Trinity Delta

Arecor Therapeutics

Update

Ambitious, focussed, and delivering on its promise

25 April 2022

Arecor has delivered FY21 results in-line with expectations. More importantly, these demonstrate continued progress and highlight the breadth of opportunities to which the Arestat platform, and in-house formulation expertise, can be applied. There are five additional technology partnerships, with sizeable players, that generate near-term value, validate the technology, and offer future significant licence potential. However, it is the in-house diabetes programmes, AT247 (ultra-rapid insulin) and AT278 (ultra-concentrated ultra-rapid insulin), that we find particularly attractive. Phase I data suggest both have highly promising, differentiated profiles that are particularly suited to emerging pump applications and high insulin users. We value Arecor at £140.9m, or 506p per share, with significant upside from clinical and operational progress.

Year-end: December 31	2020	2021	2022E	2023E
Revenues (£m)	1.7	1.2	1.4	1.6
Adj. PBT (£m)	(4.3)	(7.2)	(13.0)	(9.4)
Net Income (£m)	(2.8)	(6.2)	(9.8)	(7.2)
EPS (p)	(0.2)	(0.3)	(0.4)	(0.3)
Cash (£m)	2.9	18.3	9.0	2.4
EBITDA (£m)	(3.3)	(6.3)	(11.0)	(8.0)

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

- **Creating an attractive diabetes franchise** Encouraging results from the AT247 (ultra-rapid insulin) and AT278 (ultra-concentrated rapid insulin) Phase I trials demonstrate Arecor's formulation expertise can modulate the absorption profile of insulins selectively and consistently. The outcomes are impressive, albeit early, and suggest both have competitive clinical profiles that are well suited to the changing diabetes treatment regimens. These include the integration of wearable glucose monitoring devices and algorithm-driven insulin pumps, or "artificial pancreas".
- **Progress with partnerships and Specialty Hospital Products** The four existing licensed programmes have continued to progress during FY21, with five pre-licence programmes also added. These include milestones and royalties with clinical success set to generate medium- and longer-term revenue streams. Specialty Hospital Products development is focussed on improving "difficult" injectable products, aiming to provide clinically material benefits such as ready-to-use formats for safer, faster, and simplified delivery. Although lower profile, we view these as valuable.
- **Funded through to key value inflection points** Cash at end-December 2021 was £18.3m (FY21: £2.9m), boosted by the £20m (gross) raised during the successful admission to AIM in June 2021. These funds are sufficient, even when worst case stress tested against no revenues arising during FY22, to fund the clinical programmes for the in-house portfolio through to key value inflection points.
- **Our current valuation is £140.9m, or 506p per share** We value Arecor using an rNPV model to capture the various programmes' commercial potential. Despite conservative assumptions, our valuation is £140.9m (506p per share). Continued clinical progress, especially with diabetes, greater visibility on partnered products, and further licensing deals, would result in material upside revisions to our model.

Price	390p
Market Cap	£108.6m
Enterprise Value	£90.3m
Shares in issue	27.8m
12-month range	222p-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.

Analysts

Lala Gregorek
lgregorek@trinitydelta.org
+44 (0) 20 3637 5043

Philippa Gardner
pgardner@trinitydelta.org
+44 (0) 20 3637 5042

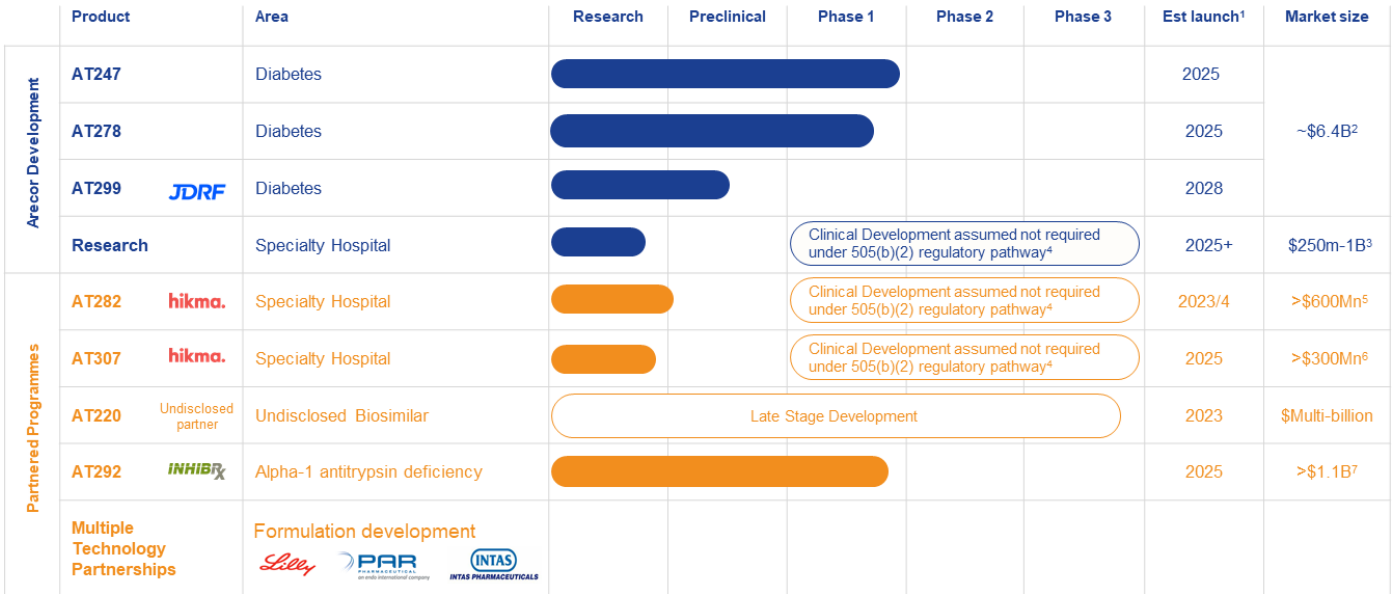
Arecor: addressing emerging diabetes needs

Arecor is exploiting its Arestat formulation platform to create a portfolio of proprietary and partnered clinical assets. There are currently four partnered products (two from technology partnerships, two from internally developed specialty hospital products) that will generate milestones, plus royalties or equivalent on sales. These should provide a blend of medium- and longer-term revenue streams. However, we view the diabetes programmes, AT247 (ultra-rapid insulin) and AT278 (ultra-rapid ultra-concentrated insulin), as particularly attractive. These are undergoing a series of Phase I studies, with early data suggesting they offer competitive and differentiated clinical profiles that may be ideally suited for use in integrated insulin delivery systems ("artificial pancreas") and more effective treatments for high insulin users. The successful IPO (June 21) raised £20m to fund these key programmes to value inflection points. We value Arecor with an rNPV model using conservative assumptions. Continued progress would see us revisit our current valuation of £140.9m (506p per share).

A proven formulation platform that creates desirable products

FY21 results are as expected and highlight the progress being made. Arecor's investment case lies in its proprietary Arestat platform to develop novel formulations of existing products. These are specifically created to offer improved attributes, ranging from better shelf life and stability, easier patient administration, and superior therapeutic profiles through tailored absorption characteristics.

Exhibit 1: A broad portfolio of de-risked and innovative assets



1. Management estimates; 2. Prandial insulin market 2019, estimate based on 2019 sales figures of Eli Lilly, Novo Nordisk and Sanofi Aventis reported in Company Annual Reports, exchange rates as at 15 February 2021; 3. Range of currently marketed products, source company annual reports and IQVIA; 4. Management assumption that new formulation will not require clinical data for approval under 505(b)(2) guidelines, to be validated for each product with US Food & Drug Administration; 5. Product towards upper end of hospital RTU/RTA market sales; 6. Company annual report; 7 2018 global AATD augmentation therapy, projected to reach $1.9B by the end 2026, Inhibrx Corporate presentation, Jan 2021

Source: Arecor Therapeutics

This is undertaken for clients through technology partnerships, which bring in near-term revenues, and licensing deals, that involve better success-based economics, including clinical and commercial milestones and net sales royalties or equivalent. Management is also developing a portfolio of in-house development programmes that are focussed on diabetes and specialty hospital products. We covered these elements in our Initiation note, with a further Update note detailing the opportunities and prospects for the diabetes franchise.

Diabetes programmes are particularly attractive

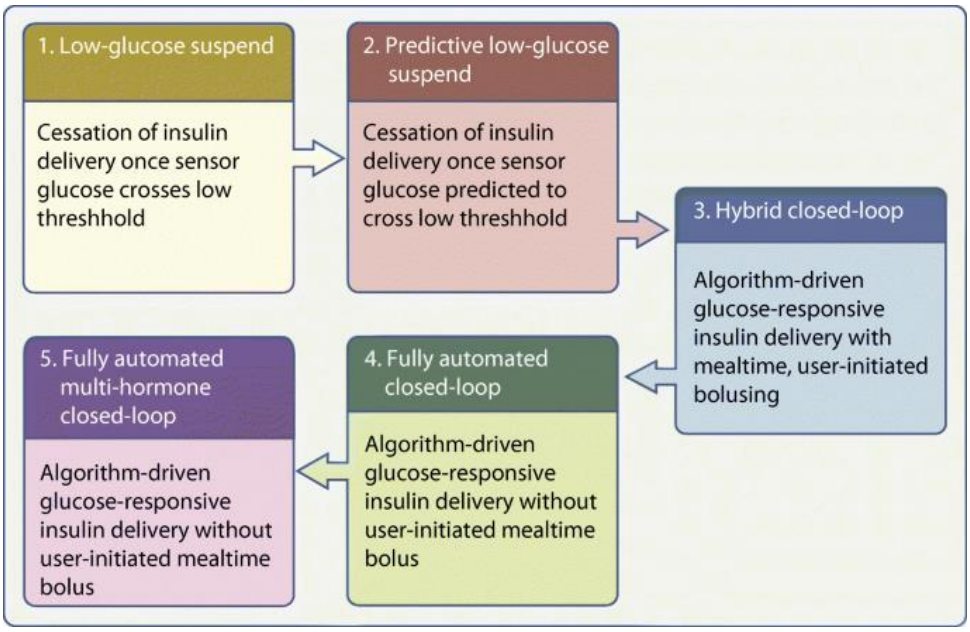
Attractive absorption profiles address emerging clinical needs

The two key clinical stage diabetes programmes are the ultra-rapid insulins (AT247 and AT278). **AT247** is a novel formulation of existing insulin that aims to materially accelerate absorption after injection, achieving a profile that closely approximates healthy (non-diabetic) physiological insulin secretion, giving more effective management of blood glucose levels. **AT278** is a novel formulation of insulin aspart with the focus on creating a highly concentrated, 500 units/ml, fast-acting insulin. Such high concentration insulins are expected to become increasingly in demand, reflecting the rising number of Type II and refractory Type I diabetics requiring higher daily dosing. These programmes offer the prospect of absorption profiles that closely match the emerging clinical needs.

Miniaturisation and advanced electronics to drive diabetes care

Advances in miniaturisation and computing power have seen the introduction of viable continuous glucose monitors (CGM). These allow patients, and clinicians, to assess trends, patterns, and time spent in range in real time. The sensor tests glucose every few minutes and sends an alarm if hypo- or hyper-glycaemia is threatened. Such devices have been transformative for some patients. In parallel, similar technological advances saw sophisticated, and reliable, wearable pumps developed. These pumps, known as continuous subcutaneous insulin infusion (CSII) therapy, have evolved rapidly and offer near-normal glucose control in previously uncontrolled diabetics. The advantage of eliminating multiple daily injections was initially particularly attractive for children and adolescents. However, the improved short- and longer-term clinical outcomes have become a key uptake driver for many Type I and, increasingly, Type II diabetics.

Exhibit 2: Key milestones towards a truly artificial pancreas



Source: New closed loop insulin systems Boughton & Hovorka Diabetologia 1007-1015 (2021)

A clear need for specialised ultra-fast acting insulins

Whilst the advances in miniaturising and integrating the various technologies have been impressive, major obstacles remain. For instance, the inherent delays in absorption of subcutaneous injected insulin compared with endogenous insulin production means that postprandial hyperglycaemia remains a challenge for these closed-loop systems. The pharmacokinetics and pharmacodynamics of current

rapid-acting insulins are known to be sub-optimal. The new ultra-rapid acting insulins, which have faster onset and offset of action, have the potential to address this issue. Small studies with Fiasp (faster aspart) and Lyumjev (ultra-rapid lispro) have not shown the hoped-for conclusive results. It is for this clear clinical need that AT278 (ultra-concentrated ultra-rapid insulin) and AT247 (ultra-rapid insulin) appear particularly well suited.

Exhibit 3: Arecor diabetes franchise development timelines

Source: Arecor Therapeutics

AT247 showed improvements in all key study parameters

AT247 was examined in a Phase I clinical trial that compared it against Novo Nordisk's NovoRapid (IAsp) and Fiasp (faster IAsp). The double-blind study tested 19 Type I diabetics using a standard glucose clamp setting to determine the pharmacokinetic (PK), pharmacodynamic (PD), and safety characteristics of AT247. Full results were published in Diabetes Care February 2021, with AT247 having successfully met all study endpoints and suggesting a best-in-class profile.

These data show that AT247 has a superior onset of action and activity throughout the important 120 minutes after dosing vs both NovoRapid and Fiasp. For instance, AT247 was nine minutes faster than Fiasp for onset of action, achieved a three-fold increase in glucose lowering in the first 30 minutes and a two-fold increase in the first 60 minutes, yet was comparable over 480 minutes. As expected, AT247 was well tolerated with no safety concerns seen.

Further studies in clinically relevant applications

A second Phase I study with c 24 Type I diabetics evaluating AT247 administered over three days through a continuous subcutaneous infusion via an insulin pump dosed its first patient in January 2022. The study design is a double blind, randomised, three-way crossover which will examine PK and PD, using a glucose clamp, against active controls (NovoRapid and Fiasp). The top-line results are anticipated in H222. A multi-centre Phase II study with c 42 diabetic patients will likely then explore AT247 against Fiasp when administered through an insulin pump over an extended period (around six weeks).

Impressive AT278 data exceeded our expectations

AT278 reported top line results from the Phase I study in Type I diabetics in September 2021. The trial met all primary and secondary endpoints, demonstrating a superior PK and PD profile to a comparable dose of a lower concentration of NovoRapid (Novo Nordisk's gold standard rapid acting insulin). The trial evaluated 38 adults with Type I diabetes in an euglycemic clamp setting aiming to establish PK/PD equivalence between subcutaneous AT278 0.3 U/kg (500 U/ml) that was five-fold more concentrated than the comparator NovoRapid 0.3 U/kg (100 U/ml). AT278 matched or exceeded key measures such as glucose lowering, onset of action, and absorption profile, and there were no safety signals.

AT278 could be a "wild card" in our modelling

The outcomes are impressive and better than we expected. The top-line results showed AT278 has, despite the five-fold greater concentration, the absorption profile not simply matching the rapid insulin criteria, but the PK/PD data justifies AT278 being labelled an ultra-rapid insulin. Full data are expected to be presented at ATTD on Thursday 28 April. The next steps should see further European and US Phase I trials in both injected and pump settings; with the first of these expected to start during H222. Assuming smooth progress through the clinical programmes and approval processes, first launch could happen as early as 2025 (we have assumed 2026 in our modelling).

Specialty Hospital Products are underappreciated

Many specialist injectables have sub-optimal formulations

Arecor's Specialty Hospital Products development is focussed on improving injectable products that have clear issues, such as the need to be reconstituted (for instance the drug is a lyophilised powder). The desire to minimise the preparation of any injectable in a clinical setting is not simply the time element, where numerous studies have shown the staff time savings comfortably justify the price premiums, but, more importantly, minimising handling materially reduces dispensing and administration errors.

Exhibit 4: Five new collaborations signed during 2021

Exclusive formulation study collaboration with Lilly	Exclusive formulation study collaboration with Par Sterile Products	Exclusive formulation collaboration with Intas Pharmaceuticals	Exclusive formulation study collaboration with leading global medical products company	Exclusive formulation study collaboration with global technology leader
Differentiated, thermostable formulation	*Differentiated ready to use formulation*	*Differentiated, improved usability formulation*	*Differentiated, stable, liquid formulation*	*Improved, stable, liquid formulation*
May 2021	*June 2021*	*September 2021*	*November 2021*	*December 2021*

Source: Arecor Therapeutics

A number of licensing deals are already in place

Arecor currently has two active licensing agreements in place for specialty hospital products. Both programmes are partnered with Hikma, with the most advanced, AT282, being a novel formulation of an already marketed product that is only available as a lyophilised powder that needs to be re-constituted before use. The new formulation is a stable RTU liquid concentrate which was initially developed to proof of concept by Arecor and then partnered. The deal was struck in January 2020 and the next milestone is expected during 2022. The regulatory pathways for AT282 are expected to be the abbreviated 505(b)(2) in the US and under the Directive 2001/83/EC Hybrid pathway in Europe. As these will reference the originator drug for evidence of clinical efficacy and safety, no major clinical trials are expected to be required. Current timelines suggest first marketing approval could happen as early as 2024.

Valuation and Financials

Valuation of £140.9m, 506p a share, leaves scope for upgrades

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 FY21 results however the closeness of key numbers to our expectations means there is no tangible change to our current valuation of £140.9m or 506p a share. 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 these arise.

As mentioned, FY21 results were in-line with our expectations. The highlight was the June AIM IPO which raised £20m gross (£18.5m net), boosting December 2021 cash to £18.3m (vs £2.9m at end-December 2020). These resources provide funding for the planned activities through 2023, a comfortable runway to achieve multiple value inflection points and upside potential.

FY21 results were as expected, with spend as planned

FY21 revenue of £1.8m (FY20: £2.2m, boosted by a £0.9m licence milestone) was primarily derived from formulation development programmes (£1.2m) and grant funding (£0.6m). The grant element was part of the £2.8m Innovate BioMedical Catalyst grant awarded in March 2021 to support the Phase II development of AT247. R&D expenditure rose to £5.3m (FY20: £3.9m), reflecting the spend on clinical trials for AT278 and AT247. G&A expenditure increased to £2.0m (FY20: £1.3m), with a further £0.5m being the non-recurring costs of the placing and AIM admission. The operating loss was £6.5m (FY20: £3.5m) and net loss was £6.2m (FY20: £2.8m).

Forecast planned spend is supported by existing resources

For FY22 onwards we expect modestly higher partnering income as infrastructure and headcount expansion increases capacity for formulation work, both in-house and with partners. Our forecasts 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). The magnitude of licence derived income will be determined by development and commercial progress of licensed 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-licensing internally developed formulations) are expected to generate development and commercial milestones, plus royalties or equivalent on sales from 2023 onwards following anticipated launches.

Exhibit 5: Summary of financials

Year-end: Dec 31	£'000s	2019	2020	2021	2022E	2023E
INCOME STATEMENT						
Revenues		**748**	**1,698**	**1,158**	**1,442**	**1,612**
Cost of goods sold		0	0	0	0	0
Gross Profit		**748**	**1,698**	**1,158**	**1,442**	**1,612**
R&D expenses		(3,085)	(3,937)	(5,283)	(11,623)	(8,136)
SG&A expenses		(1,416)	(1,642)	(2,523)	(2,382)	(2,416)
Underlying operating profit		**(3,753)**	**(3,880)**	**(6,648)**	**(12,562)**	**(8,940)**
Share-based payments		(201)	(318)	(484)	(508)	(529)
Exceptionals		0	0	(462)	0	0
Other revenue/expenses		898	452	640	1,408	752
EBITDA		**(2,688)**	**(3,259)**	**(6,299)**	**(11,001)**	**(8,046)**
Operating Profit		**(2,855)**	**(3,428)**	**(6,470)**	**(11,154)**	**(8,188)**
Financing costs/income		(15)	(84)	(21)	92	45
Profit Before Taxes		**(2,870)**	**(3,512)**	**(6,976)**	**(11,063)**	**(8,143)**
Adj. PBT		**(3,970)**	**(4,283)**	**(7,153)**	**(12,979)**	**(9,424)**
Current tax income		435	760	756	1,278	895
Net Income		**(2,435)**	**(2,752)**	**(6,220)**	**(9,784)**	**(7,248)**
EPS (p)		**(1.1)**	**(0.2)**	**(0.3)**	**(0.4)**	**(0.3)**
Adj. EPS		**(1.5)**	**(0.2)**	**(0.3)**	**(0.4)**	**(0.3)**
DPS (p)		**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Average no. of shares (m)		2.3	16.2	23.0	27.8	27.8
Gross margin		*100%*	*100%*	*100%*	*100%*	*100%*
EBITDA margin		*N/A*	*N/A*	*N/A*	*N/A*	*N/A*
Underlying operating margin		*N/A*	*N/A*	*N/A*	*N/A*	*N/A*
BALANCE SHEET						
Current assets		**4,998**	**3,822**	**20,495**	**11,401**	**4,784**
Cash and cash equivalents		3,447	2,898	18,316	9,013	2,448
Short-term investments		0	0	0	0	0
Accounts receivable		809	166	1,423	1,501	1,546
Inventories		0	0	0	0	0
Other current assets		742	758	756	887	791
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)**	**(2,298)**	**(2,451)**	**(2,567)**
Short-term debt		0	0	0	0	0
Accounts payable		(1,014)	(1,303)	(2,172)	(2,325)	(2,441)
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**	**18,498**	**9,222**	**2,502**
CASH FLOW STATEMENTS						
Operating cash flow		**(2,505)**	**(1,857)**	**(5,450)**	**(9,179)**	**(6,410)**
Profit before tax		(2,870)	(3,512)	(6,976)	(11,063)	(8,143)
Non-cash adjustments		389	614	1,156	570	625
Change in working capital		(23)	747	(388)	74	72
Interest paid		0	0	0	92	45
Taxes paid		0	295	758	1,148	991
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**	**0**	**0**
Proceeds from equity		5,424	0	18,565	0	0
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**	**(9,303)**	**(6,565)**
Exchange rate effects		(6)	(43)	5	0	0
Cash at start of year		705	3,074	2,898	18,316	9,013
Cash at end of year		**3,447**	**2,898**	**18,316**	**9,013**	**2,448**
Net cash at end of year		**3,447**	**1,200**	**18,316**	**9,013**	**2,448**

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

Philippa Gardner pgardner@trinitydelta.org
+44 (0) 20 3637 5042

Lala Gregorek lgregorek@trinitydelta.org
+44 (0) 20 3637 5043

Franc Gregori fgregori@trinitydelta.org
+44 (0) 20 3637 5041

Disclaimer

More information is available on our website: www.trinitydelta.org