Trinity Delta

Arecor Therapeutics

Update

Second in-house Specialty Hospital deal

7 December 2023

Arecor's co-development and exclusive licence option agreement with a leading global medical products company demonstrates further strategic execution in securing revenue generating partnerships for its proprietary portfolio of Specialty Hospital products. It also further validates the attractiveness and relevance of its Arestat formulation expertise in developing novel products, the first of which (biosimilar AT220) was launched earlier this year. Specialty Hospital licensing agreements form a key part of Arecor's mid-term growth prospects, and while these are typically associated with limited disclosure, prior Trinity Delta analysis provides a framework for assessing the potential value. Near-term, Arecor's investment case remains centred on its diabetes franchise, with further AT278 Phase I data anticipated during H124. Our valuation is updated to £179m, or 583p 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.

- **Specialty Hospital deal with unnamed global player** This licensing deal covers a high value, Arestat-enabled ready-to-dilute (RTD) formulation of a blockbuster oncology product. Deal economics are also undisclosed, although Arecor is eligible for potential milestones in connection with further co-development and regulatory work, plus milestones and royalties should the unnamed partner exercise its option to an exclusive worldwide development and commercialisation licence.
- **Formulation expertise provides value-add** A key challenge with Specialty Hospital products is the lack of stable liquid formulations. Many injectable products used within hospitals require some form of preparation (eg reconstitution or dilution) which has time, cost, and safety implications for patients, physicians, and payers. Formulation improvements can include ready-to-administer (RTA), ready-to-use (RTU), and RTD versions. Arecor's first Specialty Products licence covered Hikma's AT307, an undisclosed RTU formulation. This second deal is for a stable liquid RTD formulation of a lyophilised powder product with a complex reconstitution process.
- **Growth prospects becoming clearer** Our November 2023 Outlook provided a framework for assessing the cash flows from existing, and new, Specialty Hospital product licences. Upfront payments and pre-commercial milestones should limit Arecor's at-risk spend, with a profitable return from downstream commercial payments/royalties. While not from a Specialty Hospital product, first royalties will be recorded in FY23, following the European launch of biosimilar AT220.
- **Valuation updated to £179m, or 583p per share** Our Arecor valuation has been raised to £179m, or 583p per share (from £176m and 575p) with incorporation of this deal. Continued clinical progress, notably with AT278 and AT247, and execution of further partnerships, could result in material upside revisions.

Price	190.00p
Market Cap	£58.2m
Enterprise Value	£52.4m
Shares in issue	30.6m
12-month range	175p-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.

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Arecor: Specialty Hospital deal momentum builds

Arecor's track record in overcoming complex formulation challenges is becoming more widely appreciated as it secures licencing deals and technology partnerships with leading global companies. Through exploiting its proprietary Arestat platform and formulation expertise Arecor has created a portfolio of in-house and partnered programmes with otherwise unachievable enhanced clinical properties. This broad and well-balanced pipeline of innovative products offers similar milestone and royalty streams to classic drug discovery plays yet has lower development risks, and a less costly and more rapid route to market. We continue to view the emerging diabetes franchise as having the most valuation upside potential, with the competitive profiles of lead assets AT278 (ultra-concentrated, ultra-rapid insulin) and AT247 (ultra-rapid pump-optimised insulin) well suited to the changing diabetes landscape. Mid-term, the in-house Specialty Hospital portfolio could generate meaningful future income streams as further deals and partnerships are signed, with each product requiring limited at-risk spend. Pre-commercial deal milestones should offset these costs, with a return on investment from subsequent royalties (or other payments). Our updated Arecor valuation is £179m, equivalent to 583p a share.

Second Specialty Hospital deal with a leading global medical products company…

Arecor's co-development and exclusive licence option agreement with a leading global medical products company is the second licensing deal it has signed on a proprietary Specialty Hospital programme. In this case, the Arestat technology and expertise has been applied to develop a stable liquid ready-to-dilute (RTD) formulation of a lyophilised powder with a complex reconstitution process. The identity of the partner, product, and precise deal terms are undisclosed. However, as the valuation framework detailed in our November 2023 Outlook shows, while undoubtedly helpful, these details are not strictly necessary in modelling nor ascribing a valuation to the cash flows from such deals (discussed below).

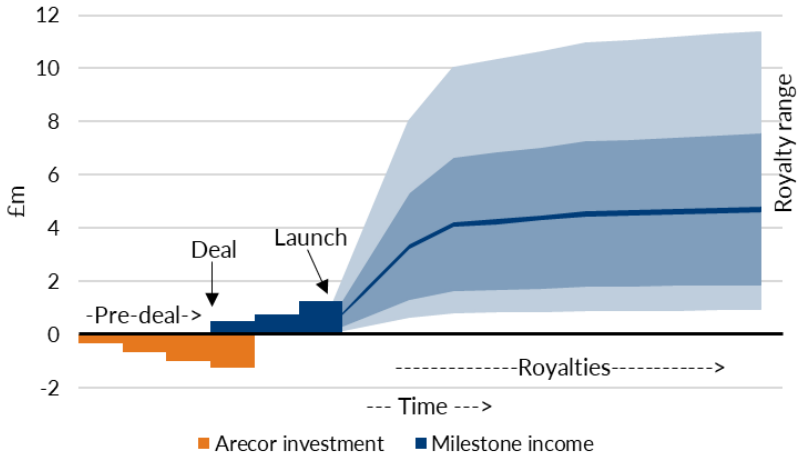
…for a RTD formulation of a blockbuster oncology product

Arecor's in-house formulation work on its proprietary Specialty Hospital pipeline has focused on creating stable liquid formulations of existing hospital-based injectable products that require preparation (eg reconstitution or dilution) before use. These formulations may be ready-to-administer (RTA), ready-to-use (RTU), or ready-to-dilute (RTD) versions, which all have the potential to confer time, cost, quality, ease of use, and safety benefits for patients, physicians, and payers. The product underlying this latest deal is a RTD reformulation of an undisclosed blockbuster oncology product that requires lengthy and complex reconstitution.

Details are limited but the market size exceeds our base case assumptions

Our base case assumptions for a typical product (Exhibit 1) are for Arecor's R&D investment pre-deal (typically over two to three years) to be at least fully recouped via upfronts and milestones by product launch (around three years post deal), with royalties on sales then generating a profitable return. We assume peak sales are achieved around three years post-launch, with peak royalties ranging from c £1m to c £11m per annum (based on market sizes up to $300m, peak sales of $20-80m and a 5-15% royalty). While we assume that Arecor will seek to develop the more commercially relevant opportunities, for the purposes of assessing the unpartnered Specialty Hospital products, our base case is that most will be around $40-50m in peak sales for peak royalties of £4m per annum, in-line with our typical conservative stance.

Exhibit 1: Illustrative Specialty Hospital product



Source: Trinity Delta. Note: Arecor investment and milestone income estimates are cumulative over time; royalty range is based on royalties of 5-15% on peak sales of $20-80m

Several large companies are involved in the hospital products market

We note that several large companies are active in the hospital products market and have indicated that they are interested in collaborations to improve and extend their product portfolios. These include Baxter, Fresenius Kabi, Hikma, Pfizer, Sandoz, and Teva which together encompass a wide range of products/areas including biosimilars, complex biologics and generics. Indeed, Arecor's first Specialty Products licence was with Hikma for AT307, an undisclosed RTU formulation of a marketed injectable.

Lilly technology partnership was recently extended

As also covered in our November 2023 Outlook, due to Arecor's greater value contribution translating into more meaningful milestones and higher royalty rates, the licensing deals for proprietary programmes should prove more lucrative than technology partnerships which centre on reformulation of the partner's own product. The first commercial Arestat-enabled product to launch, biosimilar AT220 (November 2023 Lighthouse), is an example of the latter. Pre-commercial technology partnerships are also in place with several other undisclosed and named companies, including Intas, Par Pharmaceuticals and Eli Lilly. We note that Arecor recently signed a further collaboration agreement with Lilly.

Deal execution will be key to realising value from the Specialty Hospital portfolio

The additional validation provided by the latest Specialty Hospital product deal provides us with increasing comfort around Arecor's ability to continue to identify, formulate, and develop internal programmes that are attractive to larger partners. Arecor's focus is on serious infections, cancer, and emergency care, with likely around three to five under active development at any one time. Thus, we believe that the partnering strategy for Specialty Hospital products should be sustainable and develop into a potential fruitful source of future income.

Diabetes franchise remains the key value driver

Near-term, we continue to view the in-house diabetes programmes as the main value driver for Arecor, with the greatest upside potential. The clinical data to date (December 2022 Outlook) from the two lead 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 demography 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 during H124.

Valuation and Financials

Updated Arecor valuation of £179m, equivalent to 583p per share

We value Arecor using a rNPV (risk-adjusted net present value) model, including the diabetes franchise, partnered assets, and the in-house Specialty Hospital research portfolio. More details on our valuation methodology are available in our recent note (November 2023 Outlook). Following incorporation of the latest Specialty Hospital deal, outlined below, plus rolling forwards in time and updating net cash, our valuation is increased to £179m, equivalent to 583p per share (from £176m and 575p/share). An overview of our valuation and key assumptions is summarised in Exhibit 2.

Exhibit 2: Arecor rNPV valuation

Programme	NPV (£m)	NPV ($m)	Success probability	Royalty	rNPV (£m)	rNPV ($m)	rNPV/ share (p)	Notes
Diabetes franchise (AT278 and AT247)	253.4	304.1	60%	High single to double-digit	117.2	140.6	382.7	Peak sales: c $875m; Launch year: 2026+
Research (Specialty Hospital)	39.8	47.8	Various (10-40%)	High single to double-digit	11.7	14.1	38.3	Various with peak sales of $20-80m; Launch year: 2026+
AT307 (Hikma) (Specialty Hospital)	26.2	31.5	80%	High single to double-digit	19.8	23.8	64.7	Peak sales: $65m; Launch year: 2026
Not disclosed (Specialty Hospital)	20.1	24.1	60%	High single to double-digit	12.1	14.5	39.4	Peak sales: $65m; Launch year: 2027+
AT220 (undisclosed biosimilar - partnered)	12.8	15.4	95%	Low single digit	11.3	13.5	36.8	Peak sales: $500m; Launch year: 2023
AT292/INBRX-101 (AATD - Inhibrx)	20.4	24.4	50%	Low single digit	9.7	11.7	31.8	Peak sales: $515m; Launch year: 2026
Tetris Pharma/Ogluo	7.8	9.3	100%	N/A	7.8	9.3	25.4	Peak sales: $10m; Launch year: 2021
Operating costs	(16.8)	(20.2)			(16.8)	(20.2)	(55.0)	
Net cash	5.8	7.0			5.8	7.0	19.0	
Total	**369.5**	**443.4**			**178.6**	**214.4**	**583.2**	

Source: Trinity Delta based on a 12.5% discount factor and £/$ FX rate of 1.20. Note: AATD = Alpha-1 antitrypsin deficiency.

Partnering deal prompts a standalone valuation of the undisclosed asset

Within our updated valuation, we have broken out the RTD oncology formulation as a standalone contribution, separate to the Specialty Hospital rNPV, as this is now being developed with a partner. As information is limited, we apply our Specialty Hospital framework, including launch at least three years post deal ie 2027+, and a rapid three-year ramp to peak sales. We conservatively estimate these at $65m (above our typical base case) based on the blockbuster nature of the reference product. However, we assume this will be off-patent by the time of launch, therefore reducing the market value through price discounting, while also increasing competition. We include flat royalties of c 10%, and only include a limited number of modest future milestones.

Maintain a conservative approach, based on the Specialty Hospital framework

There could be upside to both our peak sales and royalties/downstream payments, particularly on the former if the partner is able to drive higher market share and/or more of the market size is maintained, whilst the co-development nature of the deal may confer higher royalties and/or downstream milestones than our current assumptions. As the product is now partnered, we assign a 60% probability of success. The higher-than-average peak sales, plus the increased

probability on the standalone asset, means the rNPV is higher than it had been within the previous Specialty Hospital rNPV ie the Specialty Hospital rNPV has decreased by less than the value of the standalone asset.

Upside on Specialty Hospital rNPV as deals are executed…

The remaining Specialty Hospital rNPV of £12m, which is largely a conservative placeholder, consists of a blend of assets based on the framework outlined in our November 2023 Outlook, with various launch timelines and probabilities. We assume a steady flow of new assets into the portfolio, and as seen with the latest deal, there is upside as partnerships are executed.

…whilst diabetes remains the main value driver

As a reminder, the diabetes franchise (consisting largely of AT278 and AT247) remains the main value driver for Arecor and there could be material upside as development progresses and data become available. The partnered and commercial assets together could represent a meaningful source of future income with potential upside on AT220 launch in the US, as the royalty builds and/or the partner/product is disclosed/identified. We do not attribute a value to the technology formulation development collaborations, nor do we provide an indicative valuation of the Arestat technology platform.

Cash should be sufficient to execute current strategic plans

Our financial forecasts, which are unchanged, are shown in Exhibit 3. As a reminder, Arecor had cash and equivalents (including short-term investments) at end-June 2023 of £8.2m and post period end also received £0.4m in grants and £1.3m in R&D tax credits. Our model suggests 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 all 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

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