017: 42,800,067) and are potentially dilutive in the future.

Notes to the Interim Results

6. Intangible Assets

	In process R&D	Software	Patents and Licenses	Website development	Total
	€'000	€'000	€'000	€'000	€'000
Cost					
At 1 January 2017	52,515	8	—	—	52,523
Additions	—	—	—	87	87
At 31 December 2017 (audited)	52,515	8	—	87	52,610
At 1 January 2018	52,515	8	—	87	52,610
Additions	—	—	91	—	91
At 30 June 2018 (unaudited)	52,515	8	91	87	52,701
Accumulated amortisation					
At 1 January 2017	—	2	—	—	2
Amortisation charge 2017	—	2	—	—	2
At 31 December 2017 (audited)	—	4	—	—	4
At 1 January 2018	—	4	—	—	4
Amortisation charge 2018	—	1	3	15	19
At 30 June 2018 (unaudited)	—	5	3	15	23
Net book value					
Net book value at 31 December 2017 (audited)	52,515	3	—	87	52,606
Net book value at 30 June 2018 (unaudited)	52,515	4	88	72	52,679

Additions during the period relate to the cost of the licence extension to expand the territories covered under the licence agreement signed with Novelon for our commercial product, Lojuxta.

The Group reviews the carrying amounts of its intangible assets on an annual basis to determine whether there are any indications that those assets have suffered an impairment loss. If any such indications exist, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss. Impairment indications include events causing significant changes in any of the underlying assumptions used in the income approach utilised in valuing in process R&D. These key assumptions are: the probability of success; the discount factor; the timing of future revenue flows; market penetration and peak sales assumptions; and expenditures required to complete development.

Notes to the Interim Results

7. Property, plant and equipment

	Property €'000	Plant and Machinery €'000	Office Equipment €'000	Total €'000
Cost				
1 January 2017	337	801	237	1,375
Additions	—	147	96	243
Disposals	—	(43)	(6)	(49)
At 31 December 2017 (audited)	337	905	327	1,609
At 1 January 2018	337	905	327	1,609
Additions	—	6	28	34
At 30 June 2018 (unaudited)	337	911	355	1,643
Accumulated depreciation				
At 1 January 2017	61	88	43	192
Depreciation charge	87	116	54	257
Depreciation charge on disposals	—	(35)	(5)	(40)
At 31 December 2017 (audited)	148	169	92	449
At 1 January 2018	148	169	92	449
Depreciation charge	44	65	30	139
At 30 June 2018 (unaudited)	192	234	122	588
Net book value				
Net book value at 31 December 2017 (audited)	189	736	235	1,160
Net book value at 30 June 2018 (unaudited)	145	677	233	1,055

8. Share capital – Company

Details of ordinary shares of 1p each issued are in the table below:

Date	Number of ordinary shares	Number of deferred shares	Total Share Capital €'000	Total Share Premium €'000
At 31 December 2016	208,339,632	43,171,134	20,419	43,695
11 October 2017 – Issue of ordinary shares at £0.20p	66,477,651	—	754	13,639
At 31 December 2017 and 30 June 2018	274,817,283	43,171,134	21,173	57,334

On 11 October 2017, 66,477,651 ordinary shares of 1p were issued as part of a €15,083,000 (before expenses) fund raising. Share issue costs amounted to €690,000. Net proceeds amounted to €14,393,000.

9. Long term loan

	30 June 2018 €'000	31 December 2017 €'000
Long term loan	10,000	10,000
Long term loan interest	1,045	603
Long term loan and interest	11,045	10,603

In December 2016, Amryt DAC entered into a €20m facility agreement (“facility”) with the EIB on attractive terms for the Group. The facility is significant because it provides non-dilutive funding that secures the Group's near and mid-term funding needs for its lead product, AP101.

The facility is split into three tranches, with €10 million available immediately and two further tranches of €5 million available upon the achievement of certain milestones. In April 2017, the Group drew down the first tranche of €10 million. In October 2017, the terms of the second tranche of €5 million were amended by the EIB so the Group has the option to draw this amount down any time it wishes. Subsequent to the period end in September 2018 this tranche of €5 million was drawn by the Company. The third tranche is conditional on the primary clinical endpoints for the EASE Phase III clinical trials in the US or EU being achieved and therefore it can be concluded that the Phase III clinical trial has been successfully completed. The facility is secured and there is also a negative pledge whereby Amryt cannot permit any security to be granted over any of its assets over the course of the loan period.

The facility has a five-year term from the date of drawdown for each tranche. The facility has an interest rate of 3% to be paid on an annual basis, with the first instalment paid in April 2018. At 30 June 2018, the Group has short term interest payable accrued amounting to €76,000 (31 December 2017: €227,000) which covers the period from 3 April 2018 to 30 June 2018. This interest will be paid on the second anniversary of the first tranche drawdown, being April 2019.

A further annual fixed rate of 10% is payable together with the outstanding principal amount on expiry of the facility. Long-term interest payable at 30 June 2018 amounted to €1,045,000 (31 December 2017: €603,000) which represents the present value of the long-term interest accrued but not payable until April 2022.

10. Copy of the Interim Report

Copies of the Interim Report are available to download from the Company's website at www.amrytpharma.com

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Joseph Wiley – CEO
Rory Nealon – CFO
James Culverwell - Non-executive Director
Ray Stafford - Non-executive Director
Markus Ziener - Non-executive Director

Company Secretary

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