Trinity Delta

Allergy Therapeutics

Update

Record revenues demonstrate resilience of operations

3 March 2021

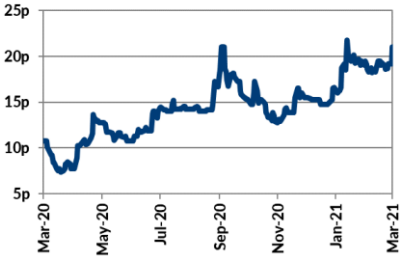
Allergy Therapeutics delivered record interim revenue of £54.0m (+7%, +5% CER) and operating profit pre-R&D of £20.5m during financial H121, emphasising the resilience of its European commercial business despite COVID-19 impacts and the spectre of Brexit. Operationally, the company is also progressing steadily with its pipeline. The G309 exploratory Grass MATA MPL Phase III study is fully enrolled, with most subjects treated ahead of the pollen season; data, anticipated in the autumn, are expected to inform design of the G306 pivotal grass trial (scheduled to start autumn 2022). The ongoing P001 *ex vivo* peanut allergy biomarker study should read out in the spring, ahead of an FDA pre-IND meeting in calendar H121 and potential IND submission by year end. Allergy Therapeutics' £48.3m cash balance (at end-December 2020) will fund both the Grass MATA MPL Phase III trial programme and the peanut allergy Phase I trial, with data from these representing material value-inflection points. We upgrade our valuation to £344.5m, equivalent to 53.8p per share.

Year-end: June 30	2019	2020	2021E	2022E
Revenues (£m)	73.7	78.2	83.8	86.7
Adj. PBT (£m)	(3.7)	3.5	(6.4)	(4.4)
Net Income (£m)	3.5	6.9	(6.2)	(4.1)
Adj.EPS (p)	0.5	1.1	(1.0)	(0.6)
Cash (£m)	27.4	37.0	30.1	23.0
EBITDA (£m)	6.5	12.2	(0.3)	0.8

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

- **A record H121 achieved** Allergy Therapeutics' robust sales performance against a background of COVID-19 restrictions and lockdowns was coupled with prudent cost management. Strong contributions from the German, Austrian, Dutch, and Swiss markets, and key products Pollinex Quattro and Pollinex, delivered revenues of £54m, up 7% (+5% CER) on £50.5m in H120. Operating profit pre-R&D was £20.5m (+18.5%), with a pre-R&D operating margin of 38% (vs 34%).
- **H221 outlook comes with COVID uncertainty** 60-70% of sales are generated in H1 given the seasonal pollen allergy market, translating into H1 profits and H2 losses. H2 gross margin will be lower than H1, but in line with FY20 for FY21. Most G309 trial costs will be incurred in calendar 2021, with doubling of R&D spend in H2 in connection with G309, pre-IND work for the VLP-peanut allergy vaccine, and the German TAV process. The German ImmunoBON launch, Brexit processes, and other projects (eg non-allergy VLP assets) will also receive investment.
- **Embarking on a crucial 12 months** Calendar 2021 is set to deliver major news flow as key studies render results. The *ex vivo* peanut allergy biomarker study will report data in spring; this will support an IND submission for this VLP-based peanut allergy immunotherapy in the autumn. Data from the exploratory G309 Phase III field study are also expected in autumn and will be used to inform the design of a pivotal G306 grass allergy Phase III trial that will support Europe and US regulatory filings.
- **Valuation uplift to £344.5m, or 53.8p/share** Following a solid H1 in a challenging period, we increase our SOTP valuation (from £325m), valuing the commercial business at £89.7m (14p/share), pipeline at £210.3m (32.8p/share), and net cash.

Price	21.0p
Market Cap	£134.6m
Enterprise Value	£90.1m
Shares in issue	640.8m
12-month range	7.0-22.0p
Free float	19.8%
Primary exchange	AIM London
Other exchanges	N/A
Sector	Healthcare
Company Code	AGY
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 Quattro platform, whilst in the medium-term the VLP platform is highly promising.

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Allergy Therapeutics: pipeline progress prioritised

Allergy Therapeutics delivered a robust financial and operational performance in H121, with record interim revenues, pre-R&D operating profit, and cash position. Despite the challenges posed by COVID-19 impacts and ongoing uncertainties, plus additional hurdles posed by Brexit, the European commercial business has proved remarkably resilient with growth across all key products and further market share gains. Progress of the high potential development pipeline should switch investor attention to the stream of anticipated news flow connected to major programmes, Grass MATA MPL and VLP-peanut allergy. Study data from both assets is anticipated during 2021, which will help define their future development paths. We upgrade our valuation on the back of solid H121 results and ahead of data points in the spring (peanut ex vivo biomarker results and FDA pre-IND meeting) and autumn (results of the G309 exploratory grass allergy field study). We now value Allergy Therapeutics at £344.5m, or 53.8p/share vs £325m (51p/share) previously.

Commercial operations continue to deliver

Allergy Therapeutics commercial business continues to provide a solid base of recurring income despite various headwinds, although the focus in calendar 2021 will be on trial data and clinical progress as key pipeline assets advance to important inflection points. Current cash resources fully fund two key R&D programmes: Grass MATA MPL Phase III and VLP peanut allergy Phase I.

Innovative Grass MATA MPL Phase III study underway

The c 150 patient multi-centre G309 exploratory Grass MATA MPL Phase III field study is fully recruited, with most subjects already treated ahead of the start of the grass pollen season. The highly innovative trial design has not been fully disclosed, as it is based on proprietary cutting-edge concepts in the allergy field. It is known to include evaluation of several different placebo options (including saline), combine several Phase II and Phase III endpoints to support the validation of the regulatory mandated primary endpoint (combined symptom medication score, CSMS, averaged over the peak grass pollen season), and includes extensive biomarker analysis.

Results due in 2021, will guide EU and US registration trial

First G309 results are expected in autumn 2021 and will be critical in informing and optimising the design of the G306 pivotal grass trial which will support European and FDA filings and potential US approval. In Europe, this will enable wider prescribing, not restricted to a 'named patient' basis; in the US, Grass MATA MPL will likely become the first available short-course, subcutaneous, aluminium-free grass allergy immunotherapy. G306 is scheduled to start in autumn 2022, over the 2022/23 allergy season, with an autumn 2023 read out.

Highly novel VLP-peanut allergy vaccine could be transformative

VLP-peanut allergy is the first Virus Like Particle-based vaccine in Allergy Therapeutics' portfolio and addresses a sizeable and underserved market. The *ex vivo* biomarker study (P001) in collaboration with Imperial College London is progressing well, and manufacturing batch scale up to 400L has been achieved. The P001 study is exploring an extensive array of functional and molecular biomarkers using blood samples from peanut allergy patients to evaluate and confirm the hypoallergic potential of the vaccine candidate and the potency of the immune response induced.

Biomarker results, expected Q1, will indicate likely potential

Biomarker study results, expected in spring 2021, will give the first indication of human reaction to the vaccine candidate, and will be used to support further clinical development, including establishing the starting dose of the first-in-human Phase I study. A pre-IND meeting with the FDA has been scheduled for calendar H121, and IND filing is planned for autumn 2021. Assuming no regulatory, or COVID-19 related clinical delays, recruitment into the Phase I study (P101) will begin in early calendar 2022.

FDA likely to support a stepwise approach in first human studies

Details on the P101 study design are expected to be disclosed following agreement with the FDA. However, it is known that given the high allergenicity of peanut, the P101 study will use a stepwise approach, with the first stage involving healthy volunteers, then proceeding to skin prick tests in peanut allergy patients, before embarking on subcutaneous injection in peanut allergy sufferers.

Regulatory hurdles in Europe are mounting and Allergy Therapeutics is set to benefit

R&D efforts continue to be directed to working to meet regulatory requirements for the German TAV (Therapy Allergy Ordinance) process, and to addressing similar legislation being implemented by Italy and Spain. The studies being carried out and the data generated will be applicable across the entire EU. We note that Venomil (bee and wasp venom allergy vaccine), already approved in Germany, has recently received regulatory approval in Austria.

Additional VLP assets are to be developed over medium-term

Early-stage work with other non-allergy VLP candidates, as well as adjuvant technologies is also ongoing, with the company seeking to secure IP and establish proof of concept for melanoma, asthma, atopic dermatitis, and psoriasis. We await further disclosures on this technology in due course.

Continued commercial success in Europe supports new product development to enter US market

Management is executing nicely against its well-articulated 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. It is this continued strong performance in Europe that is helping to fund the development of novel R&D programmes, particularly the grass MATA MPL and innovative VLP-based peanut vaccine. These highly differentiated and clinically validated products will, if successful, enable effective penetration into the commercially important US market.

Valuation

Conservative assumptions employed throughout

We continue to value Allergy Therapeutics using a sum of the parts model which couples a DCF of the base European commercial business with a pipeline rNPV model of the main developmental stage allergy immunotherapy programmes. In line with our philosophy, we use conservative assumptions throughout and have previously detailed our valuation methodology in our September 2020 Initiation.

Valuation raised to £344.5m, 53.8p a share, from our previous £325m, 51p a share

On this basis we ascribe a valuation of £344.5m (equivalent to 53.8p per share) to Allergy Therapeutics, with the commercial base business contributing £89.7m (14p/share) and the pipeline an additional £210.3m (32.8p/share). This is a modest upgrade to our prior valuation of £325m (51p/share), comprising £87m (14p/share) for the commercial operations and £204m (32p/share) for the pipeline. Exhibit 1 provides a breakdown of the various components.

Exhibit 1: Allergy Therapeutics valuation summary

Product (region)	Total NPV ($m)	Total NPV (£m)	Approval probability	rNPV ($m)	rNPV (£m)	rNPV/ share (p)	Notes
Grass MATA MPL (Europe/US)	243.9	187.6	55%	126.7	97.5	15.2	Peak sales: $216m (£166m) Launch year: 2025
Birch/Tree MATA MPL (Europe/US)	54.8	42.1	40%	26.6	20.5	3.2	Peak sales: $104m (£80m) Launch year: 2027
Ragweed MATA MPL (US)	53.9	41.4	40%	29.6	22.8	3.6	Peak sales: $124m (£95m) Launch year: 2028
Peanut SCIT	172.8	132.9	5%	90.4	69.6	10.9	Peak sales: $339m (£261m) Launch year: 2028
DCF on Commercial business	116.6	89.7		116.6	89.7	14.0	
Net cash	57.8	44.5				6.9	At end-H121 (31/12/20)
Total	**699.8**	**538.3**		**447.8**	**344.5**	**53.8**	

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

A number of value-adding events expected, such as broader European applicability

Our valuation leaves ample room for upside from various sources. For example, our commercial DCF is based on market growth of 6-7% over the next five years with no market share gains (history would suggest this is arguably over-conservative), coupled with a modest 2% terminal growth rate. However, over the medium term, the registration and approvals of the Pollinex Quattro ranges (currently sold on a 'named patient basis') across Europe would remove the current restrictions on promoting these subcutaneous immunotherapy (SCIT) products to a wider physician audience, capturing additional patients. Even modest uptake beyond the traditional prescribers should, especially outside Germany, result in a noticeable uplift in revenue growth.

Even modest US success would be transformative

In a similar timeframe, the US launch of Pollinex Quattro grass would add steadily increasing incremental sales in this new and highly attractive geographic market, boosting revenue growth into double-digits and potentially the high-teens. This would be supported by the broader roll-out of the PQ product range and the VLP peanut vaccine, which could be transformational for Allergy Therapeutics, and represents further upside potential.

Financials

Regional performance variations highlight nature of COVID impacts on patient care

Allergy Therapeutics H121 results (six months ended 31 December 2020) indicated record revenues up 7% (+5% CER) to £54.0m (H120: £50.5m), with robust growth across all key products supported by the science-based marketing approach. Sales growth varied geographically, largely influenced by COVID-19 impacts. Growth was stronger in Northern Europe (in particular, Germany, Austria, Netherlands, and Switzerland) where allergy clinics are largely standalone vs a weaker performance in Italy, Spain and the UK, due to closures of hospital-based allergy clinics as resources were diverted to the emergency setting.

A highly seasonal business, with H1 materially stronger than H2

Cost of goods increased in absolute terms as higher volumes were sold, translating into increased gross profit of £42.2m (H120: £39.1m), with a 78% gross margin. The continuing pandemic and the evolving responses cloud the H221 outlook, although management anticipate continued net sales growth on H220. Due to the seasonality of allergy treatment, 60-70% of sales are generated in H1; hence a profitable H121 is expected to be followed by a loss-making H2. The H221 gross margin, in common with prior years, will be lower than H1 reflecting lower factory volumes. However, FY21 gross margin will be in line with FY20 due to seasonality and Brexit stock building. As an export business, Brexit has so far been administratively burdensome for Allergy Therapeutics, although the company was well prepared for Brexit implementation (including with increased inventory levels) but continues to adjust and optimise relevant processes.

Resilience shows through as robust underlying profit growth

Operating profit pre-R&D was £20.5m, a record level, up 18.5% (H120: £17.3m), with a pre-R&D operating margin of 38% (H120: 34%). Sales, marketing and distribution costs reflected reduced activity and travel in the period due to COVID-19 (H121: £12.4m vs H120: £13.6m), although these savings were partially offset by higher admin spend (£9.7m vs £8.2m) on compliance and infrastructure.

R&D set to rise as development programmes progress

H121 R&D investment of £4.7m was in line with H120, although the reported figure of £1.3m for the prior period included a £3.2m exceptional received from the Inflamax litigation settlement. Current R&D spend largely reflects the progress of the Grass MATA MPL Phase III programme: the first stage (G309) is fully recruited and on track to complete dosing ahead of the allergy season. R&D expenditure is expected to double in H221 reflecting a more active period in the G309 study, with the bulk of associated costs to be incurred during calendar 2021. Investment is also being directed into pre-IND work for the VLP-peanut allergy programme and the ongoing TAV process.

Strong balance sheet means company funded to key inflection points

Cash and equivalents increased to a record balance of £48.3m (vs £37.0m at end-June 2020), representing net cash of £44.5m (£33.2m). Management expects to renew existing banking facilities in August 2021 when they fall due. We again highlight the natural H1 bias to performance and cash generation from operations (ex-R&D) due to the seasonality of the pollen allergy market and anticipate an end-June 2021 cash position of £30.1m.

We believe our FY21 forecasts are realistic and achievable

For FY21 we continue to expect full-year sales of £83.7m (+7%), pre-R&D operating profit of £11.0m, and R&D investment of £15.8m. Non-R&D operating costs should rise broadly in line with sales resulting in a reported operating loss of £4.7m, and net loss of £6.2m. Our forecasts are presented in Exhibit 2.

Exhibit 2: Summary of financials

Year-end: June 30	£'000s	2018	2019	2020	2021E	2022E
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)	(15,750)	(13,781)
S&M expenses		(27,133)	(26,995)	(24,853)	(27,960)	(29,637)
G&A expenses		(15,543)	(17,595)	(19,627)	(22,849)	(25,182)
Underlying operating profit		**(7,360)**	**(2,239)**	**4,523**	**(5,393)**	**(3,568)**
Share-based payments		(985)	(1,367)	(794)	(567)	(579)
Exceptionals		0	6,037	3,152	0	0
Other revenue/expenses		630	593	634	647	660
EBITDA		**(4,486)**	**6,481**	**12,223**	**(251)**	**802**
Operating Profit		**(6,730)**	**4,391**	**8,309**	**(4,747)**	**(2,908)**
Operating profit (pre R&D)		**9,287**	**11,341**	**14,157**	**11,003**	**10,873**
Financing costs/income		(166)	(98)	(238)	(397)	(207)
Profit Before Taxes		**(6,896)**	**4,293**	**8,071**	**(5,144)**	**(3,115)**
Adj. PBT		**(8,511)**	**(3,704)**	**3,491**	**(6,358)**	**(4,353)**
Current tax income		(637)	(826)	(1,159)	(1,103)	(1,034)
Net Income		**(7,533)**	**3,467**	**6,912**	**(6,246)**	**(4,148)**
EPS (p)		**(1.3)**	**0.5**	**1.1**	**(1.0)**	**(0.6)**
Adj. EPS		**(1.5)**	**(0.5)**	**0.5**	**(1.2)**	**(0.9)**
DPS (p)		**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Average no. of shares (m)		595.1	632.8	635.2	639.0	640.8
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**	**48,503**	**43,661**
Cash and cash equivalents		15,533	27,440	36,962	30,064	22,980
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	(224)	(224)
Non-current assets		**20,088**	**21,872**	**31,055**	**31,369**	**31,935**
Property, plant & equipment		10,096	11,481	20,417	19,443	19,434
Intangible assets		4,949	4,840	4,736	5,012	5,288
Other non-current assets		5,043	5,551	5,902	6,914	7,214
Current liabilities		**(14,631)**	**(16,859)**	**(18,227)**	**(19,058)**	**(19,120)**
Short-term debt		(644)	(694)	(829)	(229)	(79)
Accounts payable		(13,890)	(15,736)	(15,148)	(14,490)	(14,470)
Other current liabilities		(97)	(429)	(2,250)	(4,339)	(4,570)
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**	**37,709**	**34,140**
CASH FLOW STATEMENTS						
Operating cash flow		**(3,802)**	**5,600**	**12,010**	**(407)**	**(1,891)**
Profit before tax		(6,896)	4,293	8,071	(5,144)	(3,115)
Non-cash adjustments		2,834	3,531	4,736	5,037	4,495
Change in working capital		211	(2,245)	589	(126)	(1,962)
Interest paid		(318)	(204)	(489)	(397)	(207)
Taxes paid		367	225	(897)	224	(1,103)
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)**	**(2,376)**	**(900)**
Proceeds from equity		2	10,196	1	4	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**	**(6,898)**	**(7,084)**
Exchange rate effects		10	115	131	0	0
Cash at start of year		22,122	15,533	27,440	36,962	30,064
Cash at end of year		**15,533**	**27,440**	**36,962**	**30,064**	**22,980**
Net cash at end of year		**12,475**	**25,004**	**33,206**	**27,208**	**20,574**

Source: Company, Trinity Delta

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Disclaimer

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