Allergy Therapeutics

Strong performances against strategic goals

Allergy Therapeutics delivered a solid 6% revenue growth for FY20 to £78.2m, from £73.7m, despite COVID-19 impacts taking a 2% toll. The well-established European commercial platform produced operating profit before R&D of £14.2m, from £11.3m, with R&D spend of £9.0m, from £13.2m. Pollinex Quatto Grass is set to start a pilot Phase III study before initiating full registration trials. The promising VLP-based peanut vaccine reported highly encouraging preclinical data which, if maintained, could be transformational for future prospects. The fruits of the development portfolio are expected to enable the market entry into the commercially attractive US. Cash resources of £37.0m are ample to fund near-term requirements. We initiate coverage with a £325m (51p a share) valuation.

<table>
<thead>
<tr>
<th>Year-end: June 30</th>
<th>2019</th>
<th>2020</th>
<th>2021E</th>
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<tbody>
<tr>
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<td>Adj. PBT (£m)</td>
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<td>12.2</td>
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Source: Trinity Delta  Note: Adjusted numbers exclude share-based payments and exceptional.

- **Strong performance in difficult times**  FY20 results highlight the quality and resilience of the European business, marking over 20 years of sustained revenue growth. Sales were up 6.1% to £78.2m (+7% CER), against £73.7m FY19, with COVID-19 impacts costing around 2% of growth. Operating profit, ex R&D spend, grew by 2.6% to £14.2m (FY19 £11.3m), with margin of 18.2% (15.3%). R&D spend was £9.0m (£13.0m). Reported operating profit was £8.3m (£4.4m), helped by the final £3.2m Inflamax settlement (£6.0m). EPS was 1.09p (FY19: 0.55p).

- **R&D pipeline approaching key points**  The ultra-short Pollinex Quatto SCIT platform underpins future growth prospects in Europe and will enable entry into the commercially important US market. The grass pollen indication is set to begin a pilot Phase III study in 2021, ahead of the finalisation of the design of the pivotal Phase III registration trial. Success will pave the way for additional indications such as birch and ragweed being progressed. Regulatory approvals will allow greater marketing in Europe and form the basis for what could a sizeable business in the US.

- **VLP peanut allergy vaccine is attractive**  Recently published preclinical data for the proposed peanut vaccine were highly encouraging. Preparations are underway to initiate Phase I studies, with resources being focussed on ensuring development progress is maintained. Eventual success could result in a clinically transformative product, with consequent commercial benefits. Management has also acquired rights to the VLP (virus-like particle) technology for indications beyond allergy.

- **Undervalued on any measure**  We initiate coverage with a valuation of £325m, equivalent to 51p a share. This is based on a DCF of the commercial operations and an rNPV of the pipeline. The existing business is valued at £87m, 14p a share, and the R&D portfolio at £204m, 32p a share, with net cash as the residual.

Initiation of coverage

23 September 2020

<table>
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<tr>
<td>Shares in issue</td>
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<tr>
<td>12-month range</td>
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<tr>
<td>Free float</td>
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<td>Primary exchange</td>
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<td>Other exchanges</td>
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<td>Company Code</td>
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Corporate client  Yes

Company description

Allergy Therapeutics specialises in the diagnosis and treatment of allergy. The existing European business generates c. £80m annual sales. Near-term R&D efforts are focussed on the Pollinex Quatto platform, whilst in the medium-term the VLP platform is highly promising.

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Investment case

Allergy Therapeutics is a UK-based specialty pharmaceutical company focused on the diagnosis, prevention, and treatment of allergy. It has an established and productive commercial infrastructure in the major European markets and approved manufacturing capability, with validated supply chain. There are several proprietary allergy immunotherapy (AIT) vaccines in clinical development for specific grass or tree pollen allergies, as well as a novel VLP-based peanut vaccine. Allergy was formed in 1999 as a management buy-out of SmithKline Beecham’s Bencard operations (originally founded in 1934 and acquired by Beecham in 1949) and floated on AIM in 2004. It has raised c £85m in capital to date, most recently £10m in 2018. Allergy employs c 600 employees globally, with R&D mainly in the UK and the c 140-strong commercial teams based across Europe.

Valuation

We value Allergy Therapeutics using a DCF-based model for the commercial operations together with an rNPV contribution for the key elements of the R&D pipeline. Although there is also an inherent value in the technology platforms, we have opted to not include these yet and they remain as potential upside. The conservative approach is maintained across all our assumptions, yet still results in a valuation that is higher than attributed by the market. Our valuation is £325m, equivalent to 51p a share, of which the commercial operations contribute £87m and the pipeline £204m (14p and 32p per share respectively).

Financials

FY20 results showed a solid 6% revenue growth (+7% CER) to £78.2m, despite the c 2% loss due to COVID-19 impacts (notably in Southern Europe). R&D expense was £9.0m, from £13.0m, as clinical spend was lower in the period. This sum is expected to rise to c £15m as Pollinex Quattro Grass (Grass MATA MPL) starts the pivotal Phase III stages and the promising VLP Peanut vaccine enter Phase I trials. Cash resources at end-June 2020 were £37.0m, with ample capacity for borrowing if required.

Sensitivities

The key sensitivities are revenue exposure to a COVID-19 economic downturn and/or subsequent austerity measures, the long-standing changing regulatory environment in Europe, and the usual risks associated with clinical development, but notably heightened due to the perceived higher uncertainties experienced with previous high-profile allergy trials. Additional sensitivities relate to ensuring adherence to manufacturing standards, other related regulatory risks, increased competition, sustained pricing pressures, and the integrity of supply chains.
**Allergy Therapeutics: attractive yet undervalued**

Allergy Therapeutics is executing a well-proven strategy: maximising the performance of its existing commercial platform; developing a suite of innovative products that address well-documented needs; and preparing for geographic expansion, notably the US. The sustained strong European performance has helped fund the development of novel R&D programmes, particularly the grass MATA MPL and innovative VLP-based peanut vaccines. It is these highly differentiated and clinically validated products that will enable penetration into the commercially important US market. The solid balance sheet, £37.0m cash at FY20, funds a comprehensive clinical programme through to material value-inflection points. The near- and medium-term news flow should provide opportunities for us to revisit our current valuation of £325m, equivalent to 51p a share.

**Europe continues to deliver resilient sales, and profit, growth**

Allergy Therapeutics has an enviable record of growth, achieving c 9% revenue CAGR over the past 20 years. This has resulted in FY20 sales of £78.2m, arising entirely out of Europe where its commercial footprint is now well-established. Careful product positioning and consistent marketing, coupled with favourable changes in the regulatory environment, are driving sustained market share gains. The novel Pollinex Quattro range, currently only available on a “named patient” basis, accounts for 42% of revenues and Germany accounts for 61%. However, management is also seeking to exploit the existing portfolio’s value by growing sales of smaller products and optimising potential in regions where it has low market share relative to portfolio and size.

**R&D success to underpin future opportunities in Europe and US, with peanut vaccine as upside**

The Pollinex Quattro (PQ) platform’s attributes of high immunogenicity and low reactogenicity result in high, sustained efficacy with a short course of subcutaneous injections. The lead grass pollen indication is set to start a pilot Phase III study in 2021. If successful, subsequent pivotal studies would lead to approval in both Europe (initially in Germany then rolled out across other countries) and the US. Other indications such as birch and ragweed would also be progressed. Importantly, a VLP-based peanut allergy vaccine is being developed. This has successfully completed preclinical studies with highly encouraging results. Although still in the earliest, and riskiest, development stage, if the promising progress continues this could be transformative for patients and Allergy Therapeutics alike.

**Planned US entry is a key element of the growth strategy**

The commercial opportunity in the US is significant and, much like Europe, is experiencing regulatory changes that should benefit clinically-based companies. Management is driving the PQ grass indication clinical programme with the aim of being the first short course, subcutaneous and aluminium-free allergy therapy introduced. Although not without its challenges, careful market positioning and astute marketing should result in gaining a sizeable, and defensible, share of this large and growing patient demographic. These incremental sales should help drive revenue growth at the high-teens level from the mid-2020s onwards.

**Our valuation suggests the shares are undervalued**

Our valuation, using a combination of a DCF of the European business and an rNPV of the pipeline, is based on conservative assumptions. This results in a value of £325m, equivalent to 51p a share. A comparison with its peers suggests that our approach may be overly cautious.
Allergies are a common and debilitating problem...

...with well-documented quality of life and economic impacts

AIT works by addressing the underlying cause...

**The allergy market: defined by regulatory change**

Allergies are widespread, affecting all demographics, ages, and races to varying degrees. Typically, they are caused by a hypersensitivity of the immune system to what should be harmless substances commonly found in everyday life. They include hay fever, food allergies, dermatitis, and allergic asthma, with symptoms ranging from mild irritation and a runny nose to shortness of breath and anaphylaxis. Whilst various pollens account for the majority of allergies, it is sensitivities to certain foods, such as peanuts, and insect stings, such as wasps, that cause the more severe, and potentially life-threatening, reactions.

Sensitivity can arise through genetic factors and/or environmental exposures, with incidence rising due to causes as diverse as urbanisation and pollution through to "Westernisation" of lifestyles. Often allergies are mild in nature, but they can, nonetheless, have a major impact on quality of life and are, collectively, viewed as having a major economic burden.

**Exhibit 1: The basics of allergen immunotherapy (AIT)**

Allergen immunotherapy (AIT), also known as desensitisation, involves the repeated administration of specific allergens that over time provide protection against natural exposure to these allergens. The mechanisms involved remain subject to debate but there is a shift in the immunological response from a T-helper type 2 (Th2)-dominated response to a Th1-dominated response. At the risk of over-simplifying the situation, T cells originate from the same originator CD4 cells, with the Th2 pathway being associated with an inappropriate or detrimental response to environmental antigens and the amplifying and prolonging of allergic inflammation. Studies have shown an increase in the production of regulatory T cells that secrete interleukin (IL)-10 and transforming growth factor (TGF)-β, with the IL-10 inhibiting T-cell proliferative responses and reducing the Th2 cytokine production associated with allergic inflammation.
It is this ‘rebalanced’ immune response that reduces the symptoms when exposed to the allergen, with the effect being sustained for lengthy periods. This contrasts with symptomatic treatments, such as antihistamines and corticosteroids, which offer temporary symptom relief. AIT is highly effective in patients with a limited spectrum of allergies (one or two), with proven efficacy in indications such as allergic rhinitis and allergic asthma, in sensitivity to house dust mite (HDM) and animal dander, and in patients who develop systemic anaphylactic reactions to wasp/bee stings where such immunotherapy may be life-saving. Although there are risks of severe allergic reactions, necessitating access to adrenaline and resuscitative measures when administered, the overall risk/benefit ratio tends to be highly favourable.

**Sizeable markets that are set to grow**

The allergen immunotherapy market is split into subcutaneous immunotherapy (SCIT) and sublingual immunotherapy (SLIT). Market estimates vary and reflect the heterogeneity of clinical practice across geographies as well as the fragmented nature of the supply chain. For instance, in the US a large element of the market consists of unlicensed “home brew” preparations, whilst in Europe there are still a significant number of “traditional” preparations that have not been scrutinised against recent marketing approval guidelines. Regulatory standards, such as those of the FDA in the US and TAV (Therapieallergene-Verordnung) in Germany, are seeking to ensure that essential quality criteria regarding manufacture, clinical efficacy, and batch consistency are adhered to.

In Europe, partly to ensure continued treatment availability, the application of these standards has been phased in gradually; allowing sufficient time for what are typically smaller businesses to either generate the necessary clinical evidence or to decide to allow the product to be withdrawn. This is leading to industry consolidation, with the larger, better-funded companies gaining share from the smaller, often local, players. A similar effect is expected to happen in the US as more products with sound clinical data are subjected to FDA scrutiny, gain market approval and, over time, take share. Here, the approved treatments would address single allergens (or tightly related allergens), with the traditional treatments remaining the choice for multiple allergies.

The global AIT market was estimated at being worth between $1.6bn and $1.9bn in 2019. SCIT accounted for c $1.0bn, SLIT was c $0.7bn, with an overlapping eclectic mix of products (including some diagnostics) clouding the picture. A number of industry observers expect SLIT to show growth, especially in the US, as recently approved products such as Odactra and Ragwitek (ALK-Abello), Grastek (ALK-Abello/MSD), and Oralair (Stallergenes) gain market traction. Europe accounted for 69.1% of the global market in 2019, with growth driven by SLIT therapies; allergic rhinitis (due to grass, weed, and tree pollens) was the largest indication, with a 71.9% share.

Medium term growth expectations cluster around two figures: c 7% and c 10%. For instance, Industry Research is forecasting a 6.9% five-years CAGR to reach a $2.0bn value, with Technavio forecasting a similar 7.1%, whilst Grand View Research and Vision Research are expecting a more ambitious 9.0% to $3.1bn and 11.7% to $3.7bn respectively. For context, the global allergy diagnostics and therapeutics market (ie mainly symptomatic treatments) is valued at c $33.2bn.
and expected to grow at 6.2% CAGR. From our perspective, we are expecting market growth rates of c 6% CAGR over the next five years.

In the near term, COVID-19 has directly impacted volumes, notably in countries where allergy clinics are sited within hospitals rather than being standalone. This tends to be the case in Southern Europe and is particularly seen in the reduced consultations in Italy and Spain as hospitals directed scarce resources towards COVID-19 treatment. Most allergy centres were open again by late-May, but the possibility of further waves creating disruption remains a factor. Over time we expect the resultant budgetary overspends to result in pricing pressures across the industry for non-critical treatments, with allergy immunotherapies unlikely to escape unscathed.
Allergy Therapeutics is a strong player in Europe, with established commercial operations in 21 markets, either directly (in seven geographies, with c 140 salespeople) or through distribution partnerships (14 in typically smaller regions). These have been created through a combination of sustained organic investment coupled with judicious acquisitions, such as Alerpharma in 2015 that bolstered the Spanish presence. Germany is the largest revenue contributor, with 61% of sales, (Exhibit 2) followed some way behind by Spain, 10%, then Italy and Austria, 7% each, Netherlands 4%, and Switzerland and the UK, with 3% apiece.

Germany is the largest AIT market in Europe and has been a key corporate focus over the past two decades, with 140 staff at the subsidiary Bencard Allergie. Growth remains strong with consistent share gains. The aim of reducing dependence on the German market has seen targeted investment in other promising countries. The Spanish market continues to show solid growth with the preference for SCIT products playing to the company’s strengths (Acarovac Plus is their biggest seller). Italy, the fourth largest market, has been beset by pricing pressures amid economic uncertainties. It is dominated by SLIT products, but the company’s range is sufficiently distinct to maintain its market share.

Elsewhere, the Austrian market is still growing by c 7% but its appealing dynamics have attracted two new entrants. The Netherlands has been a model of success, with sales up strongly, and Allergy Therapeutics is now vying with ALK-Abello for market leadership. The UK has long been reluctant to embrace allergy vaccines, with medical preference being for use of symptom relieving products. Currently Pollinex is the only pollen SCIT product licensed in the UK.

Other markets are covered through partnerships, with the most important distributor markets being Canada, the Czech Republic, Slovakia, South Korea, Greece, the Baltics, and more recently, Belarus, Serbia, and Albania.

Examining the financial performance, FY20 revenues grew by 6.1% to £78.2m from £73.7m (+6.9% CER), underpinned by Germany growing by 6.6% to £48.0m from £45.0m (+7.8% CER). Other Central Europe increased by 11.9% to £12.3m from £11.0m, helped by a strong performance in the Netherlands. Spain grew by 8.6% to £7.9m from £7.3m, being held back by the industry-wide COVID-19
disruptions to hospital-based clinics. Italy suffered more markedly, with continuing pricing pressures too, seeing sales down 10.0% to £4.5m from £5.0m. Other Southern Europe was flat at £0.7m, as was Rest of the World (including UK) at £4.8m. Once again, a solid performance in challenging times means market share was gained and now stands at an estimated 14.2%, up from 14.1% in 2019 and 13.6% in 2018.

### Broad product ranges, with ultra-short SCIT to the fore

The marketed portfolio consists of distinct ranges, which trade under various brand names depending on the geography e.g. Pollinex Quattro, Polligoid, and TA Gräser Top. These seven product groups account for 90% of revenues:

- **Pollinex Quattro** represents 42% of sales. This flagship PQ range, first introduced in 1999, has transformed SCIT by requiring only four injections. Ultra-short course immunity is possible due to the combination of microcrystalline tyrosine (MCT) adsorbed allergoids (a modified allergen), with monophosphoryl-lipid A (MPL) as the adjuvant. The MCT allergoids provide a similar level of immunogenicity but their improved adsorption characteristics result in a lower allergenicity. The importance of using MPL as the adjuvant should not be underestimated; it not only brings improved safety benefits over traditional alum-based adjuvants, but plays an essential role in promoting the switch from a Th2-directed immune response (with IgE induction) to a Th1-directed response.

- **Pollinex**, 19% of revenues, is the range of non-MPL-based SCIT that employs the same allergoids but, due to the lack of MPL, consists of six injections. It is still considered a short-course treatment compared to traditional SCIT. Pollinex is retained to address the needs of certain, more traditional, European market segments and geographies.

- **Oralvac**, 13% of sales, is a sublingual (SLIT) range of vaccines that use native allergens. Once-daily drops are used to reduce allergic reactions to grass pollen, tree pollen and house dust mite. The compact dosing schedule allows for a rapid escalation to reach maintenance dose. These, unlike SCIT, can be safely administered at home.

- **Tyrosin S/TU**, 5% of sales, is a range of non-MPL-based long-course SCIT that consists of 12 injections. This conventional SCIT uses tyrosine as a depot component, rather than alum, and is available in a wide range of standardised allergen extracts.

- **Venomil**, 5% of sales, is a freeze-dried SCIT for the treatment of bee and wasp sting hypersensitivity that contains native allergen. This is easily reconstituted and can be administered through the more rapid “rush” dosing regimen.

- **TyroMILBE**, 5% of sales, is a family of still popular mite treatments, mainly house mites, based on native allergens and including tyrosine as the depot component.

- **Acarovac Plus**, 3% of sales, is an MCT-adsorbed allergoid product for the treatment of perennial mite allergy. This has been shown to have an
improved and longer-lasting outcome than unmodified versions. An Acarovac MPL programme is in clinical trials.

**Adjuvants are a key determinant of efficacy and safety**

Adjuvants are compounds added to antigens in vaccines to increase the body’s immune response to an antigen. Aluminium hydroxide (Alum) is the most widely used adjuvant in vaccinology, particularly for prophylactic vaccines. While good at stimulating antibody responses, alum is not biocompatible and is difficult to clear from the body; this is important in AIT, which often requires 50–80 subcutaneous injections. Additionally, Alum is associated with the stimulation of T-helper type 2 (Th2) as opposed to Th1 immune responses, leading to induction of poorly protective IgG subclasses. Hence, the use of better adjuvants has the potential to improve vaccines materially.

**Exhibit 3: Allergy Therapeutics’ technology platforms**

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<th>Approach</th>
<th>Description</th>
<th>Benefit</th>
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<tr>
<td>Allergoid</td>
<td>A chemically modified allergen</td>
<td>Reduces IgE reactivity and thus aids tolerability</td>
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<tr>
<td>Micro-crystalline tyrosine (MCT)</td>
<td>A readily metabolised amino acid</td>
<td>Retains the Allergoid and MPL at the site of injection as depot</td>
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<tr>
<td>Monophosphoryl-lipid A (MPL)</td>
<td>A non-toxic lipopolysaccharide derivative</td>
<td>Allows Specific Immunotherapy (SIT) treatment course to be shortened (with a big improvement on adherence)</td>
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<tr>
<td>Virus-like particles (VLP)</td>
<td>Non-virulent immune stimulant</td>
<td>Induces a strong cellular and humoral immune response</td>
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</table>

Source: Allergy Therapeutics

Adjuvants are an essential consideration in developing modern vaccines. Many of Allergy Therapeutics’ existing products use microcrystalline tyrosine (MCT) as a depot adsorption adjuvant; such depot formulations deliver a slow and sustained release of antigens and boost the vaccine’s efficacy. MCT has an established stability profile, is biodegradable so has no risk of injection site granuloma formation, delivers a sustained release of antigens for prolonged immune exposure, and has a high adsorptive power for proteins at neutral pH. Its value has been explored in areas outside of AIT, such as possible influenza and malaria vaccines, with Bencard Adjuvant Systems established as a separate division to explore its potential uses and commercialise them. Of particular interest has been the use of MCT in combination with MPL and VLP.

MPL (monophosphoryl-lipid A) is derived from a lipopolysaccharide (‘LPS’) which is obtained from the cell wall of the bacteria *Salmonella Minnesota* R595. MPL stimulates both cellular and humoral responses to the vaccine antigen. Many studies have shown it enhances the ability of macrophages and B cells to sensitize naïve T cells, conferring to them the capacity to induce the development of Th1 and Th2. It also upregulates co-stimulatory molecules (B7-1 and B7-2) on monocytes, macrophages, and dendritic cells and directly stimulates antibody formation. MPL was developed by GlaxoSmithKline and is employed in its HPV cervical cancer vaccine, Cervarix.

VLPs (virus-like particles) are multi-protein 3D structures that mimic the organisation and conformation of real viruses, but lack the viral genome. Typically,
they contain highly repetitive molecular structures on their surfaces and these patterns are a recognised characteristic of pathogenic microorganisms, such as viruses and bacteria, that evoke strong immunologic responses. VLP-based vaccines are known to be well tolerated and immunologically effective, for instance in prophylactic vaccination against human papillomavirus (Cervarix and Gardasil) and hepatitis B virus (Sci-B-Vac). VLPs have many properties that make them attractive antigen carriers in vaccines, ranging from their small size (c 30nm diameter allows them to drain into lymph nodes and stimulate B-cell activation) to flexibility (the surfaces can be modified to display a wide array of epitopes whilst the interiors can deliver diverse loads).

Novel peanut vaccine holds much promise

VLP-based vaccines can be easily modified to optimise the immune responses that are induced. In the case of allergy vaccination they can perform a dual function; firstly, acting as an adjuvant to facilitate antigen presentation and, secondly, helping to dampen the Th2 response by enhancing Th1 polarisation, an important aspect for sustained immunity to the allergen. Allergy Therapeutics is developing a plant-based VLP vaccine for peanut allergy, employing a single allergen that appears to provide a strong protection against all peanut allergens.

Securing exclusive licenses to other indications

The strength of the data has prompted Allergy Therapeutics to recently gain access to this VLP technology platform for additional indications, rather than just allergy applications. The deal with Saiba AG and DeepVax extends an exclusive licence for use of the proprietary CuMVtt-VLP platform across indications including solid tumours, atopic dermatitis, asthma, and psoriasis. The intention is to explore generating active vaccines against targeted cytokines in these indications, performing exploratory studies ahead of likely partnering. Four programmes are expected to be progressed initially. Management also intends to investigate the potential of combining the VLP technology with its adjuvant systems, including MCT. Importantly, the financial terms of the deal were not material, presumably being more back-end loaded.
R&D: innovation that could be life-changing

Allergy Therapeutics has invested consistently in R&D, with £9.0m spent in FY20 (£13.0m FY19), bringing the spend since 2000 to c £140m. Recent spend was lower due mainly to timings, with the focus on the Pollinex Quattro programmes and the VLP peanut vaccine. Over the near-term R&D spend should grow to around £15.0m pa as clinical programmes progress. The development priorities are:

- to comply with the TAV (Therapie allergene Verordnung) ordinance and gain regulatory approval in Europe for key product ranges;
- progress the PQ range so it becomes the first to launch a short course, subcutaneous, and aluminium-free grass allergy therapy in the US; and
- complete the preparations for the VLP peanut vaccine to enter its first clinical trial in 2021.

Exhibit 4: Allergy Therapeutics pipeline and marketed products

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<th>Pre-clinical</th>
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</table>

Source: Allergy Therapeutics  Note: SCIT = subcutaneous immunotherapy, MATA = Modified Allergen Tyrosine Adsorbed

TAV ordinance is an example of tightening regulatory controls

The move towards greater regulation of AIT products in Europe (mainly the TAV) and US (both FDA and United States Pharmacopeia, USP) is continuing, with no easing up of the desire to move products from “named patient” availability to gaining approval as biologicals. The pace is dictated by the need to balance product availability for existing patients’ needs, the processing capacity at regulatory bodies, and the financial and operational burdens on companies to complete the necessary clinical trials. The intention is that, once fully implemented, few (only exceptional) products will be exempted from regulatory compliance. Clearly, it will be the better organised and funded companies that will secure their long-term futures.

Shake out of weaker products from the market is happening

In Europe, Allergy Therapeutics has registered 10 products for approval at the Paul Ehrlich Institute (PEI), including the Pollinex Quattro (PQ) ranges as well as
selected traditional products (such as Oralvac). The TAV ordinance has already led to a reduction in the number of therapy allergen preparations, especially mixtures of questionable efficacy. For context (Exhibit 5), 123 products had originally been submitted by various manufacturers (as of 01/10/2010), but over the past decade the number of applications still active has whittled down to 65 (as of 09/02/2019) as rejections or voluntary withdrawals took their toll. It is noteworthy that only two marketing authorisations were granted during the period. The clinical trial picture suggests that the number of active applications will contract further.

Exhibit 5: AIT applications at Paul Ehrlich Institute (at Feb 2019)

<table>
<thead>
<tr>
<th>Marketing authorization applications:</th>
<th>Clinical Trial Applications on TAO Allergens</th>
</tr>
</thead>
<tbody>
<tr>
<td>123 received by PEI (1.12.2010)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>9.2.2019</td>
</tr>
<tr>
<td></td>
<td>2 marketing authorization granted (8/2018)</td>
</tr>
<tr>
<td></td>
<td>65 applications still active</td>
</tr>
<tr>
<td></td>
<td>Grass-/mixtures: 26</td>
</tr>
<tr>
<td></td>
<td>Tree pollen: 17</td>
</tr>
<tr>
<td></td>
<td>House dust mites: 17</td>
</tr>
<tr>
<td></td>
<td>Mixtures (grasses/trees): 5</td>
</tr>
<tr>
<td></td>
<td>In total: 45</td>
</tr>
<tr>
<td></td>
<td>35 approved</td>
</tr>
<tr>
<td></td>
<td>Thereof: 7 conditional approval</td>
</tr>
<tr>
<td></td>
<td>10 rejected</td>
</tr>
<tr>
<td></td>
<td>1 withdrawn</td>
</tr>
</tbody>
</table>

Source: Perspectives in allergen immunotherapy, Allergy Vol 74, Iss S108, Pag 3-25, Dec 2019

Robust clinical data will aid EU marketing and permit entry to commercially attractive US

Management has shown its confidence in the scientific rationale and merit of its products, committing sizeable resources to support its filings. It is worth highlighting, once PEI authorisation has been gained, the EU’s mutual recognition processes should allow EU-wide approvals, which typically takes up to two years. The Phase III clinical programmes underpinning these will also, where applicable, generate robust data suitable for submission to the FDA, where the approval of PQ products as biologicals would create a clear competitive advantage.

Grass MATA MPL Phase III pilot study starting shortly

The PQ Grass MATA MPL trial programme for grass pollen seasonal allergic rhinitis saw very encouraging outcomes from the Phase II study (G206), with highly statistically significant results (p<0.0001). These were presented to the PEI and FDA and the dosing, format, and design of the Phase III programme was agreed. The difficulty of replicating results seen in Phase II AIT studies in multinational, multi-centre Phase III trials, with possibly slightly different endpoints, is a recognised problem.

Hence, a pilot field study (G309) in Europe and the US is projected to start before 2020 year-end (COVID-19 permitting), to capture the 2020/21 allergy season, with the data read-out expected c 12 months later. This study’s outcomes will guide the final structure, including patient recruitment, of the pivotal Phase III field trial (G306), also in Europe and the US, that is expected to start in H2 2022 and continue through 2023. Typically, patient selection and enrolment begins in
the August of start year. The goal remains to be the first short-course, subcutaneous, and aluminium-free grass allergy therapy available in the US.

VLP peanut allergy vaccine could be a game changer

The VLP-based peanut vaccine represents a major opportunity. Peanut allergy is a leading cause of anaphylactic reactions and one of the most common food allergies, especially in children. It affects around 1.2% of Western populations, rising to about 2.5% of the paediatric population. The prevalence is rising, with the number of reported peanut allergies in the US more than tripling over a twenty-year period. The economic burden is material, with US hospitalisation costs alone estimated at c $600m pa as some 40% of children have experienced at least one anaphylactic event. Currently, most peanut allergies are managed with strict avoidance, prompt recognition of allergic reactions, and rapid use of intra-muscular epinephrine (better known by the Epipen brand name) and other supportive therapy for anaphylaxis.

Peanut allergy is a widespread problem, especially for children

A clear need for an approved and clinically validated product...

Some 127 peanut allergy clinical studies have been listed on clinicaltrials.gov and there is evidence that peanut SLIT oral immunotherapy is effective in reducing the severity, but such approaches require a long treatment and no regulated product is available. The common barriers to wider adoption cited by clinicians include:

- lack of a medicinal product that meets FDA standards for approval,
- lack of standardised dosing regimens,
- medical and legal implications of using non-FDA approved treatments,
- unclear defined criteria for appropriate patient selection,
- insufficient long-term safety and efficacy data, and
- lack of correlation between maintenance dosing and level of protection.

...with Aimmune’s Palforza succeeding...

Other related oral approaches, such as Aimmune’s Palforza have overcome a number of these issues. Palforza consists of a powder containing peanut allergens. The patient ingests increasing amounts of powder over a period of about 6 months. Over time, the patient’s immune system becomes desensitized to peanut allergen and can tolerate exposure to larger amounts of peanut protein. After the dose escalation period, the patient continues to take a daily therapeutic dose to maintain desensitization. Palforza was approved by the FDA in January 2020 however its market roll-out has been hampered by Covid-19 issues. In September 2020, Nestlé acquired the remaining shares in the business for $2.8bn.

...and DBV’s patch failing

In contrast, DBV Therapeutics explored using trans-dermal delivery through is Viaskin platform to deliver desensitising peanut allergens. Following extensive clinical trials it was submitted for FDA review but received a Complete Response Letter in August 2020 that focussed on the patch technology itself, particularly the adhesive properties. The initial reaction suggests a reworking of the device and further clinical trials are required.

A number of novel injectable approaches being explored

A number of injectable vaccines have been tried in early stage clinical studies, for instance Astellas’ ASP 0892 and Allertein’s EMP123, but systemic reactions and poor long-term tolerance induction means there is no approved vaccine as yet. Various novel approaches are being explored: Sementis, an Australian company, is investigating the use of a modified smallpox vaccine and appears to be ready for clinical development; and Aravax, also an Australian company, is in Phase I with its
PVX108 vaccine, which uses peptide fragments to reduce the risk of anaphylactic reactions. Australia has a particularly high prevalence of peanut allergies, with one in 200 adults and almost three in every 100 children affected.

Allergy Therapeutics’ approach is based on using single peanut allergens displayed on immunologically optimized Cucumber Mosaic Virus-derived VLPs (CuMVtt). Preclinical studies have shown that a single recombinantly produced allergen confers immunity against all the 12 allergens found in peanuts. The selected allergens are immunogenic, but not reactogenic, and fail to activate human mast cells. The animal studies showed an attractive safety profile, with no vaccine related allergic reactions, and a promising efficacy profile, with reduction of systemic and local allergic effects on challenge with the whole allergen extract.

These data form the basis of positive initial meetings with regulatory authorities, with a pre-IND (Investigational New Drug) meeting to discuss the protocols for the first-in-human trial expected during Q420. An ex-vivo biomarker study is planned and will be performed with the final formulation to confirm its hypoallergenic profile with human blood samples. Assuming smooth progress the Phase I study should start in 2021.

The VLP platform is a vital element in the vaccine’s effectiveness; it is derived from Cucumber Mosaic Virus and includes tetanus toxin epitopes. So, in addition to the immunogenic properties due to the repetitive three-dimensional scaffold (which gives B-cell activation) and the RNA content (stimulates Toll-like receptor 7 and Toll-like receptor 8), it contains the universal T-cell epitope derived from the tetanus toxin. Almost all people have a pre-existing T-cell memory for tetanus toxin, and its incorporation boosts T-cell responses. Similar VLP platforms have proven their ability of inducing long-term protective antibodies and their safety has been demonstrated in widespread clinical use; commercially available VLP-based vaccines include Cervarix and Gardasil (HPV) and Sci-B-Vac (hepatitis B).
US market: an attractive and sizeable opportunity

The US is a large and dynamic market, with around 50m people experiencing some form of allergy ranging from seasonal rhinitis (8.2% of the population) to severe reactions to stings, such as wasps, (5.3-7.8%) and foods, notably peanut, (10.8%). The incidence, much like all industrialised countries, is rising and, with severity increasing too, the economic and societal costs are growing. Most of this patient population is treated with symptomatic therapies, such as antihistamines and steroid preparations and/or epinephrine (adrenalin) injections, as necessary.

Whilst the number of visits to general physicians for non-emergency allergies has fallen, presumably reflecting greater self-medication, the number of visits to specialist “allergists” has risen around a third over the past decade. This rise in demand has not been matched by an increase in physicians, with the number of certified allergists remaining around 5,000 (out of 700,000 practising physicians). These specialists tend to see the more debilitating or complex cases and are the ones typically considering allergy immunotherapy (AIT) as a main treatment option. Most of these operate out of specialist clinics and within general hospitals, sited mainly in urban areas. Anecdotally, it is estimated 2m-3m patients currently receive some form of AIT.

US AIT market has different characteristics to Europe

Despite the common therapeutic rationale, there are significant differences in clinical practices between the US and Europe: ranging from diagnosis through therapy selection to product manufacture. One of the most noticeable differences is that, despite the recent FDA approval of four SLIT (sublingual) treatments, the market remains dominated by SCIT (subcutaneous). It was thought that the avoiding of a lengthy course of subcutaneous injections would tilt patient preferences towards SLIT; however, possibly due to physician reimbursement being based on patient consultations, this has yet to materialise. The stated clinical rationale is that most patients have sensitivities to more than a single allergen, which is all that a current SLIT therapy can address.

The biggest difference lies in the preparation of the SCIT; in the US, most treatments are individually prepared aqueous mixtures of allergens that are taken from standardised stock bottles. These are typically made on the clinic’s premises using simple methods, with scant, if any, regulatory oversight. With these “home brews” there is little use of allergoids, and, more importantly, adjuvants such as MCT, or even alum, are seldom employed. This results in treatment regimens that need a slow dose build up, to reduce allergenicity, and long treatment durations, because of poorer immunogenicity. Understandably, there is no rigorous clinical evidence to support their efficacy or demonstrate safety.

From the patients’ perspective such therapies are suboptimal as they usually take between six to 12 months to become effective. Whilst the prospect of treatment durations of 50 plus injections over a three to five year period may have understandable appeal for some clinicians, most patients fail to complete their courses with anecdotal evidence suggesting as few as one in six are wholly compliant. Interestingly, it is estimated that only half of patients even start their treatment.
It is into this environment that Allergy Therapeutics is seeking to be the first to introduce a registered SCIT with the Grass indication of its Pollinex Quattro range. The prospect of a standardised vaccine that is made in GMP-certified production facilities, supported by demonstrable clinical evidence, approved by the FDA, requiring only four to six injections to complete the treatment, and showing efficacy in a matter of weeks, should have significant patient appeal.

**Launching PQ Grass requires careful positioning**

Assuming management is able to successfully compete the PQ Grass clinical programme and obtain FDA approval, the key question centres on how to capture a meaningful share of this lucrative market. The obvious barrier is the inherent, and understandable, inertia of allergists to change existing practices, whilst addressing the general physician market would be time-consuming, especially the educational elements, and costly in terms of marketing and sales coverage. The general physician route would, in our view, need the help of a commercial partner with patience, deep pockets, and a sizeable commercial footprint.

**Exhibit 6: Preparing for US entry**

In contrast, targeting c 5,000 allergists can be done with a relatively small and focussed salesforce, with a limited educational need. The key step, in our view, would be to position PQ Grass as the product that could be employed with that large segment of patients whose symptoms are sufficiently severe to motivate them to visit a specialist clinic, but not debilitating enough for them to persevere to a “home brew” course completion. Essentially it would be appealing to an allergist’s financial sense in that he/she could stratify patients to achieve the optimal balance between clinical outcomes, with a short PQ course for those likely to not comply with a traditional approach, and maximising economic value. Obviously, the rollout should be expected to take time as the experience of the early adopters becomes known and accepted among the wider allergist community.

The process does require the creation of a supportive environment with extensive use of key opinion leaders (KOLs) to influence prospective users. Equally importantly, again in our view, would be the use of selective direct-to-consumer (DTC) media campaigns, including seasonally optimised television advertising. These, coupled with smart social media and PR programmes, could help drive a
sizeable new patient demographic away from symptomatic treatment (either via general physician or self-medication) to the allergist’s office for such “novel” therapeutic options. This would tip the financials favourably for even the most traditionally minded allergists and, importantly, the “capture fee” of each new patient would be particularly cost-effective for the first entrant to the market.

Management estimates its US peak sales potential at $300m-$400m pa but has yet to articulate its preferred approach. Our view suggests that to gain a meaningful share of such a large and nascent market requires bold thinking, careful planning, and the continuing devoting of sufficient resources over a number of allergy seasons. Whether this is done alone, which is a practical option, or through a partner will depend on the scenario planning that management has likely already undertaken and, to some extent, on investors’ appetite for funding such an ambitious launch campaign.

**VLP peanut allergy vaccine should be altogether easier**

In contrast to the PQ range, the marketing processes required for introducing an innovative and effective therapeutic vaccine for peanut allergies is much more straightforward. Here the unmet medical need is high, the patient (or rather carer) awareness is great, and the genuine treatment options are currently few. The VLP peanut vaccine would be ideally suited for the general physician segment as well as allergy specialists. Assuming its clinical profile does deliver on its early preclinical promise, then this could be a sizeable product with commercial potential determined largely by its pricing point rather than patient accessibility and numbers. As we mentioned earlier, this could be a game changer for Allergy Therapeutics.

We do not envisage Allergy Therapeutics launching this product alone. The commercial potential would clearly attract the larger primary care focussed pharmaceutical companies and it is unlikely that finding a suitable partner would be difficult. The caveat is that the data so far is early and requires testing in extensive clinical trials. However, the potential is such that even when adjusted for such risks the contribution that an effective peanut vaccine makes to Allergy Therapeutics’ investment case is noticeable.
Sensitivities

In common with most innovative pharmaceutical companies the three main sensitivities relate to the clinical and regulatory aspects, the execution of commercialisation plans, and the financial resources required to accomplish these. More specifically, the key near- and medium-term sensitivities are directed to the clinical progress of the two main development programmes.

- The Pollinex Ouattro Grass MATA MPL Phase III trial is a defining step for the company as it will enable regulatory approvals in Europe and the US. In Europe it will broaden its prescribing beyond “named patient” basis, but its importance lies in opening up the sizeable potential of the US market. Unfortunately, the uncertainties inherent in predicting outcomes in Phase III allergy trials are well documented. Management is seeking to reduce these risks by employing a pilot Phase III study (G309) ahead of starting the pivotal Phase III trial (G306).

- The peanut VLP vaccine is innovative in its design and execution and, whilst other VLP platforms have arguably paved the way with their market-proven safety and efficacy, the only evidence to date has been preclinical. The hard miles will be in the later development phases, especially the Phase III studies. Certainly, the clinical, societal, and commercial rewards of a successful peanut vaccine are, in our view, sufficiently plentiful to warrant any such incremental risks.

Regulatory issues affect all AIT companies, the better prepared will gain an advantage

Allergy product engagements with regulatory authorities always carry a greater degree of uncertainty compared with other pharmaceutical products. This could reflect the organic origins of the products, but this variability is materially reduced with the new semi-synthetic and standardised preparations and should be no more complex than discussions for biologicals. Nonetheless, we are aware that approval processes, especially for the existing products seeking registration as part of the TAV ordinance, could be protracted and iterative. Fortunately, sales of products on a “named patient” basis are continuing, and volumes remain robust.

Allergy Phase III trials have a history of being unpredictable

Late-stage clinical trials in allergy indications have a history of delivering negative surprises. For example, Circassia was badly dented by the high-profile demise of its cat allergy therapy in pivotal Phase III trials, as was Allergy Therapeutics itself when its study in birch disappointed. There has been much examination of the learnings from these and the G309 study seeks to ensure they have been applied.

Production excellence is a key requirement, not optional

Manufacturing and supply chain management are critical areas for all drug companies, with strict oversight of all aspects of the processes. Even minor breaches can result in serious consequences, with the associated costs and reputational damage. Allergy Therapeutics has modern, well-equipped, and high-quality production facilities in the UK and Spain that are FDA compliant.

US market is an appealing opportunity, but complexities mean careful planning essential

The US is planned to represent a major medium-term growth opportunity, with the innovative element of the R&D efforts having this commercial potential firmly in its sights. However, Allergy Therapeutics has yet to articulate its strategy to access this sizeable, but complex and fragmented, market. Whilst this may be for understandable competitive sensitivities at the moment, the lack of visibility will remain an issue until some clarity is forthcoming.
Valuation

Valuing a revenue generating pharmaceutical business, with a strong record of sales growth and a solid pipeline of new programmes, should be straightforward. However, the level of R&D investment, relative to its size, foreseen over the next five years means that any single approach will fail to capture all the inherent elements. For instance, we could simply consider the cashflows from the existing business, arising wholly from the existing European commercial footprint, and assume that the fruits, if any, from the R&D pipeline are there to replenish and grow these revenues over the medium term and beyond. Such an approach would require a simple DCF of cash flows coupled with a terminal value.

However, this would fail to reflect the potential of the R&D portfolio, particularly the peanut allergy vaccine which, if successful, could be transformational for a company the size of Allergy Therapeutics. This approach means employing a rNPV model, with risk-adjusted NPVs calculated for all the key programmes. This would be like valuing a pure-play research company; but instead of the cash flows required to progress the pipeline being furnished by investors and licensing deals, the funding would largely come from the existing internal profits. Such an approach would appeal to industry hawks who believe that the tightening of the regulatory environment will result in the disappearance of most existing products.

Exhibit 7: Allergy Therapeutics valuation summary

<table>
<thead>
<tr>
<th>Product (region)</th>
<th>Total NPV ($m)</th>
<th>Total NPV (£m)</th>
<th>Approval probability</th>
<th>rNPV ($m)</th>
<th>rNPV (£m)</th>
<th>rNPV/share (p)</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grass MATA MPL (Europe/US)</td>
<td>236.8</td>
<td>182.2</td>
<td>55%</td>
<td>123.0</td>
<td>94.7</td>
<td>14.9</td>
<td>Peak sales: $216m (£166m) Launch year: 2025</td>
</tr>
<tr>
<td>Birch/Tree MATA MPL (Europe/US)</td>
<td>53.2</td>
<td>40.9</td>
<td>40%</td>
<td>25.9</td>
<td>19.9</td>
<td>3.1</td>
<td>Peak sales: $104m (£80m) Launch year: 2027</td>
</tr>
<tr>
<td>Ragweed MATA MPL (US)</td>
<td>52.3</td>
<td>40.2</td>
<td>40%</td>
<td>28.8</td>
<td>22.1</td>
<td>3.5</td>
<td>Peak sales: $124m (£95m) Launch year: 2028</td>
</tr>
<tr>
<td>Peanut SCIT</td>
<td>167.8</td>
<td>129.1</td>
<td>5%</td>
<td>87.8</td>
<td>67.5</td>
<td>10.6</td>
<td>Peak sales: $339m (£261m) Launch year: 2028</td>
</tr>
<tr>
<td>DCF on Commercial business</td>
<td>113.6</td>
<td>87.4</td>
<td></td>
<td>113.6</td>
<td>87.4</td>
<td>13.7</td>
<td></td>
</tr>
<tr>
<td>Net cash</td>
<td>43.2</td>
<td>33.2</td>
<td></td>
<td></td>
<td></td>
<td>5.2</td>
<td>At end-FY20</td>
</tr>
<tr>
<td>Total</td>
<td>666.9</td>
<td>513.0</td>
<td></td>
<td>422.3</td>
<td>324.8</td>
<td>51.0</td>
<td></td>
</tr>
</tbody>
</table>

Source: Trinity Delta  
Note: $/£ FX rate of 1.3; 10% discount rate for commercial business, 12.5% for pipeline

Hence a DCF of the base business with an rNPV of the key development programmes

The reality, inevitably, lies somewhere between these extremes. We have opted to calculate a DCF for the base business, comprising detailed expectations of the European cash flows over a five-year forecast period. These are based on market growth of 6-7% with no market share gains (history would suggest this is arguably over-conservative), coupled with a modest 2% terminal growth rate, and 10% cost of capital. To this we add our pipeline rNPV, notably the grass and peanut programmes as these have the potential to open not only new geographic markets but also capture additional patients in existing regions. In line with our philosophy, we have adopted conservative assumptions throughout, which means any improvement would represent upside.
This results in a valuation for Allergy Therapeutics of £325m, equivalent to 51p a share. The commercial base business contributes £87m (14p/share), with the pipeline valued at an additional £204m (32p/share).

Peer comparison suggests undervalued by any measure

As a reality check we have looked at quoted peers, of which there are now only two: ALK-Abello, the Danish company that is the leading player in the allergy immunotherapy field; and DBV Technologies, essentially a research company that has developed a patch for peanut allergy immunisation.

- ALK-Abello is currently guiding for FY20 revenues of c DKK3.50-3.65bn (£430-448m), with EBITDA of DKK300-350m (£37-45m), and negative free cash flow of DKK200m (negative £25m). Net debt of c DKK925m is forecast which, with a DKK1,990 share price and market cap of DKK21.69bn, gives a 6.3-6.6X EV/Sales multiple, and EV/EDITDA of 66.0-66.1X.

- DBV Therapeutics is a clinical-stage company whose lead product, a patch for peanut allergy, recently received an FDA Complete Response Letter that effectively sets the company back several years. The shares have collapsed from a 2020 high of €23.52 to a low of €3.07. Interestingly the market cap, despite this setback, is €168.7m.

As further context, Stallergenes Greer was a quoted company but was taken private in May 2019 by Ares Life Sciences, a specialist life sciences investor, for an EV of €677m (then £604m), equating to an exit multiple of 2.3x sales.

Also for reference, Aimmune is not an SCIT or SLIT player but its Palforzia peanut allergy treatment, a peanut powder used in a treatment known as CODIT (Characterized Oral Desensitization Immunotherapy), aims to reduce peanut sensitivity. Palforzia was approved by the FDA in January 2020 and in August 2020 Nestlé acquired its remaining stake for $34.50 per share, a 174% premium, for a total equity value of $2.6bn.

In contrast, Allergy Therapeutics has an EV/Sales of 0.9X, EV/EBITDA of 6.0X and a market cap of £110m.
Financials

FY20 net sales were up 6.1% to £78.2m (+7% CER), against £73.7m in FY19, as COVID-19 restrictions saw many clinics and hospitals focus only on urgent cases. The impact, from March to May 2020, centred mainly in Italy and Spain. Management estimates this cost around 2% of sales growth. The emergence of any subsequent waves of infection could see a similar outcome in this financial year (to end-June 2021). The effect is most noticeable in Southern Europe as allergy clinics tend to be located within major hospitals, whereas in Northern Europe they are usually standalone. Despite this, growth remained positive in all markets except Italy, with Pollinex Quattro, Pollinex, and Venomil the key drivers.

Exhibit 8: Long-term revenue growth trend

Gross profit grew by 4.9% to £58.0m (FY19: £55.3m), with gross margin of 74%, against 75% previously. Operating profit, excluding R&D spend, grew by 2.7% to £14.2m (FY19: £11.3m), with margin of 18.2%, against 15.3% previously. R&D expenditure is written off as it is incurred and was £9.0m (ex the litigation credit of £3.2m), lower than last year’s £13.0m (ex the litigation credit of £6.0m), reflecting lower activity and timing differences in clinical trial spends. Non-R&D operating costs were held at £44.5m, as reduced sales, marketing and distribution costs offset an increase in administration costs due to continued investment in support functions and compliance.

The reported operating profit was £8.3m (FY19: £4.4m), helped by the final £3.2m received in settlement of the Inflamax litigation (£6.0m was received in FY19). Similarly, net profit (after tax) was £7.1m vs £3.5m in FY19. It is worth noting that implementing the complexities of IFRS 16 (Leases) effectively moves the items onto the balance sheet and boosted FY20 EBITDA by £1.9m and operating profit by £0.2m. EPS was 1.09p (FY19: 0.55p), with EPS (diluted) of 1.03p (FY19: 0.52p).

Cash and cash equivalents increased to £37.0m (FY19: £27.4m), due to: the £3.2m Inflamax legal costs settlement; additional bank loans taken out for the Spanish market; and a net cash inflow of £9.4m (FY19 £11.8m net cash inflow). Current borrowings were £0.8m (FY19: £0.7m) and long-term borrowings were £2.9m (FY19: £1.7m). There is a natural first-half bias to performance due to the seasonality of allergy treatment, with more cash being generated in the first half of the year from operations (ex-R&D).

Looking ahead, we expect sales growth of 7% to £83.7m in FY21 and 3.5% to £86.7m in FY22, driven by continued gains in the key European markets that
should offset the continuing weakness we expect in Italy. We have forecast expecting a further wave of COVID-19 impacts, with the magnitude similar to that seen in FY20. Our expectations are based on the allergy immunotherapy market maintaining growth rates of 6%-7% five-year CAGR and Allergy Therapeutics being able to maintain modest share gains over this forecast period.

The operating profit before R&D is expected to be £11.2m FY21 and £10.6m FY22, with R&D expenditures of £15.3m and £13.8m respectively as the Phase III trial programmes for Pollinex Quattro Grass and Phase I study for the peanut VLP vaccine kick in. Non-R&D operating costs are expected to rise broadly in line with sales resulting in a reported operating loss of £4.1m in FY21 and £3.2m in FY22, which equates to a net loss of £5.6m and £4.4m at FY21 and FY22 respectively. The resulting cash outflows of £7.1m and £6.6m mean we are expecting the cash position to be £29.8m at FY21 and £23.3m at FY22.

Exploring the medium term, the registration and approvals of the PQ ranges across Europe would remove the current restrictions on promoting these SCIT products to a wider physician audience (“named patient” treatments cannot be marketed actively). Even modest uptake beyond the traditional prescribers should, especially outside Germany, result in a noticeable uplift in revenue growth. It is worth highlighting we would then expect the market growth to approach the 10+% 5-year CAGR some industry observers are forecasting (as detailed earlier). In the same timeframe, we would be expecting the US launch of PQ in the US and, depending on management’s preferred strategy, debating the level of marketing support required and its funding.

Against these scenarios, it is easy to create a setting that envisages low-teens revenue growth from the core European business from the middle of this decade, boosted by steadily increasing incremental sales from the US, resulting in sustained high-teens sales growth from the end of the decade. Noticeably, this would be supported by the roll-out of the PQ product range and the VLP peanut vaccine would provide additional upside. The critical question is whether investors would, or maybe should, back management to fund the investments to achieve these appealing potential scenarios.
## Exhibit 9: Summary of financials

<table>
<thead>
<tr>
<th>Year-end: June 30</th>
<th>£’000s</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>2021E</th>
<th>2022E</th>
</tr>
</thead>
</table>

### INCOME STATEMENT

- **Revenues**: 68,346 73,717 78,204 83,788 86,710
- **Cost of goods sold**: (17,013) (18,379) (20,201) (22,623) (21,678)
- **Gross Profit**: 51,333 55,338 58,003 61,165 65,033
- **R&D expenses**: (16,017) (12,987) (9,000) (15,300) (13,770)
- **S&M expenses**: (27,133) (26,995) (24,853) (27,960) (29,637)
- **G&A expenses**: (15,543) (17,595) (19,627) (22,655) (25,494)
- **Underlying operating profit**: (7,360) (2,239) 4,523 (4,750) (3,868)
- **Share-based payments**: (985) (1,367) (794) (834) (850)
- **Exceptional**: 0 6,037 3,152 0 0
- **Other revenue/expenses**: 630 593 634 647 660
- **EBITDA**: (4,486) 6,481 12,223 (280) 629
- **Operating Profit**: (6,730) 4,391 8,309 (4,103) (3,208)
- **Operating profit (pre R&D)**: 9,287 11,341 14,157 11,197 10,562
- **Finance costs/income**: (166) (98) (238) (397) (208)
- **Profit Before Taxes**: (6,896) 4,293 8,071 (4,500) (3,416)
- **Adj. PBT**: (8,511) (3,704) 3,491 (5,981) (4,926)
- **Current tax income**: (637) (826) (1,159) (1,071) (1,033)
- **Net Income**: (7,553) 3,647 6,192 (5,571) (4,449)

- **EPS (p)**: (1.3) 0.5 1.1 (0.9) (0.7)
- **Adj. EPS**: (1.5) (0.5) 0.5 (1.2) (1.0)
- **DPS (p)**: 0.0 0.0 0.0 0.0 0.0
- **Average no. of shares (m)**: 595.1 632.8 635.2 637.3 637.3

- **Gross margin**: 75% 75% 74% 73% 75%
- **EBITDA margin**: N/A 9% 16% N/A 1%
- **Underlying operating margin**: N/A N/A 6% N/A N/A

### BALANCE SHEET

- **Current assets**: 30,928 46,625 55,170 48,514 44,205
  - Cash and cash equivalents: 15,533 27,440 36,962 29,852 23,299
  - Short-term investments: 0 0 0 0 0
  - Accounts receivable: 6,587 9,776 8,076 6,887 7,246
  - Inventories: 8,808 9,409 10,132 11,776 13,660
  - Other current assets: 0 0 0 0 0
  - Non-current assets: 20,088 21,872 31,055 32,016 32,455
    - Property, plant & equipment: 10,096 11,481 20,417 20,116 19,978
  - Intangible assets: 4,949 4,840 4,736 5,012 5,288
  - Other non-current assets: 5,043 5,551 5,902 6,889 7,189
- **Current liabilities**: (14,631) (16,859) (18,227) (18,381) (18,875)
  - Short-term debt: (644) (694) (829) (229) (79)
  - Accounts payable: (13,890) (15,736) (15,148) (14,076) (14,459)
  - Other current liabilities: (97) (429) (2,250) (4,076) (4,338)
  - Non-current liabilities: (13,351) (14,080) (24,215) (23,105) (22,338)
    - Long-term debt: (2,414) (1,742) (2,927) (2,627) (2,327)
    - Other non-current liabilities: (10,937) (12,338) (21,288) (20,478) (20,011)
- **Equity**: 23,034 37,558 43,783 39,045 35,447

### CASH FLOW STATEMENTS

- **Operating cash flow**: (3,802) 5,600 12,010 (616) (1,359)
- **Profit before tax**: (6,896) 4,293 8,071 (4,500) (3,416)
- **Non-cash adjustments**: 2,834 3,531 4,736 5,054 4,896
- **Change in working capital**: 211 (2,245) 589 (540) (1,560)
- **Interest paid**: (318) (204) (489) (397) (208)
- **Taxes paid**: 367 225 (897) (232) (1,071)
- **Investing cash flow**: (2,503) (3,353) (2,509) (4,115) (4,293)
- **CAPEX**: (2,184) (3,099) (2,547) (3,798) (3,976)
- **Acquisitions/disposals**: 0 0 0 0 0
- **Other investing cash flows**: (319) (254) 38 (317) (317)
- **Financing cash flow**: (294) 9,545 (110) (2,380) (900)
- **Proceeds from equity**: 2 10,196 1 0 0
- **Increase in loans**: (296) (651) 1,232 (900) (450)
- **Other financing cash flow**: 0 0 (1,343) (1,480) (450)
- **Net increase in cash**: (6,599) 11,792 9,391 (7,110) (6,553)
- **Exchange rate effects**: 10 115 131 0 0
- **Cash at start of year**: 22,122 15,533 27,440 26,962 29,852
- **Cash at end of year**: 15,533 27,440 36,962 29,852 23,299
- **Net cash at end of year**: 12,475 25,004 33,206 26,996 20,893

Source: Company, Trinity Delta
Company information

Contact details

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United Kingdom

Tel: +44 (0)1903 844 700

www.allergytherapeutics.com

Key personnel

<table>
<thead>
<tr>
<th>Person</th>
<th>Position</th>
<th>Biography</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peter Jensen</td>
<td>Non-Executive Chairman</td>
<td>21 years with SmithKline-Beecham, including Chairman of Consumer Healthcare Europe and President of Worldwide Supply Operations. Held Non-Executive or Chairman roles at numerous companies including Domino Printing Sciences, Glenmorangie, and Genetix Group.</td>
</tr>
<tr>
<td>Manuel Llobet</td>
<td>CEO</td>
<td>Joined as CEO in 2009. Previously Principal Consultant for Biohealth LLC and CEO of International Operations of the Weinstein family's group of companies. A chemical engineer by training, Universitat Ramon Llull, with an MBA from IESE.</td>
</tr>
<tr>
<td>Nick Wykeman</td>
<td>CFO</td>
<td>Joined in 2016 as Finance Director. Prior senior positions at Skypharma (part of Vectura Group) and Quest International (a division of ICI). A Chartered Accountant and and holds a BSc (Hons) in Economics from University of Bristol.</td>
</tr>
</tbody>
</table>

Top institutional shareholdings

<table>
<thead>
<tr>
<th>% holding</th>
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</thead>
<tbody>
<tr>
<td>CFR International Holdings</td>
</tr>
<tr>
<td>Southern Fox Investments</td>
</tr>
<tr>
<td>SkyGem Acquisition Limited (ZQ Capital)</td>
</tr>
<tr>
<td>River &amp; Mercantile Asset Management</td>
</tr>
<tr>
<td>Top institutional investors</td>
</tr>
<tr>
<td>Management and related</td>
</tr>
<tr>
<td>Other shareholders</td>
</tr>
<tr>
<td>Total shareholders</td>
</tr>
</tbody>
</table>

Source: Allergy Therapeutics
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