OPEN ORPHAN PLC (LON:ORPH)

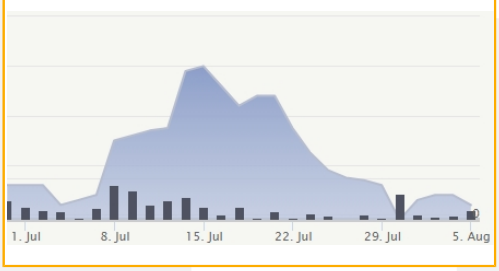
8 August 2019

proactive research

Pharmaceuticals, Biotechnology & Life Sciences

52-WEEK HIGH	8.15p
52-WEEK LOW	6.30p
PRICE	6.45p
MARKET CAP MLN	£17.24

Share Price



Major Shareholders

Cathal Friel: 16.2%	
Tony Richardson: 6.4%	
Livingbridge VC LLP: 5.2%	
Shares in issue	253,493,259
Avg Three-month trading volume	956,607
Primary Index	AIM
Next Key Announcement	Progress on buy & build strategy

Company Information

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Open Orphan: creating a valuable niche

Open Orphan (ORPH) presents an opportunity to invest in a company targeting value creation and rapid scale-up via acquisitions in the orphan and rare drugs market, which is growing at around 11% a year, around twice as fast as the global pharmaceuticals market. At the same time, there is a great disparity between the US and Europe in the number of orphan drugs on the market, which reflects an unmet need in the market for specialist services to help address the balance.

ORPH is addressing the opportunity within the pharma services market to create shareholder value by combining a number of smaller consultancies focused on the orphan and rare disease space, extracting both top-line and cost synergies. The company targets organic revenue growth as well as building critical mass from strategic acquisitions at favourable enterprise value/sales multiples.

Leveraging benefits and synergies

Following the reversal into Venn Life Sciences (Venn) ORPH benefits from excellent synergies from the base Venn business including strong industry contacts, established revenues (€14mln in the fiscal year 2018) including top biopharma customers in the orphan and rare diseases space. The combined management team has sound and tested expertise in the core areas of mergers & acquisitions (M&A), technology, orphan and rare diseases.

A two-pronged strategy

ORPH is positioned to execute its strategy and it will seek new capital to rapidly scale up to become a leading European pharmaceutical services company targeting the orphan and rare drugs market. The growth strategy is driven by its buy and build programme and by developing innovative and proprietary data platforms to help drive cross-selling opportunities across the enlarged group.

The near-term roadmap is clear

The company has set out initial priorities within the first 12 months of access to capital. Collectively, these acquisitions are planned to complement the strengths of Venn in the regulatory field and ORPH's commercialisation expertise in areas of high unmet need such as market access, consulting for orphan and rare disease drug companies as well as in specialist areas of regulatory consulting.

Strong underlying market drivers

Addressing the requirements of a buoyant orphan and rare drug market that is growing at circa 11% per annum, around twice as fast as the global pharma market, ORPH will address an unmet need for consultancy services to help launch new products and in particular, to help pharma companies negotiate the complex regulatory and reimbursement landscape in Europe. The strong growth trend is enhanced by the opportunity to address an imbalance in European vs US market approvals – as well as a favourable trend for outsourcing to contract research organisations (CROs).

Powering the growth trajectory

ORPH will execute its buy & build strategy using a combination of new funding and equity and has already raised £4.5mln in parallel with the reverse acquisition, placing it in a strong position to begin moving along its planned growth trajectory.

Cathal Friel, CEO,

Cathal was co – founder and original board member of Amryt Pharma Plc, a leading European orphan drug company listed on the London Stock Exchange. Established Raglan Capital in 2007 and helped establish Open Orphan in 2016.

Management biographies

Cathal Friel: chief executive officer

Previously the chairman of Open Orphan, which he founded in 2016, he was appointed chief executive officer on completion of the reverse takeover. Friel has significant public company experience: the co-founder of Amryt Pharma PLC, a leading European orphan drug company; founder & chairman of Fastnet Oil & Gas PLC that raised US$50mln on AIM; co-founder and director of Merrion Stockbrokers before the £80mln sale in 2006.

Professor Brendan Buckley: Non-executive Chairman

which was sold to ICON in 2011. Served on the Mergers & Acquisitions (M&A) committee while at ICON so he has significant transaction experience. He is a doctoral graduate in Biochemistry of Oxford University and has 30 years of experience in clinical research. Member of the European Medicines Agency (EMA) Committee for orphan medical products from 2000 to 2003.

Christian Milla: chief operating officer

Milla holds a PhD in neuropharmacology and has more than 20 years of industry experience. Joined Venn from Oncodesign Biotechnology where he was the chief operating officer. Previously a board member of Cromsource, a provider of outsourced services to the pharma, biotech and medical devices industries. From 2004 to 2007 he was the chief executive officer of the contract research organisation OSMO Accovion SA. Joined Venn in 2016.

Maurice Treacy: director

Founder of HiberGen & GMI, the former of which was recently sold to WuXi for $400m. Credibility in R&D investment, drug development, business strategy and business development having worked at GMI, HiberGen, Serono, Pfizer and ARCH Venture Partners. Inventor of >80 patents at Genetics Institute/Pfizer and secured US & EU regulatory & marketing approval of three biological products at Serono.

Executive Summary

Open Orphan (ORPH) is targeting rapid scale-up via acquisitions in the orphan and rare drugs market with the objective of becoming a market leader in European pharmaceutical services. Open Orphan was acquired by Venn Life sciences in June. Venn is an integrated drug development contract research organisation (CRO) offering a combination of pre-clinical and drug development expertise, clinical trial design and management. After the name change, Venn subsequently delisted from AIM. ORPH will execute its buy & build strategy using a combination of new capital and equity and has already raised £4.5mln in parallel with the reverse acquisition. The company already has two platforms related to orphan product market access services that it will continue to operate, and which will complement the business as it grows.

There are two strands to the growth strategy;

Buy & Build Strategy

ORPH is pursuing its strategy within the pharma services market to create shareholder value by combining several smaller, orphan focused consultancies, extracting both top-line and cost synergies, as well as seeking valuation arbitrage – that is to say, it is seeking to acquire smaller CROs on low valuation multiples and it seeks to add value by building a larger business and hence justify a higher valuation in line with some of the medium to large-sized CROs.

With the reverse takeover of ORPH into Venn now complete, it is ready to start executing a string of acquisitions to form an integrated services company, with

the aim of becoming a one-stop-shop for biopharma companies operating in the field of orphan and rare drugs.

ORPH is looking to scale up rapidly to around €30mln of revenues through acquisitions within a year of the reverse takeover which closed in June.

Proprietary Data Platforms & Virtual Rep offering

The group also has two platform service offerings to help its customers commercialise orphan products. Firstly, its Data Access platform, containing the contact details of more than 4,000 physicians and key opinion leaders (KOLs) across Europe that will be combined with the existing services within Venn. The Virtual Rep offering sits within the Data Access platform and offers targeted services to pharma customers that will aim to complement or in some cases replace the role of the traditional sales rep. The second platform offering targets the orphan genetic & health data market. The platform will collect genetic data from individuals with orphan conditions and charge pharma companies for access to this data for research purposes.

Addressing the requirements of a buoyant orphan and rare drug market

Market Opportunity in Orphan and Rare Drugs

Open Orphan is positioned to address the requirements of a buoyant orphan/ rare drug market that is growing at around 11% a year, about twice as fast as the global pharma market. It aims to address a need for consultancy services to help launch new products and in particular, to help pharma companies negotiate the complex regulatory and reimbursement landscape in Europe. Orphan conditions are usually inherited conditions and they are defined by their very small patient populations as follows:

- USA <200,000 patients
- EU <5 in 10,000
- Japan <50,000 patients

Despite the smaller sizes of these patient populations, there is a range of incentives available that can benefit biopharma companies in the space so that commercial prospects are sufficient to offset the costs of development. These include higher pricing, market exclusivity and accelerated approval pathways.

At the same time, there is a lack of provision in knowledge and consulting to help such companies negotiate the path to market. It is this unmet need that ORPH is looking to fill by building up a group of specialist firms with the knowledge required to tackle the distinct market access conditions within each country in Europe. The growth opportunity lies in advancing levels of progress in Europe in line with the US where there are more than 500 orphan conditions with approved treatments compared to only 180 in Europe according to IQVIA.

Deal Structure

Venn acquired Open Orphan via an all-equity transaction of £5.7mln in shares to Open Orphan shareholders (at a £4mln valuation of Venn). Following shareholder acceptance, Venn changed its name to Open Orphan and was admitted to the AIM and Euronext Growth Dublin market on 28 June with the ticker symbol ORPH.

ORPH raised £4.5 million gross in a placing issuing 80,357,142 shares at the placing price of 5.6 pence per share in parallel with the reverse acquisition. It will seek to raise additional capital, all with the aim of pursuing its buy and build growth strategy and to invest in its existing products and services including proprietary data platforms, the Virtual Rep offering and in its orphan products consulting capability. The enlarged group will benefit from management by a combination of the Venn and Open Orphan teams.

Business Model

ORPH is positioned to execute its strategy following the reversal into Venn Life Sciences (Venn), and it will seek new capital to rapidly scale up to become a leading European pharmaceutical services company targeting the orphan/rare drug market. We detail the two pillars of the growth strategy acquisition and organic means;

1. Buy & build strategy

2. Proprietary data platforms & Virtual Rep offering

Building value and expertise

Buy & Build Strategy

The company aims to consolidate a series of small to medium-sized consultancies focused on the orphan drugs markets – in the €5-15mln revenue bracket – where there is an opportunity to develop top line and cost synergies as well as by building a consolidated group that is in sum more valuable than its separate parts, potentially by exploiting arbitrage opportunities in various markets.

The first company acquired is Venn and ORPH has a pipeline of acquisitions in view in order to achieve a one-stop service to biopharma companies that would otherwise be provided by a group of service companies.

This strategy is based on the current fragmented European orphan consulting market with a number of small-sized specialist firms providing good prospects for consolidation.

Aiming for scale and efficiencies

Building a Leading Pharma Services Company

Referrals: The great variation in market access processes across Europe creates a complex and hard to navigate scenario for companies looking to launch new drugs. ORPH is aiming to bring together the expertise of the small-sized consultancies and CROs which is currently split by geography and function in many cases. The rationale for this is to provide an end-to-end service to biopharma companies as well as exploiting the benefits of cross-selling and referrals.

Cost synergies: all companies acquired will retain their existing trading names and branding. ORPH will centralise and streamline back-office functions including finance and administration, which it intends to integrate into the Dublin head office. As a result, this will help to create cost synergies.

With the reverse takeover now complete, there are efficiencies to be gained and as a result improvements in operating leverage by centralising certain functions, across the enlarged group.

The reverse takeover of ORPH for £6mln was through shares issued at a £4mln valuation of Venn, which is equivalent to an enterprise value/sales multiple of around 0.3x of Venn (based on trailing revenues of £15mln). It intends to acquire new businesses on multiples of around 1.0x – 1.5x enterprise value/sales of the target companies. So, if ORPH takes a disciplined approach to acquiring new businesses, it can build a higher valuation as it scales up the size of the business. This is in line with the valuation of larger CROs that tend to demand average enterprise value/sales multiples of 3x according to our analysis.

Setting clear priorities

EV/Sales multiples of CROs				
	Market cap (m)	*Sales 1 (m)*	*EV/Sales*	*Curr*
Lab Corp of America	16800	11500	2	US$
ICON	8500	2800	3	US$
Charles River Lab	6880	2600	3	US$
Medpace	2850	819	4	US$
Ergomed	151.8	68	2	GBP
Biocept	19	7	2	US$
Average			**3**	
Venn	4	15.5	0.3	GBP

Source: Financial Times/Proactive Investors

ORPH plans to complete the acquisitions with equity and to a lesser extent, cash

As a large-scale specialist services company, it is possible that ORPH could even become an attractive acquisition target itself – provided it achieves its objectives. There are many examples of consolidation; a notable example is the 2017 acquisition of Parexel by Pamplona Capital Management, a private equity firm, for about US$5bn. Parexel offers a range of specialist regulatory and market access services.

12-Month Roadmap

ORPH has set out the following initial targets that have been defined as priorities within the first 12 months of access to capital and which will complete the service offering. ORPH plans to complete the acquisitions with equity and to a lesser extent, cash. ORPH is aiming for €30mln of revenues by making acquisitions in the following fields:

- UK global strategic market access consulting
- European based regulatory consulting

Collectively, these acquisitions are planned to complement the strengths of Venn in the regulatory field and ORPH's commercialisation expertise.

A successful model is the buy and build strategy employed by ICON (NASDAQ: ICLR), which has an US$8bn market capitalisation, US$2.6mln of fiscal 2018 revenues and has gained critical mass through a series of acquisitions made over the last 20 years.

Summary of ICON plc acquisitions since 2011	
Acquired	Date
Medinova Research	May-19
Molecular MD	Feb-19
Mapi Group	Jul-17
Clinical Research Management	Sep-16
PMG Research	Dec-15
MediMedia Pharma Solutions	Feb-15
Aptiv Solutions	Mar-14
Cross Country Healthcare	Nov-13
PriceSpective	Feb-12
BeijingWits Medical Consulting	Dec-11

Source: CrunchBase

Most recently these acquisitions include Medinova, a provider of investigator site-based clinical research acquired in May, and Molecular MD acquired in February.

ICON demonstrates successful buy & build strategy

Source: Financial Times

Complementary and innovative data platforms

Proprietary Data Platforms

The company is implementing a buy and build strategy – and also is developing two proprietary platforms to offer various services for orphan and rare drug companies, which it will grow using cross-selling and referrals across the group as well as with the newly acquired businesses.

Data Access Platform

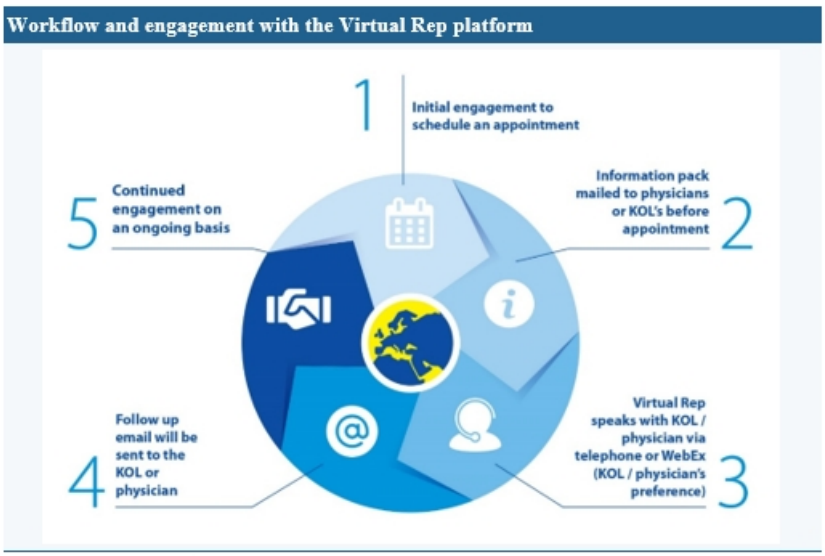
ORPH has built the Data Access platform, which contains the contact details of more than 4,000 physicians and key opinion leaders (KOLs) in Europe designed to support the development and commercialisation of drugs. The company has identified a list of more than 500 orphan or rare disease drug companies that would be the potential customers and end-users of the platform. ORPH plans to make money from the platform on a subscription fee basis.

The platform is also designed as a discussion forum to enable physicians to develop and engage with insight and opinions on new products. In this way, drug companies can contact and engage with KOLs to stimulate peer-to-peer discussion about new products. KOL insight is well established as a means of promoting debate and engagement regarding the potential outcomes and efficacy of new drugs.

Development of the Data Access platform is complete and the anticipated launch is for the first quarter of 2020.

Virtual Rep Service

This service is part of the Data Access platform and is designed to complement or even replace the role of a sales rep. Each company will be allocated to a virtual rep on the platform with deep experience in promoting drugs for orphan and rare diseases. The rep will be responsible for setting up and scheduling meetings either online or phone with the KOLS and then following up to promote these products. In this way, the rep can efficiently contact KOLs and even contact more than one specialist at a time if required. In the same way as a traditional sales rep, the virtual rep's performance can be tracked by monitoring interactions and outcomes.



Source: Company info

Moving in line with the digital healthcare trend

The Benefits of the Virtual Rep Service

There is a range of potential benefits including the relative scarcity and expense of traditional reps as well as the potential to improve their effectiveness and reach. The 2018 MedReps Pharmaceutical Salary Report found that the average compensation of a pharma sales rep was US$133.6k and at the higher end of the scale speciality pharma sales reps earn up to US$155k a year plus bonus; costs and additional benefits take this sum up much higher in some cases.

There is also a decline in face-to-face access to physicians, which has fallen from around 80% in 2008 to just 46% by 2017, with higher physician workloads and administrative duties being part of the trend. This means that competition for access is fierce.

There is instead a growing trend in favour of digital engagement, and this is in evidence with patient consulting also via digital apps; accordingly, the number of pharma sales reps has shrunk dramatically from an estimated 100k in 2005 to about 70k in 2016, with an estimated 25% of interactions replaced by digital engagement.

The Unique Selling Point of Virtual Rep

Virtual Rep service is differentiated from other platforms such as those offered by Ashfield (part of UDG Healthcare) and privately held Pharmaforce, as it specifically targets drugs for orphan and rare disease.

The fee structure will be on a monthly subscription basis depending on the number of physicians being targeted.

Development of the Virtual rep service is complete, and it is anticipated that this will be rolled out for the initial launch in the fourth quarter of 2019 with revenues anticipated to follow shortly afterwards.

Providing services that will accelerate the launch of orphan/rare disease drugs

Health Data Platform

The second platform offering targets the orphan genetic & health data market. The platform will collect genetic data from individuals with orphan conditions and charge pharmaceutical companies for access to this data for research purposes. The process can be split into three stages (see below).

Data collection: the relatively high degree of genetic testing carried out on individuals suffering from orphan or rare diseases means that generally, data

availability is good. A very high proportion - up to 80% - of rare diseases are inherited. Data collection requires patient consent but there is an incentive for patients to provide such data to raise awareness and share knowledge, Open Orphan will collect the data from a range of sources including the patient's physician, online genetic databases and other sources. ORPH will follow the General Data Protection Regulation (GDPR) ruling and data will be securely encrypted on the Health Data platform. The plan is to partner with Patient Advocacy Groups (PAGs) to raise awareness of the genetic data offering. Contributors will benefit from a profit share that can be ploughed back into services for patients.

Access: ORPH plans to charge biopharmaceutical companies a subscription fee for access to the dataset.

The model for successful genetic data platforms is illustrated by the following group although none of these specialises in orphan drugs

- Luna DNA - a shared genomic research database
- Aetion – real-world data analytics
- PatientsLikeMe – personalised health data social network
- iCarbonx – digitalised health and genomics data

The value of genetic data is reflected by significant sums being invested and supported by the trends for personalised medicine and artificial intelligence (AI) in health data. This is illustrated for example by Amgen's acquisition of Decode for US$415mln in 2012, which was subsequently spun out and reacquired by WuXi Pharmatech for US$65mln in 2015. While iCarbonX, the Chinese digital genetics and health data company founded in 2015, has built itself up to a valuation of more than US$1bn and has attained more than US$400mln in investment since inception.

The data platform is in the planning stages, and ORPH is well-positioned to draw on the experience of Maurice Treacy who co-founded Genomic Medicine Ireland (GMI) and helped engineer its sale to WuXi NextCode in 2018 - the latter committed up to US$400mln in milestone related investment at the time. ORPH anticipates that it will start to collect genetic samples in 2020.

Providing services that will accelerate the launch of orphan/rare disease drugs

Focusing on the Orphan Drug Market

Both the buy & build and digital platforms will be targeting the orphan drug market, providing a complete offering for biopharma companies, supplying genetic data for research purposes and facilitating & consulting on market access matters. The orphan drug market presents attractive dynamics including:

- It is growing at almost twice the rate of the overall pharma market.
- There are 6,000 to 8,000 rare/orphan conditions that affect 30 million Europeans according to the European Commission; however, there is a mismatch between the number of drugs on the market the US and European markets, and addressing this mismatch is where the opportunity lies for ORPH.
- 58% of all new drugs coming to the market in the US / Europe in 2018 were orphan designated (source: Regulatory Affairs Professionals Society).

Market opportunity

Open Orphan is targeting the requirement for consultancy services in the growing orphan/rare drug markets, with an emphasis on Europe. It is aiming to provide services that will accelerate the launch of orphan/rare disease drugs.

There is a significant market opportunity as 58% of all new drugs coming to Europe are orphan designated and many smaller biopharma companies lack the internal resources to develop these products in-house. It is estimated that high demand services will include assistance with EMA (European Medicines Agency) regulatory approval and with obtaining reimbursement of the orphan

drug products EU countries. Other services include help in launching an orphan drug product and dealing with the complexity of the EU landscape.

Overall R&D spend by global biopharma companies appears to be buoyant with this trend set to continue – some estimates are for more than US$200bn by 2024 (source: Evaluate Pharma).

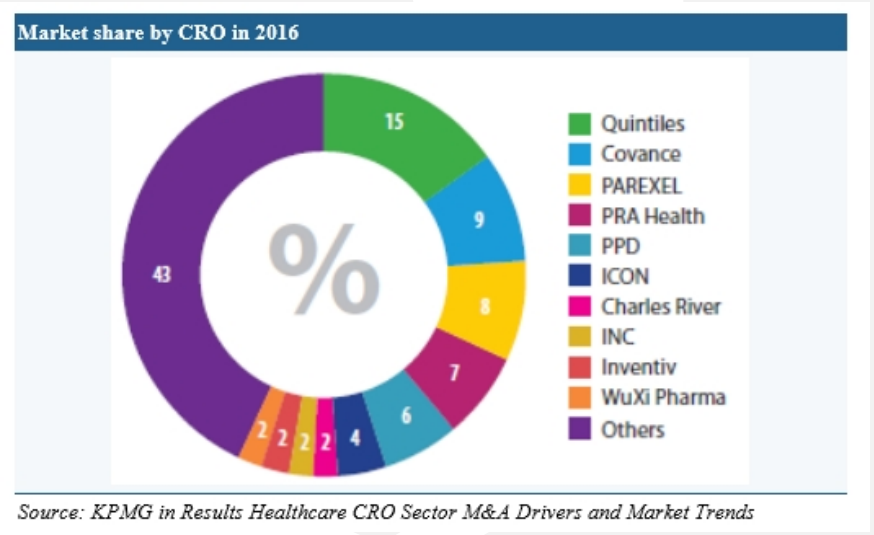
Many smaller companies lack the internal resources to carry out their own R&D

Outsourcing to CROs is a Fast Growth Trend

While exact CRO market growth forecasts differ between sources, it is expected to grow faster than the overall pharma market, largely due to increased uptake by pharmaceutical companies; some estimates see this reaching up to 50% of development by 2020 compared to 41% of outsourced clinical development in 2016.

Global Market Insights forecast a 7.5% compound annualised growth rate (CAGR) in market size to US$56.4bn by 2024 whereas Industry Standard Research forecasts 6.6% growth to US$54.7bn by 2025. The drivers behind this growth trend include the capacity to reduce costs and to accelerate the development process. In addition, many smaller companies lack the internal resources to carry out their own R&D. The market is dominated by around ten companies holding some 60% of the market so that the fragmented group of smaller companies are likely to form targets for further consolidation in the quest for greater specialisation.

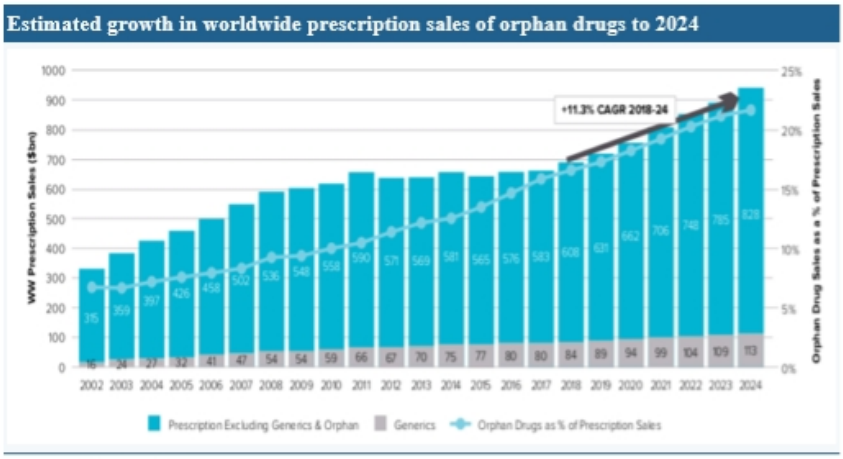
Room for Consolidation



Source: KPMG in Results Healthcare CRO Sector M&A Drivers and Market Trends

The orphan drug market is an area of the pharma market that is forecast to grow at an 11% CAGR to 2024, reaching US$262bn

The concentrated mass has been driven by very active mergers & acquisitions by these larger players over the past 10 years – ICON alone has made 10 acquisitions since 2011.



Source: Evaluate Pharma

The Orphan Drug Market Growing Faster Than Overall Market

The orphan drug market is an area of the pharma market that is forecast to grow at an 11% CAGR to 2024, reaching US$262bn (Source: EvaluatePharma, 2018).

Owing to the very small patient populations, drugs for orphan diseases would likely not be developed without incentives. Therefore, the regulatory agencies have put a structure in place to define or designate such drugs and to provide a series of incentives and benefits. The definitions across various jurisdictions differ slightly but in general rare and orphan diseases are defined as follows region by region;

- USA <200,000 patients <6.37 in 10,000
- EU <5 in 10,000 <5 in 10,000
- Japan <50,000 patients <4 in 10,000

The top five pharma companies by 2018 global sales in the orphan drug market include Celgene, J&J, Roche, Novartis and Takeda

RareDiseaseorg.UK states that there are between 6,000 to 8,000 known rare and orphan diseases affecting around 6% of the population or up to 30 million people across Europe alone.

Orphan drugs benefit from a range of incentives as well as reduced regulatory hurdles, as summarised below, to help offset the potential anti-commercial aspects of targeting the smaller patient populations. The incentives are available provided that the diseases meet the criteria on population size and that the condition is chronically debilitating or life-threatening (under EMA designation). So, the following incentives are available in Europe:

- Protocol assistance
- Access to the centralised authorisation procedure
- Marketing exclusivity – 10 years
- Pricing power up to five times higher per patient
- R&D tax credits

'Big Pharma' companies still spend a large amount on R&D and dominate the field; however, smaller companies are becoming increasingly active in the field of orphan and rare disease drug development.

The top five pharma companies by 2018 global sales in the orphan drug market include Celgene, J&J, Roche, Novartis and Takeda – all big names; however, many of the firms developing orphan drugs are small to medium-sized so they often lack the internal resources to carry out all stages of getting a product to market, so outsourcing to a CRO becomes a particularly valuable service.

Reimbursement landscape complexity can slow market access

Addressing the Imbalance in Europe's Complex Orphan Drugs Landscape

Whilst global growth in orphan drugs markets have grown faster than non-orphan markets in recent years, the rate of growth in terms of the number of drugs approved and in revenues in Europe has fallen behind the US. There is a clear opportunity to address the imbalance - there are 520 approved orphan treatments in the US vs only 180 in Europe - by assisting US companies in bringing orphan drugs to the European markets.

One of the main reasons for this disparity is the complexity of the reimbursement systems in Europe vs the US. Drug companies need to deal with each of the individual 28 European countries to receive a reimbursement and this can clearly slow market access considerably and can lead to very different outcomes and decisions on reimbursement. ORPH is going to build a very wide skill and local knowledge base through its acquisitive strategy to provide a one-stop-shop to biopharma customers.

In contrast, in the US, reimbursement is centralised at the Centres for Medicare & Medicaid Services (CMS). Different countries can have completely different conclusions on reimbursement, meaning a consultancy must have in-depth local knowledge when taking a product to market.

Building by acquisition, investing in technology platforms

Deal Structure & Roadmap

ORPH is well on the way to executing its strategy having successfully completed the first three stages and is ready to build the business through acquisitions and by investing in its proprietary platforms;

Venn acquired Open Orphan via an all-equity transaction of £5.7mln in shares to Open Orphan shareholders (at a £4mln valuation of Venn) giving a pre-money valuation of around £10mln. Following shareholder acceptance, Venn changed its name to Open Orphan and was admitted to the AIM and Euronext Growth Dublin market on 28 June with the ticker symbol ORPH.

ORPH has raised £4.5mln gross in a placing issuing 80,357,142 shares at the price of 5.6 pence per share in parallel with the reverse acquisition, and will seek to raise additional capital in future, all with the aim of

- pursuing its buy and build growth strategy;
- investing in its existing products and services including proprietary data platforms, the Virtual Rep offering and in its consulting capability;
- covering working capital needs.

The newly combined entity has implemented management changes combining expertise from the Venn and Open Orphan teams (see biography section);

Venn counts an array of leading biopharma companies among its customers across a diversified geographic base including Europe and North America

Venn Life Sciences

Venn is a European CRO providing drug development, clinical trial design and execution services from its sites in Ireland, France, Germany, the Netherlands, the UK and the US. The company was founded in 2007, listed on the AIM in 2012 via the reverse takeover of Armscote PLC and raised further funds on the Enterprise Securities Market in 2016. The company has made a series of acquisitions since 2012 to build expertise in services to both the pre-clinical and post-clinical markets.

Venn acquisitions		
Target	*Company function*	*Date acquired*
Armscote	Investment	December 2012
CRM Clinical Trials (Germany)	Clinical R&D	October 2013
Medevol (Northern Ireland)	CRO	December 2013
Evocutis plc (UK)	Skin care products evaluation	February 2014
Cardinal Systems SAS (France)	Data Management and Randomisation systems	August 2014
Kinesis Pharma BV (Netherlands)	Early stage drug development	September 2015

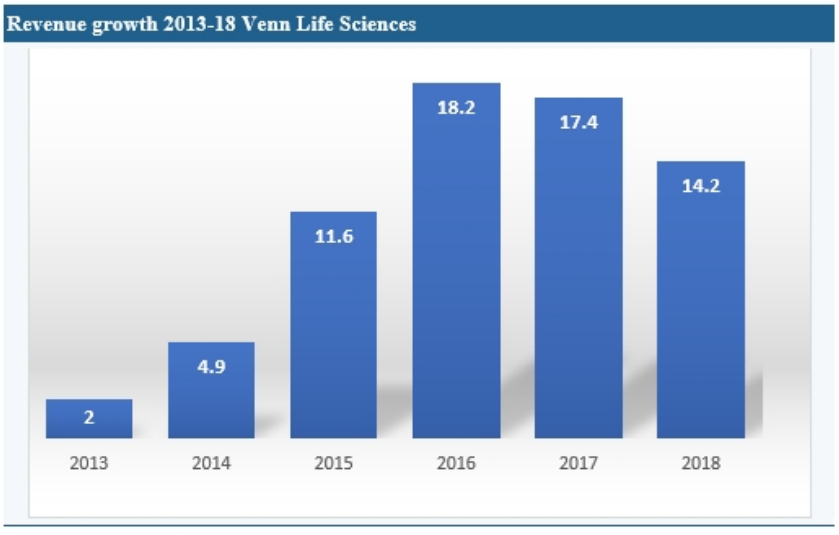
Source: Company

Venn counts an array of leading biopharma companies among its customers across a diversified geographic base including Europe and North America, many of which are household name pharmaceutical companies and a large percentage of its customers are orphan drug companies; however, the pharmaceutical market is notoriously secretive and it is normal practice across the entire pharmaceutical consulting services industry not to publish names of any of their key pharmaceutical clients. Around 80% of the consultancy clients are repeat customers. In total, Venn has more than 100 clients and the top four or five customers account for around 35-45% of revenue. A significant proportion of Venn's customers are within the rare diseases space.

Venn was identified as an excellent candidate to launch the Open Orphan platform

Financial Summary Venn

Venn's delivered top-line growth through acquisition since the reverse takeover (notably following the 2015 Kinesis Pharma acquisition) as well as by means of contract wins.



Source: Company data

In our view, ORPH is very well positioned to execute its planned rapid scale up to meet a fast-growing orphan drugs market

Revenue recognition is either via a proportional performance basis, milestones or on a time and materials basis. Revenue dropped from €17.4mln to €14mln from 2017 to 2018, as a result of the delayed win of a full-service client contract. Because of the high degree of operational leverage within the current business, this had an impact on underlying earnings (EBITDA), which fell into negative territory. Venn had €1.1mln of cash at the end of December 2018, with £1.2mln of loan notes outstanding.

Venn P&L summary €m		
	FY17	*FY18*
Revenue	17.41	14.2
EBITDA pre-exceptional items	1.0	-1.1
Pre-tax profit/(loss)	-1.67	-4.6
Basic EPS (c)	-2.55	-6.77

Source: Company data

However, Venn succeeded in securing this delayed large contract (announced November 2018) and this is expected to be recognised over the next 12-18 months.

Before the reverse takeover, the full-year forecast enterprise value/sales ratio was just 0.1x as per consensus at that time

Open Orphan – Venn synergies

Venn was identified as an excellent candidate to launch the Open Orphan platform;

- The buy and build strategy that Open Orphan will implement is aligned with Venn's acquisition rationale; however, Venn's strategy was impeded by its inability to raise sufficient capital and compounded by the falling share price. The newly combined Venn and Open Orphan teams are focused on building an enlarged group with the potential for significant top-line growth and margin accretion in this fragmented market.
- Venn has previously had contract timing issues which affected the bottom line. As we noted earlier, though, the ORPH plans to maximise synergies and efficiencies across the group by centralising certain key functions. A significant proportion of Venn's customers are within the rare diseases space meaning that it has a proven track record within this niche. ORPH is aiming to maximise this expertise and use it to complement its own specialities.
- At the smaller end of the CRO market Venn is rare in that it provides pre and post-clinical consulting services. Until the acquisition of Kinesis, Venn had been focused on the provision of services to late-phase development projects, but now can provide pre-clinical consultancy too. The range of capabilities means that Venn is well-positioned to be the basis for the bolt-on acquisitions, providing an end-to-end service to a diverse customer base. The wider group can cross-sell some of the better performing, higher-margin services of Venn such as biostatistics capability.
- Before the reverse takeover, the full-year forecast enterprise value/sales ratio was just 0.1x as per consensus at that time. The equity issuance price of £4mln of Venn represents an enterprise value/sales ratio of just 0.3x, which is a discount to some of the medium and large CROs at 3x as discussed earlier. This is one example of how companies can be acquired at a low valuation, supporting the value arbitrage that the group aims to achieve with scale.

Acquisition scenario analysis

Broadly speaking the baseline metrics for the buy & build strategy include:

- A mix of cash and equity-based on a current company valuation of £17mln
- Profitability – a margin in line with the sub US$1bn company range of 6-20%
- 1.5x sales acquisition multiple – e.g. for €15mln of revenues this would imply a total consideration of €22.5mln

Sensitivities

There are a range of factors that could affect the timing and execution of ORPH's strategy – we list a few of the main factors;

- Availability of target companies at an appropriate valuation
- Ability to raise capital or issue equity at favourable valuations minimising dilution
- Continued growth in underlying markets including outsourcing and investment in orphan drug development.

Conclusions

In our view, ORPH is very well positioned to execute its planned rapid scale up to meet a fast-growing orphan drugs market with a very experienced management team in place, a good starting cash position and the prospects of developing synergies across the enlarged company both in terms of its acquiring new businesses and in building potentially valuable and innovative data platforms. News flow over the next 12 months includes;

- Execution of the buy & build strategy
- News on meeting development targets for the data platforms starting from Q319.

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