

As at 10/29/2021	Value	1 Month (October)	YTD	Since Launch (ITD)
Share	199.60	2.9%	15.8%	129.4%
NAV	199.98	2.3%	17.6%	130.4%

Sources: Bloomberg & Bellevue Asset Management (UK) Ltd., 31.10.2021, NAV and share price returns are adjusted for dividends paid during the period, assuming reinvestment in relevant security. Full performance data is on page 6.

Note: Past performance is not a guide to future performance. The value of an investment and the income from it may fall as well as rise and is not guaranteed.

Welcome to our monthly update, from the bow of the good ship "Healthcare". The long and arduous voyage toward the calmer Sea of Stockpicking has felt rather fruitless at times, but the charts tell us that progress is being made, despite the blistering storm called Macro News continually blowing us off course. We must plot a way between the rocks of Q3 and the fourth waves, but like the son of Laërtes and Anticlea, we will not give up.

Monthly review

The wider market

So much for the market correction! In spite of the worries that weighed on indices during September, October saw the MSCI World Index rise 5.7% in dollars, reversing all of the declines seen in September and making yet another all-time high. Given all that has come to pass during 2021, it is remarkable that March is the only month this Index has not touched a new all-time high during a month and even then, a measly 10 basis points of additional performance would have seen off that "aberration".

Sterling appreciated further against the dollar on continued relative strength for economic data (US rolling over, UK beating expectations). This created a 1.6% headwind for the MSCI World Index, which rose only 4.1% when measured in sterling, almost reversing the pattern we saw through September.

The onward march of the Delta variant (and its offspring, about which we are currently unconcerned) continues, with rising case levels in the majority of major EU countries, but the UK seems to have turned a corner with a more stable outlook (probably due to half term school holidays and commensurately lower testing volumes, which still remain at multiples of any comparable country and hence cloud any relative judgement of progress into wave 4).

The steady downtrend in US cases that began in late August also looks to have arrested. Whilst a rise in cases across Continental Europe was widely expected, it is still too early in the western hemisphere's winter season to speculate about the extent to which restrictions might need to be re-imposed to manage healthcare demand versus capacity caused by the onslaught of the various respiratory pathogens that prey on the weakest during these months: not just SARS-CoV-2, but RSV, Influenza and bacterial exacerbations of pneumonia in COPD patients. These all increase demand for intensive care bed capacity during the tediously repetitive "NHS Winter Crisis".

Sentiment this month was always going to be inexorably tied to the reporting season and the tension between continued demand in the face of growing inflationary pressures versus the supply side ability to meet it (in absolute terms due to raw material/component and labour-related shortages or supply chain issues) and the market's return to positive territory would suggest that the balance of news has been to the positive.

As ever though, there is some quantification required. In terms of leaders and laggards, the best performing sector in October was Automotive (+19.4%) but this was due mainly to Tesla (39% of the sector) rising 44% on the back of its deal to supply erstwhile basket-case turned retail investor darling Hertz with 100,000 electric vehicles.

Tesla joined the trillion dollar club on the back of this move and it is worth noting that had its shares performed in line with the rest of the Automotive peer group, the sector would have risen only 2.5%, relegating it from best performing sector to third worst (out of 24). More remarkably, Tesla accounted for 14% of the MSCI World Index's 5.7% positive monthly return (i.e. it would have been +4.2% had this not happened).

Summary

BB Healthcare Trust Ltd is a high conviction, unconstrained, long-only vehicle invested in global healthcare equities with a max of 35 stocks. The target annual dividend is 3.5% of NAV and the fund offers an annual redemption option. BB Healthcare is managed by the healthcare investment trust team at Bellevue Asset Management (UK) Ltd.

The second best performing sector was Transportation (+9.2%). Never let a good crisis go to waste: the corollary of a global logistics capacity crunch is of course renewed pricing power for those who control the flow of goods. It is now begrudgingly accepted that freight rates will remain high for the medium-term and this is now baked in the earnings outlook of those who move the goods around by land, sea and air. In a similar vein, the third best performing sector was Semiconductors (+8.8%), where the realities of demand far outstripping supply can only help pricing and margins.

The laggards were a much less interesting group of classical consumer discretionary activities: the worst performer was Telecoms (-3.4%). This was seemingly a reaction to Apple and others suggesting that the chip shortage would crimp device sales and thus make it harder for Telecoms companies to lock customers into new and lucrative 3-year data contracts. Without lock-ins, more churn in the market is bad for pricing and margins).

Next worst was Consumer Services (+0.9%): this includes all the fast food and food delivery services plus leisure operators and is perceived as a loser from consumer price inflation pressures. In third from bottom place: Household and Personal Care (+2.2%). This is the branded goods sector where there is again the perceived risk that consumers will 'trade down' to less premium options in the face of mounting inflationary pressure on the weekly shop).

Healthcare

The MSCI World Healthcare Index rose 4.2% in dollars, underperforming the wider Index by 1.5% (and would have underperformed even without the wider Index's supercharging by Tesla). It rose 2.6% in sterling terms. Generally speaking, we can say that it has been a positive reporting season for the wider sector, in terms of post-reporting share price reactions.

To the extent that one can distil pre-earnings sentiment for such a diverse sector into a few lines of commentary, the main concern/risk was that elevated multiples for some growth stocks may not be supported by a healthcare operating environment where the persistence of SARS-CoV-2 and labour shortages were weighing on the ability to bring elective procedure levels into line with historical demand trends.

Save for the orthopaedic and hearing aid stocks in the Medical Technology sub-sector, where we saw downgrades to consensus ahead of the reporting season on feedback of weaker market demand/procedure volumes, companies reported in line with expectations and were cautiously optimistic for Q4 and beyond.

The subsector performance is highlighted in Figure 1 overleaf and we would make a couple of observations. Firstly, the strong performance of Managed Care was entirely unsurprising in our view. These companies have been doing their level best to play down excess profits arising from the reduced level of elective procedure activity around the pandemic and to play up the risk of future COVID-related costs.

With three quarters of the year behind them, this game gets harder and the true earnings power shines through. They also were able to assuage investors that a presumed return to normal levels of activity in 2022 would not present an insurmountable headwind versus current market expectations. We further increased our meaningful exposure to this sub-sector during the month, which benefitted performance.

Healthcare Technology was driven by Dexcom's impressive results and ongoing volume growth in the CGM sector. Tools was a relief rally to some extent, as the sector continues to trade at elevated multiples compared to history and the comps are getting tougher. Nonetheless, growth trends remained intact and there was a nice tailwind from resurgent COVID testing volumes (to which we would ascribe a low P/E). Med-Tech stocks struggled to see follow through on positive results in part due to a perception that much was already in the price.

The theme of ongoing lacklustre volumes for low acuity procedures such as orthopaedics left hospitals again benefitting from a positive patient mix toward (more profitable) high acuity caseloads but this was not rewarded in share price terms due to concerns that volume recovery to pre-pandemic levels will take longer than previously anticipated due to COVID and staffing pressures.

As noted previously, the Diversified Therapeutics category benefitted from something of a relief rally around the lack of a drug pricing element to the reconciliation bill, along with generally in-line reporting. However, once again the Focused Therapeutics names lagged despite similar positive results and arguably comparable exposure to any positive sentiment around the failure of headline drug price risk to emerge.

BENCHMARK SUB-SECTOR PERFORMANCE AND WEIGHTINGS

Sub-Sector	Weighting	Perf. (USD)	Perf. (GBP)
Managed Care	9.6%	16.3%	14.5%
Healthcare Technology	1.1%	12.7%	11.0%
Other HC	1.6%	10.3%	8.3%
Tools	9.5%	5.8%	4.2%
Diversified Therapeutics	32.7%	4.9%	3.3%
Services	3.3%	4.5%	3.0%
Healthcare IT	1.5%	4.1%	2.5%
Conglomerate	11.6%	3.9%	2.2%
Diagnostics	2.4%	2.7%	1.2%
Distributors	1.0%	1.5%	-0.1%
Facilities	1.3%	1.1%	-0.5%
Med-Tech	15.2%	0.6%	-0.9%
Dental	0.9%	0.5%	-1.1%
Focused Therapeutics	8.0%	-2.2%	-3.5%
Generics	0.4%	-3.9%	-5.4%
Index perf.		4.2%	2.6%

Source: Bloomberg/MSCI and Bellevue Asset Management (UK) Ltd. Weightings as of 30-09-21. Performance to 31-10-21.

In last month's missive, we raised the point that healthcare as a business is not entirely immune from the twin spectres of supply chain disruption and labour force shortages that were front and centre for investors going into the Q3 reporting season. We have discussed the risks around labour shortages in the June 2021 factsheet (we would remind readers that previous Monthly Musings can be accessed via the Blog Archive tab on the News section of the Trust's website).

Reassuringly, supply chain issues have been mentioned in management commentary but not directly cited as a reason for companies that have fallen short of Q3 expectations or reduced guidance for Q4. Labour-related issues have been cited more frequently, particularly around the social care and home care spheres, although so far companies are managing to bridge the gap with (more expensive) temporary staffing.

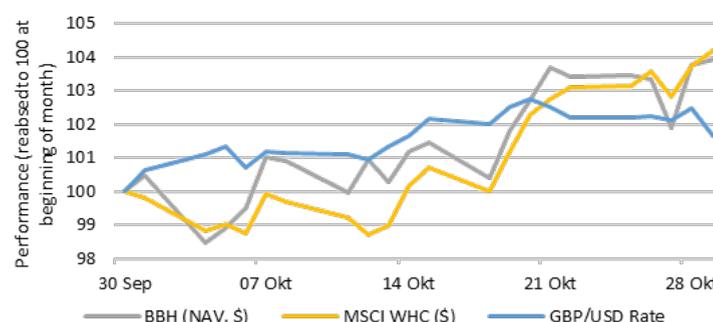
Wages are rising, but not yet at levels that we judge to represent a material headwind and the market was largely anticipating the risks here, with the most obviously exposed companies having de-rated into earnings season. We will continue to monitor these topics over the coming months but reiterate our prior view that healthcare (excluding social care and home care) is relatively insulated from these issues compared to many other industry sector groups.

We would also note that the finally announced US Medicare rebate uplift for home health in 2022 was raised from the planned 1.5% to 3.2% (the highest annual increase since 2007) to take account of wage inflation and this will likely help those stocks that have seen pressure around labour input costs in recent weeks.

In summary then, October saw a broadly positive overall narrative for the sector that once again failed to translate into appropriate momentum for the Focused Therapeutics companies. This was not just a phenomenon for the global grouping encapsulated by the large-cap focused MSCI World Index series either: the widely watched YTD performance dispersion between the US "XLV" S&P 500 Healthcare ETF and its "XBI" Biotech-focused equivalent widened from 26.6% at the end of September to 30.6% by the end of October (i.e. the YTD total return from the former is 30.6% higher than the latter, which remains well into negative territory YTD). One can but hope that the positive operational performances we can see in the Focused Therapeutics companies are recognised in due course.

The Trust

During October, the Trust's net asset value rose 2.3% to 199.98p, modestly underperforming the benchmark (-0.3%). We estimate that the adverse FX impact on the portfolio during this period from the appreciation of sterling relative to the dollar was -1.6%, in line with the impact on the comparator index. The monthly evolution of the NAV is illustrated in Figure 2:



Source: Bloomberg/MSCI and Bellevue Asset Management (UK) Ltd.

Our best performing sub-sector during this period was Managed Care (+17.1%), followed by Healthcare Technology (+12.5%) and our worst was Focused Therapeutics (-4.4%). Healthcare IT and Diagnostics also delivered negative returns this month. We completed the sell-down of our stake in Hill-Rom and also exited one of our Focused Therapeutics positions where we no longer felt confident that management could execute in line with our own and market expectations. This left us with a portfolio of 30 active investments.

We have re-deployed a substantial amount of capital over the month; re-investing all of the Hill-Rom proceeds (c£47m), new issuance proceeds (c£3.5m) and also drawing down on our leverage facility such that our net gearing rose from 0.8% (or £8.6m) to 1.7% (or £18.4m). We issued a total of 1.7m shares during the month via the tapping programme.

The evolution of our sub-sector weightings is illustrated in Figure 3. As noted above, significant capital deployment around the liquidation of the Hill-Rom position means that we have added to holdings in all of our sub-sectors this month bar Tools.

The Med-Tech weighting has declined predominantly due to Hill Rom and the most significant (i.e. disproportionate relative to our weighting in September) additions were to Managed Care. We passively reduced Tools exposure through the additions to other sub-sectors. Healthcare Technology benefitted more from performance than disproportionate capital allocation.

EVOLUTION OF PORTFOLIO WEIGHTINGS

	Subsector end Sep 21	Subsector end Oct 21	Change
Diagnostics	6.0%	6.0%	Unchanged
Diversified Therapeutics	11.9%	11.9%	Decreased
Focused Therapeutics	27.8%	27.8%	Increased
Healthcare IT	8.3%	8.3%	Increased
Healthcare Technology	3.9%	3.9%	Unchanged
Managed Care	13.3%	13.3%	Increased
Med-Tech	16.2%	16.2%	Decreased
Services	10.3%	10.3%	Increased
Tools	2.3%	2.3%	Decreased
	100.0%	100.0%	

Managers' Musings

A most contentious confabulation

Regular readers are doubtless aware that our fascination for all things healthcare sits alongside an unbridled joy for the etymological richness of the English language. We relish taking advantage of the many and varied terms that one can draw upon in written prose, if for no other reason than to make our narratives slightly less turgid. As the pandemic has doubtless reminded us all; life is simply too short not to try to inject some levity along the way.

Some words are unusual in having more than one meaning that are not obviously linked. Confabulate is just such a word – it can refer both to the initiation of a conversation (Latin: com – together and fabulari – talk) and the fabrication of an imagined experiential record to compensate for a lost memory (a psychiatry term based around fabula, which is Latin for a folktale). This apposite word was very much at the forefront of our minds during October.

The broader debate amongst healthcare investors reflects the mindset of a jilted suitor; we are all trying to figure out why the eponymous ‘generalist investor’ has seemingly fallen out of love with healthcare, when it is so obviously attractive (vanity is a terrible curse).

As we have noted several times before, the pro-cyclical, pro-growth wider macro dynamic of “re-opening” is not an obviously favourable backdrop for defensive sectors and it is only now that global GDP velocity is reaching its limits (as evidenced by labour and supply chain constraints) that the sector may now come back into favour on its growth merits, since growth is less volatile and not economically or inflation sensitive in the same way as truly discretionary activities are – there are not many discretionary healthcare customers; we tend to use these services out of need or fear. With this in mind, it is impressive that the sector has fared as well as it has versus the broader market.

Indeed, when we look back over 2021, it is a beautiful irony that the healthcare sector made itself less attractive as an overall investment in the short-term by delivering the products (i.e. vaccines, tests and treatments) that have enabled society and thus investors to look beyond the pandemic.

Nonetheless, the investor must recognise that healthcare is not an amorphous blob, but a complex ecosystem of distinct sub-sectors and the relative performance of these to one another is a more vexatious and controversial topic. Obvious macro factors aside, nature abhors a vacuum

and many financial professionals would find themselves unemployed if the role of retrofitting apparent facts to market performance were not so wildly popular (these missives would be a lot briefer as well!).

With regard to the healthcare sector, the pre-eminent question has been around why the valuation ascribed to innovative biotech/pharma companies or their products has declined over the past 6-8 months. Three factors stand out for healthcare in general and for the smaller, more focused therapeutics companies in particular:

Drug Pricing

In the US, the Democrats continue to try to append drug pricing measures to the budget reconciliation process. This has been cited by generalist investors for a reluctance to increase drug-related exposures. Although this is nothing new, and there are more reasons to believe that no egregious legislation is even possible within this Administration’s tenure than ever, investors have grown weary of this Damoclean disquietude and want something to happen, just to clear the overhang.

Even the publication of the proposed “Build Back Better” reconciliation bill in the last week of October without any of the feared ‘direct negotiation’ clauses was not enough to prompt a return to trend for the sector, with the Bloomberg US Pharmaceutical Index ending October 6% off the lows seen mid-month, but still >4% below the highs of August and back at levels seen in late July.

Perhaps Biden was being pragmatic: three centrist but very different Democratic senators opposed the sort of policies being discussed in the House (Bob Menendez of New Jersey, where most drug companies US operations are based – don’t bite the hand that feeds; coal-loving climate change sceptic Joe Manchin of West Virginia and Kyrsten Sinema of Arizona, prominent member of the Blue Dog Caucus who believe in the apparently contentious idea of cross party collaboration to actually get things done in Washington and who rightly think the House proposals would not fly with Republicans). Why include a clause in a bill that would risk your own slim majority to get it passed?

Pragmatism was never obviously a trait of the irrepressible blowhard Bernie Sanders, who controls the Senate Budget Committee. He said he would continue to work with house Democrats to fight to include some language on this topic into the final bill that goes to a vote in both houses and, as we go to press, a revised proposal has come forward.

This is much reduced in scope and probably represents a best case scenario for the industry. It was seemingly enough to win over Menendez and Sinema, who have said they would support the revised proposal. Critically, the bill focused on drugs that have lost exclusivity (9-12 years after launch) and also includes a carve out for small Biotech companies and those financially dependent on a single product revenue stream.

Even this moderate proposal may need to be watered down to get through. We continue to believe the passage of meaningful legislation on this topic is impossible at this point, just as it was for the previous Trump administration. We will monitor this situation, but the Build Back Better Bill is the only obvious vehicle (i.e. Trojan horse) for such legislation to move past the floor. We can but hope that its eventual passage in one form or another does provide some relief.

The FDA and new drug approvals

Some have argued that the rudderless US Food and Drug Administration (FDA) has become less predictable over the past year, during which it has lacked a confirmed nominee to head up the agency (Biden has struggled to get Senate confirmations for key positions across Government since his inauguration – we still do not have a US Ambassador to the UK for example), leading investors to discount more heavily any potentially material approval decision.

This uncertainty will weigh more on early stage companies than more mature large companies with many already approved products. This is definitely a topic worthy of further consideration: is there substance to it, or is it a confabulation, where a small number of unconnected data points are being weaved into a worrisome narrative?

Anti-Trust rules and the consequences for M&A

Unlike the FDA, the US Federal Trade Commission (FTC) has secured a permanent Commissioner; Lina Kahn. However, she is viewed as something of a maverick and this has prompted some to wonder if the FTC is now also harder to predict, leading companies to fret that M&A will be more time consuming and distracting to management.

Kahn's appointment in June 2021 followed an announcement by her predecessor, Acting Commissioner Rebecca Kelly Slaughter, in March of 2021 that the FTC, in collaboration with its European, UK and Canadian counterparts, would update the approach to pharmaceutical mergers moving forward. Whilst no details of what this new approach would encompass were given, the Bristol-Celgene and AbbVie-Allergan deals were cited by Slaughter as ones where the scope of the work done by competition authorities might not have been adequate.

In the months since, we have seen some oddities – Illumina closing its GRAIL acquisition ahead of FTC sign-off and some deals seeing revisions to the so-called Premerger Notification and Report system (e.g. Merck-Acceleron) adding to an already febrile atmosphere in respect of deals.

The latter is not so unusual and certainly not a prelude to a deal collapsing or being blocked (e.g. Roche-Spark went through such a revision process six months before the deal was eventually blessed by the FTC in 2019), but any such newsflow is unhelpful to broader sentiment.

Consequentially, investors appear to be discounting potential future deal volumes. An 'M&A option' premium has long propped up investor sentiment to small/mid-cap healthcare companies and some suggest this has been diminished by recent FTC actions.

Frustratingly, this is another topic where further analysis to quantify the additional risks, to the extent there are any, is all but impossible. These deals often take months to complete their review processes before any remedies are requested or a deal is blocked. It is only with hindsight and the passage of time when a number of transactions have completed one way or the other that we will be able to determine if the 'rules of engagement' have changed.

Until then, this perception will remain as a nebulous risk to the attractiveness of innovative healthcare and one can choose to cite events as evidence in one direction or the other to confabulate a narrative (we leave readers to choose which meaning they wish to ascribe to the word in this paragraph).

If we were to take a position on the topic, it would be similar to our stance on drug pricing. It is all well and good to talk about changing things, but the risk that all of this results in a legislative change that meaningfully alters the landscape for healthcare seems slim to us (and we never presume M&A as an exit route in our investment theses anyway).

Save for a few egregious examples of price gouging that were really limited to some generics companies that took the "buy and promote" business model to extremes (Valeant being the most well-known example in its 2008-2016 "heyday"), where is the evidence that consumers have been harmed in the current situation? Few small companies have the financial capacity to bring drugs to market on their own and acquisition is really just the apotheosis of the licensing discussion.

We cannot recall an example of a company being acquired to stop a product being launched (which is the criticism levelled at the Tech industry), and this is unsurprising since this market is defined by limited periods of exclusivity/patent protection and continuous innovation. You really cannot afford not to launch something if it has the potential to be a good product.

The broken cannon

Let us return then to topic of the FDA. History is littered with politicians of meagre accomplishment. Some are lazy, others self-serving, but many are simply victims of the lassitude of the civil servants beneath. Grand visions are well and good, but if those tasked with implementation are unwilling or unable to make those ideas material, then nothing gets done. The General Patton quote seems more than apt: civil servants can be like a broken cannon - they won't work and you can't fire them.

However, not all civil service organisations are temples to mediocrity. When one considers the dominance of the US-based healthcare companies in global innovations, there are many factors that one could point to (and that we have articulated previously). Indubitably, the private sector has been helped greatly by the accommodative and pro-innovation stance of the FDA.

This agency has undeniably led the world in finding ways to break down those barriers between novel devices and drugs and the patients who desperately need them. It has also brought transparency to its decision-making processes and clarity on timelines that especially helps small companies plan their activities and capital requirements.

Many of these regulatory innovations (for that is what they are) have been copied around the world, but some still remain the preserve of the FDA (principally in respect of flexibility of trial design, conditional approvals and surrogate endpoints). That the organisation will perform at a high level and continue to support such innovations became an axiomatic assumption, and with some justification: the following three charts are taken from the FDA's annual report to Congress, as required under the Prescription Drug User Fee Act (PDUFA) that funds the agency.

Figure 4 shows the total number of drug applications for novel products submitted to the agency. This reflects the industry's overall performance in terms of R&D productivity. What is notable from an FDA perspective is the growing proportion of the total that are committed to an accelerated review cycle, which has risen from 22% in 2011 to 47% in 2020:

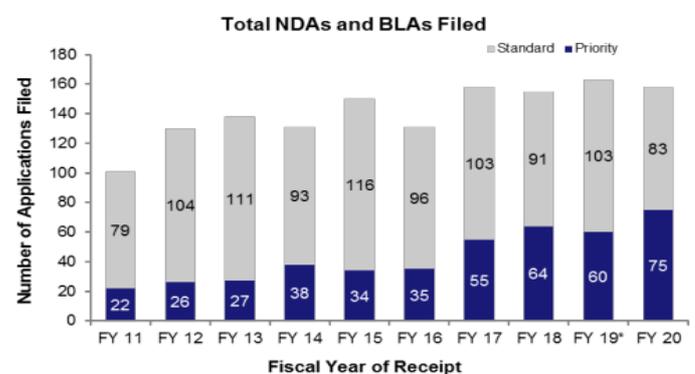
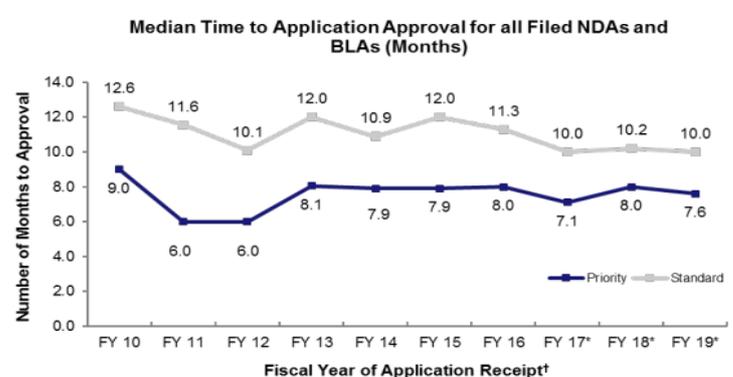
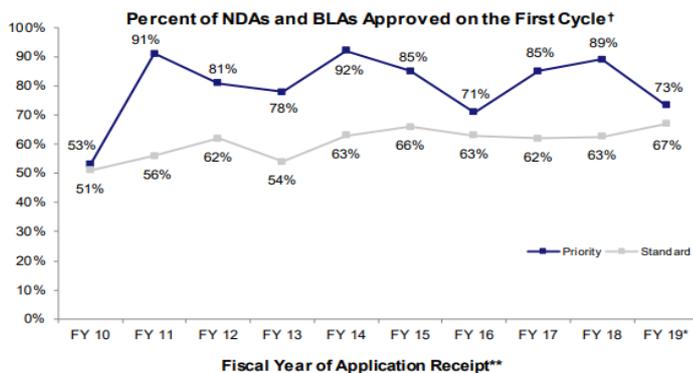


Figure 5 illustrates the time to approval for these applications and again paints a pattern of continuous productivity improvements. Even through the pandemic, it is not really obvious that the agency has suffered a deterioration in performance:



One could counter that Figure 5 is self-serving as it only covers a sub-set of applications. What about those that did not get approved? Figure 6 illustrates the proportion of applications that were approved on their first cycle (i.e. not subject to delay, even though the reason for delay is most likely a deficiency on the part of the filing, not the agency failing to complete its work). Again, there is little here to suggest that the FDA fell apart during the pandemic:



Contrived conniptions

At this point, the cynical reader might wonder if your managers have simply made up this list of issues and there is no fretting about the FDA in reality. However, a cursory examination using everyone's favourite web search engine will turn up many a news article on this topic. What is going on?

The first argument is that Congress' failure to appoint a permanent Commissioner is demoralising staff. This may be true, but the failure to make such appointments is a government-wide phenomenon born of the partisan politics in Washington. The FDA is far from rudderless: the acting Commissioner, Dr Janet Woodcock, is an agency veteran of more than 30 years and a previous Commissioner herself.

There are limitations to not being a confirmed appointee, but these are unlikely to figure into day-to-day operations. If the FDA is indeed demoralised, it is not yet showing up in reduced approvals; there were 48 so-called novel drug approvals in 2019, 53 in 2020 and there have been 42 so far this year with two months to go.

That said, the last twelve months has probably been a very politically charged period for the agency with all the pressure around rapidly approving SARS-CoV-2 vaccines and treatments. Some mistakes were made and there is also the Aduhelm controversy, which continues to be the subject of Congressional scrutiny. Perhaps the agency has never needed an advocate and defender more than it does today.

We do see some evidence that manufacturing site inspections have slowed; this is not surprising when many of these are abroad and the pandemic has played havoc with travel planning, especially in and out of China, which is a major source of raw pharmaceutical ingredients.

The idea that the FDA has got tougher in some way seems to hinge around accelerated approvals. Under this system, the drug company conducts a smaller study to evidence that the drug impacts the levels of a measurable compound in the body that is widely associated with a disease state.

This type of biomarker study is known as a surrogate endpoint and the approval granted under such circumstance is "conditional". The filer will have pre-agreed to running a further trial with a hard endpoint (i.e. a measurable disease outcome such as heart attacks, or death). If the latter trial confirms the positive hypothesis, the conditional approval converts to a normal approval. If it does not, then...

The FDA withdrew two conditional approvals, both for specific tumour types for immuno-oncology drugs in early 2021 (Merck's Keytruda and Astra's Imfinzi); both drugs remain on the market for a number of other cancers. Whilst these withdrawals have been cited as cumulative evidence of a changing approach from the agency, it is merely sticking to previous agreements that date back several years.

If there is a question here, it should be why such a long period of time elapsed between the negative trial results for Imfinzi being reported and the indication being pulled (one year for Imfinzi, two months for Keytruda, so they ended up happening within weeks of each other despite the data being temporally distant).

Contemporaneousness is not evidence of correlation or causality and the answer to this question is that a committee is convened to discuss these conversions and withdrawals and the availability of other treatment options is a factor in the committee's deliberations.

Whilst a trial may fail to hit the confirmatory endpoint, it may have some activity. Thus the FDA might be inclined to keep the indication on the label. However, if another drug comes along that shows better or more definitive efficacy in that same population then of course it makes sense to prevent the use of the less effective option and withdraw the conditional approval.

It is also worth noting that the FDA's most recent acceleration programme for cancer medicines ("RTOR") continues to pay dividends with rapid (i.e. earlier than expected) approvals coming through in 2021 for Roche's Tecentriq.

Finally, for all the noise about conditional approvals, we would highlight that, since the label amendment for gastric tumours in March 2021, the FDA has granted a different conditional approval for Keytruda in another oncology indication (1st line cervical cancer) and converted a conditional approval to a full approval (2nd line cervical cancer). There is hardly a pattern here at all.

Another cited piece of evidence was the non-approval of Tricida's veeverimer in August 2020. The company received a "complete response letter" despite the TRCA-301 trial seeming to meet its pre-agreed primary endpoint. The FDA was clear (to the company) what issues it had with the study and these were confirmed to investors in October 2020, once Tricida had met with the agency to discuss the issues in detail. Again, it would be unfair to suggest (as some did) that the FDA moved the goalposts here; the trial's unusual recruitment pattern raised serious questions over statistical validity and Tricida will have to wait for the outcomes study to file for an approval.

We could continue in this vein for several more pages, but hopefully our point is made. Whilst the healthcare investment cognoscenti continue to debate this topic (and, as we noted last month, successful stockbroking for the sell-side is all about having a compelling narrative), we find the prima facie evidence that the FDA has changed to be either less forgiving or less productive to be weak and circumstantial at best.

As such, we have not altered any of the discount rates or probabilities of regulatory success that we use in our scenario modelling when it comes to products that have yet to receive formal approvals. What does this mean? We are beginning to see some compelling opportunities emerging in the Focused Therapeutics space and we fully intend to take advantage of them.

We always appreciate the opportunity to interact with our investors directly and you can submit questions regarding the Trust at any time via: shareholder_questions@bbhealthcaretrust.co.uk

As ever, we will endeavour to respond in a timely fashion. We thank you for your ongoing support of BB Healthcare Trust.

Paul Major and Brett Darke

Standardised discrete performance (%)

	1 year Oct 20 - Oct 21	2 years Oct 19 - Oct 21	3 years Oct 18 - Oct 21	4 years Oct 17 - Oct 21	since inception
12-month total return					
NAV return (inc. dividends)	26.0%	63.9%	69.8%	96.5%	129.4%
Share price	26.0%	65.8%	70.7%	101.1%	130.4%
MSCI World Healthcare Index (GBP)	23.6%	35.9%	48.6%	68.0%	92.3%

Sources: Bloomberg & Bellevue Asset Management (UK) Ltd., 29.10.2021

All returns are adjusted for dividends paid during the period, assuming reinvestment in relevant security.

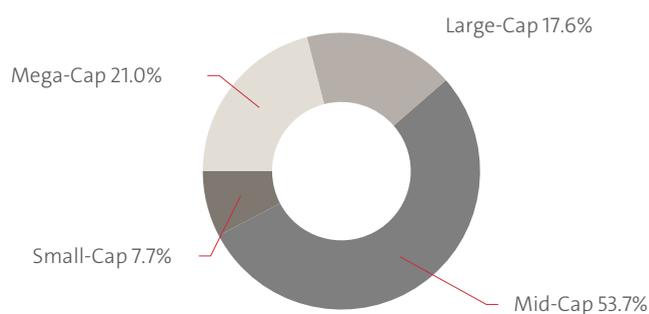
Note: Past performance is not a guide to future performance. The value of an investment and the income from it may fall as well as rise and is not guaranteed

TOP 10 HOLDINGS

Jazz Pharmaceuticals	6.9%
Insmed	6.9%
Vertex Pharmaceuticals	6.3%
Anthem	5.9%
Humana	5.8%
Option Care Health	4.8%
Bristol Myers Squibb	4.8%
Unitedhealth Group	4.5%
Tandem Diabetes Care	4.4%
Accolade	3.8%
Total	54.2%

Source: Bellevue Asset Management, 29.10.2021

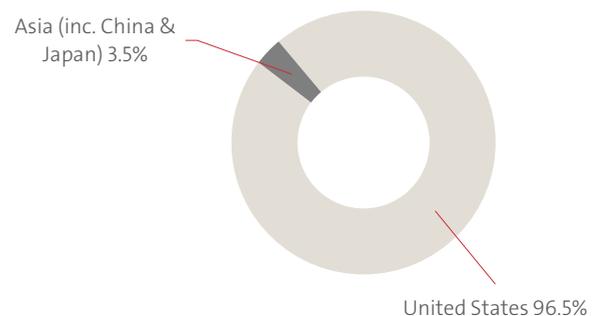
MARKET CAP BREAKDOWN



Source: Bellevue Asset Management, 29.10.2021

"Mega Cap >\$50bn, Large Cap >\$10bn, Mid-Cap \$2-10bn, Small-Cap <\$2bn."

GEOGRAPHICAL BREAKDOWN (OPERATIONAL HQ)



Source: Bellevue Asset Management, 29.10.2021

Sustainability Profile – ESG

Norms-based exclusions:	<input checked="" type="checkbox"/> Compliance UNGC, HR, ILO	<input checked="" type="checkbox"/> Controversial weapons
ESG Risk Analysis:	<input checked="" type="checkbox"/> ESG Integration	
Stewardship:	<input checked="" type="checkbox"/> Engagement	<input checked="" type="checkbox"/> Proxy Voting

CO2 intensity (t CO2/mn USD sales): 23.6 t (low) MSCI ESG coverage: 100%

Based on portfolio data as per 30.09.2021 (quarterly updates) – ESG data base on MSCI ESG Research and are for information purposes only; compliance with global norms according to the principles of UN Global Compact (UNGC), UN Guiding Principles for Business and Human Rights (HR) and standards of International Labor Organisation (ILO); no involvement in controversial weapons; ESG Integration: Sustainability risks are considered while performing stock research and portfolio construction; The CO2 intensity expresses MSCI ESG Research's estimate of GHG emissions measured in tons of CO2 per USD 1 million sales; for further information c.f. www.bellevue.ch/en/corporate-information/sustainability

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INVESTMENT FOCUS

- The BB Healthcare Trust invests in a concentrated portfolio of listed equities in the global healthcare industry (maximum of 35 holdings)
- Managed by Bellevue group ("Bellevue"), who manage BB Biotech AG (ticker: BION SW), Europe's leading biotech investment trust
- The overall objective for the BB Healthcare Trust is to provide shareholders with capital growth and income over the long term
- The investable universe for BB Healthcare is the global healthcare industry including companies within industries such as pharmaceuticals, biotechnology, medical devices and equipment, healthcare insurers and facility operators, information technology (where the product or service supports, supplies or services the delivery of healthcare), drug retail, consumer healthcare and distribution
- There will be no restrictions on the constituents of BB Healthcare's portfolio by index benchmark, geography, market capitalisation or healthcare industry sub-sector. BB Healthcare will not seek to replicate the benchmark index in constructing its portfolio
- The Fund takes ESG factors into consideration while implementing the aforementioned investment objectives

DISCLAIMER

This document is only made available to professional clients and eligible counterparties as defined by the Financial Conduct Authority. The rules made under the Financial Services and Markets Act 2000 for the protection of retail clients may not apply and they are advised to speak with their independent financial advisers. The Financial Services Compensation Scheme is unlikely to be available.

BB Healthcare Trust PLC (the "Company") is a UK investment trust premium listed on the London Stock Exchange and is a member of the Association of Investment Companies. As this Company may implement a gearing policy investors should be aware that the share price movement may be more volatile than movements in the price of the underlying investments. **Past performance is not a guide to future performance. The value of an investment and the income from it may fall as well as rise and is not guaranteed. An investor may not get back the original amount invested.** Changes in the rates of exchange between currencies may cause the value of investment to fluctuate. Fluctuation may be particularly marked in the case of a higher volatility fund and the value of an investment may fall suddenly and substantially over time. This document is for information purposes only and does not constitute an offer or invitation to purchase shares in the Company and has not been prepared in connection with any such offer or invitation. Investment trust share prices may not fully reflect underlying net asset values. There may be a difference between the prices at which you may purchase ("the offer price") or sell ("the bid price") a share on the stock market which is known as the "bid-offer" or "dealing" spread. This is set by the market markers and varies from share to share. This net asset value per share is calculated in accordance with the guidelines of the Association of Investment Companies. The net asset value is stated inclusive of income received. Any opinions on individual stocks are those of the Company's Portfolio Manager and no reliance should be given on such views. This communication has been prepared by Bellevue Asset Management (UK) Ltd., which is authorised and regulated by the Financial Conduct Authority in the United Kingdom. Any research in this document has been procured and may not have been acted upon by Bellevue Asset Management (UK) Ltd. for its own purposes. The results are being made available to you only incidentally. The views expressed herein do not constitute investment or any other advice and are subject to change. They do not necessarily reflect the view of Bellevue Asset Management (UK) Ltd. and no assurances are made as to their accuracy. ©

FIVE GOOD REASONS

- Healthcare has a strong, fundamental demographic-driven growth outlook
- The Fund has a global and unconstrained investment remit
- It is a concentrated high conviction portfolio
- The Trust offers a combination of high quality healthcare exposure and targets a dividend payout equal to 3.5% of the prior financial year-end NAV
- BB Healthcare has an experienced management team and strong board of directors

MANAGEMENT TEAM



Paul Major



Brett Darke

GENERAL INFORMATION

Issuer	BB Healthcare Trust (LSE main Market (Premium Segment, Official List) UK Incorporated Investment Trust
Launch	December 2, 2016
Market capitalization	GBP 1109.2 million
ISIN	GB00BZCNLL95
Investment Manager	Bellevue Asset Management (UK) Ltd., external AIFM
Investment objective	Generate both capital growth and income by investing in a portfolio of global healthcare stocks
Benchmark	MSCI World Healthcare Index (in GBP) - BB Healthcare Trust will not follow any benchmark
Investment policy	Bottom up, multi-cap, best ideas approach (unconstrained w.r.t benchmark)
Number of ordinary shares	553 999 086
Number of holdings	Max. 35 ideas
Gearing policy	Max. 20% of NAV
Dividend policy	Target annual dividend set at 3.5% of preceding year end NAV, to be paid in two equal instalments
Fee structure	0.95% flat fee on market cap (no performance fee)
Discount management	Annual redemption option at/close to NAV
EU SFDR 2019/2088	Article 8

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