

Arecor Therapeutics

Update

Broadening opportunities and preparing for the future

21 September 2022

Arecor is successfully progressing its in-house pipeline, with both key diabetes programmes, AT247 (ultra-rapid insulin) and AT278 (ultra-concentrated ultra-rapid insulin), undergoing Phase I studies. Recent AT278 data demonstrated the promising profile, which is especially suited to high-dose insulin users and will be further explored in an upcoming Phase I study in Type II diabetes. AT247 data from a US insulin pump trial is expected shortly and will similarly guide its likely role in the nascent, and commercially important, insulin pump market. The recent acquisition of Tetrus Pharma, supported by a £6m equity raise in August, brings near-term revenues and longer-term operational flexibility. Updating our rNPV model for H122 results and the acquisition generates an Arecor valuation of £177m, or 581p per share.

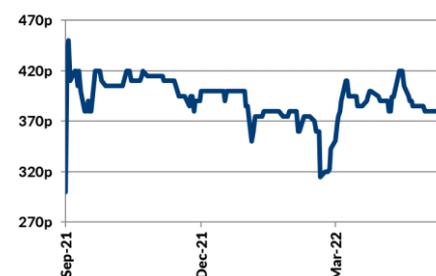
Year-end: December 31	2020	2021	2022E	2023E
Revenues (£m)	1.7	1.2	2.2	4.6
Adj. PBT (£m)	(4.3)	(7.1)	(12.7)	(14.1)
Net Income (£m)	(2.8)	(6.2)	(10.1)	(11.2)
EPS (p)	(0.2)	(0.3)	(0.3)	(0.4)
Cash (£m)	2.9	18.3	12.6	2.6
EBITDA (£m)	(3.3)	(6.3)	(10.9)	(12.4)

Source: Trinity Delta Note: Adjusted numbers exclude share-based payments and exceptionals.

- Creating an attractive diabetes franchise** Arecor's investment case centres on its emerging diabetes franchise, where its two key assets, AT247 (ultra-rapid insulin) and AT278 (ultra-concentrated rapid insulin), appear particularly well suited to address the needs of insulin pump delivery systems. These novel and technically sophisticated systems require specific absorption profiles that are more rapid and highly consistent. Early data are impressive and suggest competitive profiles well suited to the changing diabetes treatment regimens. Important AT247 US Phase I pump data and start of a further trial with AT278 are both expected during H222.
- Tetrus Pharma acquisition brings optionality** Tetrus Pharma, acquired in August, has exclusive rights to Xeris Pharmaceuticals' ready-to-use glucagon auto-injector pen, Ogluo, for the UK and Europe. This should bring additional near-term revenues and fits in well with the focus on improving "difficult to use" injectable products. The glucagon commercial opportunity is attractive in its own right and, in the longer term, Tetrus Pharma provides Arecor with the infrastructure to directly market selected niche products from its Specialty Hospital Products franchise.
- Funded through to key value inflection points** Cash at end-June 2022 was £13.7m (H121: £22.9m, FY21 £18.3m), boosted by the £6m (gross) raise in August to support the Tetrus Pharma acquisition. This should be sufficient to fund the clinical programmes for the in-house portfolio through to key value inflection points.
- Our current valuation is £177m, or 581p per share** We value Arecor using an rNPV model to capture the various programmes' commercial potential. Updating our model for H122 results, the equity raise and Tetrus Pharma acquisition sees our valuation rise to £177m (581p per share). This compares with our previous £159.8m (equivalent to 574p per share). Continued clinical progress, especially with AT247 and AT278, could result in material upside revisions to our model.

Price	265p
Market Cap	£80.8m
Enterprise Value	£67.1m
Shares in issue	30.5m
12-month range	252p-472p
Free float	34.2%
Primary exchange	AIM London
Other exchanges	N/A
Sector	Healthcare
Company Code	AREC

Corporate client Yes



Company description

Arecor Therapeutics is a revenue-generating clinical stage drug developer, with a well-balanced portfolio of in-house and partnered programmes. Its proprietary Arestat formulation platforms result in enhanced products with lower development risks and less onerous regulatory approvals.

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Arecor: Tetris Pharma adds an extra dimension

Arecor's H122 results confirmed progress is being maintained as we expect. The two in-house diabetes programmes, AT247 (ultra-rapid insulin) and AT278 (ultra-rapid and ultra-concentrated insulin) are on track with their Phase I clinical trials. The key near-term news will be data from the AT247 insulin pump study, expected during H222, which should establish whether AT247 has a suitable absorption profile for use in "closed loop" insulin pumps (also known as an "artificial pancreas"). The recent £6m equity raise supported the acquisition of Tetris Pharma, a sales and marketing business whose main attraction is exclusive UK and European rights to Xeris' Ogluo, a ready-to-use glucagon rescue pen. Longer term, Tetris Pharma will provide the commercial infrastructure for selected niche programmes within the Specialty Hospital Products pipeline. Cash of £13.7m should fund the proprietary programmes through a number of value inflection points. We value Arecor at £177m, equivalent to 581p a share.

Cash of £13.7m supports key development programmes

H122 results were as expected and confirm continued operational progress. Financially, total income was £1.1m (H121: £0.6m), which consisted of formulation development revenues of £0.7m (H121: £0.5m) and grant income of £0.4m (H121: £0.1m). The latter is part of the March 2021 £2.8m Innovate UK grant to support AT247's development. The investment in R&D increased to £4.8m (H121: £1.9m), reflecting the spend on the Phase I programmes for AT247 and AT278. SG&A costs were maintained at £1.6m (H121: £1.5m). R&D tax credits of £0.9m (H121: £0.3m) resulted in a loss after tax of £4.3m (H121: £3.1m). The cash balance at end-June 2022 was £13.7m, down from £22.1m at H121 and £18.3m at FY21. These resources, coupled with continuing partner development incomes and the £6m placing, are ample to fund the key activities through to several important value inflection points.

Tetris Pharma acquired for an initial £2m in shares with up to £4m in future earn-outs

Post-period, the most recent highlight was the August 2022 acquisition of [Tetris Pharma](#) for an initial consideration of 651,726 new shares, with an aggregate value of £2m, with further earn-outs worth up to £4m payable on revenue and EBITDA targets being achieved on the first, second, and third anniversaries of deal completion. Tetris Pharma is a commercial specialty pharma company that sells and distributes injectable specialty products across the UK and Europe. Its key asset currently is Ogluo, the first ready-to-use glucagon auto-injector pen that is used to treat severe hypoglycaemia in patients with diabetes.

Near- and longer-term synergies for both Specialty Hospital Products and diabetes franchises

The Tetris Pharma acquisition complements Arecor's formulation and development efforts and brings several strategic benefits across both Specialty Hospital Products and for the important diabetes franchise:

- **Strategic benefits:** Tetris Pharma offers a low-cost, and low-risk, way to capture greater long-term value for Arecor's development efforts in Specialty Hospital Products. Tetris Pharma's emerging sales and marketing infrastructure for Ogluo addresses a largely specialist and targeted audience. As this grows and Ogluo roll-out is increased, this should lead to an acceleration in revenue generation. Once the

infrastructure is fully established, this could be employed to market selected future niche products directly across Europe. While we expect the majority of the proprietary Arestat derived projects to be partnered, the Tetris Pharma organisation will provide additional options and offer the means to crystallise further value. The marketing of Ogluo to diabetic specialists, patient groups, and payors should also provide valuable insights for Arecor's key AT278 and AT247 programmes.

- Complementary products:** As an easy-to-use autoinjector pen, Ogluo fits well within Arecor's formulation and development efforts, which seek to create products that are more effective, easier to use, more stable, clinically optimised, and commercially relevant. In addition, as a product for patients with diabetes, it fits well with Arecor's diabetes franchise.

Brings options to commercialise select niche in-house products

Exhibit 1 shows the complementarity of Tetris Pharma with Arecor's strengths and how it helps accelerate the goal of becoming a research-led self-sustaining pharmaceutical company.

Exhibit 1: Tetris Pharma's fit within Arecor's existing skill sets

	Innovative proprietary technology platform	Best-in-class product pipeline	Focus on specialty hospital products	Focus on diabetes products	Revenue generating	Launched products	Commercial sales operation	Operational /distribution logistics
	[Skill Set]							
			[Skill Set]					

Source: Arecor Therapeutics

Ogluo is an easy-to-use glucagon injection

Ogluo is the pan-European name for Xeris' [Gvoke](#). Ogluo/Gvoke is a stable glucagon formulation available in a pre-mixed, pre-filled autoinjector pen that is rapidly and easily administered through a two-step process, versus a complex eight stage process which is the current standard of care for hypoglycaemic emergencies in the UK. The UK reimbursement price for Ogluo is £73 per single-use pen. Ogluo became available in December 2021 with active launch in March 2022. There have been 1,729 units sold to end June, contributing to Tetris Pharma's H122 sales of c £600k. Xeris launched Gvoke in the US in Q419 and it now has a 22.8% US glucagon market share. Xeris retains US rights and has granted a minimum 16-year licence agreement to Tetris Pharma. Ogluo is patent protected across Europe until at least 2035.

Traditional glucagon kits have well known limitations

Severe hypoglycaemia (very low blood sugar) is generally related to diabetic treatment, including insulin and sulfonylureas, and affects both Type I and Type II diabetes patients. It can lead to seizure and loss of conscious and is generally an emergency situation that requires rapid treatment, often administered by another person. Glucagon is an effective treatment for severe hypoglycaemia, however until recent years, it was only available as part of a kit, including from Eli Lilly (Glucagon Emergency Kit, GEK, which will be discontinued from 31 December 2022) and Novo Nordisk's GlucaGen Hypokit. These kits have to be prepared for use, often via multiple steps, which takes time, and the complexities can lead to

limited [7.9% treatment success](#), compared to 90.6% for a nasal glucagon spray, and 99% for Gvoke/Ogluo, according to Xeris.

New ready to use products are likely to increase patient uptake...

Since the availability of easier to use options, such as rescue pens and nasal sprays, the more complex glucagon kits are now being superseded, evidenced by Eli Lilly's decision to discontinue its kit. Ready-to-use glucagon options now include: Eli Lilly's Baqsimi, a nasal spray; Xeris' Gvoke/Ogluo, a rescue pen; and Zealand Pharma's Zegalogue, a rescue pen, which will now be [marketed](#) by Novo Nordisk. Ogluo is the only glucagon rescue pen currently approved in Europe.

...suggesting greater penetration into the diabetic population

It is [reported](#) that Type I diabetes patients have 1.15 severe hypoglycaemic events per year, and Type II patients have 0.35 events per annum, suggesting a significant opportunity. Not all patients who are prescribed insulin are also prescribed a glucagon for use in case of severe hypoglycaemia. However, glucagon prescriptions in the US have risen since the availability of more convenient options. It is this market that Arecor/Tetris Pharma is seeking to develop in the UK in the near-term and in Europe via a phased launch over the next 24 months.

Diabetes programmes are the main focus

Technological advances are set to alter the insulin marketplace

We view the in-house diabetes programmes as underpinning Arecor's investment case. Both AT247 (ultra-rapid insulin) and AT278 (ultra-rapid ultra-concentrated insulin) are progressing through clinical trials. The clinical appeal and patient relevance of these programmes, as well as the commercial opportunities and prospects, were covered in our [September 2021 Initiation](#) and expanded in our [January 2022 Update](#). The positive results of AT278's Phase I trial were presented at [ATTD](#) in April and their importance discussed in our [May 2022 Update](#) note.

Exhibit 2: A broad portfolio of de-risked and innovative assets

	Product	Area	Research	Preclinical	Phase 1	Phase 2	Phase 3	Est launch ¹	Current Market size	
Arecor in-house	AT247 & AT278	Diabetes	[Progress bar]					2025	~\$6.4B ²	
	AT299	Diabetes	[Progress bar]				2028			
	Specialty Hospital	RTA/RTU	[Progress bar]		Limited or no clinical development required under 505(b)(2) regulatory pathway ⁴			2025+	\$250m-1B ³	
Partnered Programmes	AT282 & AT307 Specialty Hospital	RTU undisclosed products 	[Progress bar]		Limited or no clinical development required under 505(b)(2) regulatory pathway ⁴			From 2024+	>\$300m ⁵⁺	
	Ogluo®	RTU Glucagon Pen 						Launched UK	~£100m	
	Niche Specialty Hospital (9 licenses)	UK sales & distribution rights						Launched UK	Undisclosed	
	AT220	Undisclosed Biosimilar & Partner	[Progress bar]			Late Stage Development			2023	\$Multi-billion
	AT292	Alpha-1 antitrypsin deficiency 		[Progress bar]					2025	>\$1.1B ⁷
Technology Partnerships	Formulation development ⁺	  								

Source: Arecor Therapeutics Note: 1, 2, 3, and 5 Management estimates; 4 based on FDA 505(b)(2) guidelines; 6 Company annual report; 7 Inhibrx Corporate presentation.

AT247 could offer the “close to ideal” absorption profile

The focus is now on AT247, which is completing a US Phase I trial evaluating its use in a three-day insulin pump study. The aim is to establish the evidence base to support AT247's use in fully closed insulin pump systems, which are also known as the artificial pancreas. The format is a three-way crossover examining AT247 and

Novo Nordisk's NovoLog and Fiasp in 24 patients with Type I diabetes. All will be delivered subcutaneously by CSII (continuous subcutaneous insulin infusion) using the popular Medtronic 670G pump. The study will examine the onset of insulin action following bolus dose (PK) and the glucose lowering action (PD) of AT247 compared to both NovoLog and Fiasp, as well as safety and tolerability. The top-line results of this study are expected to be known during H222 and given dosing was completed in July, we expect these could become available in early Q422.

AT220 could be the first launched partner programme

AT220 biosimilar could become the first approved product using Arecor's technology

Within Specialty Hospital Products and technology partnerships, in June 2022 a formulation study collaboration was agreed with a global top five pharmaceutical company to employ Arestat to develop improved formulations of a number of their existing products. Of the four existing licensed programmes, AT220, an undisclosed biosimilar addressing a blockbuster market, is the most advanced and on track for approval during 2023. This would trigger a milestone payment and then royalties (or equivalent) on commercialisation.

Valuation and Financials

Valuation of £177m, 581p per share

We value Arecor using an rNPV model, explicitly valuing the diabetes franchise, four partnered assets, and the in-house Specialty Hospital Products research programme(s). We have updated the model to reflect the H122 results, the £6m equity raise in August, and the subsequent acquisition of Tetris Pharma. This sees our valuation rise to £177m (581p per share), which compares with our previous £159.8m (equivalent to 574p per share). The details are summarised in Exhibit 3. We are aware there is a raft of potential news flow, notably clinical trial related, over the coming months and intend to revisit our assumptions as they arise.

Tetris Pharma will build on Arecor's current revenues

Arecor is revenue generating, with relatively predictable income from its formulation development partnerships and more variable income from licence agreements, which consist of upfront payments when licences are granted and milestones which are contingent on development progress and commercialisation. The Tetris Pharma acquisition will bring an income stream from commercial sales, principally Ogluo as it gains traction in the UK and then benefits from subsequent launches across Europe.

Tetris Pharma valued at £6.9m based on conservative assumptions

We have modelled the Ogluo sales uptake conservatively, in line with our philosophy of employing modest assumptions throughout, with break-even occurring no earlier than year 3 post-launch in any major market. This results in an rNPV of £6.9m, which feels intuitively appropriate for this stage of the launch rollouts. For context, Zealand Pharma's agreement with Novo Nordisk for its ready-to-use glucagon, Zegalogue, saw an upfront of DKK25m (c \$3.3m) and subsequent development, regulatory and manufacturing-based milestones of DKK45m (c \$6m), plus up to DKK220m (c \$30m) in sales milestones and royalties of high single- to low double-digit percent.

Cash sufficient to value inflection points

H122 cash of £13.7m, together with the August £6m (gross) placing, should enable Arecor to progress its in-house diabetes and Specialty Hospital Products to partnering inflection points, as well as expanding its internal capabilities to support progression and growth in its earlier-stage formulation portfolio. Assuming continued progress, we anticipate a significant increase in R&D

investment to £10.0m for FY22e and £11.0m for FY23e (FY21: £5.4m) as the more extensive (and expensive) Phase II diabetes trials are initiated. We expect only modest growth in underlying Arecor SG&A spend, with a base run rate of c £3.0m, but the Tetris Pharma spend in supporting Ogluo's UK launch and subsequent European marketing plans means we forecast SG&A of £4.4m in FY22e (consolidating 5 months of Tetris Pharma) and £7.2m in FY23e.

Exhibit 3: Arecor rNPV valuation

Programme	Total NPV (£m)	Total NPV (\$m)	Success probability	Royalty	rNPV (£m)	rNPV (\$m)	rNPV/share (p)	Notes
AT247 (Type I diabetes)	95.9	115.1	60%	High single to double-digit	43.4	52.0	142.2	Peak sales: \$358m; Launch year: 2025
AT278 (Type II diabetes)	120.7	144.9	60%	High single to double-digit	55.5	66.6	181.9	Peak sales: \$516m; Launch year: 2026
AT299 (Diabetes)	18.8	22.5	10%	Low single digit	1.9	2.3	6.4	Peak sales: \$200m; Launch year: 2028
Research (Specialty Hospital)	21.6	25.9	20%	High single to double-digit	5.2	6.2	17.0	Peak sales: \$100m; Launch year: 2025+
AT282 (Specialty Hospital - Hikma)	60.7	72.8	75%	High single to double-digit	43.9	52.7	144.1	Peak sales: \$150m; Launch year: 2024
AT307 (Specialty Hospital - Hikma)	23.5	28.2	60%	High single to double-digit	13.1	15.7	42.9	Peak sales: \$75m; Launch year: 2025
AT220 (undisclosed biosimilar - partnered)	10.8	13.0	80%	Low single digit	7.7	9.3	25.4	Peak sales: \$500m; Launch year: 2023
AT292/INBRX-101 (AATD - Inhibrx)	15.0	18.1	30%	Low single digit	5.3	6.4	17.4	Peak sales: \$390m; Launch year: 2025
Tetris Pharma/Ogluo	6.9	8.3	100%	N/A	6.9	8.3	22.7	Peak sales: \$10m; Launch year: 2021
Operating costs	(18.5)	(22.1)			(18.5)	(22.1)	(60.5)	
Net cash at FY22e	12.6	15.2			12.6	15.2	41.4	
Total	368.0	441.6			177.1	212.5	580.9	

Source: Trinity Delta Note: AATD = Alpha-1 antitrypsin deficiency; assumptions include a 12.5% discount factor, £/\$ FX rate of 1.20, and 10% taxation from 2026 (UK patent box).

Greater visibility, coupled with continued progress, should provide material upside

Our forecasts (in Exhibits 3 and 4) are deliberately conservative and do not include any assumptions on potential conversion(s) of pre-licence technology partnerships to longer-term licence agreements (which bring the potential for small upfront payments, plus future milestones and single-digit royalties). Similarly, the magnitude of licence derived income will be determined by development and commercial progress of licenced programmes, the timing and terms of new partnership deals (particularly for the in-house diabetes assets), and product launches. Arecor's four existing partnered products (two that emerged from technology partnerships, two from out-licencing internally developed formulations) are expected to generate development and commercial milestones, plus royalties or equivalent on sales from 2023 onwards following anticipated launches (obviously these will build over time).

Exhibit 4: Summary of financials

Year-end: Dec 31	£'000s	2019	2020	2021	2022E	2023E
INCOME STATEMENT						
Revenues		748	1,698	1,158	2,195	4,617
Cost of goods sold		0	0	0	0	0
Gross Profit		748	1,698	1,158	2,195	4,617
R&D expenses		(3,085)	(3,937)	(5,386)	(9,964)	(10,961)
SG&A expenses		(1,416)	(1,642)	(2,389)	(4,408)	(7,199)
Underlying operating profit		(3,753)	(3,880)	(6,617)	(12,177)	(13,542)
Share-based payments		(201)	(318)	(484)	(629)	(654)
Exceptionals		0	0	(462)	0	0
Other revenue/expenses		898	452	640	1,120	1,040
EBITDA		(2,688)	(3,259)	(6,268)	(10,904)	(12,360)
Operating Profit		(2,855)	(3,428)	(6,439)	(11,057)	(12,502)
Financing costs/income		(15)	(84)	(21)	92	63
Profit Before Taxes		(2,870)	(3,512)	(6,945)	(10,966)	(12,439)
Adj. PBT		(3,970)	(4,283)	(7,122)	(12,715)	(14,133)
Current tax income		435	760	776	897	1,206
Net Income		(2,435)	(2,752)	(6,169)	(10,069)	(11,233)
EPS (p)		(1.1)	(0.2)	(0.3)	(0.3)	(0.4)
Adj. EPS		(1.5)	(0.2)	(0.3)	(0.4)	(0.4)
DPS (p)		0.0	0.0	0.0	0.0	0.0
Average no. of shares (m)		2.3	16.2	23.0	28.8	30.0
<i>Gross margin</i>		100%	100%	100%	100%	100%
<i>EBITDA margin</i>		N/A	N/A	N/A	N/A	N/A
<i>Underlying operating margin</i>		N/A	N/A	N/A	N/A	N/A
BALANCE SHEET						
Current assets		4,998	3,822	20,515	16,417	7,023
Cash and cash equivalents		3,447	2,898	18,316	12,630	2,633
Short-term investments		0	0	0	0	0
Accounts receivable		809	166	1,423	1,804	1,898
Inventories		0	0	0	309	743
Other current assets		742	758	776	1,673	1,750
Non-current assets		452	462	406	377	390
Property, plant & equipment		353	375	328	305	323
Intangible assets		51	38	30	24	19
Other non-current assets		48	48	48	48	48
Current liabilities		(1,107)	(1,408)	(2,267)	(2,119)	(2,318)
Short-term debt		0	0	0	0	0
Accounts payable		(1,014)	(1,303)	(2,141)	(1,993)	(2,192)
Other current liabilities		(93)	(105)	(126)	(126)	(126)
Non-current liabilities		(128)	(2,102)	(105)	(105)	(105)
Long-term debt		0	(1,698)	0	0	0
Other non-current liabilities		(128)	(403)	(105)	(105)	(105)
Equity		4,216	774	18,549	14,569	4,990
CASH FLOW STATEMENTS						
Operating cash flow		(2,505)	(1,857)	(5,450)	(11,022)	(10,842)
Profit before tax		(2,870)	(3,512)	(6,945)	(10,966)	(12,439)
Non-cash adjustments		389	614	1,156	691	733
Change in working capital		(23)	747	(419)	(1,706)	(327)
Interest paid		0	0	0	92	63
Taxes paid		0	295	758	867	1,128
Investing cash flow		(65)	(49)	(68)	(124)	(155)
CAPEX		(73)	(52)	(69)	(124)	(155)
Acquisitions/disposals		0	0	0	0	0
Other investing cash flows		9	3	1	0	0
Financing cash flow		5,317	1,774	20,931	5,460	1,000
Proceeds from equity		5,424	0	18,565	5,460	1,000
Increase in loans		0	1,840	2,500	0	0
Other financing cash flow		(107)	(67)	(134)	0	0
Net increase in cash		2,748	(132)	15,413	(5,686)	(9,997)
Exchange rate effects		(6)	(43)	5	0	0
Cash at start of year		705	3,074	2,898	18,316	12,630
Cash at end of year		3,447	2,898	18,316	12,630	2,633
Net cash at end of year		3,447	1,200	18,316	12,630	2,633

Source: Company, Trinity Delta Note: Due to subsequent restatement of accounts FY19 relates to the 12 month period ending 31 May 2019.

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