Trinity Delta

Arecor Therapeutics

Outlook

Appreciating a well-executed development strategy

30 November 2023

Arecor is leveraging its Arestat formulation expertise to create an attractive and well-balanced pipeline of in-house and partnered products. These are novel formulations of existing drugs that offer clinically significant benefits, carry lower development risk, and have faster regulatory pathways to market. Investor attention is, rightly, focused on the attractive diabetes assets (the ultra-rapid insulins AT278 and AT247), but the Specialty Hospital products tend to be overlooked. This is understandable as commercial sensitivities limit information flow, yet the milestones and royalties have the potential to build into a valuable recurring revenue stream. Progress across the mix of in-house and partnered programmes should provide a meaningful blend of value inflection points. Our valuation is £176m, or 575p a 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

- **Poised to exploit the emerging insulin pump market** Diabetes is a huge and growing global problem. The clinical shifts underway with novel therapeutic classes are overshadowing dramatic advances in insulin pumps driven by transformative technologies. Such sophisticated pumps require specialist insulins to capitalise on their groundbreaking potential benefits. AT278 is an ultra-rapid ultra-concentrated insulin ideally suited to miniaturised patch pumps with long wear times. AT247 is a complementary ultra-rapid insulin optimised for use in pumps, offering a near-physiological insulin profile, which is key to enabling artificial pancreas systems.
- **Specialty Hospital portfolio could lead to meaningful future income** Arestat's formulations offer improved ready-to-use and ready-to-administer versions of existing injectables. We believe each product requires fairly minor at-risk spend, with pre-commercial milestones from later deals offsetting these costs, and subsequent royalties (or other downstream payments) generating a return. Portfolio progress, expansion, and deals could drive multiple potential launches over the coming years, generating meaningful future royalties, in our view. The Hikma deal validates this approach and launch of lead AT307 is anticipated from 2026.
- **Multiple value inflection points as programmes progress** Near-term, we expect first recurring royalties on undisclosed biosimilar AT220, which recently launched in Europe, and topline AT278 Phase I data in Type II diabetes in early 2024. Further licensing agreements as well as technology partnerships are also expected. This year three new collaborations have been signed, totalling 11 since IPO in June 2021.
- **Valuation of £176m, or 575p per share** Our Arecor pipeline rNPV valuation is £176m (575p per share), based on conservative assumptions. 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	186.0p
Market Cap	£57.0m
Enterprise Value	£48.8m
Shares in issue	30.6m
12-month range	182p-270p
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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Investment case

Arestat formulation technologies underpin the pipeline and partnering opportunities

Arecor Therapeutics was formed in 2007 as a spin-out of Insense (formerly part of Unilever). The initial focus was reformulating existing products using a proprietary technology platform to address known issues on a fee-for-service basis. This built both the platform and industry awareness, over time augmenting and broadening the Arestat formulations, adding greater functionality and applicability. In 2016 the current CEO (appointed in 2015) implemented a decisive strategy shift to develop a portfolio of in-house products alongside a technology licensing model to build and retain more value. Technology partnerships typically involve research fees, milestones, and low-single digit percentage royalties or equivalent on sales. In-house programmes are expected to be self-funded through to an optimal point for licencing (Specialty Hospital products at an earlier stage than diabetes assets) then out-licenced for an upfront, milestones, and mid/high single- to double-digit sales royalties. To date, Arecor has raised £42.3m in equity (including £20m gross via its June 2021 IPO, and £6m in August 2022) and secured c £8.1m in grants. Arecor is based in Chesterford Research Park, near Cambridge, UK.

Valuation

rNPV model yields a valuation of £176m, or 575p per share

Our current Arecor £176m valuation (575p/share), is based on a sum-of-the-parts pipeline rNPV model (including conservative assumptions for the diabetes franchise, partnered assets, and in-house Specialty Hospital portfolio) netted against costs and cash. The internal diabetes assets, AT278 and AT247, are the main value drivers: AT278 alone underpins the current share price. Significant upside potential could include progress with the diabetes programmes, refined AT220 forecasts as the royalty builds and/or the partner/product is disclosed, plus from the Specialty Hospital portfolio (as explored in this note).

Financials

Sufficient cash to execute on current strategic plans

Arecor is generating growing revenues, helped by Ogluo sales in Europe. Growth should also expand once various royalty bearing products are launched over the coming years. These include undisclosed biosimilar AT220, plus lead Specialty Hospital product AT307 partnered with Hikma. The Specialty Hospital portfolio should become a meaningful source of recurring royalties as deals are executed and products are launched. Cash and equivalents of £8.2m (end-June 2023) plus post period grants and tax credits should be sufficient to fund current strategic plans, including the ongoing Phase I AT278 trial, and provides optionality into 2024 to prepare for potential future development plans as these are refined.

Sensitivities

Usual small development company risks apply

Arecor's in-house assets address commercially attractive market segments but as it currently develops novel formulations of existing approved drugs, it inherently carries a lower risk profile to a classic drug discovery play. However, typical industry risks relating to clinical data (albeit superiority rather than safety/ efficacy), navigating regulatory hurdles, ensuring sufficient financing, partnering discussions, and pricing, reimbursement, and commercialisation still apply.

Arecor: inherent strengths are under-appreciated

Arecor is exploiting its proprietary Arestat platform and formulation expertise to create a portfolio of in-house and partnered programmes with enhanced clinical properties that would otherwise be unachievable. It has created a broad and well-balanced pipeline of innovative products that offer similar milestone and royalty streams to classic drug discovery plays, yet with lower development risks and in a less costly and more rapid manner. The mix of in-house and partnered assets provide an attractive blend of value inflection points. We view the emerging diabetes franchise as particularly interesting, with the most valuation upside potential. The lead assets 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. However, the investment appeal of the Specialty Hospital products tends to be overlooked, mainly due to limited disclosures; we believe their value is also underappreciated. We value Arecor at £176m, equivalent to 575p a share.

Commercially attractive and lower risk development pipeline

Arecor's management continues to deliver on the Arestat platform's ability to create novel and clinically attractive formulations of existing products. There is a balanced clinical pipeline of in-house and partnered assets that share improved PK/PD (pharmacokinetic/pharmacodynamic) profiles or offer enhanced physical characteristics, such as being ready-to-use (RTU) or ready-to-administer (RTA). The in-house programmes centre on two ultra-rapid insulins that are progressing through early clinical trials. Understandably investor attention is focused on these as they are well positioned for the exciting developments (explored in detail in several previous notes) underway in the treatment of diabetes.

Novel insulins are ideally placed for emerging pump revolution

AT278 is a unique ultra-concentrated, ultra-rapid insulin that could disrupt the insulin market. It appears to be ideally placed to enable, among other things, the delivery of compact integrated patch pumps with the long wear times that patients and clinicians are seeking. AT247 is a complementary ultra-rapid insulin that has been optimised for pumps to deliver near-physiological PK/PD insulin profiles. These programmes form a large element of our rNPV-based valuation and, if they prove to be successful, would contribute material upside.

Specialty Hospital products is all too easy to overlook, but has sizeable inherent value

Against this backdrop the Specialty Hospital products tend to get overlooked. In part this reflects their diversity and characteristics, typically targeting smaller addressable markets, but also, competitive sensitivities limit disclosure. However, lack of commercial insights should not be confused with a lack of commercial opportunity. These programmes can be biosimilars or formulations of existing products that offer enhanced properties. This means they tend to have shorter development times and simpler regulatory pathways, which can result in more rapid achievement of milestones and royalties. Equally, as the number of partnered programmes continues to increase, their collective impact grows.

Collectively Arecor's assets are, in our view, underappreciated

In this note we explore how to assess, despite limited available information, the likely future revenue streams that could accrue with the partnered Specialty Hospital products. Our analyses suggest that Arecor's initial R&D investment in a subsequently partnered asset could be recouped by the time it is commercialised, with royalties therefore representing pure profit. Thus, the value inherent in this franchise, in common with the emerging diabetes franchise, is underappreciated.

Investment case: platform, pipeline, & partnering

Arestat formulation expertise underpins the pipeline

Arecor is a clinical stage development company that has built a balanced pipeline of in-house and partnered assets, all produced by the application of its Arestat formulation technology platform. It is this proprietary platform that underpins the investment case. These consists of a series of over ten different families of formulation techniques that employ different combinations of excipients and formulation methods to achieve enhanced or superior product features and physical properties. The platform is used primarily to develop improved novel formulations of established drugs which would otherwise be not feasible. An overview of Arecor's development pipeline is shown in Exhibit 1.

Exhibit 1: Arecor pipeline summary

Product	Indication/Area	Partner	Stage	Notes/Comments
AT278	Diabetes	Own	Phase I	Ultra-concentrated ultra-rapid insulin aspart. Second Phase I trial to read out early 2024
AT247	Diabetes	Own	Phase I	Ultra-rapid insulin aspart formulation. Phase II trial programme in planning
AT299	Diabetes	JRDF collaboration	Preclinical	Insulin pramlintide co-formulation
Research	Specialty Hospital	Own	Research	Limited or no clinical development needed under 505(b)(2) pathway
AT307	Specialty Hospital	Hikma	Pre-commercial	
AT220	Biosimilar	Undisclosed	Approved (EU)	Launched in Europe
AT292	AATD	Inhibrx	Phase II	Initial data read out of potentially registration-enabling ElevAATe study in late-2024; initiation of clinical studies in GvHD in H124
Tech partnerships	Formulation development	Lilly, PAR, Intas, plus ≥ 4 others	Pre-licence	Includes thermostable, high concentration, RTU, or RTA liquid formulations
Ogluo	RTU Glucagon Pen	Xeris (Tetris Pharma)	Commercial	Launched UK, Germany, Austria, Denmark and Norway, other EU launches to follow
Niche hospital products	Various	Various	Commercial	Antibiotics, endocrine, CVD, and paediatric anaesthesia

Source: Trinity Delta, Arecor Therapeutics Note: AATD - Alpha-1 antitrypsin deficiency; GvHD – graft vs host disease; RTU - ready to use; RTA – ready to administer; CVD – cardiovascular disease * licence and distribution agreements from Tetris Pharma

Well-balanced portfolio: timings, commercial potential, risks, and investment are actively managed

The pipeline is well-balanced, both in terms of timings, spanning preclinical through to late-stage development, and mix, with an attractive blend of in-house and partnered programmes. Partnered assets include Specialty Hospital products and range from early-stage technology partnerships through to commercially available biosimilars (eg AT220) under licensing agreements. The wholly owned assets are focused on clinical diabetes programmes, notably the ultra-concentrated and ultra-rapid insulin (AT278) and the pump optimised ultra-rapid insulin (AT247), as well as the Specialty Hospital portfolio. This mix of partnered and in-house programmes should generate news flow providing multiple potential value inflection points over the next 12 to 18 months.

Partnerships are a core element of the investment case

Partnerships are an important part of management's strategy, reducing development risk and providing cashflow. The fees and milestones from these technology partnerships and licence agreements, together with the contribution from Tetris, mean that - unusually within the sector - Arecor is revenue

generating. The timings of expected new product flows reflect the decisive move in 2016 to shift away from providing a straightforward formulation service, the historic "fee-for-service" type model, towards an integrated and higher value-add technology partnership. A typical partnership brings income for the formulation work undertaken with an upfront fee payable on grant of the licence, payments on the achievement of agreed development milestones, and single- to low double-digit royalties (or equivalent amounts) on eventual in-market sales. These milestones and royalties may appear modest in comparison with some high-profile biotech deals, however there are many potential programmes, and they rapidly stack up into meaningful sums.

Arestat revenues come from Technology partnerships and Licencing agreements…

Arestat-based revenues arise from two primary activities:

- **Technology partnerships:** Also known as research-derived income, these involve a formulation development collaboration where selected elements of the Arestat platform are applied to reformulate and develop enhanced versions of one or more of a partner's own products or product candidates. Such collaborations are revenue generating from day one through research fees and represent upside licence potential should these deals ultimately convert to licences. Arecor has a portfolio of pre-licence formulation partnerships, with two having transitioned to a licence: AT220, a biosimilar which is launched in Europe (undisclosed partner) and AT292, a clinical orphan drug project (Inhibrx).
- **Licence agreements:** These result from two sources: the conversion of technology partnerships or the out-licensing of internally developed products. The first includes an upfront fee on grant of the licence, with further modest payments on the achievement of agreed development milestones, and low (typically single-digit) royalties, or equivalent, on eventual sales. The second has more attractive economics reflecting Arecor's greater value contribution and has been commercially validated by the Specialty Hospital deal with Hikma. While proprietary licence deals are structured similarly to those for technology licences, they are associated with larger development and commercial milestones and higher royalties, typically ranging from high-single to low-double digit.

…with Tetris Pharma bringing growing sales and…

Tetris Pharma, acquired August 2022, adds another revenue stream. It has exclusive European commercial rights to Xeris Pharmaceuticals' RTU glucagon auto-injector pen for people with diabetes, Ogluo, and has launched in five territories (the UK, Germany, Austria, Norway, and Denmark) with further European roll-outs underway. More broadly, Tetris Pharma complements Arecor's acknowledged strength in formulation development and focus on diabetes and Specialty Hospital products, bringing several strategic benefits across both of these franchises.

…additional strategic flexibility for new product opportunities

In our September 2022 Update we gave the background and explained the rationale underlying the Tetris Pharma acquisition. To summarise, Ogluo's profile fits well with Arecor's skillset in improving "difficult to use" injectable products and the glucagon commercial opportunity is attractive on a standalone basis. In addition, over the longer term, Tetris Pharma also provides Arecor the option to exploit the infrastructure to directly market selected future niche products from its Specialty Hospital products franchise. This should accelerate Arecor's goal of becoming a research-led self-sustaining pharmaceutical company.

Specialty Hospital: small investment, big returns

Specialty Hospital products could generate meaningful future income and...

Arecor's Specialty Hospital products are focused on improving existing hospital-based injectable products. Application of the Arestat technologies to such products could unlock the potential of combining better quality, improved safety, and ease of use, with probable cost savings and superior patient outcomes. While the main value driver for Arecor are the in-house diabetes programmes, which have the largest upside potential, we believe the Specialty Hospital products are a potential fruitful source of future income.

...should not to be overlooked, even in absence of product details

The lack of attention on the Specialty Hospital products is unsurprising, given limited information on the programmes within the growing portfolio, coupled with few details from existing partners, or visibility on progress with potential new partners. However, our analysis suggests that detailed information is not required to assess the portfolio. Furthermore, for limited investment, this business could generate a reliable and growing source of profitable income for Arecor in the future, which should not be overlooked.

What are Specialty Hospital products?

Arestat formulations bring clear economic and safety benefits

There are many injectable products used within hospitals that require some form of preparation eg reconstitution or dilution. Not only does this take time, which comes at a cost, but it can also lead to dosing errors, product waste, bottlenecks in workflows, and potential safety issues for hospital personnel through exposure to toxic compounds during the preparation process. Hence, there is a desire to minimise the preparation of any injectable in a clinical setting as this: (1) saves time, with numerous studies showing the time savings comfortably justify a price premium; and, more importantly (2) reduces the handling, which can materially lessen dispensing and administration errors. Improved formulations can include:

- RTU (ready-to-use), which refers to injectable drugs that are prepared to the right concentration and volume but require transfer to the final device, such as an infusion bag; and
- RTA (ready-to-administer), which are injectable drugs that are already in the final administration form (often an IV bag).

Manufacturers are understandably keen to address these market needs. However, the lack of a RTU or RTA presentation is usually due to the challenges and complexities in developing stable liquid formulations.

Specialty hospital pipeline is progressing and deals are expected over the next six months

The Arestat platform is proficient at reformulating complex existing products into RTU and RTA injectables and Arecor has a dedicated research group that aims to maintain a continuous pipeline, with a focus on serious infections, cancer, and emergency care. There are a number of internal programmes, with likely around three to five under active development at any one time, several assets within existing technology partnerships, and AT307 partnered with Hikma Pharmaceuticals. Arecor earmarked c £3m of the gross £20m IPO proceeds to progress the Specialty Hospital programmes to partner-ready stage and further expand the pipeline, with progress made and deals expected over the next six months. None of the underlying products have been disclosed but management estimates that each product addresses a total market size of $250m-$1bn.

Hikma partnership validates the approach

AT307 is partnered with Hikma and heading towards launch in 2026

The most advanced product in the Specialty Hospital product franchise is AT307, which was partnered with Hikma in October 2020. It is a RTU injectable of an undisclosed already marketed specialty hospital product. The novel formulation of AT307 was completed and fully transferred in January 2023, with Hikma taking full responsibility for the product in Hikma's licensed territories, which include the US. It was confirmed in September 2023, following an FDA pre-IND meeting, that Hikma will seek approval for AT307 in the US under the abbreviated 505(b)(2) approval pathway. We forecast launch in 2026.

Abbreviated regulatory pathway has been confirmed in the US

In the US, the 505(b)(2) approval pathway is an abbreviated route to market. The equivalent in Europe is the Directive 2001/83/EC Hybrid pathway. These reference the originator drug for evidence of clinical efficacy and safety. Hence no major clinical trials are expected to be required, allowing for significantly more rapid development than a typical new drug. Confirmation that Hikma can follow the 505(b)(2) pathway in the US for AT307 further supports the likelihood that this route could apply across Arecor's internal Specialty Hospital pipeline of enhanced RTU and RTA formulations of existing drugs.

Deal terms are not disclosed but further milestone(s) are expected plus future royalties

While AT307's underlying asset has not been disclosed due to commercial sensitivities, Arecor management estimates that the total addressable market size is in excess of $300m. Specific deal terms are also undisclosed, although it is known that Arecor received an upfront payment from Hikma in 2020, and a transfer milestone in 2023. Arecor is also eligible for further payments as development, regulatory and commercial milestones are achieved. Undisclosed royalties on sales are also payable, which are expected to be in the high-single to double-digit percentages. Hikma is responsible for funding and generating the necessary data to support approvals in its territories (Arecor has retained commercial rights in certain, undisclosed but assumed to be relatively minor, markets). Hikma will also be responsible for manufacturing and commercialisation in its chosen geographies.

Portfolio assessment is possible even with limited info

Each product is unique and deal terms can be variable…

One of the challenges with assessing the Specialty Hospital portfolio is the limited available information. Each product and opportunity will be unique, meaning appropriate R&D investment levels will depend on the product's potential. Deal terms, if successfully executed, will also differ, with these based on the product's potential and also with a balance to be struck between milestones (including upfronts) vs royalties (or other downstream sales-related payments). All these variables will depend on potential partners and interest levels, the product and stage of development, and the addressable market.

Given this, we have explored various parameters in order to better understand the potential financial and valuation impacts for Arecor. We also provide a simple framework that can be used to assess the Specialty Hospital Products opportunity for a 'typical' individual product and for the portfolio as a whole assuming that, over time, multiple products are partnered.

…hence scenario analysis is a useful tool

We have used scenarios analyses to examine the peak sales range (in $m) for products in the Specialty Hospital portfolio assuming market sizes of up to $300m

(in-line with the opportunity for AT307) and market shares of 10%-30% (left hand table of Exhibit 2). From these peak sales we can then estimate the present value of the future royalty stream for Arecor (in £m) per product, based on fixed royalty rates of 5%-15% (right hand table of Exhibit 2).

Exhibit 2: Potential $m peak sales (left hand side) and £m royalty income for Arecor (right hand side)

Potential peak sales ($m) based on market size ($m) and market share (%)					
	$100m	**$150m**	**$200m**	**$250m**	**$300m**
10%	$10m	$15m	$20m	$25m	$30m
20%	$20m	$30m	$40m	$50m	$60m
30%	$30m	$45m	$60m	$75m	$90m

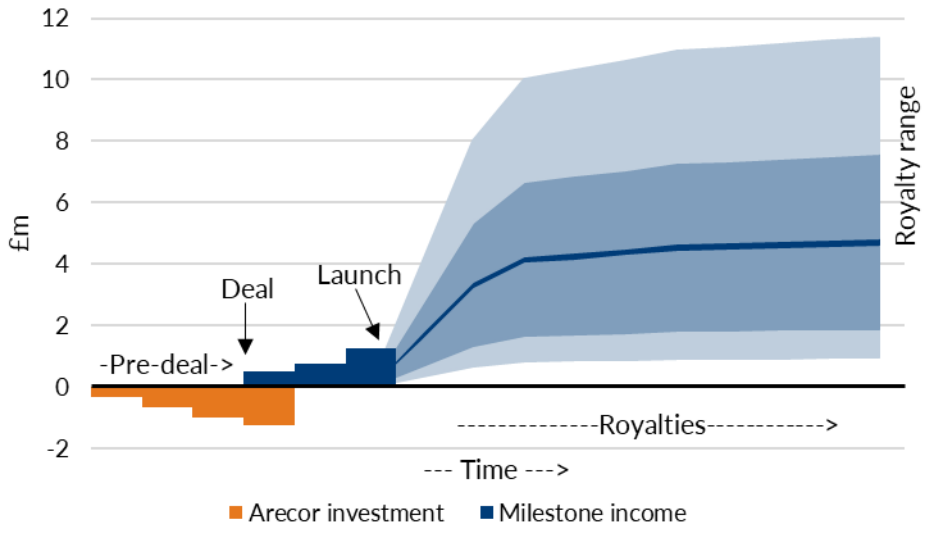
Present value of future royalties (£m) based on peak sales ($m) and royalty rate (%)					
	$10m	**$30m**	**$50m**	**$70m**	**$90m**
5%	£2m	£6m	£9m	£13m	£17m
10%	£4m	£11m	£19m	£27m	£34m
15%	£6m	£17m	£28m	£40m	£51m

Source: Trinity Delta based on £/$ FX rate of 1.20 and a 12.5% discount factor

We expect milestones to offset costs, with royalties driving a return

We take a simple, but not unrealistic view that any R&D spend by Arecor pre-deal (typically two to three years) will be fully recouped via upfronts and milestones by the time the product is launched, perhaps around three years post deal, with royalties on sales then driving a profitable return on the original investment. We assume peak sales are attained fairly rapidly, within about three years of launch (as these products are improved versions of existing products, hence the market already exists). This is shown illustratively in Exhibit 3.

Exhibit 3: 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.

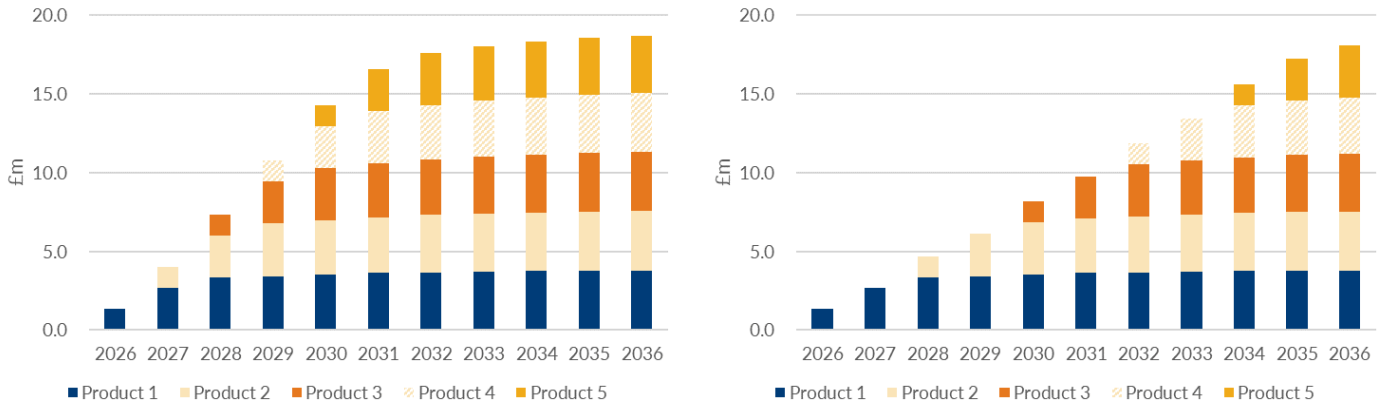
A reasonable base case assumption is peak royalties of c £4m pa, which are worth c £17m in NPV

As can be seen in Exhibit 3, peak royalties could range from c £1m to c £11m per annum (based on peak sales of $20-80m and royalties of 5-15%). We assume Arecor will seek to develop the more commercially relevant opportunities, but in-line with our typical conservative stance, the higher end royalties are perhaps aspirational (but not impossible). Hence, in order to assess the potential future stack as multiple products launch (discussed below), we conservatively use peak annual royalties of £4m per annum, below the mid-point, which over ten years are worth around £17m in present value (assuming near-term launch and using a 12.5% WACC).

Multiple product launches could generate meaningful future income for Arecor

Royalties will build as each product is launched. Given a deal is already in place with Hikma, with launch expected from 2026, and that further deals could be executed from the next six months onwards, if we assume first product launch in 2026, the royalty stack could exceed £15m by 2031e if a product is launched every year, or in 2034e if a product is launched every other year. Exhibit 4 provides an illustrative royalty stack for the first five products. Upside could come from more frequent or additional launches, and/or higher peak sales or royalties.

Exhibit 4: Potential royalty stack based on five partner product launches (LHS: every year; RHS: every two years)



Source: Trinity Delta

Formulation expertise and deal execution will be key to crystallising value

Clearly not every product will be partnered, nor will every partnered product be successfully launched. Hence, the challenges to Arecor in realising this potential include: (1) careful selection of products that appeal to potential partners, including rapid go/no go decisions on portfolio programmes to minimise costs; (2) the technical challenges associated with formulating RTU and RTA versions of existing products; and (3) successfully executing licensing deals with favourable terms. However, if management can continue to navigate these points, as already demonstrated with Hikma, then the Specialty Hospital products could become a meaningful source of income.

There is a broad range of specialty hospital products that could be improved with Arestat

In our view, there are large markets with a broad range of existing specialty hospital products which could be prime candidates for Arecor to improve through application of its Arestat technologies and expertise. Companies involved in this space include existing partner Hikma, plus the likes of Pfizer, Fresenius Kabi, Sandoz, Teva and Baxter, which together encompass a wide range of products/areas such as biosimilars, complex biologics and generics:

- **Hikma**, already an existing partner, generated revenue of $2.5bn in 2022, with $1.1bn from injectables.
- **Pfizer**, whose Specialty Care business (H123 revenues of $7.26bn) includes its Hospital Business Unit, is 'actively seeking partnerships and collaborations to develop differentiated products with meaningful impact to patients'.
- **Fresenius Kabi**, which booked €7.85bn of revenue in 2022, is working on broadening its current product portfolio that spans complex biologics and biosimilars to IV generic drugs and IV fluids, and on the 'continuous improvement' of already marketed IV drugs (eg new formulations and dosage forms).

- **Sandoz**, which was spun out of Novartis in October 2023 and reported FY22 net sales of $9.1bn and 9M23 sales of $7.1bn (split roughly 20% from biosimilars and 80% generics) also has a strategy to improve its product mix, leverage partnerships, and expand the breadth and depth of its pipeline. Its recent acquisition of anti-fungal Mycamine from Astellas is one example that bolsters Sandoz's anti-infective portfolio and global hospital offering.
- **Baxter**, which provides a variety of products and therapies to hospitals and clinics, and reported Q323 sales of $3.7bn, of which Pharmaceuticals (which includes injectables and compounded hospital products) were $580m ie a 12-month run rate of $2.3bn.

Plus a broad range of biopharma companies open to collaborating to improve their product portfolios

Interestingly, several major biopharma companies with a significant global footprint in specialty hospital products have publicly stated a desire to expand their portfolios, including through partnerships and/or collaborations. Near-to-medium term revenue guidance of mid-single digit growth for these franchises, given the largely generic and volume driven nature of the market, suggests that the ability to differentiate their products will increasingly come to the fore and the potential to enter additional addressable market segments is also seen as attractive. Hence, we believe there is significant scope for Arecor to proactively identify products for reformulation, with a view to subsequently partnering. In addition, some select opportunities that can be self-commercialised in certain territories through Tetris Pharma may be retained.

AT220: first launched product incorporating Arestat

AT220 is the first commercially available product incorporating Arestat

Whilst not strictly a typical Specialty Hospital product, it is worth highlighting that AT220 was recently launched in Europe and is the first commercially available product that incorporates the Arestat formulation technology. It is an undisclosed novel and differentiated formulation of a biosimilar product developed in partnership with an undisclosed global pharmaceutical company. None of the financial terms of the deal, executed in 2017, have been made public, however, two milestone payments have been received, and the first commercial sale also triggered a milestone to Arecor. Arecor is also eligible to receive royalties on sales.

AT220 forecasts can be refined as the royalty builds and/or if the partner/product is disclosed

Although the reference biologic remains unknown, it has been disclosed that AT220 addresses a multi-blockbuster market. Based on this, our valuation includes peak AT220 sales of $500m, which assumes a $2bn reference biologic and that AT220 is the first biosimilar to launch. We will seek to refine our forecasts as the royalty stream builds, particularly with launch in the US, and/or if the partner/product is disclosed. Our December 2022 Outlook identified several potential candidates for the reference biologic.

Diabetes: the key in-house development assets

Novel insulins that address the emerging clinical needs

Arecor's lead in-house assets are innovative formulations that address the emerging needs within diabetes care. We discussed the diabetes opportunity, with a focus on the complex but commercially important US market, extensively in our April 2023 Update.

Diabetes is a huge and growing global health issue

Briefly, diabetes is a global issue with a 2021 incidence of 537m (10th IDFDA fact sheets) that is forecast to rise to 643m by 2030, up 19.7% over the period, and to rise to 784m by 2045, a 46.0% increase. The US market may not be the largest in terms of population, or future growth, however its commercial importance remains decisive. The diagnosed diabetic population is estimated to be 27.9m, of which 1.9m are Type I diabetics and 26.9m are Type II, with forecast growth rates of 3.0% and 4.0% (five-year CAGR) respectively. Additionally, a further 7.5m may be undiagnosed, with these being Type II diabetics. Type I diabetes is largely caused by the pancreas failing to make sufficient insulin, with a typical early onset; with Type II diabetes, the pancreas may still produce sufficient insulin but blood sugar regulation (insulin resistance) has been disrupted.

Advances in pump technologies are set to alter the Type I diabetes treatment landscapes

Obviously Type I diabetes patients are initiated on insulin therapy from diagnosis, with the individual patient treatment variations centred around how the intensive management of time in range is achieved. For the majority this is still based on multiple daily injections (MDI), typically using a single bolus long-acting insulin coupled with more frequent injections of a rapid-acting formulation. An increasing number are migrating onto automated insulin delivery (AID). The advances in miniaturisation and AI-driven algorithms now allow the full integration of continuous glucose monitoring systems with sophisticated insulin pumps. The patients selected for pump-based therapy currently are those that are difficult to manage and maintain optimal time in range with MDI, yet the Type I "patient journey" is shifting notably towards an earlier and broader adoption of AID.

The differing patient journeys means Type II diabetes requires a variety of treatment options

With Type II diabetes the patient journey is dependent on the point of diagnosis. For many (c 38%) a regimen of increased activity coupled with improved diet is sufficient to achieve the target HbA1c (blood sugar) levels. Those able to adhere to these lifestyle changes may remain stable for many years, however experience shows a large proportion progress and require medication. Treatment involves the use of multiple drugs, with the combination selected to best suit a patient's needs. Despite the advent of newer drug classes, the mainstay is metformin (still used in 61% of newly-diagnosed Type II patients globally despite changes in guidelines), an oral generic with a proven profile that is well understood. Historically, patients not controlled on exercise/diet and metformin had drugs like sulphonylureas, thiazolidinediones, and DPP-4 inhibitors (gliptins) added.

Newer drug classes are in the spotlight as their broad clinical benefits gain acceptance

The improved clinical benefits (including superior HbA1c reductions, cardio-renal protection, and weight loss) seen with newer classes, notably SGLT-2s (Sodium Glucose Transport 2 inhibitors) and GLP-1s (Glucagon-Like Peptide-1 Receptor agonists), have seen these used much earlier and more widely. The SGLT-2 class is gaining clinical traction for its ability to manage multiple Type II comorbidities, especially serious cardiovascular and renal damage, with impressive "real world" data demonstrating the value of this class. Boehringer Ingelheim/Eli Lilly's Jardiance (empagliflozin) and AstraZeneca's Farxiga (dapagliflozin) are the SGLT-2 class leaders. Extensive supportive clinical data for time in range and HbA1c

reduction have seen injectable GLP-1s, ie Novo Nordisk's Ozempic (semaglutide) and Eli Lilly's Trulicity (dulaglutide) and more recently Mounjaro (tirzepatide), effectively supplant long-acting insulin as next line treatment for many Type II patient groups. The outcomes for weight loss, c 10% consistently, have made household names of drugs such as Ozempic.

Experience with newer classes, specifically GLP-1s is building, although challenges remain

Nevertheless, the newer GLP-1s currently have limited on market experience and challenges with the class mean that it is unlikely that GLP-1s would fully displace insulin's role in diabetes management. These challenges include pricing and affordability, patient access, manufacturing capacity issues, and questions regarding long-term adherence and treatment compliance given common gastrointestinal side effects. However, the clinical outcomes of GLP-1 use, including the impact on BMI (obesity and diabetes are common co-morbidities), could work synergistically with insulin in Type II diabetics at both the personal and population level.

Insulin set to remain a core treatment for diabetics

Despite the rise of the GLP-1 and SGLT-2 drug classes, the majority of Type II patients (excluding those whose diabetes is controlled through diet and exercise alone) are currently treated with multiple daily injections of insulin. Clearly, all Type I diabetes patients require insulin injections but the majority of the c 7m (estimates range from c 5m to over 10m) US patients who use insulin daily are Type II diabetics. While it is hoped that optimised combination therapy with the newer agents will delay, or even negate, the need to introduce insulin for many Type II diabetics, the harsh reality is this patient group will likely remain the largest users of insulin.

Exhibit 5: Benefits of an insulin pump over equivalent multiple injections

- Programmable insulin delivery allows closer match with physiologic needs
- Uses only short- or rapid-acting insulin, minimizing peaks and absorption-related variability
- Uses one injection site for up to 72 hours, thus reducing variations in absorption and treatment-related burden from multiple injections
- Reduction in glycemic variability and improved glycemic control
- Decreased risk of severe hypoglycemia and need for emergent medical attention
- Reduction in need for hospitalization and cost of care
- Improved quality of life and treatment satisfaction

Source: Adapted from McAdams and Rizvi, Journal of Clinical Medicine 16 5(1) 5

Technological advances are driving transformational changes in insulin pumps…

The excitement around the newer anti-diabetic classes is understandable, but this overlooks one of the major transformations underway for not just Type I diabetes patients but also those difficult to treat Type II patients. We have covered the technological advances that are driving the pump market in earlier notes and Exhibit 5 shows a useful overview of the clinical benefits that such advanced pumps can bring. Briefly, it is the improvements in continuous glucose monitoring (CGM) and the corresponding miniaturisation of the pump technologies, coupled with the software that allows genuine real-time responses, that have led to the development of current highly sophisticated "artificial pancreas" (Automated

Insulin Delivery) systems. As these compelling devices approach commercial reality, the remaining obstacles to be addressed are shifting from the physical and software aspects to the characteristics of the insulins that are now required.

...which in turn is driving a need for faster acting, and more concentrated, insulins

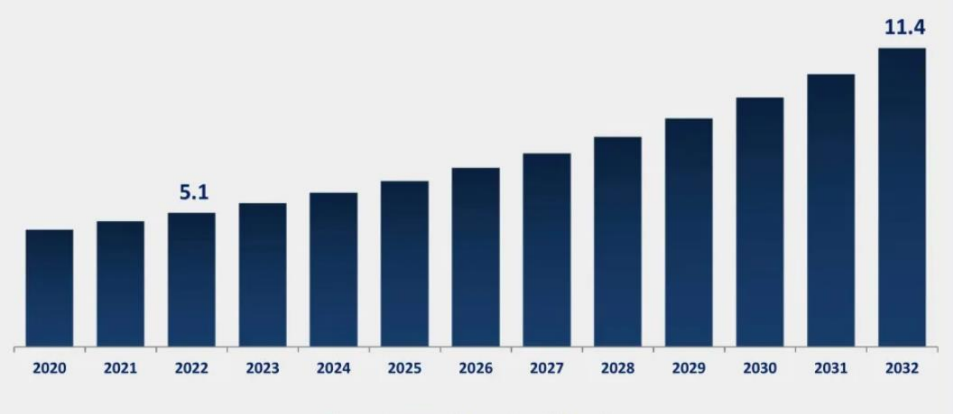
For example, the inherent delays in absorption of subcutaneous injected insulin compared with how endogenous insulin is produced means postprandial hyperglycaemia is still a challenge for these fully automated pump systems. The pharmacokinetics and pharmacodynamics of current rapid-acting insulins are known to be suboptimal, hence the expectation that the new ultra-rapid acting insulins, which have faster onset and offset of action, have the potential to address this issue. It is for this clear clinical need that AT247 (ultra-rapid insulin) and AT278 (ultra-rapid and ultra-concentrated) appear particularly well suited. It is also worth emphasising miniaturisation and extended wear times are major drivers of the market demand for an ultra-concentrated ultra-rapid insulin.

AT278 and AT247: addressing evolving insulin needs

AT278 and AT247 are insulins that are perfectly positioned to address emerging needs

Arecor's two key clinical stage diabetes programmes are the ultra-rapid insulins AT278 and AT247, both of which are novel formulations of insulin aspart, the active ingredient in Novo Nordisk's well-characterised, proven, and off patent Novolog (US)/NovoRapid (ex-US). The clinical appeal and patient relevance of these programmes, as well as the commercial opportunities and prospects, were covered in detail in several previous notes (see earlier). Both these formulations are well-placed for the needs of the growing insulin pump market (Exhibit 6).

Exhibit 6: Global insulin pump market 2020-2032 ($bn)



Source: Acumen Research and Consulting (July 2023)

AT278's ultra-concentrated and ultra-rapid profile could make it a market disruptor

AT278 has the potential to be a disruptive insulin. It is a highly concentrated (500 units/ml, U-500) and ultra-fast-acting insulin aspart. Ignoring the evolving need for the new pump applications for a moment, high concentration insulins are expected to become increasingly in demand due to the rising number of Type II and refractory Type I diabetics that require higher daily dosing. The increase is being driven by rising obesity rates across most geographies such that average usage for Type II diabetics is now 97 units of insulin daily, with a growing number needing 200 units or more. Yet, despite this expanding addressable population, only three concentrated bolus insulins are available: Humulin R U-500 (human insulin, Eli Lilly) which has similar profile to a basal insulin, and two more rapid acting (not ultra-rapid) but less concentrated products, Humalog U-200 and Lyumjev U-200 (both lispro, Eli Lilly).

A clear need in MDI patients but ideally placed for miniature long wear insulin pumps

Yet the need for a concentrated rapid insulin for use in the injecting patient population is overshadowed by the emerging demand created by technological developments. To recap, the pumps of the future are designed to be compact integrated units (no external tubing or separate glucose monitor and pump) that are attached directly to the skin and are inconspicuous in appearance and use. Due to their smaller design, these next-generation patch pumps have limitations on battery capacity and, importantly for AT278, the insulin reservoir size. Hence, to achieve the required near-physiological insulin delivery and still have the extended wear time desired, an ultra-rapid and ultra-concentrated insulin becomes an essential enabler for device manufacturers.

Currently completing a Phase I trial programme, with data due in Q124

AT278 has successfully completed one Phase I trial in Type I diabetics, with all primary and secondary endpoints met. Comprehensive PK/PD data from 38 adults in an euglycemic clamp setting comparing AT278 with NovoRapid (IAsp, Novo Nordisk's gold standard rapid acting insulin) were presented at the April 2022 Advanced Technologies and Treatments for Diabetes (ATTD) meeting and are comprehensively reviewed in our May 2022 Update. These data showed that, despite a five-fold greater concentration, AT278 has an absorption profile that does not simply match the criteria for a rapid insulin but can justifiably be classified as an ultra-rapid insulin. A similar Phase I study, but in Type II diabetics, is currently underway. The size of the study has recently been increased from 32 patients to 42, with the additional patients increasing the power of the study and the robustness and value of the results. Preliminary data are expected in Q124.

AT247 is a next-generation ultra-rapid pump optimised insulin

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. AT247 has successfully completed two Phase I clinical trials in Type I diabetics: one evaluating the PK/PD of a single subcutaneous injection and the second the PK/PD over three days of continuous subcutaneous infusion via pump. The data, also covered in our May 2022 Update, met all primary and secondary endpoints, with the PK/PD profiles suggesting it has the potential to be an ideal pump insulin. From a commercial and partnering perspective, AT247 complements AT278 well with its activity profile suggesting it has the potential to be the fastest acting and most physiological insulin available.

Marketplace: vibrant and increasingly dynamic

Innovative devices coupled with superior formulations could be transformational

Innovation in diabetes care is increasingly converging on improved devices, particularly towards small longer wear insulin pumps (including patch pumps) and closed loop AID systems. The hardware, software and algorithm development has advanced sufficiently that the characteristics of the drug component of these drug-device combinations is now the rate limiting step and is key to their success. As outlined earlier, the profiles of the ultra-rapid/near physiological insulin AT247 and the ultra-rapid/ultra-concentrated insulin AT278 mean that these formulations are well positioned to address needs of AIDs (and the ability to close the loop) and of miniaturised longer wear pumps respectively.

Advances across numerous device applications…

This past year has seen many advances in diabetes care. Notably, all three of the major pump manufacturers now have access to patch pump technology. Hence, we believe that the choice of insulin formulation could provide important competitive differentiation, facilitate penetration of the high insulin use Type II

diabetes market, and likely be a determinant of market share capture and, ultimately, commercial success.

...with M&A activity a strong feature

Medtronic, a global leader in smart dosing systems, gained FDA approval in April 2023 for its MiniMed 780G automated insulin pump, which has been available in Europe since late 2020. This can be worn for up to seven days and when used with SmartGuard Technology and Guardian 4 sensors requires no finger sticks. Subsequently, in May 2023, Medtronic announced the proposed acquisition of the Korean wearable insulin patch pump manufacturer EOFlow for $738m (although the deal has not yet closed). Its flagship product is the EOPatch slimline disposable pump and Medtronic aims to rapidly integrate this with its next-generation glucose sensor and clinically proven algorithms to create a seamless delivery platform. Tandem Diabetes received FDA clearance for its Tandem Mobi pump in July 2023. This is significantly smaller than the existing t:slim X2 pump and runs on the highly rated Control-IQ predictive software. This successful integration of the sensor, pump, and software will be applied to the Sigi Patch Pump acquired in January 2023 when it purchased Swiss-based AMF Medical for $216m. Insulet continues the roll-out of its Omnipod 5 automated insulin delivery. In February 2023, it also acquired Automated Glucose Control, the developer of the technology underpinning Omnipod, and Bigfoot Medical, a developer of intelligent connection systems.

Sanofi appears to be back into the diabetes field

Elsewhere, Sanofi appeared to row-back on its previous (December 2019) decision to exit its R&D efforts in diabetes with its $2.9bn acquisition of the innovative Prevention Bio, which has the immunotherapy Tzield for the prevention of newly-diagnosed Type I diabetes. We note that Sanofi has also negotiated a partnership with Adocia for global rights to M1Pram, an insulin and pramlintide combination.

The platform: what it does and what it means

Proven expertise in formulating difficult compounds

Arecor's key strength is its ability to formulate a broad variety of challenging molecules into clinically viable, and commercially attractive, drugs. The Arestat platform consists of a series of over ten different families of formulation techniques. These employ different combinations of excipients and formulation methods to achieve enhanced or superior product features and physical properties. They are particularly helpful in improving the profiles, kinetics, and stabilities of complex biological products such as antibodies, biosimilars, vaccines, and peptides. The creation of stable liquid formulations is notoriously difficult and the Arestat platform produces products that are easier to use and to administer.

Exhibit 7: How Arestat can make a difference

- **Developing formulations of products with superior kinetics targeting improved clinical and patient outcomes;**
- **Making stable liquid ready-to-use (RTU) and ready-to-administer (RTA) products for IV delivery, improving patient safety, speed of administration, and clinician convenience;**
- **Producing convenient, concentrated liquid doses for self-administration via a single injection (eg IV to SC administration);**
- **Creating heat-stable products that maintain product integrity and so allow supply chain simplification; and**
- **Generating new versions of existing products with robust intellectual property, effectively extending commercial life spans.**

Source: Arecor Therapeutics, Trinity Delta

Adding real value for patients, clinicians, and client companies

The various techniques and subtle interplays between formulation excipients that result in an improved product were covered in detail in our September 2021 Initiation and December 2022 Outlook. Briefly, they have been applied to create improved formulations of an array of existing products; ranging from enhancing stability (eg extending the shelf-life of protein products), changing supply chain requirements (eg the greater temperature stability eliminating the need for cold chains), and creating stable aqueous formulations (eg converting lyophilised powders to ready-to-use liquid dosage forms). They can also alter and improve therapeutic profiles, with the most pertinent examples being the in-house insulin programmes, AT278 and AT247, showing greatly improved speed of onset and early glucose lowering action even at low concentrations.

Reformulation can be applied at any point in a product's lifecycle

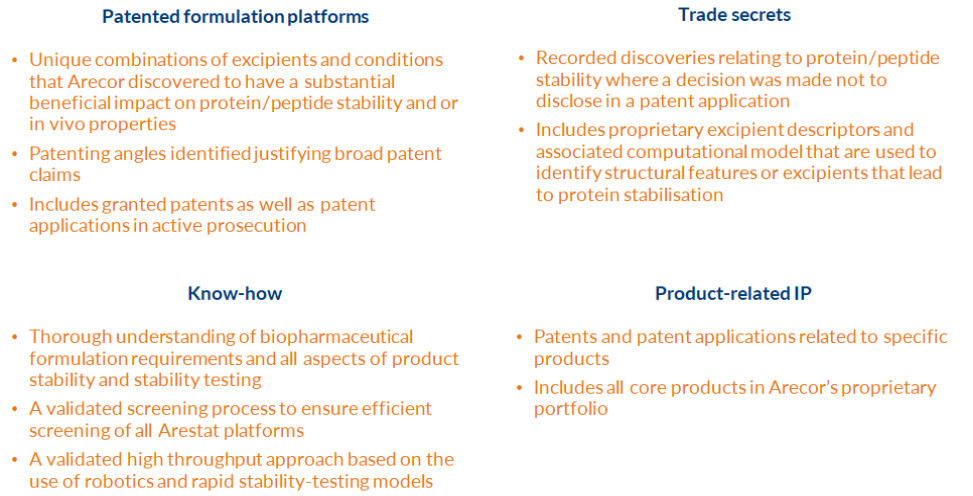
The versatility of the Arestat technologies means they can be applied to a variety of therapeutic modalities for many diverse purposes, depending on the need or commercial priorities of Arecor's clients or partners. The result is programmes can range from early preclinical evaluations through life cycle management of existing products to gaining a competitive edge with a differentiated, and IP protected, product that improves patient outcomes. The new product's patent protection, coupled with the additional clinical benefits, means a partner's established franchise can be sustained beyond the original product's patent expiry.

Arestat is well protected by an array of methods…

The various elements employed have been developed and refined over the past 15 years and these form the basis of the Arestat technology platform. The now more than ten different families of formulation techniques are protected through

a combination of over-lapping approaches (Exhibit 8). The patent estate is substantial, with over 50 patents granted and a further over 70 pending, across the major geographies, including US, Europe, Japan, India, and China. These can be classified into 36 patent families covering areas such as displaced buffer technologies, stabilised protein formulations containing amphiphilic excipients, stabilised antibody formulations, and stabilised Fc protein construct formulations. The robustness of these has been demonstrated by court rulings upholding these protections (eg GSK in 2021).

Exhibit 8: Four pillars of Arestat technology and associated IP



Source: Trinity Delta, Arecor Therapeutics

...resulting in novel formulations with comprehensive IP in place

Elements from each of these families, as applicable, form the 'background IP' employed to resolve a particular formulation problem, with any resulting insights used to create new 'foreground IP'. Any novel formulations generated can then be protected specifically by elements of background IP, new foreground IP, or a selected combination of both. Importantly, with partnered programmes Arecor usually retains IP ownership, licensing the right of use to its partner. The platform's broad applicability and flexibility means future revenues are not limited to a particular therapeutic segment or product type while, unlike a traditional fee-for-service model, the IP estate generated results in an attractive combination of development milestones and long-term royalty streams.

Sensitivities

All the usual industry risks for a small, innovative company apply

In common with most innovative healthcare companies, Arecor's three main sensitivities relate to clinical and regulatory aspects, commercial execution, and the financial resources required to accomplish these. More specifically, the key near- and medium-term sensitivities are directed to clinical progress of the two in-house diabetes assets (AT278 and AT247) and partnered programmes:

- AT278 and AT247 are both based on aspart, a well-characterised insulin, hence development risk is lowered, especially as Phase I PK/PD data have confirmed their differentiated profiles. However, the next generation insulin delivery market is evolving rapidly and ensuring the clinical programme addresses all the key data requirements may not be straightforward. Arguably, this only becomes a real issue if Arecor selects to develop these assets beyond Phase II studies.
- Partnered assets include those licenced to Hikma (AT307), to Inhibrx (AT292), and AT220 (undisclosed partner). In all cases clinical and commercialisation plans are under partner control and, apart from Inhibrx, there is limited disclosure on timelines, or the identity of the underlying asset or indication targeted. This makes valuing these assets more challenging, hence our conservative approach for each.

Lower development risks than typical industry rates

More generally, clinical development risks are known and documented; <8% of preclinical assets reach the market. Success probabilities improve as a programme progresses through development, with a key inflection point at the Phase II proof-of-concept stage. This is viewed as attractive timing for value optimisation as the risk profile improves materially, but expensive pivotal Phase III trials still lie ahead. As mentioned earlier, Arecor's focus on improving existing products means much of the clinical/regulatory risk inherent with novel molecules is minimised, hence the risk of failure is much lower.

Partnering and quality of deals will define future revenues

The partnering process is a key test of a management's strategy. A well-struck deal validates the attractiveness of the proprietary technology and scientific skills, and the commercial terms provide a tangible insight into management acumen. The majority of Arecor's future revenue streams depend on how partners perform in competitive markets, where it will have no control or influence on commercial process or strategy. This contrasts with the commercialisation of Ogluo, and other assets in future, through its acquired Tetris Pharma subsidiary. Nonetheless, we would argue this is an industry-wide risk, where Arecor is no different to other similarly sized companies. However, where Arecor may have an advantage is through its pipeline of superior differentiated formulations of existing therapeutics, which offer a potential competitive edge given lower development risk and improved outcomes that may support attractive pricing/reimbursement.

Funding needs alleviated in part by revenue generation and potential for non-dilutive financing

As with any development stage company, availability of sufficient and timely financing is a constant sensitivity. Arecor's strategy of developing selected assets to an optimal inflection point is sound, the inherent scientific expertise is proven, and the current management is respected. Its ability to generate revenues and potential for non-dilutive financing from partners eases financing pressure, however the real question is whether investors appreciate the investment case and can support Arecor through to the next phase of its journey.

Valuation

We value Arecor at £176m, equivalent to 575p per share based on an rNPV model

We value Arecor using an rNPV (risk-adjusted net present value) model, including the diabetes franchise, partnered assets, and the in-house Specialty Hospital research portfolio. The rNPV of the individual projects are assessed and success probabilities adjusted for the inherent clinical, regulatory, commercial, and execution risks, whilst factoring in Arecor's lower development risk profile given most programmes are based on well-characterised existing products. These are summed and netted against central costs and net cash. Our key assumptions are summarised in Exhibit 9, which are regularly reviewed as development progresses. Our current valuation is £176m, equivalent to 575p per share.

Exhibit 9: 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	Various with peak sales of $20-80m; Launch year: 2026+
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: 2026
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 based on a 12.5% discount factor and £/$ FX rate of 1.20. Note: AATD = Alpha-1 antitrypsin deficiency.

Further potential upside as AT220 assumptions are refined

The internal diabetes programmes, AT278 and AT247, are the main value drivers for Arecor, with AT278 alone underpinning the current share price. 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.

Specialty Hospital valuation is currently a conservative placeholder

The Specialty Hospital rNPV of £16.5m is largely a conservative placeholder given limited visibility. As we have highlighted in this note, peak annual royalties of £4m per annum are worth around £17m in present value per product. Hence, there could be significant upside as deals are executed and products are launched. We also do not attribute a value to the technology formulation development collaborations, nor do we provide an indicative valuation of the Arestat technology platform.

Financials

Three revenue streams with varying predictability

Arecor is revenue generating (FY22: £2.4m), with revenues growing and set to become better defined and more predictable once various royalty bearing products are launched in coming years. Revenues stem from three main sources:

- **Formulation development (FY22: £1.4m):** this is relatively steady income from various partnerships.
- **Licensing agreements (FY22: £nil):** this includes non-recurring upfront payments and variable milestones that are contingent on development progress and commercialisation, on which we typically have limited visibility. No milestones were received during 2022, but the transfer of AT307 to Hikma in January 2023 was a milestone triggering event, leading to H123 licensing revenues of £0.1m.
- **Product sales (FY22: £1.0m):** this currently largely consists of Ogluo sales in Europe, which was incorporated from August 2022. Product sales of £1m during 2022 were for the five months post-acquisition (4 August to 31 December 2022), with this increasing to £1.2m in H123.

Revenues are set to grow, driven by product sales and product-related royalties

We expect revenues to grow in the coming years; we forecast £4.8m in FY23e and £7.1m in FY24e. The uptick is largely driven by product sales and royalties (we include some modest milestone income for known triggering events, but do not include any significant unknown or uncertain milestones), with both a full year of Tetris Pharma sales in 2023, plus underlying growth and expansion, coupled with first recurring royalties, specifically on AT220, which recently launched in Europe. The next product where we have potential launch visibility is Hikma's AT307, on which Arecor will also receive recurring royalties (and potential additional milestones), with launch expected 2026. As highlighted earlier, additional Specialty Hospital deals could drive further milestones and royalties.

SG&A base should stabilise in FY23; future R&D spend will depend on development plans

In terms of costs, the main elements relate to R&D investment (FY22: £8.6m) and SG&A spend (FY22: £5.4m). For R&D, the majority of costs arise from the ongoing European Phase I trial of AT278; this was initiated in December 2022, with topline data expected in early 2024. Given this ongoing trial, we forecast R&D spend of £5.9m in FY23e, which is relatively predictable, in our view. For FY24e, we forecast R&D of £6.2m, assuming some growth over FY23e, albeit this is largely illustrative and future R&D investment will depend on clinical trial plans, likely to be refined as data become available (and subject to sufficient finances). For SG&A, we forecast £9.0m in FY23e, with this including a full year of Tetris Pharma spend vs five months in 2022, then rising slightly to £9.5m in FY24e.

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 and, post period end also received £0.4m in grants and £1.3m in R&D tax credits. Our forecasts (Exhibit 10) 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 all extend the runway.

Exhibit 10: 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

Company information

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Top institutional shareholdings

	% holding
BGF Investment Management Ltd	12.28
Unilever	9.57
Calculus Funds	7.92
Downing LLP	5.66
Lombard Odier Asset Management	5.64
Oxford Technology 2 VCT	5.19
Stewart Newton	4.72
Chelverton Asset Management	4.65
The Wood Family	4.19
Albion Capital Funds	4.05
Unicorn AIM VCT	3.92
Sarah Howell (CEO)	2.83
Amati AIM VCT	2.76
Top investors	**73.38**
Other shareholders	26.62
Total shareholders	**100.00**

Source: Arecor Therapeutics Note: as at 1 November 2023

Key personnel

Person	Position	Biography
Andy Richards	Non-Executive Chair	Appointed 2008. Chair of Congenica, Abcodia, Ieso Digital Health, and Closed Loop Medicine, and a director of Owlstone Medical, Cancer Research Technology (the commercial board of Cancer Research UK) and The Scale-Up Institute. Also a council member of the UK Medical Research Council. Previously a founder of Chiroscience and director of Chiroscience, Vectura, Ixico and Silence Therapeutics. Holds a PhD from Cambridge University.
Sarah Howell	CEO	Joined as COO in 2011, appointed CEO in 2015. Responsible for Arecor's transformative switch from a third-party reformulation contractor to a development specialist with in-house clinical programmes. Previously Vice President CMC & Technical Development at BTG and Director of Outsourced Manufacturing at UCB-Celltech. Holds a BSc in Chemistry from the University of Birmingham and a PhD in Physical Organic Chemistry from the University of St Andrews.
Susan Lowther	CFO	Joined as CFO in 2019. Extensive board level experience of public and private life sciences companies. Previously CFO at IXICO, Novacyt SA, and BioWisdom. Before this, Finance Director at RiboTargets and Head of Finance at Lonza Biologics. A Fellow of the Chartered Institute of Management Accountants since 2003.
Jan Jezek	CSO	CSO since 2007. Responsible for all R&D activities, platform development, and IP strategy. Instrumental in creating the various interlocking Arestat formulation technologies and translating these into commercial applications. Previously Principal Scientist at Insense Limited, also a spin-out from Unilever. Holds a joint Doctorate from the University of Bedfordshire and the University of Chemical Technology, Prague.
Manjit Rahelu	CBO	Joined as CBO in April 2023. Over 25 years of technical, commercial and financial experience across large and mid-sized pharma and biotech companies. Founder partner of Alcheme Advisors, previously CBO and COO at Calchan, VP Business Development at Convergence Pharmaceuticals, and held positions with increasing responsibilities at Sandoz, Pfizer, Sanofi and UCB. Holds a PhD in Immunology from the University of Birmingham.

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Disclaimer

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