Shard Capital RESEARCH

Pharmaceuticals & Biotech

Amryt Pharma

Building a Specialty Pharma business

Amryt Pharma was established as a platform to acquire, build, develop and commercialise a range of drugs targeted at niche, orphan diseases, thereby creating a Specialty Pharmaceutical business. The company has acquired two companies which have brought in two products, one with European regulatory approval, which it is looking to expand into more indications. The company is led by a strong management team with considerable pharmaceutical experience. Amryt has a market capitalisation of £50m which compares very favourably with peers developing similar orphan assets, suggesting there is solid upside potential.

- **Strategy**: Management aims to acquire and develop more orphan drug assets that target significant commercial opportunities to create a Specialty Pharma company. The acquisitions of Birken and Som are the first steps in delivering this strategy and others are likely to follow as and when appropriate.

- **Products:** On Admission, Amryt had two drug assets. Episalvan (from Birken) is a relatively de-risked asset targeted at a rare childhood disease that causes severe skin conditions, and a market opportunity of $1,370m. AP102 (from Som) is focused on acromegaly/Cushing's disease, a $1.2bn market.

- **Valuation:** Amryt has an EV of £39.1m compared to six quoted peers trading on a range of £48m (Phase 1 assets) to £1,608m (Phase III), suggesting that there is considerable upside potential in Amryt's Phase II/III assets. This is also borne out by M&A activity for similar assets, in the range $97-842m.

- **Risks:** As with all drug companies, the main risk is that a product fails in clinical trials. However, Amryt's lead drug Episalvan already has EU regulatory approval which makes it largely de-risked. Rising cash burn on R&D investment will require further capital, some of which could come from licensing partners.

- **Investment summary:** The traditional pharmaceutical model of developing and commercialising new drugs that target very large patient populations is being superseded by the model that targets orphan diseases – rare conditions in less than 200k patients. Amryt is in this latter category. Specialty pharma companies are interesting in their own right and are also attractive to bigger players. The EV leaves plenty of scope for upside compared to quoted peers.

Financial summary and valuation

Year end Dec (€m)	2014	2015E	*2016E	2017E
Sales	0.88	0.93	0.9	0.9
R&D spend	-	-	-1.0	-4.0
Underlying EBIT			-5.5	-8.5
Reported EBIT			-7.0	-8.5
Underlying PTP			-5.4	-8.5
Statutory PTP			-6.9	-8.5
Underlying EPS (p)			-3.5	-4.1
Statutory EPS (p)			-4.4	-4.1
Net (debt)/cash			9.5	1.0
Capital increase	-	-	13.0	0
P/E (x)	-	-	-	-
EV/sales (x)	-	-	-	-

Pro-forma; Source: Hardman & Co Life Sciences Research

Source: Fidessa

Market data

EPIC/TKR	AMYT
Price (p)	24.0
12m High (p)	-
12m Low (p)	-
Shares (m)	208.3
Mkt Cap (£m)	50.0
EV (£m)	39.1
Free Float*	39%
Market	AIM

**As defined by AIM Rule 26*

Description

Amryt was incorporated in 2015 as a platform to acquire, build, develop and commercialise pharmaceutical assets targeted at orphan diseases. Its lead candidate Episalvan is focused on the treatment of a rare skin condition called *Epidermolysis Bullosa.*

Company information

CEO	Joe Wiley
CFO	Rory Nealon
Chairman	Harry Stratford

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www.amrytpharma.com

Key shareholders

Concert Party	40.1%
Software AG (Birken)	20.9%
AXA Framlington	9.9%
Alan Harris (Som)	4.2%
(Directors*	31.5%)

**Mostly included in concert party*

Next event

19 April	Admission
Jun-16	FY 2015 results
Jun-16	AGM
Sep-16	Interims
Mch-17	FY 2016 results

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Evolution of Amryt Pharma

Amryt Pharmaceuticals was incorporated in August 2015 as a vehicle to identify, acquire, develop and commercialise pharmaceutical assets. During its first eight months, it has acquired a German pharmaceuticals business, Birken AG, and a Swiss-based company, SomPharmaceuticals SA, both of which satisfy the management strategy to acquire assets that are directed towards rare medical conditions – Orphan Drugs – thereby creating, over time, a Specialty Pharmaceutical business. Fastnet Equity was a quoted non-trading cash shell with a strategy to identify and acquire pharmaceutical assets, and through its common shareholder base was well-known to Amryt. Therefore, Amryt has reversed into Fastnet to create an entity that has allowed closure of these deals, and the enlarged entity has been renamed Amryt Pharma which will trade on AIM under the ticker AMYT.

Reversing into Fastnet Equity

Target	Consideration
Acquisition of Amryt Pharmaceuticals	Shares
Acquisition of Birken AG	Cash & shares
Acquisition of SomPharmaceuticals SA	Cash (small) & shares

Source: Fastnet Equity Admission document; Hardman & Co Life Sciences Research

Birken AG

Birken was founded in 2000 and has, to date received €54m of investment for the clinical development of products using the active ingredient, betulin. To date, the company has developed and launched a skin emollient, Imlan, and received EU regulatory approval for Episalvan for the treatment of partial thickness wounds (PTW). The core consideration for these assets is €22.0m/£17.7m.

- €1.0m on signature, plus €10m on first regulatory approval of lead product Episalvan – this €11m up-front has been paid already by Amryt
- Shares equivalent to 30% of the fully diluted enlarged capital of the new group (before the Placing), valued at €11.0m/£8.9m at the price of Admission (24p)
- €5.0m milestone on launch of Episalvan – or €2.0m in Jan 2018 in the event that Amryt decides not to launch the product
- €35.0m stepped milestones based on defined future sales levels
- 9% royalty on Episalvan sales (only 6% on other betulin (active ingredient) products)

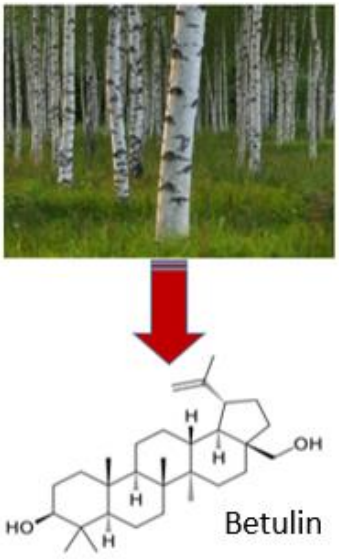
SomPharmaceuticals SA

Som was originally incorporated as Somtherapeutics Inc in 1999, focused on identifying and developing novel somatostatin analogues for the treatment of rare neuroendocrine disorders that result in either over-production or under-production of key hormones released from the pituitary gland. For example, over-production of growth hormone which leads to acromegaly; and over-production of adrenocorticotropic hormone which causes Cushing's disease. Over time, Somtherapeutics Inc, together with its sister company SomPharmaceuticals, has become a Swiss-based group. The consideration for Som was a modest cash payment of €100k plus new ordinary shares in Amryt Pharma.

- US$4.15m payable in new ordinary shares (12.28m) in Amryt

Episalvan

Source of Episalvan



Source: Hardman & Co Life Sciences Research

Episalvan is the leading product in Birken's pipeline having received approval from the European regulator (EMEA) for treatment of PTW in January 2016. Episalvan is based on the active pharmaceutical ingredient (API), betulin, which is derived from the bark of birch trees using a patented extraction process. Betulin can be easily formulated as an ointment (oleogel) or cream (emulsion) without the need for excipients or surfactants, both of which can lead to skin irritation. Betulin and the other components of the API are known to have anti-microbial and anti-inflammatory effects and are able to enhance keratinocyte migration which are believed to be important features for accelerating the healing process of the skin.

A key feature of the formulation of Episalvan is that it provides an important air and water barrier to the wound. Additionally, it is not sticky which is important for wound use. As part of the regulatory process, Episalvan was shown to be safe, efficacious and well tolerated in three Phase III clinical trials. Accelerated wound healing was clearly demonstrated compared with standard of care therapy for the treatment of second degree burns and for the treatment of split thickness skin graft donor sites. The EMEA has approved Episalvan for the treatment of partial thickness skin wounds where the upper layers of the skin have been lost (eg after surgery and partial burns).

Amryt will retain all commercial rights for Episalvan for European and US markets. However, management might consider licensing out this drug in some territories for PTW, such as Japan, Latam, and the Middle East. This may be a source of future funding that underpins the clinical trial programme for epidermolysis bullosa.

Epidermolysis bullosa

Definition

Epidermolysis bullosa (EB) is a term to describe a group of rare genetic skin disorders and literally means the breakdown and blistering of the outer skin, which exactly describes what people suffering this condition face every day. The skin naturally consists of two layers: the outermost layer called epidermis and the inner layer: the dermis. In healthy skin, these two layers are anchored to each other by structural proteins (keratins, laminins, collagens and integrins); whereas in EB subjects, they move independently because the structural proteins are missing. This causes friction, ultimately blisters, shears and burn-like pain. Children affected by this condition are called butterfly children, reflecting the fragility of their skin, as delicate as the butterfly's wings. The condition is always painful, disabling and life threatening and could be fatal in infancy in its most severe forms. People enduring EB suffer from itching and have hard-to heal-wounds.

Epidemiology

EB is rare, affecting an estimated 1 in 17000 live births, and it is believed that 500,000 people worldwide live with EB[1] – 30,000 in the US; 35,000 in Europe. Being a genetic disease, EB carries no risk of contagion. Parents are usually unaware they are bearing the autosomal genes responsible as they can be dominant or recessive, depending of the type of EB. To date, 13 faulty genes have been identified to be responsible for this skin disorder. There have been some cases reported where the mutation occurs in the womb during foetal development. There is no distinction between the different ethnic groups and both genders are equally affected.

[1] DEBRA website

Symptoms

EB is diagnosed usually at birth, when the neonatal team notices some skin problems, blisters and other skin damage. However, for some, symptoms can be mild and develop later, so may not be diagnosed until childhood or even adulthood. After the visual diagnosis, a biopsy and histology and genetic testing will be performed to assess the severity of the disease.

Types of epidermolysis bullosa

There are a number of variants within three different types of EB – Simplex (EBS), Dystrophic (DEB), and Junctional (JEB) – with severity increasing with each type. Simplex EB is the most common and least severe and occurs in an estimated 70% of cases. In contrast Junctional EB is very severe and results in low life expectancy, but is extremely rare. Amryt will be targeting all three types of EB, but expects the greater use of Episalvan for the more severe types.

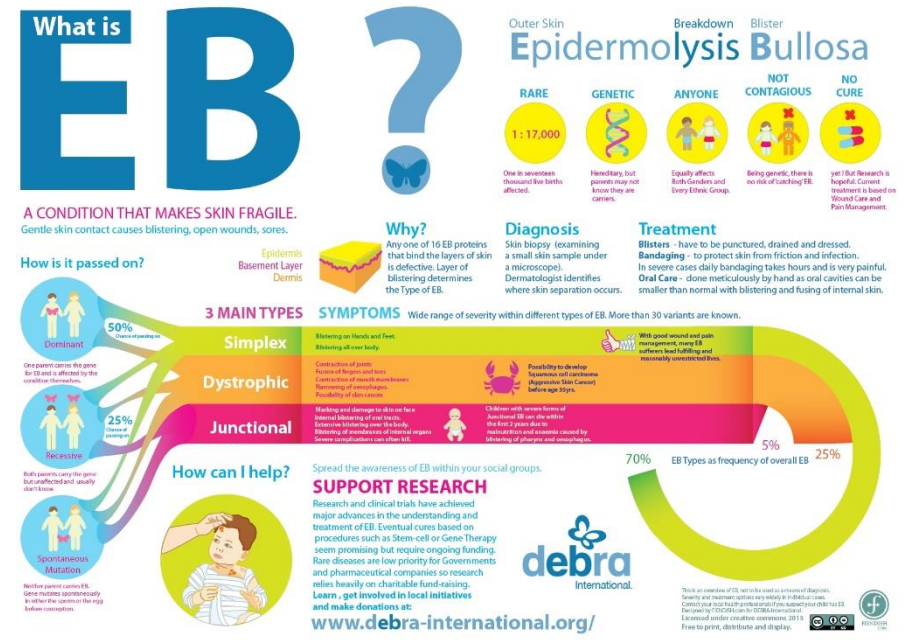
Different types of epidermolysis bullosa

Type	Condition	Frequency
Simplex	Least severe condition Affecting the hands and the feet	70%
Dystrophic	Leads to disability and reduces life expectancy Blisters heal with scares Contraction of joins, fusion of fingers and toes Contraction of the mouth membranes and narrowing of the oesophagus Could lead to skin cancer	25%
Junctional	As above and most severe condition Low life expectancy (~2 years) Serious blistering in the pharynx and the oesophagus	5%

Source: DEBRA; Hardman & Co Life Sciences Research

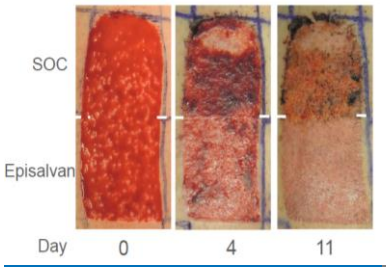
The whole arena of EB is incredibly well described by the following infographic available on the website of DEBRA International, a global support organisation.

Summary of EB



Source: www.debra-international.org

Episalvan trial results



Source: Amryt Pharma

Treatment

There is no cure for EB. The standard of care is to use bandaging in an attempt to protect the skin and prevent friction which leads to blisters, and to prevent infection. Bandaging is changed every 3-4 days and in some severe cases might involve hours of laborious and painful work. The aim of treatment is to prevent complications, help the itching, and ease the pain.

- **Prevent blister** – Keeping the skin moist, wearing soft clothes and mittens and room temperature constant
- **Treat blisters** – Puncture, drain and dress. Aim to reduce pain and discomfort as well as preventing wound infection. Painkillers are prescribed usually and special bandages that create a favourable environment for healing
- **Treating infection** – Antibiotics taken orally, or topical in the form of an ointment over the blister. Special wound coverings are used over lesions that don't heal
- **Nutritional problems** – Some EB patients suffer from blisters in the mouth and throat leading to malnutrition and slow growth. A special diet under the guidance of a dietician is often needed

Commercial opportunity

Statistics regarding the incidence of EB around the world vary considerably. The most reliable data appears to be on the various DEBRA websites, which estimate that there are 1:5,000 live births per annum of babies born with Simplex EB in the US, and 1:20,000 for DEB, suggesting that there are 1,000 new cases per annum in the US. The NHS estimates that the incidence in the UK is 1:17,000 live births and that there are currently 5,000 people living with the condition. Extrapolating these data out across Europe would indicate about 1,250 new cases across Europe per annum.

Our model assumes that dressings are changed every 3 days, implying 120 treatments per annum per patient. At this stage, it is difficult to predict how much a tube of Episalvan will cost, but we have used our best estimates of the annual treatment cost. In addition, it is difficult to predict how many tubes will be used each time the bandaging is changed because this will vary on the severity of the condition and also the body surface area. For Simplex, we have assumed only one tube will be required for each treatment, but higher levels will be needed for DEB and JEB. The average utilisation is shown in the table below. On the basis of these assumptions, the addressable market calculates to $1.37bn.

EB commercial opportunity

	Total cases	Treatments per annum	No. of tubes per treatment	Market opportunity ($m)
US	30,000	120	2-4	676.8
Europe	35,000	120	2-3	377.0
RoW	40,000	120	1-3	316.8
Global	**105,000**			**1,370.6**

Source: Hardman & Co Life Sciences Research estimates

This is likely to be an underestimate of the market potential for the following reasons. First, the number of tubes used per treatment could well be more than we have estimated; and secondly, we have assumed that only 30% of the body area is affected, which may well be an underestimate in the more severe cases (DEB and JEB).

Competition

The development of Episalvan is currently behind Zorblisa (Amicus), which completed a Phase II clinical trial in 48 patients in 2015. The trial protocol had three arms, 3% and 6% Zorblisa against placebo. Results demonstrated an acceleration in wound healing and closure of wounds with Zorblisa 6% compared to placebo but no effect was observed with the lower 3% dose. Amicus has moved the product forward and embarked upon a pivotal Phase III trial in 150 patients being recruited across all three types of EB. Although the development of Episalvan is currently behind the development of Zorblisa, the pivotal trial being performed by Amicus sets a precedent with a protocol that has been accepted by the FDA.

This will save considerable time and money when designing a similar trial for Episalvan. In addition, the trial commissioned by Amicus requires patients to have their bandaging changed every day, compared to every 3-4 days that is normally used as it can be quite distressing to have bandages changed. This might provide Amryt with a significant advantage over Zorblisa, if Episalvan can continue to be applied on the more usual 3-day cycle.

Novel somatostatin analogues

Amryt's interest in somatostatin came with its acquisition of SomPharmaceuticals. This company was founded by the clinical scientist that was responsible for the first regulatory approved analogue of somatostatin for the treatment of acromegaly, when working at Sandoz (now part of Novartis). Very little has changed since the first launch of Octreotide (Sandostatin®) in 1989 apart from the increasing incidence of acromegaly patients that are resistant to Somatostatin.

Acromegaly

Acromegaly is a rare condition caused by over-production of growth hormone which affects approximately 62,000 (NHS: 4 to 13 in every 100,000) people globally. It has a distinct phenotype, with sufferers having enlarged hands and feet and coarsened, enlarged facial features. Joint pain and muscle fatigue are observed also and internally, organs such as the liver, heart, kidneys and spleen can become enlarged. Acromegaly is additionally often associated with a number of health problems if left untreated, including Type 2 diabetes, colon polyps, osteoarthritis, cardiovascular disease, high blood pressure, uterine fibroids, and sleep apnoea.

Cushing's syndrome

Cushing's disease is the result of over-production of adrenocorticotropic hormone from the pituitary and affects 1 in 50,000 people. It is characterised by a variety of symptoms, which can develop rapidly and be very severe, or can present more gradually and be milder in nature. Symptoms include weight gain and fat deposition and skin changes such as thinning and bruising. Musculoskeletal weakness in the hips, shoulders, arms and legs are also common, as are mental health issues such as depression and rapid mood swings.

AP102

AP102, a cyclopeptide targeting the somatostatin receptors (SSTR), is the lead compound in Som's pipeline. Amryt has acquired a small molecule that shows excellent binding with below nanomolar affinity to two of the key somatostatin receptors: SSTR2 and SSTR5. AP102 has comparable activity against SSTR2 and 10x greater activity against SSTR5 compared to the market leader Octreotide. Amryt believes that this dual targeting will result in improved clinical outcomes.

Comparison of AP102 activity

Compound		SSTR1	SSTR2	SSTR3	SSTR4	SSTR5
Somatostatin-14	-	2.3	0.2	1.4	1.8	0.9
Octreotide		>1000	0.6	34.5	>1000	7.2
Lanreotide	IPSEN	>1000	0.8	107	>1000	5.2
Somatoprim	STRONGBRIDGE BIOPHARMA	>1000	3.0	>100	7.0	6.0
Pasireotide		9.3	1.0	1.5	>100	0.2
AP102	AMRYT	>1000	0.6	>1000	N/A	0.7

Source: Fastnet Admission document

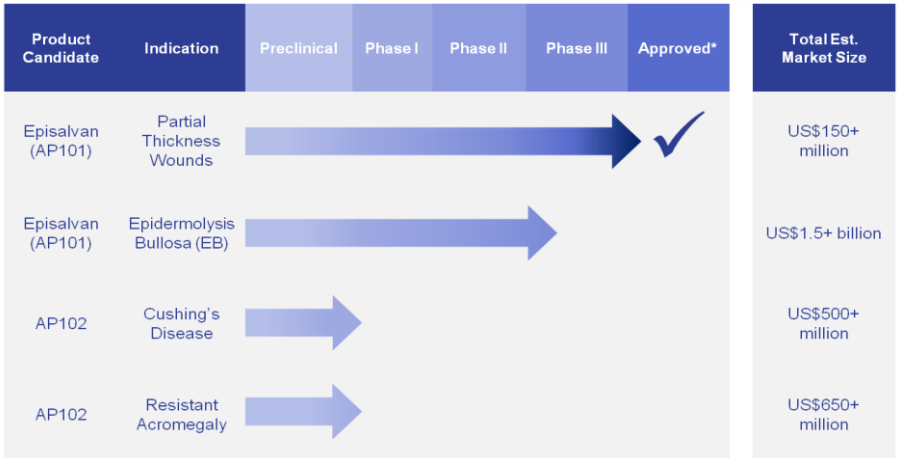
Commercial opportunity

The market is dominated by Novartis' original drug Octreotide (Sandostatin®) with annual sales of $1.63bn (2015), even though only 30-35% of patients respond to the drug. Since launch in 1989 cumulative ex-factory sales of Octreotide have been $19.1bn. Patients unresponsive to Octreotide are being tried on Novartis' follow-up drug, Pasireotide (Signifor®), but this has failed to gain acceptance due to side effects (diabetes) and sells less than $200m pa. Pre-clinical data with AP102 suggest that it is as effective as Pasireotide but without the side effects. There are an estimated 62,000 patients with acromegaly worldwide, so there is a natural target market of 43,400 unresponsive patients. At a price of $15k p.a., this implies a market opportunity of $651m for a new efficacious drug entering the market.

Amryt pipeline

The graphic below represents the pipeline of Amryt currently. To date, Episalvan has been approved for the treatment of partial thickness wounds in Europe and licensing partners are being sought for other territories. Management is focused on approval of Episalvan for epidermolysis bullosa and a successful pivotal Phase III trial in EB could see the product on the market during 2019.

Amryt development pipeline



Source: Amryt Pharma

Company matters

Registration

Amryt was incorporated in August 2015 as a vehicle to acquire, build, develop and monetise a pipeline of patent protected products targeting rare medical conditions. It is registered in the England & Wales with company registration number: 5316808

Registered office:

Ivybridge House

1 Adam Street

London

WC2N 6LE

Board of Directors

On Admission, the Board will be composed as set out in the following table. The current non-executive Chairman and an NED will switch roles. Under the Birken Acquisition Agreement, the sellers have the right to nominate a person to be appointed as a non-executive director of the enlarged group.

Board of Directors

Position	Name	Nominations	Remuneration	Audit
Non-exec Chairman	Harry Stratford	M	C	
Chief Executive Officer	Joseph Wiley	M		
Chief Financial Officer	Rory Nealon	M		
Non-executive director	James Culverwell	M		C
Non-executive director	Cathal Friel	M		M
Non-executive director	Ray Stafford	M	M	

M = member; C = chair
Source: Company reports

Harry Stratford – Non-executive Chairman (69)

Has worked in pharmaceuticals industry for >40 years and has built two successful publicly listed companies – Shire Pharma and Prostrakan, which was acquired by Kyowa Hakko Kirin in 2011. Mr Stratford holds a BSc. in Chemistry from the University of London and was awarded an OBE in the 2007 New Year's Honours list for his contribution to the Scottish Life Sciences Industry.

Joe Wiley – Chief Executive Officer (45)

Founder of Amryt Pharma. Trained in general medicine at Trinity College Dublin, specialising in neurology, and is a member of the Royal College of Physicians in Ireland. MBA from INSEAD. Over 20 years' experience in medical, pharmaceutical (with Astellas Pharma) and venture capital industries, opening and leading Sofinnova Ventures' European office.

Rory Nealon – Chief Financial Officer/Chief Operating Officer (48)

Bachelor of Commerce degree from University College Dublin; Rory is a Fellow of the Institute of Chartered Accountants in Ireland, a member of the Institute of Taxation in Ireland and a member of the Institute of Corporate Treasurers in the UK. Previously a Board member of Trinity Biotech plc, being Chief Financial Officer (2003) and Chief Operations Officer (2007) until leaving in 2014.

Acquisition of Birken AG

Amryt agreed to purchase the entire share capital of Birken AG on 16th October 2015, which has resulted in the issue of new Amryt shares equivalent to 30% of the fully diluted share capital, but before the Placing. Birken sellers invested €2m in the Placing and will hold 21% of the enlarged capital base. In addition, €10m was paid to Birken on EU regulatory approval of Episalvan. Further milestone payments up to €40m based on future regulatory hurdles and sales targets and a 9% royalty on Episalvan sales (6% on betulin products) could become payable also in the future.

Acquisition of SomPharmaceuticals SA

Amryt agreed to purchase the entire share capital of SomPharmaceuticals SA (Som), a Swiss-based drug development company, on 15th December 2015. An upfront $100k cash sum was paid, but this agreement was predominantly all-share that resulted in the issue of 12.28m new Amryt shares equivalent to US$4.15m, or 5.9% of the enlarged share capital, with the Founder of Som owning 4.2%.

Share capital

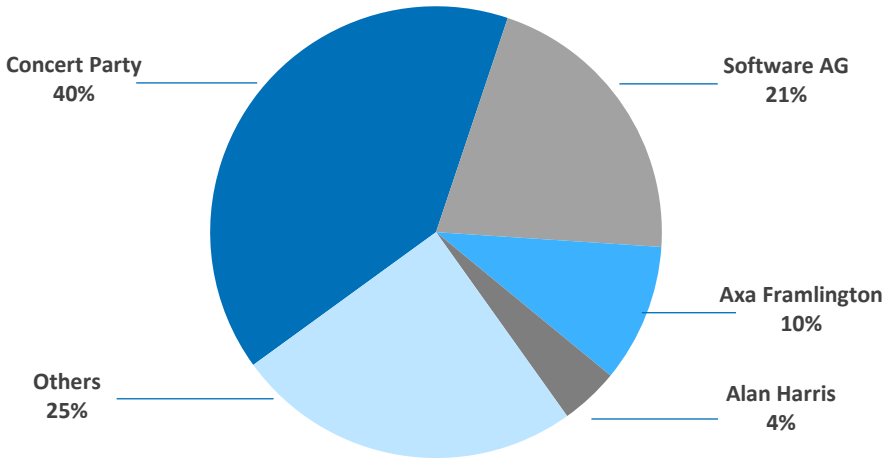
For Admission, the entire share capital has been reorganised. Fastnet shares were consolidated, consideration shares have been issued for Birken and Som, as mentioned above, and to existing Amryt shareholders for the acquisition of Amryt Pharmaceuticals. There was also a Placing of 41.7m ordinary shares at 24p per share to raise £10m/€12.4m of new funds for working capital purposes. Taken together the enlarged share capital on Admission was 208.3m shares, which valued the company at £50m. The enlarged entity has been renamed Amryt Pharma plc.

Share capital at time of Admission – 19th April 2016

	Number
Existing (consolidated) Fastnet ordinary shares	43,171,134
Consideration shares for purchase of Amryt, Birken and Som	123,495,096
Number of Placing shares to be issued at 24p per share	41,673,402
Enlarged share capital on Admission	**208,339,632**
Warrants	23,401,463
Options outstanding	4,946,162
Fully diluted share capital	**236,687,257**

Source: Fastnet Admission document; Hardman & Co Life Sciences Research

Shareholders at time of Admission – 19th April 2016



Source: Fastnet Admission document; Hardman & Co Life Sciences Research

All these transactions resulted in the formation of a Concert Party under Stock Exchange Rules that controls 40.1% of the issued capital, which was fully disclosed within the Admission document. The main participants in the concert party are the Executive Directors and the non-executive director, Cathal Friel.

A number of shareholders are subject to a lock-in period and, once expired, for an extended period can only dispose of shares in an orderly manner. There is full disclosure in the Admission document, but the most relevant shareholders subject to these restrictions are the Directors and the vendors of Birken and Som. This group has signed a lock-in period of 12-18 months and have agreed to a further 12 month period when shares may be sold only in an orderly and disclosed manner through the company's nominated broker (Shore Capital) or broker (Davy).

Financial analysis

- Of the acquired businesses, only Birken has trading activities at present. These relate to local (German) sales of Imlan (betulin) skin care products of ca.€900k per annum. These are expected to continue in the future.
- A pro-forma balance sheet was provided in the Admission document based on the position at 30th September 2015 and assuming a €10.7m Placing of shares for working capital purposes. This suggested that the net cash position of the enlarged group would be €16.0. The trade receivables and trade payables at that point in time were evenly balanced.
- Gross proceeds from the Placing were £10.0m/€12.4m, which were reduced to £8.44m/€10.47m after allowing for all costs (15.6%) related to the transactions of £1.56m/€1.93m. Taking everything into account we anticipate that Amryt Pharma has started trading with a net cash position of €13.5m.

The future financial statements and forecasts for Amryt will be fairly straight-forward and dominated by two figures. First, the amount of cash being invested into R&D to support the clinical trial programme that is expected, ultimately, to drive value. Secondly, the ongoing SG&A costs to execute on the company's strategy. These, in turn, drive the cashflow and determine the point at which management will need to raise more capital, which could come through a combination of up-front receipts from licensing deals and a capital increase.

Pro-forma balance sheet – 30th September 2015

€000	Fastnet	Amryt	Birken	Som	Acquisitions	Placing	Pro-forma
Tangible assets	4	-	1,557	-	-	-	1,561
Intangible assets	-	-	5	2	61,220	-	61,227
Inventories	-	-	1,208	-	-	-	1,208
Trade & other	52	1,599	108	156	-	-	1,915
Cash	13,836	171	3,008	279	-11,239	10,666	16,721
Total assets	**13,892**	**1,770**	**5,886**	**437**	**49,981**	**10,666**	**82,632**
Loans	-	-	-	-692	-	-	-692
Deferred consideration	-	-	-	-	-40,000	-	-40,000
Trade payables	-482	-487	-686	-20	-	-	-1,675
Financial liabilities	-	-2,476	-	-	2,476	-	0
Total liabilities	**-482**	**-2,963**	**-686**	**-712**	**-37,524**	**-**	**-42,367**
Net assets	**13,410**	**-1,193**	**5,200**	**-275**	**12,457**	**10,666**	**40,265**

Source: Fastnet Admission document

Valuation

To provide potential investors with some guidance to valuation, we have constructed a table of specialty pharmaceutical companies which has products at similar stages in the development cycle and are quoted on various stock exchanges or which have raised capital recently. This is not comprehensive, but it does provide the best peer comparators for companies developing similar Phase III assets. Rather than simply taking the market capitalisation, we prefer to take away cash on the balance sheet to obtain enterprise values which are more comparable. The EV range of this group is wide at £48m (Phase I assets) to £1,608m (Phase III assets), compared to that for Amryt (£39.1m) for Phase II/III assets, which suggests there is plenty of upside potential for investors.

An alternative is to look at the prices that big pharma has been prepared to pay for similar assets. There have been several recent deals ranging from $97-842m, again suggesting that Amryt has solid upside potential as its assets are developed.

Comparator valuations

Company	Amryt Pharma	Bellicum	Fibrocell Sciences	Omeros	Marinus Pharma	Sage Therapeutics	Ultragenyx
	AMRT	BLCM	FCSC	OMER	MRNS	SAGE	RARE
	£/p	$	$	$	$	$	$
Share price (lc)	24.0	11.3	2.6	15.1	6.4	37.0	72.0
Shares in issue (m)	208.3	27.0	43.9	38.3	19.5	32.0	39.0
Market cap (lcm)	50.0	304.0	113.7	576.5	123.9	1,185.1	2,807.3
Mkt cap (£m)	50.0	215.3	80.5	408.3	87.7	839.3	1,988.2
Cash (lcm)	10.9	150.4	29.3	28.3	56.2	186.8	536.3
Debt (lcm)	0.0	0.0	-10.7	-49.8	0.0	0.0	0.0
EV (lc)	39.1	153.6	95.1	598.0	67.7	998.3	2,271.0
EV (£m)	**39.1**	**108.8**	**67.3**	**423.5**	**47.9**	**707.0**	**1,608.4**
2015 Product sales	0.9	0.0	0.3	13.3	0.0	13.3	13.3
EV/sales	65.2	-	317.0	45.0	-	75.1	170.8
Stage	Phase II/III	Phase I/II	Phase I/II	PC/PhI	Phase I/II	Phase III	Phase II/III

Share prices taken at close of business on 18th April 2016
Source: Hardman & Co Life Sciences Research

Risks

As with many small cap companies listed on AIM, there can be difficulty in buying and selling shares in volume. Market makers only guarantee prices for a small number of shares. With Amryt, this is exacerbated by large holdings of the Concert Party and the vendors of Birken and Som. Other risks that need to be considered:

- **Financial** – very limited operating history for any of the companies
- **Clinical trials** – Investors should be aware of the cost, time-lines and probability of success in clinical trials
- **Regulatory** – As with all drug development companies, there is regulatory risk. It is important to liaise with regulators on a regular basis throughout the trial programme. However, Episalvan has been de-risked to a certain extent following regulatory approval from the EMEA for the treatment of PTW
- **Dilution** – More funding will be required over time to delivery management's stated objectives, some of which could come from licensing partners
- **Strategy** – Management might be unsuccessful in identifying and acquiring more assets at sensible prices

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