



Amryt Pharma plc

Interim Report June 2017

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Chairman's Statement

Introduction

We are pleased to report on the progress of Amryt Pharma plc ("Amryt" or the "Company") and present the unaudited interim results for the six-month period ended 30 June 2017.

Overview

Amryt is a 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. The Company is building a diverse portfolio of best-in-class, proprietary new drugs to help address some of these rare and debilitating illnesses where there is significant unmet medical need.

In December 2016 the Company entered into an exclusive licence agreement with Aegerion Pharmaceuticals Inc ("Aegerion") to sell Lojuxta (lomitapide) for adults, across the EU and other territories, including MENA, Turkey and Israel ("Licence Agreement"). Lojuxta is used to treat Homozygous Familial Hypercholesterolemia ("HoFH"), a rare, life-threatening disease that impairs the body's ability to remove low density lipoprotein ("LDL") 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. If left untreated, heart attack or sudden death may occur in childhood or early adulthood.

The Licence Agreement has an initial term until 1 January 2024. On expiry of the initial term, Amryt may, at its discretion, extend the Licence Agreement for a further five years initially, with the right to extend in further five year periods, subject to certain conditions. The key terms of the Licence Agreement are as follows:

- royalty payments to Aegerion, paid quarterly, based on a percentage of net sales during a calendar year. The royalty percentage is 18% of net annual sales less than US\$15,000,000 in a calendar year and 20% of net annual sales more than US\$15,000,000;
- Amryt must make one-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
- Amryt has also taken on the on-going regulatory and post-marketing obligations and commitments in support of Lojuxta including a paediatric study which, subject to success, could open up the market to all HoFH patients

The Company has now established the commercial, medical and regulatory infrastructure required to support the commercialisation of Lojuxta across its licenced territories utilising 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/ in-licensed in the future.

Amryt's lead development drug is AP101, which is being developed as a new treatment for Epidermolysis Bullosa ("EB"). EB is a rare, distressing and painful genetic skin condition that causes the skin layers and internal body linings to separate and is characterised by extreme skin fragility from birth resulting in EB patients suffering from partial thickness wounds ("PTWs"). AP101 uses a betulin-rich extract as its Active Pharmaceutical Ingredient ("API"). The API is believed to act by promoting the differentiation and migration of keratinocytes (skin cells with wound repair capabilities) as well as transiently increasing the level of pro inflammatory mediators (which also promote healing). AP101 has completed three positive Phase III studies, two in the indication of split thickness skin graft donor sites (219 patients) and one in the indication of Grade 2a burn wounds (61 patients), and one positive Phase IIa study (in the indication of EB). All of these wound types are PTWs and the repair mechanism for each of these wound types is believed to be the same.

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AP101 has Orphan Drug Designation as a treatment for EB in both Europe and the US and has in addition already received marketing approval for the treatment of PTWs in adults from the European Commission in January 2016. Of note, EB also causes PTWs. The Company has also secured key patents for AP101 in Europe, the US and Japan with expiry dates in 2030. The Company is currently conducting a Phase III pivotal study in EB which, if successful, could result in Orphan Drug Approval in EB in both the US and Europe.

The Company also has an early stage asset, AP102, that is in development to target Acromegaly and Cushing's disease. AP102 is a novel somatostatin analogue, which could treat patients that are resistant to current therapy, potentially without causing some of the severe side effects associated with these therapies. The Board intends to complete pre-clinical development of AP102 in the second half of 2017, and to seek approval from the regulatory authorities to commence clinical trials in humans in 2018.

Growth of the Business and Future Developments

Since the RTO on 18 April 2016 the Group has made excellent progress. This included advancing its development product candidates, completing the Licensing Agreement for Lojuxta, and securing access to non-dilutive funding from the European Investment Bank ("EIB") of €20 million.

Lojuxta

With the completion in December 2016 of the Lojuxta in-licensing deal, Amryt is now a commercial pharmaceutical company with sales across Europe and the Middle East. Amryt's Lojuxta business has grown significantly in the nine months since the Company entered into the Licence Agreement with sales growing by over 50%. Sales of Lojuxta for the six months ended 30 June 2017 were €5.75 million. This has been achieved through the roll-out of our commercial infrastructure, combining new affiliates together with a number of third party consultants and distributors.

A recent independent study evaluated the benefits of Lojuxta in the treatment of HoFH. The study results have been presented in a paper entitled, "*Efficacy of Lomitapide in the Treatment of Familial Homozygous Hypercholesterolemia: Results of a Real-World Clinical Experience in Italy*", and published by Advances in Therapy, an international, peer-reviewed journal. This real-world study has shown Lojuxta to be a very powerful and well tolerated LDL cholesterol-lowering agent in patients with HoFH and proved that some patients using Lojuxta were able to stop apheresis and still achieve LDL cholesterol target levels. Prior to treatment, some of these patients had LDL cholesterol levels up to eight times the recommended level.

An additional study, published in July 2017 and titled "*Long-Term Efficacy and Safety of the Microsomal Triglyceride Transfer Protein Inhibitor Lomitapide in Patients With Homozygous Familial Hypercholesterolemia*", evaluated the benefits of Lojuxta over the long term. Following patients for up to 5.7 years, it showed that Lojuxta is highly effective at lowering LDL cholesterol levels with acceptable tolerability and no new safety signals.

The Board estimates that the annual market for HoFH in our territory of the EU, MENA, Israel and Turkey is approximately €100 million, providing the opportunity for significant on-going growth from our current base. The Company is currently actively focused on targeting new markets within these licensed territories and the Board is optimistic that Amryt will secure reimbursement of Lojuxta in some of these additional new markets in 2018.

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AP101

The Company has continued to make good progress in developing its lead product AP101 as a new treatment for EB. In February 2017 Amryt was granted a patent in Japan for AP101. On 6 March 2017 Amryt completed its discussions with both the FDA and EMA regarding the design of its pivotal Phase III clinical trial for AP101. Subsequently, on 27 March 2017, the Company 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. A total of 164 evaluable patients across approximately 32 sites in 15 countries will be treated for a 90-day blinded period. 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).

As part of the approved protocol for the study, an independent data monitoring committee will conduct an un-blinded interim efficacy analysis after 50% enrolment. The potential outcomes of this interim analysis include continuation of the study unchanged, discontinuation of the study for futility, or an increase in the number of patients in the study to preserve adequate statistical power. The study has been powered to provide an 80% chance of success based on various assumptions. If the decision at the interim analysis is to continue the study, the ability to increase the number of patients at that time enables the Company to maintain an 80% chance of success in the event that the placebo rates and/or efficacy rates seen in the study vary from the initial assumptions used.

The first patient was enrolled to EASE in April 2017 and the interim analysis readout is expected in the first half of 2018 with top-line data expected in the second half of 2018. We believe that the market for AP101 as a treatment for EB is greater than €1.3 billion worldwide.

In addition, the Company secured a patent in Japan in the period for AP101.

AP102

Amryt is currently conducting various AP102 pre-clinical studies in advance of seeking approval from the relevant regulatory authorities to commence studies in humans in 2018. The Company expects to complete these pre-clinical studies in Q4 2017 and to commence first in human studies in 2018, followed by a proof of concept study that, if positive, could demonstrate the potential for AP102 to become a best-in-class treatment for acromegaly patients.

Financial Performance

The results for the current period are those of the Group for the six months to 30 June 2017.

The results for the year end 31 December 2016 combine those of Amryt DAC for the period from 1 January 2016 to 18 April 2016 and those of the enlarged group for the period from 19 April 2016 to 31 December 2016, which includes the reverse takeover of Fastnet Equity plc and acquisitions of Birken and SOM ("RTO").

The Group's financial results for the half year are ahead of the Board's expectations.

Total revenues for the period amounted to €6,180,000. Lojuxta generated revenues of €5,751,000 and revenues from Imlan, the Company's derma-cosmetics range of products, amounted to €429,000. This compares to total revenues for the period from the completion of the RTO on 18 April 2016 to 31 December 2016 of €1,351,000. In the period ended 31 December 2016 Lojuxta generated revenues of €775,000 and Imlan generated revenues of €576,000. Gross margin for the six months to 30 June 2017 was 59.3% compared to 56.6% for the year ended 31 December 2016.

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The operating loss before finance expense for the period amounted to €5,789,000 which includes non-cash depreciation and amortisation of €131,000 and non-cash share based payments of €312,000. This compares to an operating loss before finance expense for the year ended 31 December 2016 of €7,683,000.

The loss on ordinary activities of €13,826,000 includes €7,706,000 relating to a non-cash movement on contingent consideration which arose as part of the acquisition of Birken 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 non-cash financing charge in the statement of comprehensive income over the life of the obligation. The loss before interest, tax, depreciation and amortisation for the period excluding non-cash financing costs and non-cash share based payments is €5,346,000. The loss on ordinary activities for the year ended 31 December 2016 was €7,804,000. The loss before interest, tax, depreciation and amortisation for 2016 excluding all reverse takeover and acquisition related costs, non-cash financing costs and non-cash share based payments was €5,422,000.

As at 30 June 2017, the Company had cash on hand of €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 on 3 April 2017.

Senior Management and Board Change

The Company is led by an experienced senior management team which has been enhanced further in recent months by the appointment of a number of senior managers.

In March 2017, we appointed David Allmond as Chief Commercial Officer. David has over 20 years' experience in the pharmaceutical industry in commercial roles. He joins the Company from Aegerion where he was President of EMEA and, in particular, involved in the commercialisation of Lojuxta (lomitapide). 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.

The Company also recently appointed Kieran Rooney, Ph.D., as Vice President of Strategic Alliances and Licensing. 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.

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 instrumental to the RTO of Fastnet Equity plc and creation of Amryt in April 2016. We would like to thank him for his important contribution to the business and his guidance during our first year as a public company.

Outlook

The Company achieved significant milestones during the first six months of 2017 and we remain confident of continuing material progress over the remainder of 2017 and into 2018.

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We are very positive about the growth prospects for our Lojuxta business. Revenues for the first six months 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 product AP101 has commenced. The results of our interim analysis on EASE are due in the first half of 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 topline data in the second half of 2018.

During the second half of the current financial year, we expect to complete our pre-clinical assessment of AP102, our potential treatment for acromegaly. We then intend to seek approval from the regulatory authorities to commence clinical trials in humans in 2018.

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

4 September 2017

Consolidated Statement of Comprehensive Income

For the six months ended 30 June 2017

	Note	Unaudited 6 months to 30 June 2017 €'000	Unaudited 6 months to 30 June 2016 €'000	Audited 12 months to 31 December 2016 €'000
Revenue		6,180	161	1,351
Cost of sales		(2,515)	(94)	(586)
Gross profit		3,665	67	765
Research and development expenses		(5,359)	(597)	(2,344)
Administrative, selling and marketing expenses		(3,783)	(1,560)	(4,037)
Reverse takeover and acquisition costs	4	—	(867)	(867)
Non-cash deemed cost of reverse takeover	4	—	(971)	(971)
Share based payment expenses	7	(312)	(71)	(229)
Operating loss before finance expense		(5,789)	(3,999)	(7,683)
Non-cash financing cost on contingent consideration	4	(7,706)	—	—
Net finance expense		(331)	(115)	(121)
Loss on ordinary activities before taxation		(13,826)	(4,114)	(7,804)
Tax on loss on ordinary activities		—	—	—
Loss for the period attributable to the equity holders of the Company		(13,826)	(4,114)	(7,804)
Other comprehensive loss attributable to the equity holders of the Company				
Exchange translation differences which may be reclassified through the profit and loss account		(5)	(2)	(5)
Total other comprehensive loss		(5)	(2)	(5)
Total comprehensive loss for the period attributable to the equity holders of the Company		(13,831)	(4,116)	(7,809)
Loss per share:				
Loss per share – basic and diluted, attributable to ordinary equity holders of the parent (cent)	3	(6.64)	(3.48)	(4.78)

Consolidated Statement of Financial Position

As at 30 June 2017

	Note	Unaudited 30 June 2017 €'000	Audited 31 December 2016 €'000
Assets			
Non-current assets			
Intangible assets	4	52,520	52,521
Property, plant and equipment	5	1,061	1,183
Total non-current assets		53,581	53,704
Current assets			
Trade and other receivables		4,917	2,540
Inventories		985	770
Cash and cash equivalents		10,941	8,271
Total current assets		16,843	11,581
Total assets		70,424	65,285
Equity and liabilities			
Equity attributable to owners of the parent			
Share capital	6	20,419	20,419
Share premium	6	43,695	43,695
Other reserves		(21,772)	(22,079)
Retained deficit		(22,824)	(8,998)
Total equity		19,518	33,037
Non-current liabilities			
Contingent consideration	4	31,020	23,314
Long term loan	8	10,250	—
Deferred tax liability		5,384	5,384
Total non-current liabilities		46,654	28,698
Current liabilities			
Trade and other payables		4,252	3,550
Total current liabilities		4,252	3,550
Total liabilities		50,906	32,248
Total equity and liabilities		70,424	65,285

Consolidated Statement of Cash Flows

For the six months ended 30 June 2017

	Unaudited 6 months to 30 June 2017	Unaudited 6 months to 30 June 2016	Audited 12 months to 31 December 2016
	Note	€'000	€'000
Cash flows from operating activities			
Loss on ordinary activities before taxation		(13,826)	(4,114) (7,804)
Net finance expense		331	115 121
Depreciation and amortisation		131	519 194
Share based payment expense	7	312	71 229
Non-cash deemed cost of reverse takeover	4	—	971 971
Non-cash financing cost on contingent consideration		7,706	— —
Movements in working capital and other adjustments:			
Change in trade and other receivables		(1,331)	6 (1,975)
Change in trade and other payables		(380)	(491) 2,236
Change in inventories		(215)	79 (83)
Net cash flow used in operating activities		(7,272)	(2,844) (6,111)
Cash flow from investing activities			
Cash consideration on acquisition of Birken AG	4	—	(10,150) (10,150)
Cash consideration on acquisition of SOM		—	— (89)
Cash inflow on acquisition of Birken AG	4	—	705 705
Cash inflow on reverse takeover of Fastnet Equity plc		—	11,993 11,993
Payments for property, plant and equipment	5	(8)	(11) (12)
Cash inflow on sale of property, plant and equipment		5	— 10
Deposit interest received		—	1 1
Net cash flow (used in)/from investing activities		(3)	2,538 2,458
Cash flow from financing activities			
Proceeds from issue of equity instruments - net of expenses		—	11,251 11,251
Issue of convertible debenture securities		—	545 545
Long term loans received	8	10,000	— —
Repayment of short term loans		(47)	— (47)
Net cash flow from financing activities		9,953	11,796 11,749
Exchange movements		(8)	7 4
Net change in cash and cash equivalents		2,670	11,497 8,100
Cash and cash equivalents at beginning of period		8,271	171 171
Cash and cash equivalents at end of period		10,941	11,668 8,271

Consolidated Statement of Changes in Equity

For the six months ended 30 June 2017

	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 2016 (Audited)		1	—	—	—	—	—	(1,194)	(1,193)
Loss for the year		—	—	—	—	—	—	(7,804)	(7,804)
Translation reserve		—	—	—	—	—	(5)	—	(5)
Total comprehensive income		—	—	—	—	—	(5)	(7,804)	(7,809)
Issue of shares by Amryt DAC on acquisition of Birken		—	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 (Audited)		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 period		—	—	—	—	—	—	(13,826)	(13,826)
Translation reserve		—	—	—	—	—	(5)	—	(5)
Total comprehensive income		—	—	—	—	—	(5)	(13,826)	(13,831)
Share based payments	7	—	—	312	—	—	—	—	312
Balance at 30 June 2017 (Unaudited)		20,419	43,695	4,527	35,818	(62,107)	(10)	(22,824)	19,518

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 (“**Amryt**” or 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 section 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 specialty biopharmaceutical company focused on the development and commercialisation of new medicines for rare conditions with unmet needs and is committed to bring new hope to people affected by these rare diseases.

The interim results of the Company for the six-month period ended 30 June 2017 comprise the Company and its subsidiaries (together the “**Group**”). The information for the year ended 31 December 2016 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 2016 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. 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 neither been audited nor 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 Company’s audited financial statements for the year ended 31 December 2016 and those which are expected to be used in the 31 December 2017 year-end financial statements.

The financial information for the six months ended 30 June 2017 is unaudited. 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.

Comparative Information

On 18 April 2016 Fastnet Equity plc (“Fastnet”) became the legal parent company of Amryt Pharmaceuticals DAC (“Amryt DAC”) in a share for share transaction, and on the same date changed its name from Fastnet to Amryt Pharma plc (“Amryt”). On the same date Amryt DAC completed the acquisitions of Birken AG (“Birken”) and SomPharmaceuticals (“SOM”). The acquisition of Birken by Amryt DAC constitutes a business combination. Due to the relative size of Amryt DAC and Fastnet, Amryt DAC’s shareholders became the majority shareholders of the enlarged share capital (before a share placing on the same date). In addition, the Company’s continuing operations and executive management became those of Amryt DAC. Management considers that the acquisition constituted a reverse acquisition of Fastnet by Amryt DAC. It would normally be necessary for the Company’s consolidated accounts to follow the legal form of the business combination – with Amryt DAC’s results from the acquisition date of 18 April 2016 consolidated into the Group results. However, as a result of the transaction being accounted for as a reverse acquisition in this case the consolidated accounts for

Notes to the Interim Results

the year ended 31 December 2016 have been treated as being a continuation of the accounts of Amryt DAC with Fastnet being treated for accounting purposes as the acquired entity.

As the consolidated group results for the year ended 31 December 2016 represent a continuation of the financial statements of the legal subsidiary (Amryt DAC), the assets and liabilities of Amryt DAC have been recognised and measured in the consolidated results at their pre-combination carrying amounts. The accumulated deficit and other equity balances recognised are the accumulated deficit and other equity balances of Amryt DAC immediately before the business combination and the amount recognised as issued equity instruments has been determined by adding to the issued equity of Amryt DAC immediately before the business combination the cost of the combination, being the value of notional shares issued by Amryt DAC. To comply with UK company law, adjustments have been made to the consolidated reserves to reflect the equity structure of the legal parent company, Amryt Pharma Plc.

The interim results for the period to 30 June 2016 are presented in these financial statements. However some changes were made to these numbers to reflect the updated position as reflected in the financial statements for the year ended 31 December 2016. Reverse takeover and acquisition costs changed from €887,000 for the 6 month period to June 2016 to €867,000 and proceeds from the issue of equity instruments- net of expenses changed from €11,250,000 to €11,251,000.

Summary of Significant Accounting Policies

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 Company. Accordingly, all of the Company’s costs related to research and development projects are recognised as expenses in the income statement in the period in which they are incurred.

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. In the consolidated Financial Statements, acquisition costs incurred are expensed and included in general and administrative expenses.

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.

Acquired Intangibles Assets

Acquired intangible assets 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 and are tested for impairment annually. 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.

Notes to the Interim Results

Share based payments

The Group 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 Group may issue warrants to key consultants, advisers and suppliers in payment or part payment for services or supplies provided to the Group. 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. Loss per Share – Basic and Diluted

For the period ended 30 June 2016, the weighted average number of shares in the loss per share ("LPS") calculation represents the actual number of shares in issue. For the year ended 31 December 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	55,683,886
18 April 2016 - Issue of shares by Amryt DAC on acquisition of Birken	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	7,503,786	
19 April 2016 - Issue of share by Amryt Pharma plc – share consolidation	43,171,134	
19 April 2016 - Issue of share by Amryt Pharma plc – share placing	41,673,402	
30 June 2016	208,338,632	118,346,111
31 December 2016	208,338,632	163,339,632
30 June 2017	208,339,632	208,339,632

Notes to the Interim Results

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

	6 months to 30 June 2017	6 months to 30 June 2016	12 months to 31 December 2016
Loss after tax attributable to equity holders of the parent (€'000)	(13,826)	(4,114)	(7,804)
Weighted average number of Ordinary Shares in issue	208,339,632	118,346,111	163,336,437
Fully diluted average number of Ordinary Shares in issue	208,339,632	118,346,111	163,336,437
Basic and diluted loss per share (cent)	(6.64)	(3.48)	(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 30 June 2017 totalled 37,430,035 (30 June 2016: 30,289,331) (31 December 2016: 39,102,583) and are potentially dilutive in the future.

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 Birken AG ("Birken") 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.

The value of these notional shares issued by Amryt DAC was compared to the Net Asset value of Fastnet on the date of acquisition and the excess (€971,000) was charged to the Statement of Comprehensive Income in 2016 as a deemed share based payment cost of the business combination.

In addition, €867,000 in professional fees was charged to the Statement of Comprehensive in 2016 as part of the costs associated with the reverse acquisition and acquisition of Birken and SOM. These costs include legal, due diligence, accounting and tax advisory and corporate finance.

Notes to the Interim Results

Acquisition of Birken

Amryt DAC signed a conditional share purchase agreement to acquire Birken on 16 October 2015 ("Birken SPA"). The Birken SPA was completed on 18 April 2016 with Amryt DAC acquiring the entire issued share capital of Birken. 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 AP101, paid on the completion date (18 April 2016);
 - Either (i) €5,000,000 once net ex-factory sales of AP101 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 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 AP101 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 Birken 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 Birken 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 Company to meet its forecast revenue targets and therefore the milestone targets which underpin the contingent consideration payments. At present management anticipate that AP101 for EB will be ready to launch in 2019. However, management note 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. The first review of the contingent consideration was completed for the period from April 2016 to 30 June 2017 resulting in a non-cash finance cost of €7,706,000, increasing the initial estimate of €23,314,000 to €31,020,000. This adjustment arises as a result of timing because the probability of the adjusted present values now reflect the 18 month periods since the initial calculation of the contingent consideration in April 2016. The company will continue to adjust the value of the contingent consideration over the life of the obligation.

Notes to the Interim Results

Final & Provisional Fair Value Measurement of Assets Acquired

A fair value exercise was performed on the identifiable assets and liabilities of Birken AG as at the acquisition date and again 12 months after the acquisition date an income based approach was used to value the intangible assets acquired. Key assumptions of the approach include the probability of success, the discount factor applied, the timing of future revenue flows, market penetration and peak sales and expenditure required to complete development.

Assets acquired and liabilities acquired:

	Final & Provisional FV of assets acquired €'000
Assets	
Intangible assets	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

SOM Acquisition

Amryt DAC entered into conditional stock purchase agreements to acquire SomPharmaceuticals SA and SomTherapeutics, Corp on 15 December 2015 and 4 December 2015 respectively ("Som SPAs"). The aggregate consideration payable under the Som SPAs was US\$4.25 million which was satisfied by the issue of US\$4.15 million in new ordinary shares in Amryt DAC and US\$100,000 (€89,000) in cash to the shareholders of SOM. The SOM SPAs were completed on 18 April 2016. The SOM sellers received 12,277,102 of Consideration Shares for their shareholding in Amryt DAC. The acquisition of SOM has been treated for accounting purposes as an asset acquisition with the value of the consideration issued, €4,062,000, recognised as an Intangible Asset.

Amortisation during the period

The Company acquired Intangible Assets with a fair value of €52,523,000 (Birken acquired intangible Assets: €48,461,000, SOM Acquired Intangible Assets: €4,062,000). During the current period an amortisation charge arising on the acquisition of software of €1,000 (2016: €2,000) has been included in the statement of comprehensive income.

Notes to the Interim Results

5. Property, plant and equipment

	Property €'000	Plant and Machinery €'000	Office Equipment €'000	Total €'000
Cost				
1 January 2016	—	—	—	—
Additions	—	—	12	12
Disposals	—	(10)	—	(10)
Acquired on acquisition of Birken AG	337	811	225	1,373
At 31 December 2016 (Audited)	337	801	237	1,375
At 1 January 2017	337	801	237	1,375
Additions	—	—	8	8
Disposals	—	—	(5)	(5)
At 30 June 2017 (Unaudited)	337	801	240	1,378
Accumulated depreciation				
At 1 January 2016	—	—	—	—
Depreciation charge	61	88	43	192
At 31 December 2016 (Audited)	61	88	43	192
At 1 January 2017	61	88	43	192
Depreciation charge	44	60	26	130
Depreciation on disposals	—	—	(5)	(5)
At 30 June 2017 (Unaudited)	105	148	64	317
Net book value at 31 December 2016	276	713	194	1,183
Net book value at 30 June 2017	232	653	176	1,061

6. 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 2015	43,171,134	—	18,336	35,221
19 April 2016 – Share consolidation	(43,171,134)	—	(18,336)	—
19 April 2016 – Issue of new ordinary share on share consolidation	43,171,134	—	603	—
19 April 2016 - Creation of deferred shares on share consolidation	—	43,171,134	17,733	—
19 April 2016 - Issue of ordinary shares at £0.24p on acquisition of Amryt Pharmaceuticals DAC	123,495,096	—	1,557	—
19 April 2016 – Issue of ordinary shares at £0.24p	41,673,402	—	526	8,474
At 30 June 2016, 31 December 2016 and 30 June 2017	208,339,632	43,171,134	20,419	43,695

On 19 April 2016, every 8 ordinary shares of par value 3.8p in the Company at close of business on 18 April 2016 (total shares 345,369,071) became 1 new ordinary share of par value 1p (total shares 43,171,134) and 1 deferred share of par value 29.4p (total shares 43,171,134). The rights attaching to the new ordinary shares of 1p are identical in all respects to those of the old ordinary shares of 3.8p.

Notes to the Interim Results

The deferred shares created are effectively valueless as they do not carry any rights to vote or dividend rights. In addition, holders of deferred shares are only entitled to a payment on a return of capital or on a winding up of the Company after each of the holders of ordinary shares of 1p each have received a payment of £10,000,000 on each such share. The deferred shares are not and will not be listed or traded on the Official List, AIM, the ESM or any other investment exchange and are only transferable in limited circumstances.

On 19 April 2016, 123,495,096 ordinary shares of 1p were issued as part of the completion of the acquisition of Amryt Pharmaceuticals DAC by the Company. Under section 612 of the Companies Act 2006, the premium on these shares has been included in the merger reserve.

On 19 April 2016, 41,673,402 ordinary shares of 1p were issued at 24p per share as part of a £10,000,000 (before expenses) fund raising.

7. 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 key consultants and advisers in payment or part payment for services or supplies provided to the Group. All share options granted during the period were granted under the terms of the Amryt Share Option Plan and are subject to vesting conditions. No warrants were granted in the 6 month period to 30 June 2017. 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 2017 that relate to the old oil and gas business.

Each share option and warrant converts 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.

Share options and warrants in issue:

	Share Options ¹		Warrants ¹	
	Units	Weighted average exercise price	Units	Weighted average exercise price
Balance at 1 January 2016	815,954	84.0p	491,512	102.4p
Granted during the period	6,071,914	22.10	22,909,951	24.0p
Balance at 30 June 2016	6,887,868	29.4p	23,401,463	25.6p
Exercisable at 30 June 2016	815,954	84.0p	21,328,208	25.8p
Balance at 1 July 2016	6,887,868	29.4p	23,401,463	25.6p
Granted during the period	9,379,650	17.2p	—	—
Lapsed during the period	(472,204)	110.0p	(94,194)	112.0p
Balance at 31 December 2016	15,795,314	19.8p	23,307,269	25.3p
Exercisable at 31 December 2016	343,750	48.0p	21,234,014	25.4p
Balance at 1 January 2017	15,795,314	19.8p	23,307,269	25.3p
Granted during the period	3,308,683	18.96p	—	—
Lapsed during the year	(4,777,443)	23.20p	(203,788)	88.0p
Balance at 30 June 2017	14,326,554	18.44p	23,103,481	24.7p
Exercisable at 30 June 2017	2,674,089	20.82p	21,030,336	24.8p

Notes to the Interim Results

¹ Following the 19 April 2016 share consolidation, as described in note 6, all existing rights attached to share options and warrants were amended to reflect the new share structure. The rights are now over Amryt Pharma plc new ordinary shares of 1p, with the original units divided by a factor of 8 and the original exercise price increased by a factor of 8. The pre 19 April 2016 numbers included in the table above have been adjusted to take into account the share consolidation.

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. The following are the inputs to the model for the equity instruments granted during the period:

Options Inputs	
Days to Expiry	2,555
Volatility	44%-48%
Risk free interest rate	0.42%- 0.67%
Share price at grant	18.18p-25.88p

During the current period a total of 3,308,683 share options exercisable at a weighted average price of £0.1896 were granted. The fair value of share options granted during the period is €1,941,000. The share options outstanding as at 30 June 2017 have a weighted remaining contractual life of 6.10 years with exercise prices ranging from £0.155 to £0.48.

The warrants outstanding as at 30 June 2017 have a weighted remaining contractual life of 1.71 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 2017 €'000	6 months to 30 June 2016 €'000	12 months to 31 December 2016 €'000	
	Share options	312	71	229
	Total	312	71	229

In addition to the above charges, a further €2,251,000 was charged to share premium in 2016.

8. Long term loan

In December 2016, the Group entered into a €20,000,000 facility agreement with the European Investment bank ("EIB"). The facility is significant because it provides non-dilutive funding that secures the Company's near and mid-term funding needs for its lead product, AP101. It also provides the funding required to progress the Company's acromegaly drug compound, AP102, through pre-clinical development and into the clinic. At 30 June 2017, the Group has drawn-down €10,000,000 of the available facility from the EIB. Total Interest accrued at 30 June 2017 amounted to €325,000, of which €250,000 is due for payment at the end of the loan period. The remaining interest accrued of €75,000 is included in trade and other payables and is repayable on an annual basis. A condition of this facility from the EIB required the Company to grant security over the intellectual property assets of the Company and also to grant a negative pledge to the EIB over its assets.

9. 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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Rory Nealon – CFO/COO
James Culverwell - Non-executive Director
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