Trinity Delta

Arecor Therapeutics

Update

Growth plans starting to stack up

14 September 2023

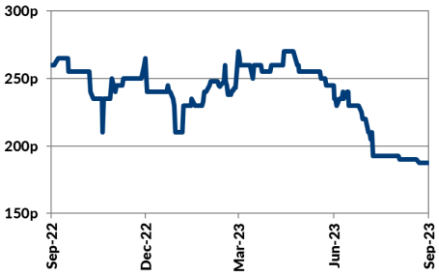
Arecor's innovative and lower risk pipeline is making tangible progress; at partners where assets are under licence, and internal in-house development of the proprietary diabetes and specialty hospital programmes. The growth potential is becoming better defined as the first partnered asset approaches commercialisation. While near-term revenues will continue to include a variable milestone element, over the medium-to-longer term, income streams will be comprised of success-based milestones coupled with recurring sales-based royalties or equivalent. Upcoming catalysts include key Phase I data in Type II diabetes for AT278 (ultra-concentrated rapid insulin), anticipated milestones from partners, and the prospect of further licensing agreements for its proprietary assets as well as technology partnerships. Ahead of these catalysts our Arecor valuation remains £176m, or 575p per share.

Year-end: December 31	2021	2022	2023E	2024E
Revenues (£m)	1.2	2.4	4.8	7.1
Adj. PBT (£m)	(7.1)	(11.7)	(10.3)	(9.1)
Net Income (£m)	(6.2)	(9.1)	(8.3)	(7.9)
EPS (p)	(0.3)	(0.3)	(0.3)	(0.3)
Cash (£m)	18.3	12.8	5.8	1.0
EBITDA (£m)	(6.3)	(10.2)	(8.5)	(8.0)

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

- **Investment case centres on diabetes franchise** Clinical data to date from Arecor's two key diabetes assets, AT278 (ultra-concentrated rapid insulin) and AT247 (ultra-rapid insulin), suggest competitive profiles well suited to the changing diabetes landscape in terms of demographics and the technological advances in treatment. Specifically, this includes addressing the needs of novel insulin pump delivery systems which require precise absorption profiles that are more rapid and highly consistent. Further AT278 Phase I clinical data are anticipated by early 2024.
- **Partnering prospects look rosy** Recent progress with licenced assets includes: (1) potential for first sales of undisclosed biosimilar AT220 in late 2023/early 2024, subject to approval(s); (2) imminent dosing of the first patient in Inhibrx's AT292 pivotal ElevAATe study; and (3) confirmation of FDA 505(b)(2) regulatory pathway for Hikma's AT307. New technology partnerships (with potential for conversion to licences) as well as licensing deals for the in-house specialty hospital products portfolio could expand the partnered pipeline. So far in 2023, three new revenue-generating collaborations have been signed, bringing the total to eleven since IPO.
- **Growing revenues with cash to execute current plans** H123 revenues were driven by Ogluo sales, which should continue to grow. Future revenues will also be boosted by first recurring AT220 royalties once launched, and from non-recurring milestones from licenced assets (AT220, AT292), albeit the timing is dependent on partners. Cash should be sufficient to execute on current strategic plans.
- **Valuation of £176m, or 575p per share** Our unchanged Arecor pipeline rNPV valuation is £176m (575p per share). Continued clinical progress notably with AT278 and AT247, disclosure around AT220, and execution of further partnerships, could result in material upside revisions to our model.

Price	187.50p
Market Cap	£57.4m
Enterprise Value	£49.2m
Shares in issue	30.6m
12-month range	180p-322p
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 platform results 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: low-risk innovation

Arecor is leveraging its proprietary Arestat platform and formulation expertise to create a portfolio of internal and partnered clinical assets with enhanced properties that would otherwise be unachievable. This has created a broad and well-balanced pipeline of innovative products that offer similar milestone and royalty streams to classic drug discovery companies, yet with lower development risks and in a less costly and more rapid manner. A mix of in-house assets and partnered products provide an attractive blend of value inflection points. We view the emerging diabetes franchise as particularly interesting, with the most upside potential within our valuation. The two lead compounds are AT278, an ultra-concentrated, ultra-rapid insulin, and AT247, an ultra-rapid pump-optimised insulin. If successful, these could be ideally placed for the notable shifts underway in diabetes therapy. Our Arecor valuation is £176m, equivalent to 575p a share.

Well-balanced pipeline of in-house and partnered assets with multiple catalysts

Arecor's lead in-house assets are the Phase I diabetes programmes AT278 and AT247, while the three most advanced partnered programmes are: (1) AT220, an undisclosed partnered biosimilar which is likely to be the first product employing the Arestat technology to launch pending regulatory approval(s) expected this year; (2) a specialty hospital product licenced to Hikma (AT307); and (3) a late stage clinical orphan disease drug with Inhibrx (AT292/INBRX-101). An overview of Arecor's pipeline is shown in Exhibit 1.

Exhibit 1: Summary of Arecor's current pipeline

Source: Arecor Therapeutics

In-house programmes address diabetes

A high-profile focus on diabetes, with lead compound AT278 a potentially disruptive insulin

Arecor's two key in-house clinical stage programmes are the ultra-rapid insulins **AT278** and **AT247**, both of which are innovative formulations of insulin aspart, the active ingredient in Novo Nordisk's well-characterised, proven and now off patent Novolog (US)/NovoRapid (ex-US). AT278 is well positioned for the demographic and technology shifts that are underway within diabetes (outlined in our April 2023 Update) and AT247 has an ideal profile for "artificial pancreas" pumps. AT278 and AT247 Phase I data to date show highly promising, differentiated profiles that could capture larger market shares and open new market opportunities (discussed in detail in previous reports including December 2022 Outlook). There are also two further diabetes assets: **Ogluo**, a ready-to-use glucagon auto-injector pen, which is commercially available in select European countries; and **AT299**, a preclinical stage co-formulation of pramlintide and insulin.

AT278 is unique as both an ultra-fast and ultra-concentrated insulin

AT278 is currently in a second Phase I trial in patients with Type II diabetes. Recruitment is progressing well and Arecor is evaluating the opportunity to increase the powering of the study (enrolling 42 subjects instead of the planned 32) for a modest increase in investment. This would increase the robustness and value of the data generated from a highly variable Type II diabetes population, and would shift the data read out into early 2024 (from Q423). AT278 has the potential to be a disruptive insulin as an ultra-concentrated U-500 (500 units/ml) and ultra-fast acting insulin formulation. Such high concentration insulins are expected to become increasingly in demand, reflecting the rising number of people with Type II and refractory Type I diabetes that require higher daily dosing. The increase in incidence of both Type I and Type II diabetics is being driven by rising obesity rates across most geographies, which result in a greater incidence of obesity-related insulin resistance, such that average usage for Type II diabetes patients is now 97 units of insulin daily, with a growing number needing 200 units or more. For context, the average adult needs between 0.5 and 1.0 units/kg daily. The challenges in formulating a higher concentration (>200 U/ml) rapid or ultra-rapid acting insulin mean there are no such options commercially available, nor do we know of any in clinical development.

AT247 is an ultra-fast insulin optimised for use in pumps

AT247 is a next-generation ultra-rapid prandial insulin analogue of U-100 insulin aspart. It has been specifically formulated to materially accelerate absorption after injection, achieving a profile that closely approximates healthy (non-diabetic) physiological insulin secretion. The goal is to improve control of postprandial glucose and increase time in range (the percentage of time spent in the target glucose range). It is suitable for both Type I and Type II diabetes patients who self-administer insulin either via pen devices (also known as multiple daily injections, MDI) or any insulin pump system. Importantly, AT247's attractive PK/PD profile suggests it has the potential to be an ideal pump insulin, enabling optimal use of automated continuous subcutaneous insulin infusion (CSII) devices, and ultimately a fully closed loop artificial pancreas system.

First commercial Arestat-based product in sight

AT220 could be the first Arestat-based product to launch

Arecor has three partnered programmes with future milestone and recurring royalty potential: one internally generated specialty hospital product (AT307), and two from technology partnerships (AT220 and AT292).

Biosimilar AT220 is closest to approval and commercialisation

The most advanced partnered asset, AT220, is likely to be the first product incorporating the Arestat technology to launch. It is an undisclosed biosimilar product under development with a global pharmaceutical company for a multi-billion market. Regulatory approval(s) continue to be expected this year, with potential for first sales in 2023/4. A further milestone is expected to be triggered prior to the receipt of royalties on sales, although none of the financial terms have been made public. Disclosure of the underlying reference biologic and partner would enable a review and refinement of our current conservative forecasts and assumptions.

Partner Hikma has made further progress with specialty hospital product AT307

Further progress has been made by partner Hikma with AT307, a ready-to-use (RTU) injectable of an undisclosed already marketed specialty hospital product. Following a recent FDA pre-IND meeting, Hikma has confirmed that AT307 development in the US will continue under the abbreviated 505(b)(2) approval pathway. As this references the originator drug for evidence of clinical efficacy and safety, no major clinical trials are expected to be required, allowing for significantly more rapid development than a typical new drug, in-line with our 2025/6 launch expectations. In addition, this further supports the likelihood that the 505(b)(2) pathway will apply across Arecor's internal specialty hospital pipeline of enhanced RTU and RTA (ready-to-administer) formulations of existing drugs.

The Inhibrx collaboration continues to advance

AT292, partnered with Inhibrx as part of a multi-product collaboration, is a novel, enhanced formulation of INBRX-101, a recombinant Alpha-1 Antitrypsin Fc-fusion Protein. It was recently granted Fast Track Designation in the treatment of emphysema due to alpha-1 antitrypsin deficiency (AATD), and a registration-enabling trial, ElevAAte, in this indication was initiated in April. Dosing of the first patient in this trial will trigger the next milestone to Arecor under the terms of the licencing agreement. Top line data from ElevAAte are expected in late-2024.

Additional revenue generating deals are expected

A growing number of revenue generating collaboration with large pharma and biotech

Since IPO, Arecor has secured eleven revenue-generating collaborations with major pharmaceutical and biotechnology companies, including technology partnerships (typically formulation development using the Arestat platform to develop novel formulations of partner proprietary products) and licence agreements (either through the conversion of technology partnerships, or the out-licensing of internally developed products). These agreements provide near-term revenue via research fees, with upside potential from licencing (clinical/commercial milestones and royalties or equivalent). Three new deals have already been signed during 2023, and further collaborations are expected:

- an additional formulation agreement with an existing top five pharma partner, building on a 2022 collaboration to develop stable injectable high concentration formulations of the partner's proprietary products; the partner will fund initial development work and has the option to acquire new formulations under a typical technology licensing model;
- an additional agreement with a leading biopharma supporting biosimilar development following an earlier technology partnership; and
- a collaboration with a top 10 pharma company to develop a novel, stable formulation of a liquid, high concentration antibody.

Valuation and Financials

We value Arecor at £176m, equivalent to 575p per share

We continue to value Arecor using an rNPV model, explicitly valuing the diabetes franchise, partnered assets, and the in-house specialty hospital product research programme(s). More details on our valuation methodology and key assumptions are available in previous notes (December 2022 Outlook and April 2023 Update). Our valuation is £176m, equivalent to 575p per share. An overview of our valuation is provided in Exhibit 2.

Exhibit 2: Arecor rNPV valuation

Programme	NPV (£m)	NPV ($m)	Success probability	Royalty	rNPV (£m)	rNPV ($m)	rNPV/ share (p)	Notes
AT247 (Type I diabetes)	104.7	125.7	60%	High single to double-digit	50.4	60.4	164.5	Peak sales: $358m; Launch year: 2025
AT278 (Type II diabetes)	128.7	154.4	60%	High single to double-digit	61.2	73.4	199.7	Peak sales: $516m; Launch year: 2026
AT299 (Diabetes)	20.4	24.5	10%	Low single digit	3.0	3.6	9.9	Peak sales: $200m; Launch year: 2028
Research (Specialty Hospital)	55.0	66.0	30%	High single to double-digit	16.5	19.8	54.0	Peak sales: $350m; Launch year: 2025+
AT307 (Hikma) (Speciality Hospital)	30.0	35.9	75%	High single to double-digit	20.9	25.1	68.2	Peak sales: $100m; Launch year: 2025
AT220 (undisclosed biosimilar - partnered)	11.2	13.5	90%	Low single digit	9.6	11.5	31.4	Peak sales: $500m; Launch year: 2023
AT292/INBRX-101 (AATD - Inhibrx)	18.5	22.2	50%	Low single digit	9.1	10.9	29.6	Peak sales: $515m; Launch year: 2026
Tetris Pharma/Ogluo	7.9	9.5	100%	N/A	7.9	9.5	25.8	Peak sales: $10m; Launch year: 2021
Operating costs	(15.4)	(18.4)			(15.4)	(18.4)	(50.2)	
Net cash	12.8	15.4			12.8	15.4	41.8	
Total	**402.6**	**483.2**			**176.0**	**211.2**	**574.7**	

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).

Growing revenues driven by product sales

Revenues in H123 were £1.7m (H122: £0.7m) comprising £0.3m of formulation development (H122: £0.7m), milestones of £0.1m (H122: nil), and product sales of £1.2m (H122: nil). The latter largely relate to Ogluo sales in select EU countries, following the Tetris Pharma acquisition. This was incorporated from August 2022, hence no product sales were recorded in the prior period. For reference, product sales during H222 for the five months post-acquisition (4 August to 31 December 2022) were £1.0m. Arecor also recorded £0.6m (H122: £0.4m) of other operating income as part of a £2.8m grant awarded from Innovate UK in March 2021. We note that sales and EBITDA targets to trigger the first contingent Tetris Pharma earn-out of £1m were not deemed achieved, and hence this is not payable.

R&D decreased owing to AT247 trial completion, whilst SG&A SG&A increased with Tetris Pharma spend

R&D investment decreased to £2.9m in H123 (H122: £4.8m) following completion of the US Phase I trial of AT247 in October 2022. The main clinical trial costs now relate to the ongoing European Phase I trial of AT278, which was initiated in December 2022. SG&A spend increased to £4.4m (H122: £1.6m), as this now includes Tetris Pharma related costs, which were not included in the prior period.

When adjusting for Tetris Pharma SG&A, like-for-like underlying H123 Arecor SG&A was £1.9m (H122: £1.6m), suggesting core costs remain controlled. Pre-tax loss was £4.8m (H122: £5.2m), and net loss was largely unchanged at £4.5m (H122: £4.4m).

Future revenue growth will be driven by product sales and from potential first recurring royalties

We have made minor adjustments to our FY23e revenue forecast and now forecast £4.8m (from £4.9m) based on the H123 trends. Our FY24e revenue forecast remains £7.1m. Following H123, we have decreased our R&D spend forecasts to £5.9m in FY23e (from £6.3m) and to £6.2m in FY24e (from £6.6m) to reflect H123 trends, albeit the latter is largely illustrative and future R&D investment will depend on clinical trial plans, likely to be refined as data become available. We have increased SG&A forecasts reflecting higher Tetris Pharma spend in H123; we now forecast SG&A of £9.0m in FY23e (from £7.1m), rising to £9.5m in FY24e (from £7.9m).

Cash should be sufficient to execute current strategic plans

Arecor had cash and equivalents (including short-term investments) at end-June 2023 of £8.2m (end-June 2022: £13.7m; end-December 2022: £12.8m). Post period end, Arecor also received £0.4m in grants and £1.3m in R&D tax credits. Our updated forecasts (Exhibit 3) indicate that Arecor has sufficient funds to execute on current strategic plans, including the ongoing Phase I trial of AT278, and to provide optionality into 2024 to prepare for potential future development plans, as these are refined. Our forecasts do not assume any potential conversion(s) of pre-licence technology partnerships to longer-term licence agreements, nor any significant uncertain milestones. Hence partnering and/or licence income from upfront payments, development milestones, or higher revenues from product sales and royalties, could extend the runway.

Exhibit 3: Summary of financials

Year-end: Dec 31	£'000s	2020	2021	2022	2023E	2024E
INCOME STATEMENT						
Revenues		**1,698**	**1,158**	**2,403**	**4,805**	**7,057**
Cost of goods sold		0	0	0	0	0
Gross Profit		**1,698**	**1,158**	**2,403**	**4,805**	**7,057**
R&D expenses		(3,937)	(5,386)	(8,613)	(5,857)	(6,150)
SG&A expenses		(1,642)	(2,389)	(5,381)	(9,010)	(9,472)
Underlying operating profit		**(3,880)**	**(6,617)**	**(11,591)**	**(10,063)**	**(8,564)**
Share-based payments		(318)	(484)	(503)	(523)	(539)
Exceptionals		0	(462)	(171)	0	0
Other revenue/expenses		452	640	1,132	925	103
EBITDA		**(3,259)**	**(6,268)**	**(10,289)**	**(8,541)**	**(7,961)**
Operating Profit		**(3,428)**	**(6,439)**	**(10,630)**	**(9,137)**	**(8,462)**
Financing costs/income		(84)	(21)	88	272	29
Profit Before Taxes		**(3,512)**	**(6,945)**	**(10,542)**	**(8,866)**	**(8,432)**
Adj. PBT		**(4,283)**	**(7,122)**	**(12,006)**	**(10,314)**	**(9,074)**
Current tax income		760	776	1,282	527	553
Net Income		**(2,752)**	**(6,169)**	**(9,260)**	**(8,339)**	**(7,879)**
EPS (p)		**(0.2)**	**(0.3)**	**(0.3)**	**(0.3)**	**(0.3)**
Adj. EPS		**(0.2)**	**(0.3)**	**(0.4)**	**(0.3)**	**(0.3)**
DPS (p)		**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Average no. of shares (m)		16.2	23.0	28.9	30.6	30.8
Gross margin		*100%*	*100%*	*100%*	*100%*	*100%*
BALANCE SHEET						
Current assets		**3,822**	**20,515**	**17,477**	**12,731**	**7,859**
Cash and cash equivalents		2,898	18,316	4,765	5,826	1,023
Short-term investments		0	0	8,041	0	0
Accounts receivable		166	1,423	2,215	4,212	4,060
Inventories		0	0	1,131	1,556	1,632
Other current assets		758	776	1,325	1,136	1,143
Non-current assets		**462**	**406**	**4,288**	**4,011**	**3,857**
Property, plant & equipment		375	328	838	722	693
Intangible assets		38	30	3,402	3,242	3,116
Other non-current assets		48	48	48	48	48
Current liabilities		**(1,408)**	**(2,267)**	**(3,728)**	**(6,645)**	**(7,459)**
Short-term debt		0	0	0	0	0
Accounts payable		(1,303)	(2,141)	(3,526)	(6,443)	(7,257)
Other current liabilities		(105)	(126)	(202)	(202)	(202)
Non-current liabilities		**(2,102)**	**(105)**	**(582)**	**(458)**	**(458)**
Long-term debt		(1,698)	0	0	0	0
Other non-current liabilities		(403)	(105)	(582)	(458)	(458)
Equity		**774**	**18,549**	**17,455**	**9,639**	**3,799**
CASH FLOW STATEMENTS						
Operating cash flow		**(1,857)**	**(5,450)**	**(10,780)**	**(6,536)**	**(5,956)**
Profit before tax		(3,512)	(6,945)	(10,542)	(8,866)	(8,432)
Non-cash adjustments		614	1,156	687	848	1,010
Change in working capital		747	(419)	(1,659)	494	890
Interest paid		0	0	0	272	29
Taxes paid		295	758	734	716	547
Investing cash flow		**(49)**	**(68)**	**(7,993)**	**7,721**	**(347)**
CAPEX		(52)	(69)	(345)	(320)	(347)
Acquisitions/disposals		0	0	284	0	0
Other investing cash flows		3	1	(7,932)	8,041	0
Financing cash flow		**1,774**	**20,931**	**5,160**	**(124)**	**1,500**
Proceeds from equity		0	18,565	5,648	0	1,500
Increase in loans		1,840	2,500	0	0	0
Other financing cash flow		(67)	(134)	(488)	(124)	0
Net increase in cash		**(132)**	**15,413**	**(13,613)**	**1,061**	**(4,803)**
Cash at start of year		3,074	2,898	18,316	4,765	5,826
Cash at end of year		**2,898**	**18,316**	**4,765**	**5,826**	**1,023**
Net cash at end of year		**1,200**	**18,316**	**12,806**	**5,826**	**1,023**

Source: Company, Trinity Delta. Note: FY24e R&D is largely illustrative pending development plans

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