



20 September 2021

*This announcement contains inside information
for the purposes of Article 7 of Regulation (EU) No 596/2014 as it forms part of UK law
by virtue of the European Union (Withdrawal) Act 2018 ("MAR")*

OPEN ORPHAN PLC
("Open Orphan" or the "Company")

Interim Results for six months ended 30 June 2021

Major year-on-year revenue growth and profitable H1 2021 performance following a year of turnaround and transition in 2020

Open Orphan (AIM: ORPH), a rapidly growing specialist contract research organisation (CRO) and a world leader in vaccine and antiviral testing using human challenge clinical trials, announces its unaudited interim results for the six months ended 30 June 2021. These results show a continued pattern of profitability from Q4 2020 to a firmly profitable position delivering a positive EBITDA profit of £2.1 million compared to an EBITDA loss of £4.1 million in H1 2020. We look forward to achieving record revenues in 2021 in our first full year of EBITDA profitability with recent contract wins and exceptional pipeline growth fueling revenues into 2022.

In the past 12 months, the Company has received international recognition and media attention for its excellence in delivering human challenge studies as a partner in the world's first COVID-19 human challenge characterisation study. The Company now has a broad range of human challenge study models, focusing on leveraging the major growth opportunities presenting in infectious and respiratory disease markets, including RSV, Influenza, Asthma, HRV, COPD and Malaria.

Profitable Financial Performance in H1 2021:

- Continuing from a profitable Q4 2020, the Company has moved the business to a firmly profitable position with losses consigned to the past
 - 242% reported revenue growth in H1 2021 (£21.9m) versus H1 2020 (£6.4m). Other income grew to £1.2m in H1 2021 from £0.7m in H1 2020
 - EBITDA profit of £2.1m (2020: EBITDA loss of £4.1m)
 - Revenue has more than tripled reflecting six active challenge studies in H1 2021 vs two active challenge studies in H1 2020 and a solid performance in Early Clinical / Biometry Services
 - In H1 2021, non-COVID-19 related work accounted for 75% of revenues
 - Gross margin has grown from 6% to 28% of revenue, reflecting that the Company is driving substantial operating leverage through cross selling, restructuring, functional integration and operational productivity
- Cash and cash equivalents were £14.9m at 30 June 2021, primarily reflecting the operating cashflow cycle of the business with new contract prepayments expected in H2 2021
- The Company has executed a share capital re-organisation as an important enabler to progress the monetisation of non-core assets via distribution of dividend in specie. In June, it completed the first distribution in specie back to the shareholders worth £26.2m at 16 September 2021, in relation to the demerging of certain non-core assets into Poolbeg Pharma Limited ("Poolbeg Pharma")

Open Orphan Plc Group
(Results as Reported)

	Unaudited	Unaudited
	6 months ended	6 months ended
	30 June 2021	30 June 2020
<u>Income Statement</u>	<u>£'000</u>	<u>£'000</u>
Revenue (incl. other income)	23,166	7,078
Gross Profit	6,041	390
Operating Profit (Loss) after exceptional items	1,629	(6,340)
EBITDA before exceptional items	2,073	(4,145)

Operational highlights

- Delivered a strong and growing pipeline of new challenge study contract wins across a broadening range of challenge studies including influenza, RSV, hRV, Asthma, etc. Strong growth from Big Pharma clients which will deliver revenues across H2 2021 and into FY 2022
- Continued to diversify services offering and associated activities such as virus manufacturing and lab services enabled by CAP and UKAS accreditations which are progressing, as well as the development of new challenge study models (Malaria, COVID-19) as part of its broadening portfolio of challenge models
- Leveraged its state-of-the-art facilities, including the new 19-bedroom quarantine facility (Whitechapel Clinic) beside the existing 24-bedroom Queen Mary's BioEnterprises Centre facilities also in Whitechapel (QMB). All COVID-19 characterisation study activities conducted in the 19-bedroom quarantine facility in Royal Free Hospital in London. We have delivered a record volume of quarantine studies on an increasingly cost-efficient basis with ample capacity to further grow the business
- Increased volunteer recruitment capacity through the opening of a new volunteer screening centre in Manchester and also a new dedicated street level screening facility in QMB increasing screening capacity to 520 visits per week
- Disease in Motion® launched as a first step towards its spin off as a standalone company, with the intention that the value will be delivered to our shareholders via dividend in specie in the same format as was successfully completed with Poolbeg Pharma plc. This unique data-focused platform has multiple infectious disease applications for a wide variety of end users including big tech, wearables, pharma and biotech companies

Post-period end

- Multiple high value human challenge study contracts signed – £5.7m Influenza study (September 2021), £8.1m asthma study (August 2021), significant hRV & Influenza study (July 2021)
- Successful Phase 2a RSV human challenge studies completed for a top tier pharma company and for Bavarian Nordic highlight the value of human challenge studies, their role in mainstream clinical trial design, and hVIVO's industry leading position
- Successfully monetised the first non-core asset via spin-out and AIM IPO of Poolbeg Pharma plc through a dividend in specie to Open Orphan shareholders, which was non-dilutive to existing shareholdings in the Company
 - As of 16 September 2021, the Open Orphan shareholders' value in Poolbeg Pharma plc is £26.2
 - Poolbeg Pharma raised £25m in fresh funds from new investors in an IPO in July 2021
 - Created substantial value for Open Orphan shareholders who received these dividend shares in Poolbeg Pharma with no income tax due as part of a HMRC approved statutory demerger
- Additional 1.3m shares in Open Orphan, valued at £350,000, purchased by Company Directors (Cathal Friel and Prof. Brendan Buckley)

Outlook

- Post-pandemic, the infectious and respiratory disease market is seeing exponential growth, with an expected global market value of \$250bn by 2025. This is resulting in a vastly increased market for Open Orphan to test a new range of infectious and respiratory disease products as the world leader in the provision of human challenge studies
 - The Company is experiencing a major increase in negotiations, contract wins, and repeat contract wins with Big Pharma, while also seeing increased wins from biotech companies with major deals expected to now sign in Q4 2021 driving revenue in 2022
 - Open Orphan is expanding its focus and service offering in providing infectious and respiratory disease challenge studies
- Full year guidance of c. £40m revenue (incl. other income) with full year EBITDA profitability for FY 2021, with non-COVID-19 work expected to represent c. 70% of FY 2021 revenue mix. While 2021 will represent record revenues for the Company and a return to full year EBITDA profitability, it is somewhat behind analyst expectations as the anticipated COVID-19 challenge studies will now likely commence in 2022 on

foot of the successfully completed quarantine phase of the Human Challenge Programme characterisation study

- Year-end cash balances expected to close in line with the half year position of £14.9m
- Targeting revenues in the region of £50m for 2022 in non-COVID-19 work, reflecting signed contracts and contracts in advanced negotiations, ongoing momentum in the core business and ongoing market growth. COVID-19 revenue for 2022 will be in addition to this and will depend on the eventual timing of these studies
- The Company continues to work towards the monetisation of all remaining non-core assets and to hand these back to Open Orphan shareholders via dividend in specie allowing the Company to focus on its core offering
 - These spin-offs / demergers offer an excellent opportunity for shareholders to maximise value in separate shareholdings in both exciting pharma product commercialisation companies, in addition to a profitable and world leading CRO
 - Opportunity to complete spin-off of Disease in Motion® platform along with plans to monetise the other non-core assets, namely the Company's 62.6% stake in PrEP Biopharm, and 49% stake in Imutex Limited

Cathal Friel, Executive Chairman of Open Orphan plc commented:

“Open Orphan has delivered very strong progress both operationally and financially. The Company's H1 2021 revenues grew by 242% versus H1 2020, which continues a pattern of profitability from Q4 2020 and transitions the business to a firmly profitable position, having delivered a positive EBITDA profit of £2.1 million in H1 2021. The business is now well positioned to capitalise on the significant growth in the infectious disease market, which is expected to grow to in excess of \$250bn by 2025 and we have seen our business development pipeline grow accordingly.

“I am delighted and hugely satisfied with the fantastic turnaround and team effort by everyone in the Open Orphan organisation; they have completely transformed the business following the acquisition of both hVIVO and Venn in the past two years. These two companies are now fully integrated and, in the process, we have created the world leader in the testing of vaccines, antivirals and other infectious and respiratory disease products using human challenge studies. With a broadening portfolio of human challenge studies, we are well placed to continue working with Big Pharma and biotechs alike to move their products through the clinic as the infectious disease market experiences one of the largest pharmaceutical growth cycles ever, with the market expected to grow significantly by 2025. We look forward to further progress and a profitable H2 as the business continues to attract additional clients.

“Additionally, we will look to provide further shareholder value through the monetisation of our non-core assets, as we did post-year end with the successful spin-out, listing and distribution in specie of Poolbeg Pharma plc.”

Analyst Briefing

An online briefing for Analysts will be hosted by Cathal Friel, Executive Chairman, and Leo Toole, Group Chief Financial Officer, at 9.30am (BST) on 20 September 2021 to review the results and prospects. Analysts wishing to attend should contact Walbrook PR on openorphan@walbrookpr.com or on 020 7933 8780.

Investor presentation

OPEN ORPHAN PLC is pleased to announce that Cathal Friel and Leo Toole will also provide a live presentation relating to **H1 2021 Interim Results** via the Investor Meet Company platform on **20 September 2021 at 6:00pm (BST)**.

The presentation is open to all existing and potential shareholders.

Investors can sign up to Investor Meet Company for free and add to meet **OPEN ORPHAN PLC** via:

<https://www.investormeetcompany.com/open-orphan-plc/register-investor>

Investors who already follow **OPEN ORPHAN PLC** on the Investor Meet Company platform will automatically be invited.

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Notes to Editors

[Open Orphan plc](#) (London and Euronext: ORPH) is a rapidly growing pharmaceutical service/contract research company that is a world leader in testing vaccines and antivirals using human challenge clinical trials. The Company provides services to Big Pharma, biotech and government/public health organisations.

Open Orphan runs challenge studies in London from both its 19-bedroom Whitechapel quarantine clinic and its state-of-the-art 24-bedroom QMB clinic with its highly specialised on-site virology and immunology laboratory. Open Orphan has a leading portfolio of human challenge study models for infectious and respiratory diseases and is developing a number of other models. There has been an explosion in the growth of the infectious disease pharmaceuticals market, which is estimated to grow to in excess of \$250bn by 2025. The Group is focused on refreshing its existing challenge models and develop new models, such as Malaria, to address the dramatic growth potential of the global infectious disease market.

Building upon its many years of challenge studies and virology research, the Company is developing an in-depth database of infectious disease progression data. Based on the Company's Disease in Motion® platform, this unique dataset includes clinical, immunological, virological and digital (wearable) biomarkers. The Disease in Motion platform has many potential applications across a wide variety of end users including big technology, wearables, pharma and biotech companies.

Open Orphan's Paris office has been providing biometry, data management and statistics to its many European pharmaceutical clients for over 20 years. For over 15 years, the Company's Netherlands office has been providing drug development consultancy and services, including CMC (chemistry, manufacturing and controls), PK and medical writing, to a broad range of European clients. Both offices are now also fully integrated with the London office and working on challenge study contracts as well as supporting third party trial contracts.

OPEN ORPHAN PLC
("Open Orphan" or the "Company")

Interim Results for six months ended 30 June 2021

Executive Chairman's Statement
For the six months ended 30 June 2021

Dear Shareholder,

I am very happy to report to you on the strong operational and financial progress made in the first half of 2021.

Having completed the integration of hVIVO plc with our existing Venn Life Sciences and Open Orphan DAC operations in 2020 and building on the profitable results in Q4 2020, we have successfully brought the combined business to EBITDA profitability, reversing a significant EBITDA loss and delivered 242% reported revenue growth in H1 2021 versus H1 2020.

This represents the culmination of almost 18 months of work by our dedicated staff to turn around the business by building out an enhanced portfolio of contracts with world leading established pharma players and innovative pharma start-ups driving leading edge novel technologies. During this time, we have also restructured and integrated our core functions while driving significant synergies; this has enabled the Group to enhance revenue generation and profitability through substantially increased operating leverage and margins.

As we move into a post-pandemic world, there has been an enormous expansion of investment in the infectious and respiratory disease market, which is estimated to grow to in excess of \$250bn by 2025. We are already benefitting from this rapidly expanding market, with our 242% revenue growth period on period, driven by six active challenge studies in the period (vs two in H1 2020), a testament to the increased demand for testing infectious disease products. The Group has further established its position as the world leader in the testing of vaccines and antivirals through human challenge studies by investing in refreshing its existing challenge models and developing new models, such as Malaria, to address the enormous expansion of the global infectious disease market.

We are actively engaging with a large number of the world's leading pharma companies who are stepping up their research in the areas of infectious disease. Two of our recent clients a top tier pharma company and Bavarian Nordic have referenced in their market updates the important contribution made by the Open Orphan plc subsidiary hVIVO in their Phase 2a challenge studies that we recently completed on both their RSV vaccine programmes. An increasing number of our recent deals and contract negotiation pipeline are from repeat Big Pharma clients. As such, we believe that Open Orphan is very well placed to capitalise on the rapidly growing market for human challenge trials to test infectious disease products with an expanding pipeline of major contracts. H1 2021 has also seen us diversify our associated services offering with our virus manufacturing and lab services continuing to play an important role in our mix of services.

Our core business of non-COVID-19 work reflected 75% of revenues in H1 2021 (£16.4m), with the balance (£5.6m) relating to COVID-19 projects. Given the strong growth trends towards infectious diseases, we expect our revenue mix to be increasingly weighted towards traditional challenge models for H2 2021 and into 2022.

As noted previously, we have substantially increased the number of quarantine beds that we have access to. We have grown from the original 24 quarantine bedrooms in our Queen Mary's BioEnterprises Centre in Whitechapel in East London, by adding 19 additional bedrooms through the conversion of the Whitechapel Hotel into the Whitechapel Clinic. Additionally, all COVID-19 characterisation study activities were conducted in the 19-bedrooms quarantine facility at the Royal Free Hospital in London. We have also increased our volunteer recruitment capacity through the opening of a new volunteer screening centre in Manchester and also a new dedicated street level screening facility in QMB, increasing our weekly screening capacity to in excess of 520 volunteers which is a five-fold increase over the prior years' screening capability.

Non-core asset monetisation

In May this year, we completed a share capital reduction within the Company as an important enabler to progress the monetisation of non-core assets via distribution in specie. In June, we completed a first distribution in specie in relation to the demerging of certain non-core assets into Poolbeg Pharma Limited (“Poolbeg Pharma”), which subsequently in July raised £25m and completed an IPO on the AIM market of the London Stock Exchange. The value of the distribution in specie shares for Open Orphan shareholders is valued at £26.2m as of 16 September 2021. The IPO was non-dilutive to Open Orphan and created substantial value for Open Orphan shareholders who received these dividend shares in a tax efficient manner as part of a HMRC approved statutory demerger, meaning this dividend in specie had no income tax liability for shareholders.

The Group is actively progressing our efforts to monetise our Disease in Motion® platform, which leverages a unique data-focused platform, comprising clinical, immunological, virological, and digital (wearable) biomarkers with multiple infectious disease applications for a wide variety of end users including Big Tech, wearables, pharma, and biotech companies. Over the coming months, we will advance the opportunity to spin-out the Disease in Motion platform, building on our success with Poolbeg Pharma plc. We continue to work towards monetising our existing joint ventures (49% share in Imutex Limited, developing vaccines against Influenza and universal mosquito borne diseases, and 62.62% of PrEP Biopharm Limited focused on the prevention of respiratory infections).

Financial Results

Continuing from a profitable Q4 2020, the Company has moved the business to a firmly profitable position, delivering revenue of £21.9m (vs £6.4m in H1 2020) and a positive EBITDA of £2.1m (vs an EBITDA loss of £4.1m in H1 2020). Other income grew to £1.2m in H1 2021 from £0.7m in H1 2020.

A strong series of new contract wins coupled with a focus on restructuring, integration and operating synergies, has driven significant year on year performance improvements, with gross margin having grown to 28% (H1 2020: 6%).

In light of the merger of Open Orphan plc and hVIVO plc on 17 January 2020, financial results are presented below on a reported basis and on a proforma basis to show a full calendar year comparison.

	Open Orphan plc Group (Results as Reported)		Open Orphan plc Group (Proforma results on a combined basis for half year)	
	Unaudited 6 months ended 30 June 2021	Unaudited 6 months ended 30 June 2020	Unaudited 6 months ended 30 June 2021	Unaudited 6 months ended 30 June 2020
Income Statement	£'000	£'000	£'000	£'000
Revenue (incl. other income)	23,166	7,078	23,166	7,441
Gross Profit	6,041	390	6,041	372
Operating Profit (Loss) after exceptional items	1,629	(6,340)	1,629	(6,977)
EBITDA before exceptional items	2,073	(4,145)	2,073	(4,734)

Cash and cash equivalents were £14.9m as 30 June 2021, this primarily reflects the operating cashflow cycle of the business with new contract prepayments expected in H2 2021. Year-end cash balances are expected to be in line with the half year position. The Company only has total debt of £323k which resulted from a loan note structure that was exercised prior to the IPO of Open Orphan in 2019. This £323k is due to be paid back in full by year end 2023.

Building on strong H1 2021 performance, which maintains a strong trend that began in Q4 2020, we continue our efforts to strengthen and optimise EBITDA margins by driving improved capacity utilisation across our quarantine units and labs, leveraging technology to improve operational efficiency, and driving full revenue recovery for billable time across all service lines. In addition, we have renegotiated operating leases to optimise rental costs in light of our core operational footprint and evolving post pandemic work practices.

Outlook

Going forward, the Group is focused on the strong growth prospects in the infectious and respiratory disease market, which has an expected global market value of \$250bn by 2025. The Company is well placed to continue working with Big Pharma and biotech companies to progress their infectious and respiratory disease products through the provision of human challenge studies in diseases such as RSV, Influenza, Asthma, hRV, COPD and Malaria.

The Company is targeting revenue in the region of £50m for 2022 in non-COVID-19 work, reflecting signed contracts and contracts in advanced negotiations, ongoing momentum in the core business and ongoing market growth. COVID-19 revenue for 2022 will be in addition to this and will depend on the eventual timing of these studies.

Our clinical science teams and laboratory development teams continue to address ground-breaking research projects with major pharmaceutical players.

The Group intends to continue the process of monetising its non-core assets to focus on building its position as the world leader in testing vaccines, antivirals, infectious and respiratory disease products.

I look forward to updating you in due course as we progress our exciting plans for the future.

Cathal Friel
Executive Chairman
20 September 2021

Consolidated Statement of Comprehensive Income
For the six months ended 30 June 2021

	6 Months ended 30 June 2021 Unaudited	6 Months ended 30 June 2020 Unaudited	Year ended 31 Dec 2020 Audited
Note	£'000	£'000	£'000
Continuing operations			
Revenue, from contracts with customers	21,946	6,416	20,602
Direct Project and Administrative costs	(21,537)	(13,418)	(32,437)
Other operating income	1,220	662	1,393
Operating profit/ (loss) after exceptional items	1,629	(6,340)	(10,442)
Depreciation and amortisation	(1,409)	(860)	(2,052)
Exceptional Item	965	(1,335)	(2,125)
EBITDA before exceptional items	2,073	(4,145)	(6,265)
Finance Expense	(111)	(200)	(374)
Share Based Payment charge	-	(176)	(240)
Share of loss of associate using equity method	5 (64)	(38)	(107)
Profit/(Loss) before income tax	1,454	(6,754)	(11,163)
Income tax (charge)/credit	(187)	264	372
Profit/(Loss) for the period	1,267	(6,490)	(10,791)
Profit/(Loss) for the period is attributable to:			
Owners of the parent	1,267	(6,490)	(10,791)
Other comprehensive income			
Currency translation differences	(336)	561	318
Total comprehensive profit/(loss) for the period	931	(5,929)	(10,473)

Earnings per share from continuing operations attributable to the owners of the parent during the period

Basic and diluted Profit/(loss) per ordinary share

	Note	£ Pence	£ Pence	£ Pence
From continuing operations	3	0.19	(1.22)	(1.80)
From Profit/ (loss) for the period		0.19	(1.22)	(1.80)

Consolidated Statement of Financial Position

As at 30 June 2021

		6 months ended 30 June 2021	6 months ended 30 June 2020	Year ended 31 Dec 2020
	Note	Unaudited £'000	Unaudited £'000	Audited £'000
Assets				
Non-current assets				
Intangible assets		6,194	5,832	6,127
Property, plant and equipment		1,077	591	1,068
Investment in associates	6	7,012	7,145	7,076
Right-of-use leased assets		2,358	3,873	4,230
Total non-current assets		16,641	17,441	18,501
Current assets				
Inventories		729	982	953
Trade and other receivables		8,977	2,612	9,806
Current tax recoverable		28	8	80
Cash and cash equivalents		14,910	14,651	19,205
Total current assets		24,644	18,253	30,044
Total assets		41,285	35,694	48,545
Equity attributable to owners				
Share capital	4	671	728	731
Share premium account	4	-	44,420	44,480
Merger reserve		(6,856)	(6,856)	(6,856)
Foreign currency reserves		1,106	1,685	1,442
Share Option and Warrant Reserve		493	429	493
Retained earnings	4	26,353	(13,692)	(17,993)
Total equity		21,767	26,714	22,297
Liabilities				
Non-current liabilities				
Trade and other payables		-	24	2
Lease Liabilities		520	2,247	2,194
Leasehold Provision		20	-	20
Total non-current liabilities		540	2,271	2,216
Current liabilities				
Trade and other payables		16,934	3,480	21,396
Deferred taxation		25	38	32
Lease Liabilities		1,696	1,873	2,245
Borrowings		323	1,318	359
Total current liabilities		18,978	6,709	24,032
Total liabilities		19,518	8,980	26,248
Total equity and liabilities		41,285	35,694	48,545

Consolidated Statement of Changes in Shareholders' Equity

	Share capital £'000	Share premium £'000	Merger reserves £'000	Share Option & Warrant reserve £'000	Foreign Currency reserve £'000	Retained earnings £'000	Total £'000
At 1 January 2020	317	15,214	(6,856)	253	1,124	(7,202)	2,850
Changes in equity for 6 months ended 30 June 2020							
Total loss for the period	-	-	-	-	-	(6,490)	(6,490)
Currency translation differences	-	-	-	-	561	-	561
Total comprehensive loss for the period	-	-	-	-	561	(6,490)	(5,929)
Transactions with the owners							
Shares issued	411	29,206	-	-	-	-	29,617
Share Option provision reserve	-	-	-	176	-	-	176
At 30 June 2020	728	44,420	(6,856)	429	1,685	(13,692)	26,714
Changes in equity for 6 months ended 31 December 2020							
Total loss for the period	-	-	-	-	-	(4,301)	(4,301)
Currency translation differences	-	-	-	-	(243)	-	(243)
Total comprehensive loss for the period	-	-	-	-	(243)	(4,301)	(4,544)
Transactions with the owners							
Shares issued	3	60	-	-	-	-	63
Share Option provision reserve	-	-	-	64	-	-	64
At 31 December 2020	731	44,480	(6,856)	493	1,442	(17,993)	22,297
Changes in equity for 6 months ended 30 June 2021							
Total profit for the period	-	-	-	-	-	1,267	1,267
Currency translation differences	-	-	-	-	(336)	-	(336)
Total comprehensive profit for the period	-	-	-	-	(336)	1,267	931
Transactions with the owner							
Shares issued	3	36	-	-	-	-	39
Capital Reduction	(63)	(44,516)	-	-	-	44,579	-
Distribution in Specie	-	-	-	-	-	(1,500)	(1,500)
At 30 June 2021	671	-	(6,856)	493	1,106	26,353	21,767

Consolidated Statement of Cash Flows

For the 6 months ended 30 June 2021

	6 Months ended 30 Jun 2021 Unaudited £'000	6 Months ended 30 Jun 2020 Unaudited £'000	Year ended 31 Dec 2020 Audited £'000
Cash Flow from operations			
Profit/(Loss) before income tax – continuing operations	1,454	(6,754)	(11,163)
Adjustments:			
- Depreciation & Amortisation	1,409	860	2,052
- Exceptional Items	(965)	1,335	2,125
- Net finance costs	111	200	374
- Share Option reserve	-	176	240
- Share of loss of associate using equity method	64	38	107
- R & D Credit Incl. in other income	(1,067)	-	(778)
Changes in working capital			
- Lease Payments	(1,176)	(889)	(1,999)
- Decrease/(Increase) Trade and other receivables	881	477	(2,800)
- Decrease/(Increase) Inventories	224	(982)	(28)
- (Decrease)/Increase Trade and other payables	(4,464)	1,025	14,410
Cash used in operations	(3,529)	(4,514)	2,540
Income tax (R & D) received	-	1,395	1,631
Net cash (used)/generated by operating activities	(3,529)	(3,119)	4,171
Cash flow from investing activities			
Cash acquired with acquisition of subsidiary	-	2,276	2,276
Purchase of property, plant and equipment (PPE)	(259)	(93)	(818)
Purchase of intangible assets	(132)	-	(274)
Net cash (used)/generated by investing activities	(391)	2,183	1,184
Cash flow from financing activities			
Proceeds from issuance of ordinary shares & options	21	16,603	18,031
Costs of fund raising	-	(1,335)	(1,335)
Exceptional Costs	(472)		(2,108)
Repayment of invoice discounting	-	(155)	(156)
Interest Paid	(5)	(100)	(188)
Loan Note Redemptions	(45)	-	(1,205)
Net cash(used)/generated by financing activities	(501)	15,013	13,039
Net (decrease)/increase in cash and cash equivalents			
	(4,421)	14,077	18,394
Cash and cash equivalents at beginning of period	19,205	1,037	1,037
FX translation	126	(463)	(226)
Cash and cash equivalents at end of period	14,910	14,651	19,205

NOTES FORMING PART OF THE INTERIM FINANCIAL STATEMENTS

1. General information

Open Orphan Plc is a company incorporated in England and Wales. The Company is a public limited company, limited by shares, listed on the AIM market of the London Stock Exchange. On 18 January 2016, the company also listed on the ESM market of the Irish Stock Exchange. The address of the registered office is Queen Mary Bio Enterprises, Innovation Centre, 42 New Road, London, E1 2AX, UK.

The principal activity of the Group is that of a rapidly growing specialist CRO pharmaceutical services company which is the world leader in the testing of vaccines and antivirals using human challenge clinical trials. The Group has a presence in the UK, Ireland, France and Netherlands.

The financial statements are presented in GBP£'000 (except where indicated otherwise), the currency of the primary economic environment in which the Group's trading companies operate. The Group comprises Open Orphan Plc and its subsidiary companies.

2. Basis of Preparation and Accounting policies

The consolidated financial statements of Open Orphan Plc have been prepared in accordance with International Financial Reporting Standards as adopted by the European Union (IFRSs), IFRIC interpretations and the Companies Act 2006 applicable to companies reporting under IFRS.

The consolidated financial statements have been prepared under the historical cost convention.

The accounting policies applied by the Group in this financial information are the same as those applied by the Group in its financial statements for the year ended 31 December 2020 and which will form the basis of the 2021 financial statements.

The financial information presented herein does not constitute full statutory accounts under Section 434 of the Companies Act 2006 and was not subject to a formal review by the auditors. The financial information in respect of the year ended 31 December 2020 has been extracted from the statutory accounts which have been delivered to the Registrar of Companies. The Group's Independent Auditor's report on those accounts was unqualified, did not include references to any matters to which the auditor drew attention by way of emphasis without qualifying their report and did not contain a statement under section 498(2) or 498(3) of the Companies Act 2006. The financial information for the half years ended 30 June 2021 and 30 June 2020 is unaudited and the twelve months to 31 December 2020 is audited.

There are no material events to report after the end of the reporting period.

The Interim Financial Statements were approved by the Board of Directors on 17 September 2021.

3. Earnings per share

(a) Basic

Basic earnings per share is calculated by dividing the profit/ (loss) attributable to equity holders of the Company by the weighted average number of ordinary shares in issue during the period.

6 Months ended 30 Jun 2021 Unaudited £'000	6 Months ended 30 Jun 2020 Unaudited £'000	Year ended 31 Dec 2020 Audited £'000
---------------------------------------------------------------	---------------------------------------------------------------	---------------------------------------------------------

Profit/(Loss) from continuing operations attributable to equity holders of the Company	1,267	(6,490)	(10,791)
Total	<u>1,267</u>	<u>(6,490)</u>	<u>(10,791)</u>
Weighted-average Ordinary Shares in issue	669,501,577	532,315,656	599,920,207
Earnings per Share (£ pence)	0.19	(1.22)	(1.80)

(b) Diluted

Due to the profitable result in the period, the effect of the share options and warrants noted below may be considered to be dilutive. In prior periods due to losses the share options and warrants were considered anti-dilutive.

	6 Months ended 30 Jun 2021 Unaudited	6 Months ended 30 Jun 2020 Unaudited	Year ended 31 Dec 2020 Audited
Potential dilutive ordinary shares:			
Options	8,467,525	15,899,111	9,516,111
Warrants	2,264,427	4,455,114	4,185,248
	<u>10,731,952</u>	<u>20,354,225</u>	<u>13,701,359</u>

4. Capital Reduction and Distribution-in-Specie

On 19 May, Open Orphan PLC received Court approval for reduction in its capital. Consequently, the deferred share capital balance of £62,833 was bought back by the Company and the balance in the Share Premium account of £44,516,591 of the Company was transferred to retained earnings.

On 18 June, Open Orphan Plc made a distribution in specie of £1,500,000 to all shareholders on the share register at close of business on 17 June 2021. Shareholders received shares in Poolbeg Pharma Ltd. These shares are to be held in trust by Croft Nominees Limited for a period of 9 months following Poolbeg Pharma Ltd.'s admission to the AIM market of the London Stock Exchange. Poolbeg Pharma Ltd changed its name to Poolbeg Pharma Plc on 23 June 2021. Following a successful period of fund-raising, Poolbeg Pharma Plc was admitted to AIM on 14 July.

5. Share of loss of associates and joint ventures

hVIVO Limited holds equity investments in development stage bio-pharmaceutical companies. As the invested companies are incurring research and development expenditure to develop products, no revenue will be generated, and losses will be presented, until the products are successfully commercialised.

At 30 June 2021, the Group held an investment in one associate, PrEP Biopharm Limited, and one joint venture, Imutex Limited (see Note 6).

The carrying amount of PrEP Biopharm Limited was fully impaired to £nil as at 31 December 2018 due to consideration of the then economic performance of this asset. This impairment was not an indication or an opinion on the utility of PrEP-001 but recognised that further development would need additional investment and at that time this was no longer part of hVIVO's re-focused business model.

The carrying amount of the investment in Imutex Limited is considered to be fully recoverable.

The Group's share of after- tax losses of its joint venture is set out below:

	6 Months ended 30 Jun 2021 Unaudited £'000	6 Months ended 30 Jun 2020 Unaudited £'000	Year ended 31 Dec 2020 Audited £'000
Share of loss of joint venture	(64)	(38)	(107)
Share of total comprehensive loss	(64)	(38)	(107)

6. Investment in associates and joint ventures

A reconciliation of the carrying value of the Group's investments in joint ventures and associates is as follows:

	6 Months ended 30 Jun 2021 Unaudited £'000	6 Months ended 30 Jun 2020 Unaudited £'000	Year ended 31 Dec 2020 Audited £'000
At start of period	7,076	7,183	7,183
Share of loss of associate using equity method	(64)	(38)	(107)
At end of period	7,012	7,145	7,076

7. Share based payments

There was no share-based payment charge in the period.

8. Press

A copy of this announcement is available from the Company's website, being www.openorphan.com. If you would like to receive a hard copy of the interim report, please contact the Open Orphan Plc offices on +353 1 644 0007 to request a copy.