



# Biopharma and Medtech Half-Year Review 2021

By Amy Brown, Edwin Elmhirst and Elizabeth Cairns | JULY 2021

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# Foreword

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The pandemic is far from over, but for many in biopharma business returned to almost normal in the first half of 2021. Companies are successfully operating remotely, deals are getting done, and clinical research has largely recommenced, aside from areas involving patients particularly vulnerable to Covid-19.

Developers that brought pandemic treatments or vaccines to market are busy reaping the benefits – those that chose to profit, at least. Concerted industry-wide efforts to find novel ways to suppress the viral disease have ebbed to small pockets of discovery work.

The flood of public investors taking defensive positions in the sectors that came to the world's aid last year has also receded. This meant that certain drug and medtech indices had not performed as strongly as some others at the half-year stage. But with global interest rates at record lows growth stocks remain in demand, and developers with a strong story to tell have benefited in particular.

Moderna, riding high on the success of its mRNA Covid-19 vaccine Spikevax, is the standout example in biotech. The largely research-stage company's market cap touched an unfathomable \$196bn in early August, making the group worth more than established big pharma players AstraZeneca and Bristol Myers Squibb.

Winners and losers are just as clearly delineated in medtech. In a reversal of fortune from this time last year, companies producing tests for Covid-19 or the ventilators and other technologies used to treat patients with the disease have lost ground. Those making devices used in orthopaedics or cardiovascular procedures, for instance, are surging back as non-urgent procedures start back up with a huge backlog to get through.

Unjustifiable valuations in both biotech and medtech are not just confined to the stock market. Concerns are growing that the richly endowed venture capital industry is driving asset prices too high in the private sphere, particularly in competitive areas like oncology. A wide-open IPO window is helping the financing wheels turn quickly, by allowing these funds to flip early-stage developers rapidly into the hands of equity investors.

These trends have caused record-setting numbers to emerge in the first half of the year, this report reveals. Biotech flotations raised \$9bn, while private start-ups raised \$15bn in venture cash, according to *Evaluate Pharma*. In medtech mergers are happening at a healthy pace, but a quiet six months for M&A in biopharma suggests that high valuations are having an effect on dealmaking.

But biopharma remains a highly active in-licensor of innovation. For the first time this report contains insights from BioSciDB, acquired by *Evaluate* earlier this year, revealing a busy licensing deal scene. Almost \$6bn was spent on up-front fees in the first half, putting the year on track to match last year's record, with price inflation also evident in this dataset.

This report is a combination of articles published by *Evaluate Vantage* examining the emerging trends shaping the biopharma and medtech sectors. Read on for a deeper dive into the data, collated by *Evaluate Pharma*.

*Unless stated, all data are sourced to Evaluate and were accessed in July 2021.*



# Contents

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## Biopharma Half Year Review 2021

Alzheimer's and Covid-19 developers lead biopharma's stock market gainers	4
The financing boom continues for listing biotechs	10
Venture investors still love drug developers	14
Biopharma takeovers dry up but licensing deals still hot	16
Outlook	21

## Medtech Half Year Review 2021

Role reversal for large-cap medtechs	22
Medtech gears up for a vintage acquisition year	25
Medtech venture funding hits new heights	28
Floating medtechs go big or go home	31
The FDA takes its foot off the pedal	34
Outlook	37



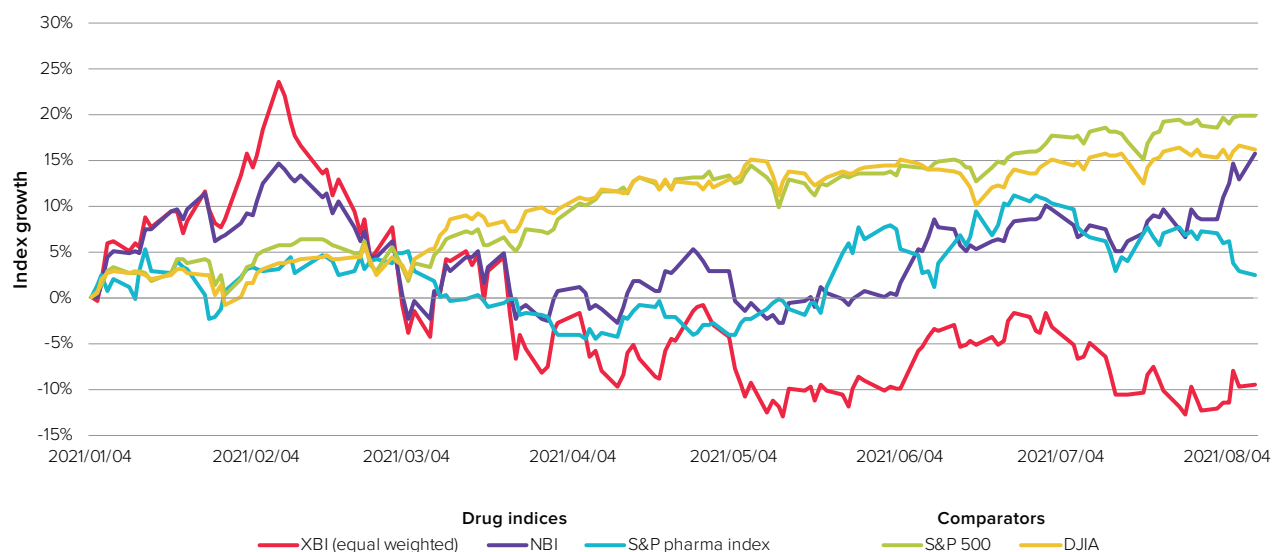
# Biopharma Half Year Review 2021

## Alzheimer's and Covid-19 developers lead biopharma's stock market gainers

The pandemic tide that lifted biopharma last year has receded, leaving developers that managed to bring Covid-19 treatments to market among the sector's best performing stocks in 2021. Alzheimer's disease players are also doing very well, thanks to the FDA's controversial approval of Biogen's Aduhelm, which is thought likely to open the gates to contenders coming behind.

Relatively speaking, however, drug indices underperformed broader indices in the first half of 2021. Partly this was because the reopening of Western economies prompted investors to flock back to industries most damaged by the outbreak of Covid-19, chasing recovery stories.

Relative performance of selected drug indices YTD



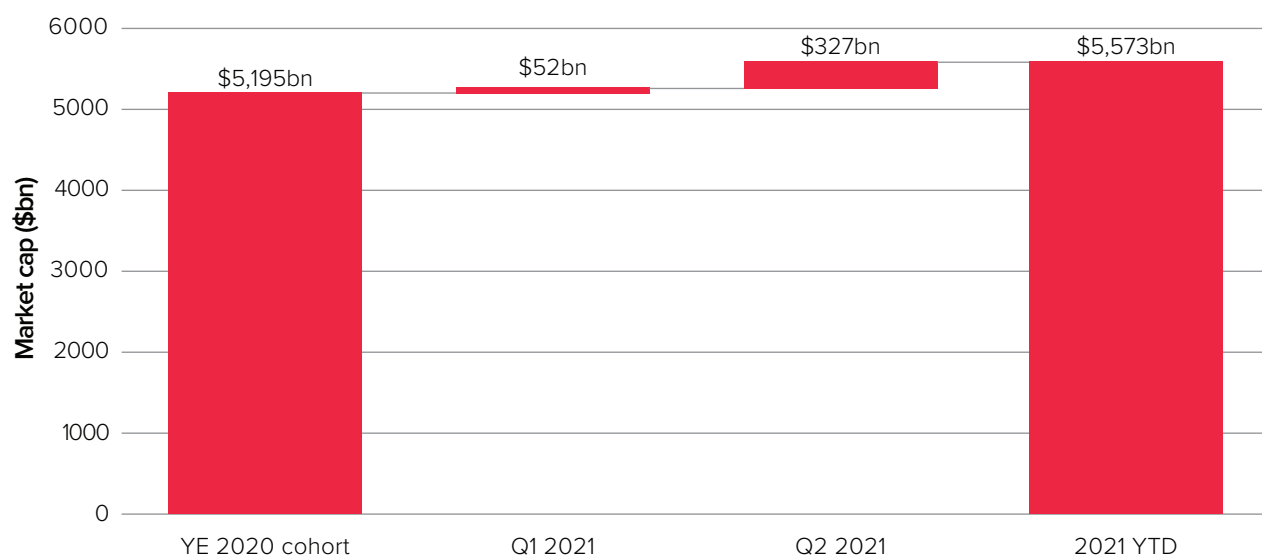


This is not to say that biopharma shares have disappointed – the Evaluate Pharma global drug stock universe put on \$379bn in market cap across the first six months of the year. By comparison, half a trillion in value was added in 2020.

This analysis tracks the stock market performance of just over 700 global biopharma groups covered by *Evaluate Pharma*; it includes only pure-play drug developers with a market capitalisation of more than \$250m at the start of the year.

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### The shifting valuations of global drug makers

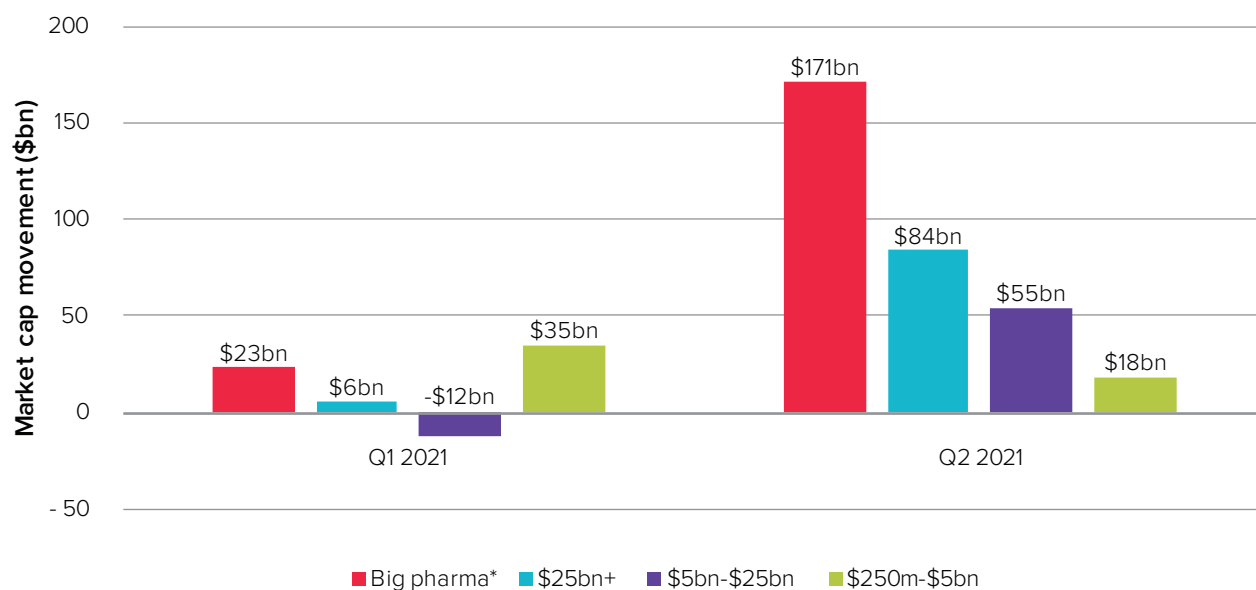




Huge gains from Eli Lilly and Roche account for more than half of the big pharma group's market cap expansion over the six months. Hopes are high that their respective Alzheimer's assets, donanemab and gantenerumab, will be launched sooner than anticipated.

To construct this analysis companies in the Evaluate universe are split into the valuation brackets below based on their market cap at the end of 2020, and remain in that cohort throughout the year.

### Absolute market cap gains and losses, by market cap bracket



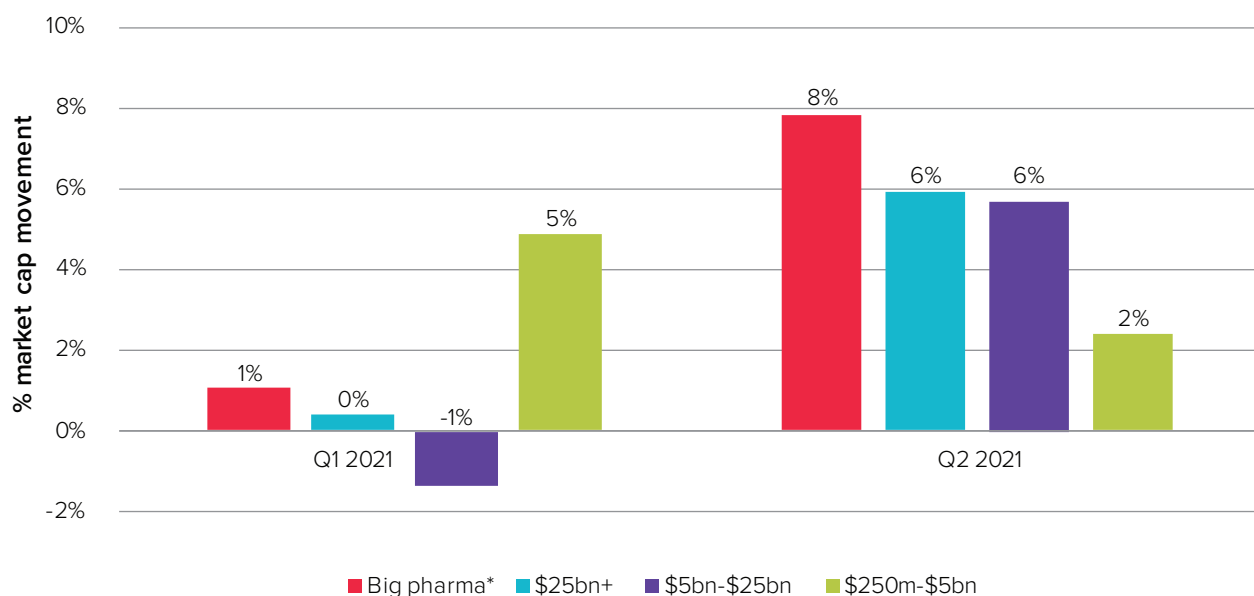
\*Big pharma comprised of: Abbvie, AstraZeneca, Bristol Myers Squibb, Eli Lilly, Glaxosmithkline, J&J, Merck & Co, Novartis, Pfizer, Roche, Sanofi.



In the big cap cohort the company that started the Alzheimer's renaissance, Biogen, was outdone by Moderna.

Indeed much of the universe's gains over the first half of the year are derived from a small group of very strong performers among the larger developers. This became particularly apparent in the second quarter, with smaller developers performing the worst percentage-wise, a reversal of the trend seen in the opening months of 2021.

#### Percentage market cap gains and losses, by market cap bracket



\*Big pharma comprised of: Abbvie, AstraZeneca, Bristol Myers Squibb, Eli Lilly, Glaxosmithkline, J&J, Merck & Co, Novartis, Pfizer, Roche, Sanofi.



Drilling down to the biggest winners and losers over the first half, the Covid-19 and Alzheimer's themes are readily apparent. Lilly, Moderna and Biontech top the tables for their respective cohorts.

A strong showing by other Covid-19 vaccine developers suggests that investors still see plenty of profit potential in the pandemic, even for those that have yet to make it to market.

Novavax has been beset by delays and now does not expect to file its jab with the FDA until the fourth quarter. Ocugen is up strongly despite the chances of a US nod for its Bharat Biotech-partnered vaccine, Covaxin, being far from clear.

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### Biggest share price gainers of H1 2021

Company	Share price change	Market cap change (\$bn)	Market cap at June 2021 (\$bn)
<b>Big pharma</b>			
Lilly (\$)	36%	58.6	220.1
Astrazeneca (\$)	20%	26.1	157.3
Roche (SFr)	13%	45.3	337.6
<b>Big drug makers (\$25bn+)</b>			
Moderna (\$)	125%	53.0	94.4
Biogen (\$)	41%	14.5	52.1
Novo Nordisk (DKK)	23%	40.8	196.9
<b>Mid caps (\$5-25bn)</b>			
Biontech (\$)	175%	34.4	54.1
Novavax (\$)	90%	8.6	15.7
Sumitomo Dainippon Pharma (JPY)	53%	2.7	8.5
<b>Small caps (\$250m-5bn)</b>			
Ocugen (\$)	339%	1.3	1.6
Prothena (\$)	328%	1.8	2.3
Anavex Life Sciences	323%	1.2	1.6





As usual the biggest moves percentage-wise can be seen among the smaller players, driven by clinical successes or failures. While all the risers are either pandemic or Alzheimer's plays, the fallers have tumbled for wider reasons.

For example, the failure of Sarepta's Duchenne muscular dystrophy gene therapy burst that company's bubble, while Acadia dropped after its Parkinson's disease psychosis drug Nuplazid was rejected by the FDA in a new indication, dementia-related psychosis.

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### Biggest share price fallers of H1 2021

Company	Share price change	Market cap change (\$bn)	Market cap at June 2021 (\$bn)
<b>Big pharma</b>			
Merck & Co (\$)	-5%	-10	196.9
Novartis (\$)	-3%	-9.9	204.8
<b>Big drug makers (\$25bn+)</b>			
Celltrion (KRW)	-25%	-9.4	32.9
Daiichi Sankyo (JPY)	-34%	-30.9	42.8
Jiangsu Hengrui Medicine (CNY)	-39%	-20.8	67.5
<b>Mid caps (\$5-25bn)</b>			
Sarepta Therapeutics (\$)	-54%	-7.3	6.2
Acadia Pharmaceuticals (\$)	-54%	-4.6	3.9
Amicus Therapeutics (\$)	-58%	-3.5	2.6
<b>Small caps (\$250m-5bn)</b>			
Chemocentryx (\$)	-78%	-3.4	0.9
Graybug Vision (\$)	-81%	-0.5	0.1
Odonate Therapeutics (\$)	-82%	-0.6	0.1

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More detailed analyses of this data can be found here:

[Big pharma leads the way in stock market resurgence](#)

[Alzheimer's and Covid-19 developers make hay on the stock markets](#)



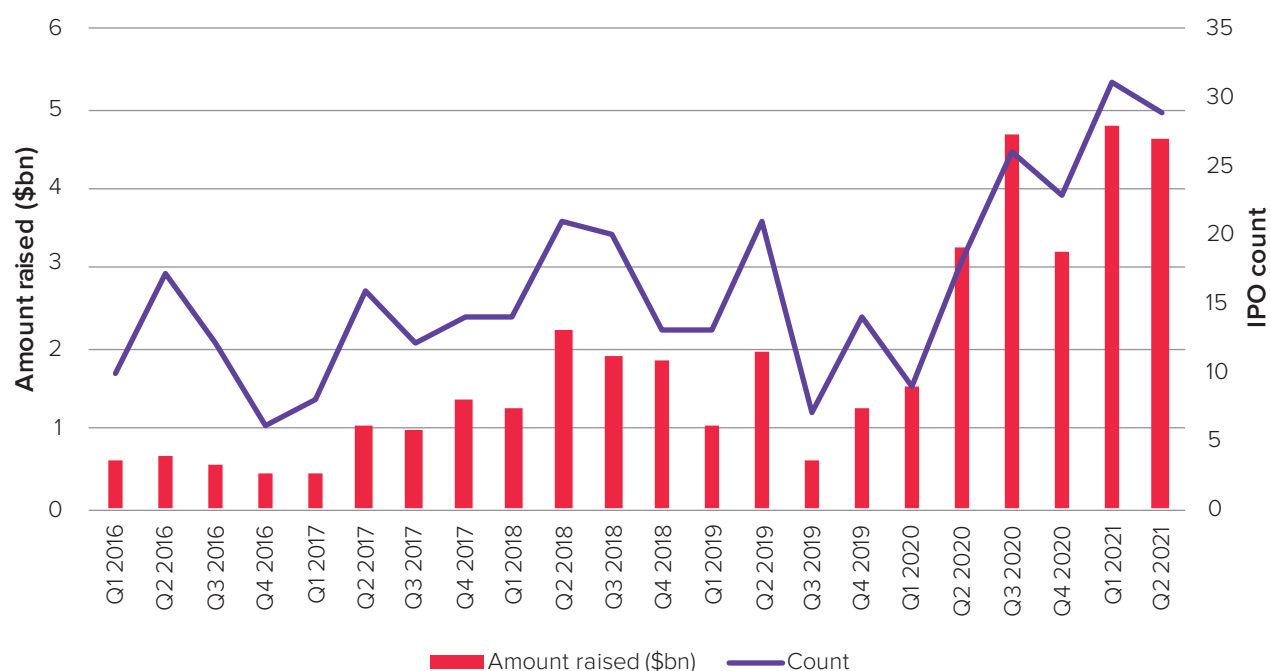
## The financing boom continues for listing biotechs

Strongly performing big caps might be dominating biopharma's stock performance, but the financing climate is still very clement for smaller developers. Younger groups raised \$9bn in initial public offerings over the first half, putting 2021 on track to break [last year's record-setting haul](#).

There are some signs of cooling: bumps to proposed price ranges are no longer the norm, for example, and the average amount raised has nudged down a touch. But the IPO window was firmly open in the first half of the year – the burning questions is whether the remainder of the year will continue to be as strong.

This analysis, as with all data in the biopharma section of this report, covers only pure-play drug developers – sectors like medtech or digital health are excluded. For IPOs, listings only on Western stock exchanges are tracked.

Biotech IPOs by quarter on Western exchanges



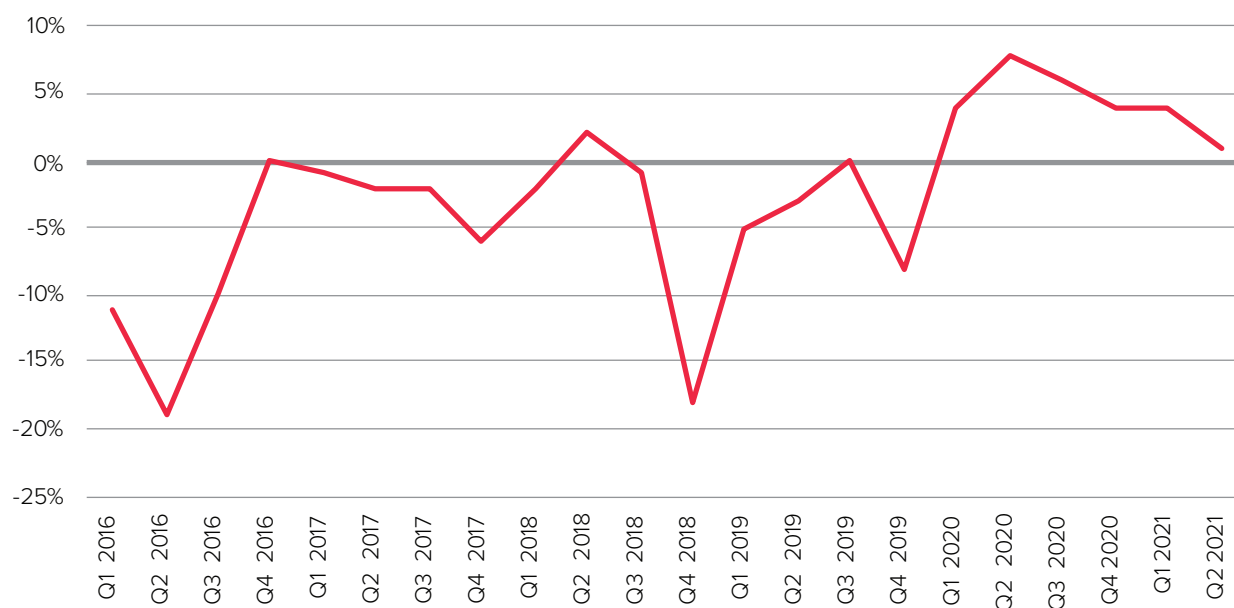


This flotation record is dominated by Nasdaq, however. *Evaluate Pharma* captured only one non-US listing in the first half – Car-T researcher Chimeric Therapeutics raised \$35m in Australia in January. European companies are floating, but they are largely opting to travel to the US to tap its deeper pools of capital, rather than pursue a local listing.

Where a pullback can be seen is in the price that these news issues are achieving. Last year virtually every IPO managed to achieve an uplift on the initially proposed price range, which can no longer be considered the norm.

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#### Average NASDAQ premium/discount to IPO price range



*This analysis charts the percentage difference between an IPO's initially proposed price range and the final price at float, averaged across all biotech Nasdaq IPOs each quarter.*



The performance of these new issues post-float is another big indicator of investor support, and signs of diminishing exuberance can be found here. The latest Hans Bishop vehicle, Lyell Immunopharma, has yet to settle above its float price, for example.

Not that this was a “weak” offering: the company raised a huge \$425m despite being years from the clinic. So while bankers and private companies eyeing a listing will be carefully monitoring signals of support in the coming months, demand for biotech flotations appears to still be relatively high.

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### Biggest biotech IPOs by sum raised in H1 2021

Company	Primary focus	Amount raised	Premium/(discount); float price to initial offer	Share price change since float to end H1
Sana	Cell therapies for oncology and rare diseases	\$676m	6%	-21%
Recursion Pharmaceuticals	Technology-enabled drug discovery and development	\$436m	6%	103%
Lyell Immunopharma	T-cell therapies for solid tumours	\$425m	0%	-4%
Centessa Pharmaceuticals	Various assets developed by subsidiaries	\$330m	5%	11%
Immunocore	T-cell receptor-based therapies for oncology and infectious diseases	\$297m	8%	50%



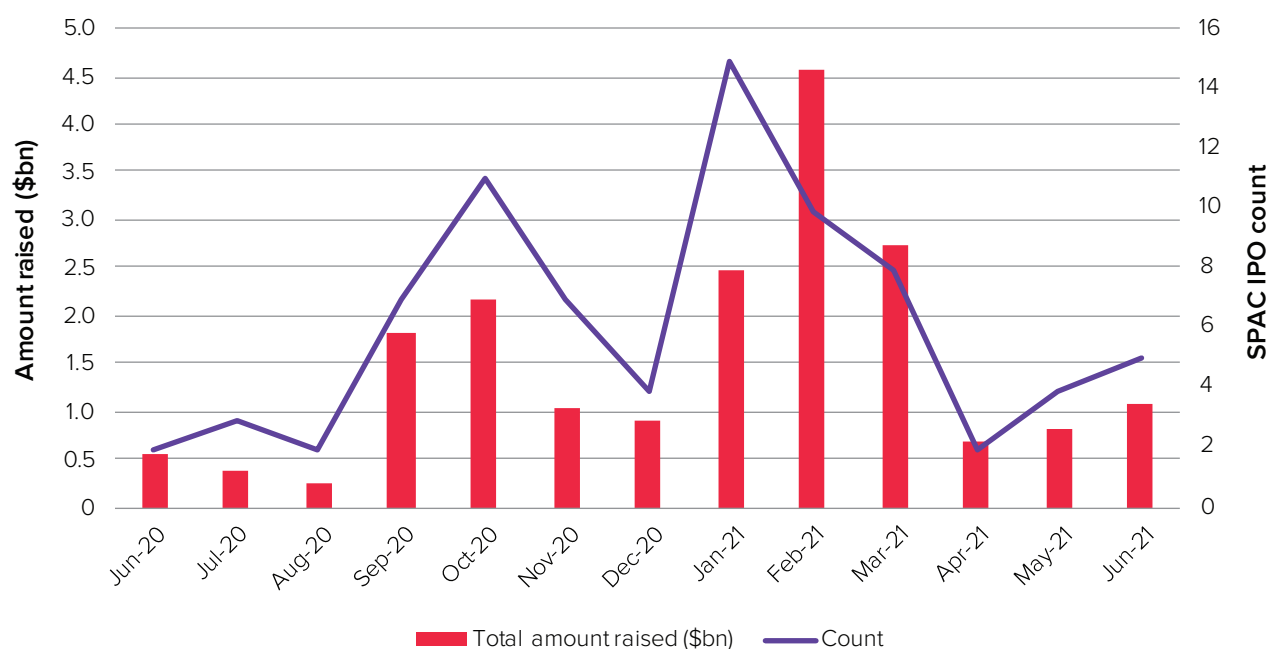
IPOs of Spacs – special purpose acquisition companies – have picked back up again after an SEC clampdown caused activity to drop off in April. These so-called blank-cheque companies offer private biotechs an alternative route to a stock market listing, via a combination with what is effectively an already listed cash shell.

Cerevel became the star of the Spac scene in June when encouraging early data in schizophrenia caused its stock to double. The Pfizer spin-out had been bought by the hedge fund Perceptive Advisors' second Spac, Arya Sciences II, in a deal completed last October.

Performance of other developers that arrived via a Spac is much more mixed, however, and more success stories are needed to assuage growing doubts about Spacs' ability to deliver high-quality companies. But with many of these vehicles hunting for a target in healthcare, more deals can be expected.

The chart below counts only Spacs that have floated with a disclosed focus on the life science or drug development sectors.

#### IPOs of healthcare-focused Spacs



Source: SpacInsider

More detailed analyses of this data can be found here:

[Spac listings slow as the hunt for deals continues](#)

[Biotech listings shows few signs of cooling](#)



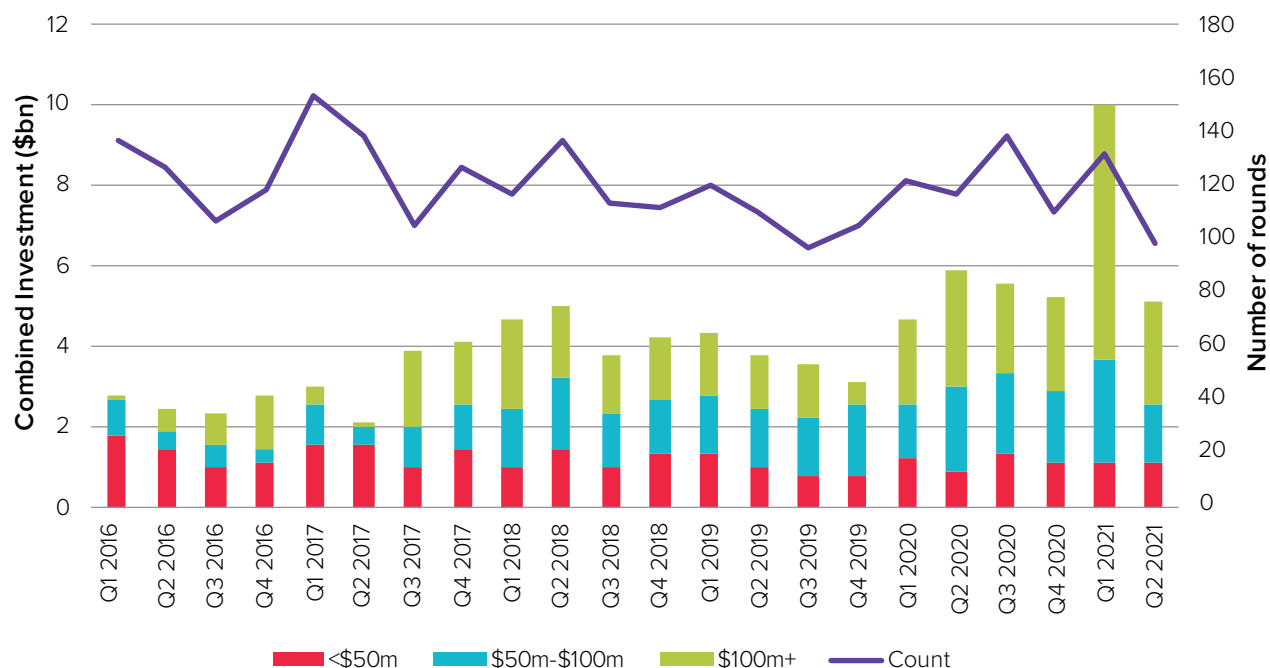
## Venture investors still love drug developers

With \$15bn raised in the first half of the year, another huge year is building for biopharma venture investment. That sum already matches 2019's total venture haul, and the year is well on the way to rival 2020's record figure, when young start-ups raised \$21.6bn.

Strong equity markets and a venture sector flush with cash means that financing wheels are turning quickly, driving both venture capital and IPO stats higher. This is largely because rich venture funds are able to quickly flip cashed-up private developers on to the stock market.

The vast majority of the financings counted here were raised by drug developers based in Europe and the US.

Quarterly biopharma VC rounds





Huge pre-IPO mega rounds are driving the top-line numbers higher. Financings of all stages are growing in size, however, as venture funds move to quickly deploy their cash.

As such, overinvestment is a concern right now: a surplus of cash can persuade companies to pursue higher-risk projects that are more likely to fail. The downstream fallout of this would be down rounds or even company collapses, neither of which is being seen at any volume.

For now, the steady flow of cash into the sector will be masking any such issues. When the money dries up the story will change, but there are few signs of that happening any time soon.

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### Biggest venture rounds of H1 2021

Company	Description	Sum raised	Round
Elevatebio	Cell and gene therapy researchers and company incubator	\$525m	Series C
EQRx	Development of affordable medicines, oncology initial focus	\$500m	Series B
Adagio Therapeutics	US-based; working on MAbs against coronaviruses, including SARS-CoV-2	\$336m	Series C
Insilico Medicine	Hong Kong-based; AI drug discovery	\$255m	Series C
Centessa Pharmaceuticals	Asset-centric developer created from merger of 10 private biotechs	\$250m	Series A

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More detailed analyses of this data and more can be found here:

[Venture investors still love drug developers](#)

[Biotech venture financing starts the year with a bang](#)

[The retreat of corporate venture funding?](#)

[Europe's venture boom trails the US](#)

Evaluate Vantage's recent in-depth report on venture financing, which includes analyses of investment stage and therapy area trends, can be downloaded for free here:

[Biopharma and venture capital: a deep dive](#)

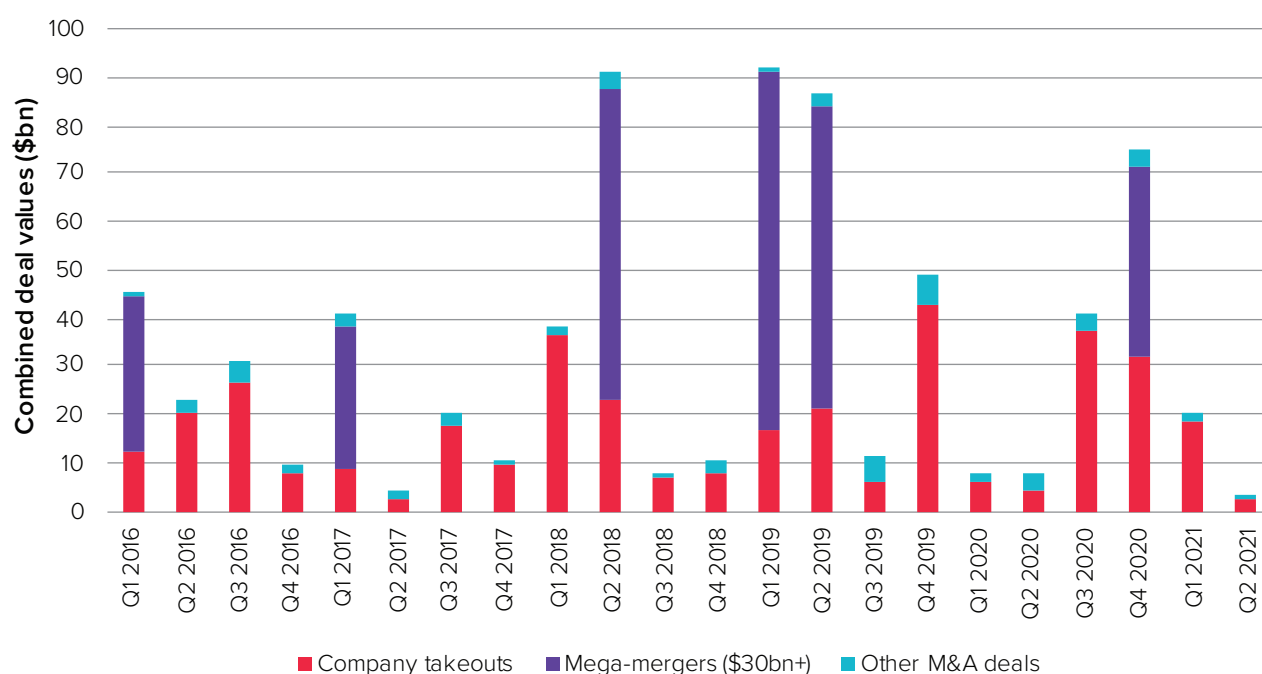


## Biopharma takeovers dry up but licensing deals still hot

The biopharma M&A scene started the year quietly and dried up further as the months progressed. Remarkably, only one takeover breached the \$500m mark in the second quarter – Morphosys's \$1.7bn takeover of Constellation – a deal that only just scrapes into the first half's top five.

Surging company valuations and a fruitful financing scene for smaller developers have been holding back buyouts for some time now. Investors waiting for a big ticket buyout with the potential to lift the sector will have to hope that the second half contains more substantial news.

### Combined biopharma M&A spend



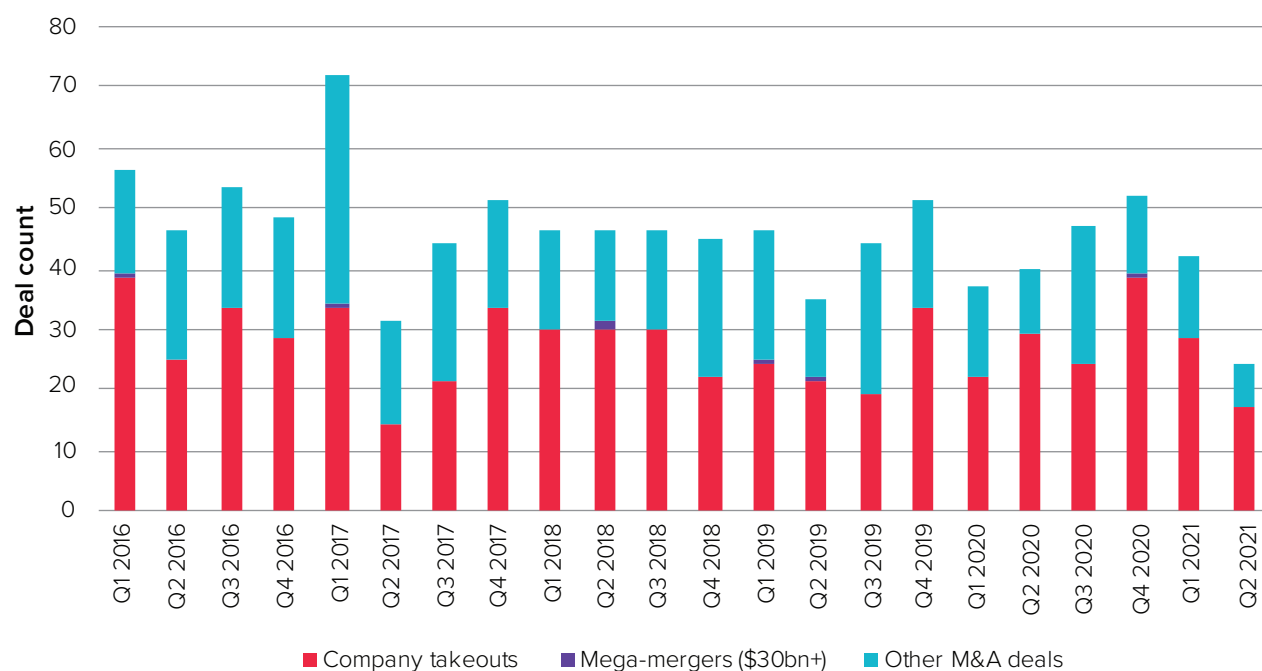




This analysis concerns transactions struck by pure-play drug developers only; other deal types, in the graphs above and below, refers to majority and minority stake purchases, product acquisitions and option deals.

The rumbling threat of regulatory action to counteract M&A, motivated by a desire to curb companies' pricing power and lower drug prices, could well be giving buyers pause. However the scope of these proposals remains vague, and it is notable that AstraZeneca's \$39bn move on Alexion, which contained overlaps, was cleared without conditions.

### Quarterly biopharma M&A deal counts





Jazz's \$7.2bn acquisition of the GW Pharmaceuticals remains 2021's biggest takeout. GW's pivot to focusing on rare childhood epilepsy and a softening stance towards cannabis-derived therapeutics finally made the UK developer an economically viable proposition – helped in no small part by the company moving its listing to Nasdaq.

Those hungry for M&A news will have taken some comfort from two August deals: Sanofi's buy of mRNA player Translate Bio for \$3.2bn and Bayer's August takeout of a preclinical platform company, Vividion, for \$1.5bn up front. This shows that buyers are willing to pay up when they feel they need to, even for technology that remains high risk, as in the latter case.

A greater volume of transactions would certainly be welcomed, however.

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### Biggest M&A deals announced in H1 2021

Acquirer	Target	Status	Value
Jazz Pharmaceuticals	GW Pharmaceuticals	Closed	\$7.2bn
Horizon Therapeutics	Viola Bio	Closed	\$3.1bn
Amgen	Five Prime Therapeutics	Closed	\$1.9bn
Merck & Co	Pandion Therapeutics	Closed	\$1.9bn
Morphosys	Constellation Pharmaceuticals	Closed	\$1.7bn

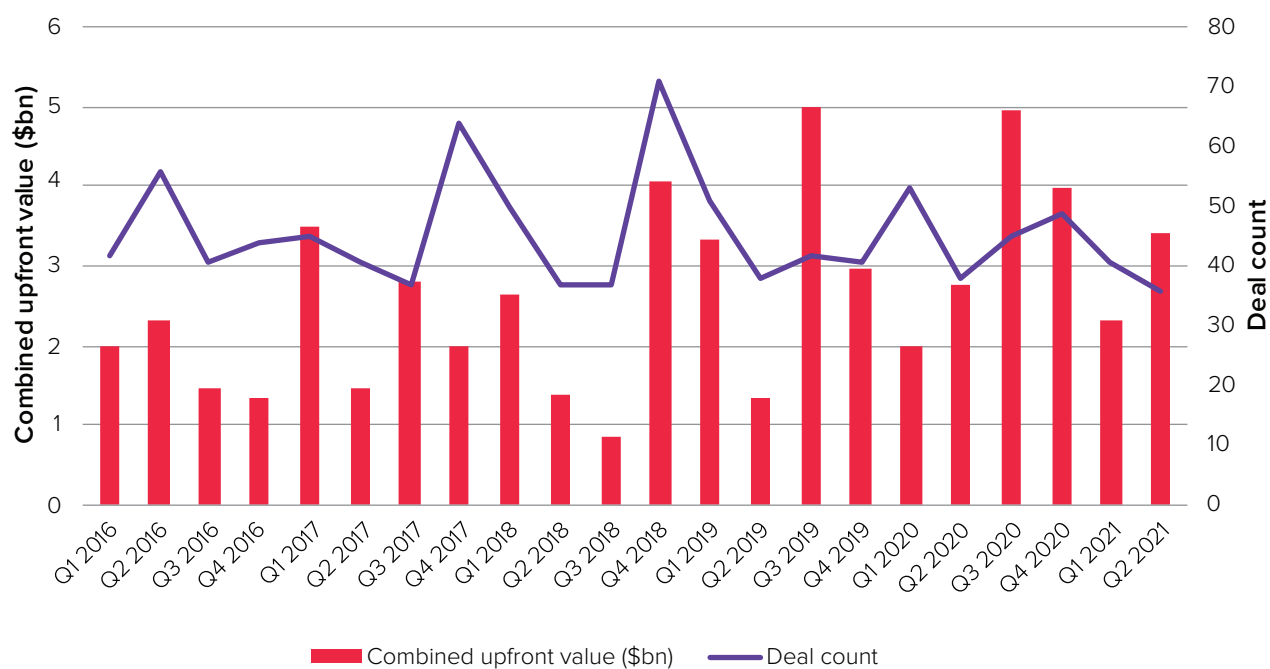


Biopharma is still striking deals, of course, as the buoyant licensing deal scene shows. Larger developers remain motivated to buy in innovation from elsewhere, albeit without taking out the entire target. Ballooning up-front fees suggest that this access is coming with an ever higher price tag, however.

Developers paid out a record \$13.7bn in up-front fees in 2020, according to *BioSciDB*, and this year is tracking not too far behind. This analysis concerns only licensing deals with a disclosed up-front value – these comprise about a third of all licensing transactions – while collaborations involving medical devices and diagnostics have been excluded.

The total deal value, which includes milestones payments and royalties that might never be paid out, is also not considered.

### Licensing deals with disclosed up-fronts

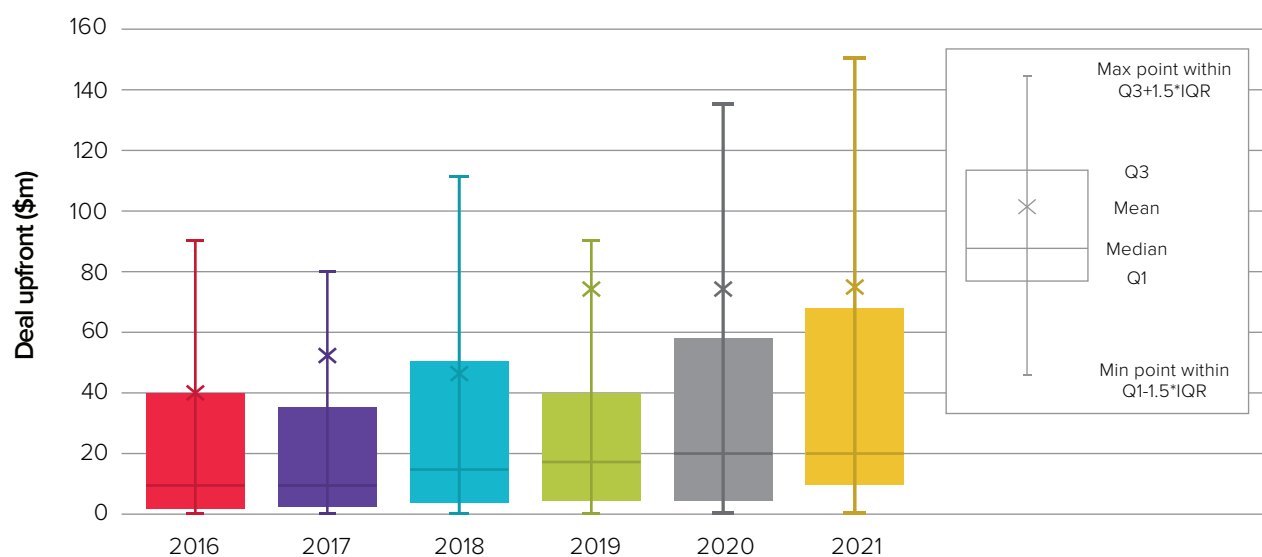




A deeper dive into the data finds that up-front costs have jumped markedly since 2016, on both mean and median measures. This upswell has been driven by deals struck over preclinical assets and those in phase 2.

Soaring valuations in the oncology and immunology space will also be responsible for price inflation being seen in these top line numbers. A separate *Evaluate Vantage* analysis found recently that the five largest phase 1 up fronts had all been struck since 2020, four of which involved cancer projects ([\*Bristol and Glaxo's oncology deals vault into the top five\*, June 18, 2021](#)).

### Licensing deal upfront distributions



The coloured boxes represent the middle quartiles of up-front fees, the whisker lines show maximum values, excluding outliers.

More detailed analyses of this data and more can be found here:

[Biopharma takeovers dry up](#)

[Biopharma throws grease on the deal wheels](#)

[Biopharma's ballooning licensing deal bill](#)



## Outlook

Concerns about overinvestment and inflated valuations in certain areas of the drug development sector look set to persist in the second half of 2021. Signs of a cooling are emerging, however, and these will be closely monitored in the coming months.

IPOs are not getting away as easily as a few months ago, while several firms from outside healthcare have withdrawn flotation plans. Should market conditions deteriorate more broadly the high-risk drug development sector will certainly feel it.

On the regulatory front the biggest event of the year – approval of Biogen’s Alzheimer’s drug Aduhelm – has happened. Some big decisions are still pending, however, and what the FDA decides to do with the Jak inhibitor class has perhaps the broadest repercussions.

Here, several verdicts have been delayed, including a first-time decision on Pfizer’s abrocitinib and important label expansions for Abbvie’s potential blockbuster Rinvoq. The strength of any efforts by the regulator to cap the use of these agents will be scoured for read-throughs to other areas.

Another big verdict looming concerns Argenx’s efgartigimod. Not only is this a big test of a small, European developer’s ability to cross the finish line, an approval would be a first for the FcRn class. This novel mechanism, which addresses various autoimmune conditions, has spurred much deal making and there are several other projects coming along behind.

Other potential clouds on the horizon include any fallout from Aduhelm’s controversial approval. For now, the FDA is considered one of biopharma’s friends, but this could change should a permanent commissioner – whose identity remains unknown – arrive with a mandate to tighten the screws on approvals.

The biopharma sector remains largely well supported by investors and awash with cash, however, so is well positioned should storms arrive.

Five biggest pending FDA decisions in 2021 (ranked on 2026 forecast sales)				
Project	Indication	Company	Pdufa date	2026e sales
Efgartigimod	Generalised myasthenia gravis	Argenx	Dec 17	\$3.0bn
Bimekizumab	Psoriasis	UCB	Oct 15	\$2.0bn
TransCon Growth Hormone (lonapegsomatropin)	Paediatric growth hormone deficiency	Ascendis Pharma	Sep 25 (extended by three months)	\$1.5bn
Faricimab	Wet age-related macular degeneration and diabetic macular oedema	Roche/Chugai	Estimated by YE	\$1.1bn
Abrocitinib	Atopic dermatitis	Pfizer	Decision delayed pending safety review	\$1.0bn

Source: Evaluate Pharma



# Medtech Half Year Review 2021

## Role reversal for large-cap medtechs

Elective procedures are back with a vengeance. A glance at the big-cap companies whose share prices grew the most over the first half of 2021 reveals robotic surgery, imaging and hearing aid developers to have benefited from the relaxing of rules banning non-urgent healthcare appointments as Covid-19 vaccination programmes take effect.

And the converse is true of the fallers, with telemedicine and Covid-19 testing groups having shed the most value over the past six months. These technologies might be here to stay, but demand for them will have fallen from their lockdown peak.

The overall climate for medical device, diagnostics and digital health companies, as indicated by health tech indices, is steadfastly average – and therefore far better than it was a year ago. Perhaps this indicates a belief among investors that the sector is returning to normal after a turbulent 18 months.

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### Indices

Stock index	% change in H1 2021
Refinitiv Europe Healthcare	7%
Dow Jones U.S. Medical Equipment Index	10%
S&P Composite 1500 HealthCare Equipment & Supplies	10%

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Judging by the extent of share price gains and losses the market is indeed more placid than it was last year. The top riser, China's Microport Scientific, saw a 68% uptick in its US listing, markedly lower than the biggest climb in any period since the first half of 2017.

Much of the resurgence in demand for Microport's devices comes from its home market. Official figures suggest that China has controlled Covid-19 transmission very effectively since April 2020, and hospitals are very much open for business.



## Large cap (\$10bn+) medtech companies: top risers and fallers in H1 2021

	Share price 6-mth change	Market cap at Jun 30 (\$bn)	Market cap 6-mth change (\$bn)
<b>Top 5 risers</b>			
Microport Scientific (\$)	68%	16.2	6.4
Hitachi (¥)	56%	56.5	19.1
Sonova (SFr)	51%	24.3	8.4
Demant (DKr)	47%	13.8	4.7
Straumann (SFr)	43%	26.0	8.0
<b>Top 5 fallers</b>			
Teladoc Health (\$)	-17%	25.7	-3.3
Biomérieux (€)	-15%	14.1	-2.0
Masimo (\$)	-10%	13.3	-1.4
Hologic (\$)	-8%	17.1	-1.6
Exact Sciences (\$)	-6%	21.3	1.4

The presence of two hearing aid manufacturers and a dental company in the risers also points to a reopening. Stock in Sonova and Demant crashed horribly in March 2020 as shareholders realised that lockdowns could leave hearing aid users unable to replace or upgrade their devices, and new customers would also be thin on the ground.

Reversals of fortunes are also clear in the fallers. Teladoc, for example, which as the name suggests specialises in connecting patients with doctors via phone and video calls, was the top riser last year, its shares climbing 139% across 2020. Now that patients can visit their doctors in person investor confidence has ebbed.

Both Biomérieux, which has developed diagnostics for Covid-19, and the patient monitoring specialist Masimo also appeared in the risers in last July's analysis.



At some point, presumably, the Covid-19 pandemic will no longer be the major influence on the largest medtech companies' share price movements. For now its retreat means that developers of less urgent technologies are riding high.

Among smaller device makers, however, the improving pandemic situation in the West has been the main driver of the largest share price rises in the first half of the year. Groups whose products are used in elective surgeries are soaring on increased demand as lockdown measures lift.

Interestingly, though, the biggest share price declines among these two cohorts have nothing to do with the pandemic, instead being attributable to a partnering bust-up and a reimbursement catastrophe.

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#### Other significant risers and fallers in H1 2021 (ranked on market cap)

	Share price 6-mth change	Market cap at Jun 30 (\$m)	Market cap 6-mth change (\$m)
<b>Top 5 risers</b>			
Getinge (SKr)	68%	9,814	4,287
Penumbra (\$)	57%	9,998	3,644
Sientra (\$)	105%	459	263
Cutera (\$)	103%	880	455
Castlight Health (\$)	102%	316	162
<b>Top 5 worst performers</b>			
Haemonetics (\$)	-44%	3,396	-2,634
Asahi Intecc (¥)	-29%	6,393	-2,937
Quidel (\$)	-29%	5,452	-2,105
Irhythm Technologies (\$)	-72%	1,850	-4,999
Nanosonics (AUS\$)	-30%	1,321	-401

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Irhythm Technologies suffered a shocking decline in fortunes in the first half of this year. It had been one of the top risers of last year, but has now dropped out of the mid-cap cohort entirely to lead the small-cap fallers.

This is all to do with a sharp cut in reimbursement for Irhythm's wearable cardiac monitor, Zio XT, a stick-on designed to detect irregular heartbeat. At the half-year point Irhythm was \$5bn poorer than it had been at the end of 2020, a neat illustration of a nightmare scenario for a one-product company.

More detailed analyses of these data can be found here:

[Role reversal for large-cap medtechs](#)

[Smaller medtechs suffer, but not from Covid-19](#)





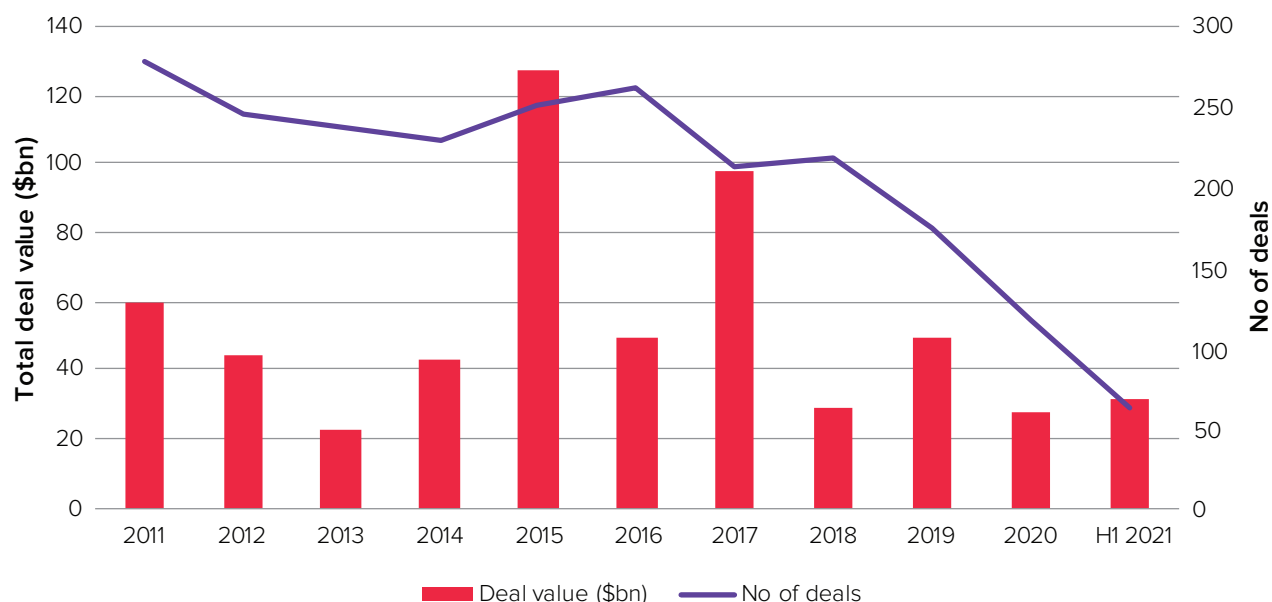
## Medtech gears up for a vintage acquisition year

Judging by the merger and acquisition activity among medical device makers so far this year the pandemic is a thing of the past. Deals worth \$31.5bn were closed in the first six months of 2021, outstripping the total for all of 2020.

The main factor behind this resurgence of acquiring is probably pent-up demand owing to the deals put on hold last year. Only 118 transactions closed in 2020, less than half the 10-year average, as buyers waited out the Covid-19 storm.

The below analysis, as with all data in the medtech section of this report, considers deals done by device, diagnostics and digital health companies, excluding drug makers. It also excludes Spac deals, the mechanism by which half a dozen medical technology groups have gone public this year, collectively raising billions of dollars.

### Medtech M&A over the past decade





The biggest deal to close this year was done by a company keen to bounce back from the Covid-19 doldrums.

Siemens Healthineers was by no means the worst-hit big medtech during the lockdown period, but it was hit. Its \$16.4bn move on Varian puts it in a commanding position in diagnostic imaging and radiotherapy just as hospitals are reopening for more routine procedures in which these technologies are used.

Other deals look in the other direction. Philips bought Biotelemetry for its remote patient monitoring technology, reasoning that the shift to telehealth, already apparent before the pandemic but very much accelerated by it, is here to stay.

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### Top 5 deals closed in H1 2021

Completion date	Acquirer	Target	Value	M&A focus
Apr 15	Siemens Healthineers	Varian Medical Systems	\$16.4bn	Diagnostic imaging
Jun 2	Steris	Cantel Medical	\$4.6bn	Endoscopy, general & plastic surgery, nephrology
Feb 9	Philips	Biotelemetry	\$2.8bn	Patient monitoring
Jan 5	Exact Sciences	Thrive Earlier Detection	\$2.2bn	In vitro diagnostics - liquid biopsy
Jun 17	Hologic	Mobidiag	\$795m	In vitro diagnostics - infection

*Source: Evaluate Medtech*



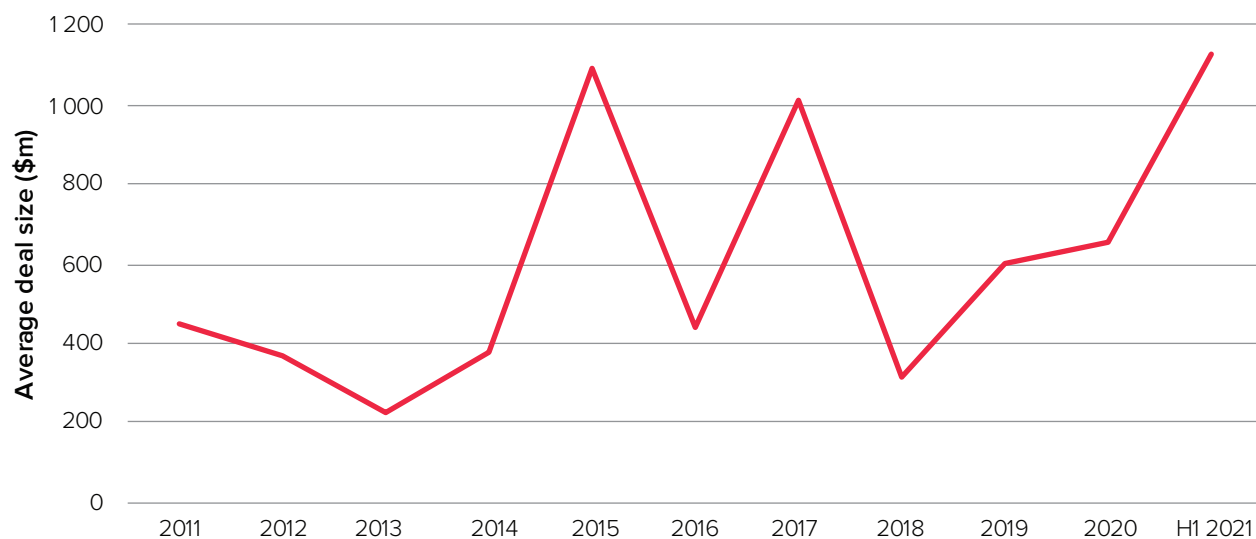
With mergers worth a total of \$11.6bn currently open, 2021 could end up having the biggest annual M&A total since 2017.

There are, however, reasons to believe that the rate of M&A deal making might slow in the second half of 2021. Several publicly listed companies previously talked of as targets have seen startling growth in valuations, which might price them out of a potential buyer's reach.

Still, deals have been relatively substantial this year, and the average deal value in the first half of 2021 was \$1.1bn, the largest amount for a decade.

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#### Medtech M&A average deal size



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A more detailed analysis of these data can be found here:

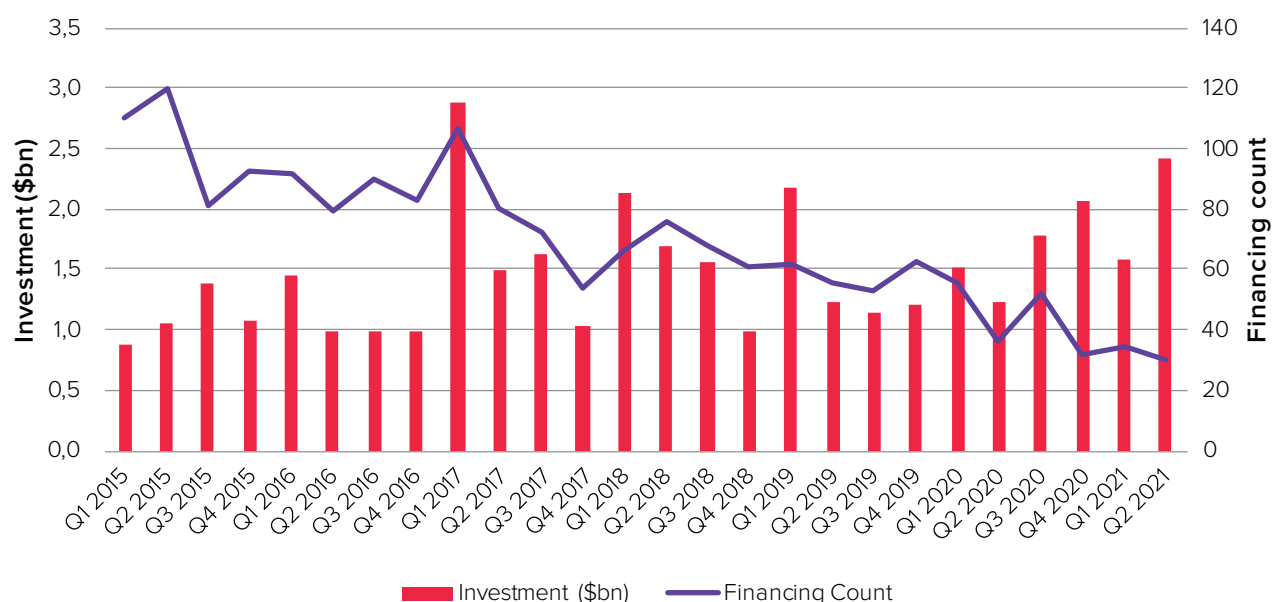
[Medtech gears up for a vintage M&A year](#)



## Medtech venture funding hits new heights

An eye-watering \$4bn has been invested in private medtechs between January and June 2021, and the second quarter's haul of \$2.4bn is the largest since the first quarter of 2017. Easy money has been around for a while, and M&A and IPO deals are getting done at very healthy rates, so backers clearly feel justified in making substantial bets.

Medtech quarterly VC investments 2015-2021



As with the greatest share price moves among listed medtechs, the pandemic has driven much of the action. Some of the biggest rounds have gone to companies active in telehealth, digital therapies and home treatment, all of which have seen increased uptake under lockdown. Covid-19 diagnostics developers, too, are present and correct.

Telehealth companies such as the Swedish company Kry, which does business in the UK and US as Livi, and Zocdoc, all facilitate virtual doctor's appointments and electronic prescriptions. Wuxi and Binx have both developed tests for Covid-19, and Color straddles telehealth and testing, having developed its own Covid-19 diagnostics and offering a tech to schedule these, and other, tests.



## Top 10 VC rounds of H1 2021

Date	Company	Investment	Round	Focus
Jun 28	CMR Surgical	\$600m	Series D	Robotic surgery
Apr 27	Livi/Kry	\$316m	Series D	Telehealth
Jun 23	Quanta	\$245m	Series D	Home dialysis
Jan 4	Color	\$167m	Series D	In vitro diagnostics
Feb 11	ZocDoc	\$150m	Undisclosed	Telehealth
Feb 23	Wuxi Diagnostics	\$150m	Series B	In vitro diagnostics
Apr 13	CeQur	\$115m	Series C	Diabetic care
May 26	Akili Interactive Labs	\$110m	Series D	Digital health
Feb 16	Mainstay Medical	\$108m	Series D	Neurology
May 27	Binx Health	\$104m	Series E	In vitro diagnostics

Source: Evaluate Medtech

There are also signs that VCs have their eyes on the post-Covid-19 era. One of the last rounds of the first half was also the biggest: the UK-based robotic surgery company CMR Surgical, a unicorn since 2019, scored a £425m (\$600m) series D, which it will use to increase sales of Versius, its system to aid soft tissue procedures.

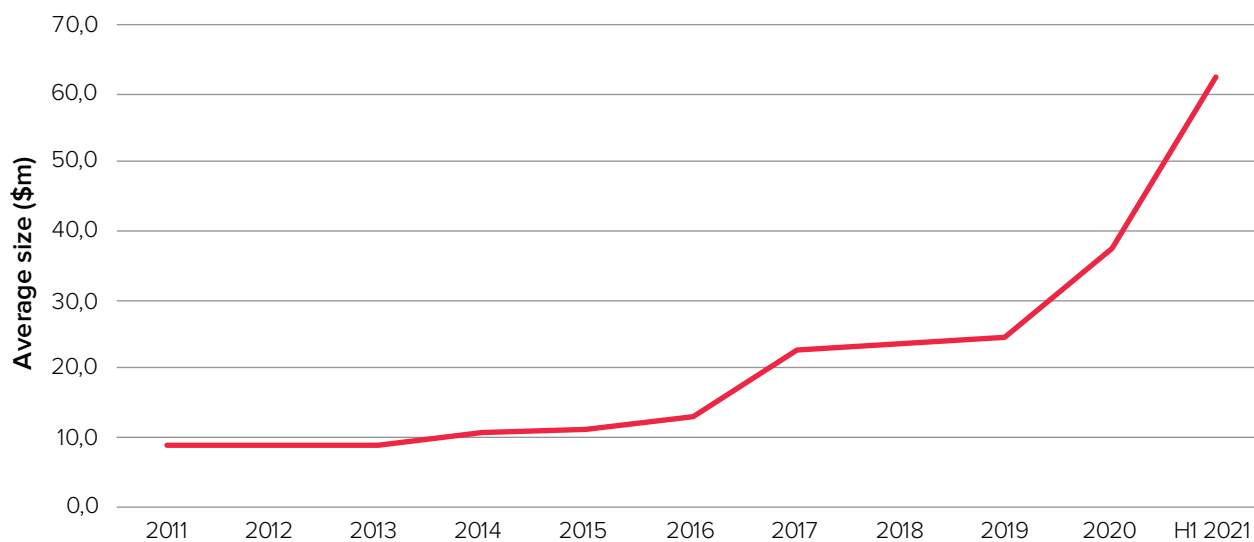
The machine is on sale in Europe, Australia, India and the Middle East, and US approval could come this year. Taking share from the market leader, Intuitive Surgical, will be no easy task, but VCs clearly have faith.

These biggest rounds are not going to start-ups; the companies in the top 10 are an average of 10 years old. And the overall trend in the sector to larger, later rounds has reached a new pitch.

Only nine rounds in the first half of this year were series A, and just three were seed capital. For the true start-ups the financing climate is not nearly as rosy as it might first appear.



### Average size of Medtech VC deals 2011-2021



More detailed analyses of these data and more can be found here:

[Medtech venture funding hits new heights](#)

[Venture-backed medtechs rush for the exit](#)

[Medtech venture backers go in early](#)



## Floating medtechs go big or go home

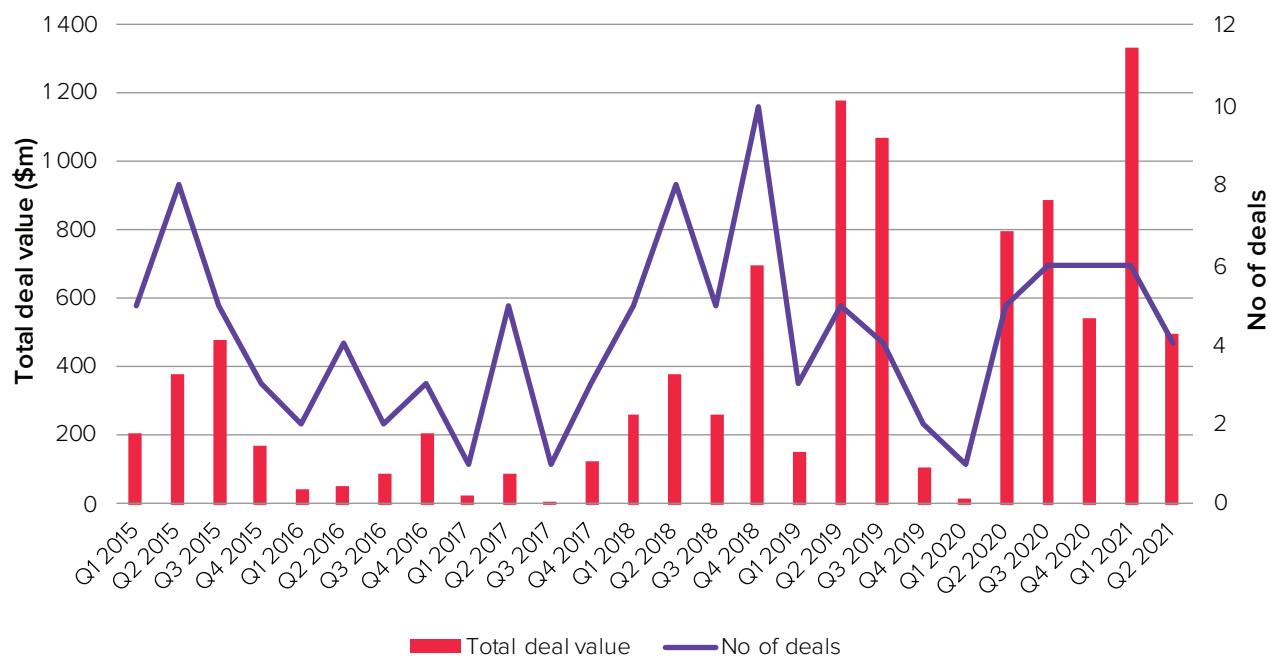
So far in 2021 the public markets have proved remarkably receptive to floating medical device companies. 10 device and diagnostics groups listed on Western exchanges in the first half, and the total raised, at \$3.3bn, is the largest six-month figure for three years.

The second quarter did see a decline from the first in both the number of flotations and the amount raised, but it is surely too early to conclude that the window is creaking shut.

The first IPO of 2021 was also the biggest. Ortho-Clinical Diagnostics, formerly a J&J unit sold to private equity in 2014, floated on Nasdaq in a deal worth nearly \$1.5bn. These mega-IPOs, once unheard of in the medical device sector, are becoming more common: one billion dollar-plus IPO has occurred every year since 2016, with the exception of 2017.

The chart below does not include Ortho-Clinical's IPO or any of the other megadeals, to give a better picture of the underlying IPO trends in the medical technology industry.

Medtech quarterly IPOs 2015-2021





Ortho-Clinical is unusual in that it had to price its offering at a steep discount to its preannounced range to get investors on board. The only other group that had to do this was the orthopaedics firm Bioventus, which went out with a 13% haircut.

The preponderance of in vitro diagnostics companies among the medtechs that have gone public so far this year is a continuation of a trend that has been clear for some time; of the 19 medtechs to float last year, six were diagnostics groups.

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### 5 biggest medtech IPOs of H1 2021

Date	Company	Focus	Amount raised	Discount/ premium	Share price change to June 30
Jan 28	Ortho-Clinical Diagnostics	In vitro diagnostics	\$1.5bn	-21%	26%
Feb 11	Signify Health	Healthcare IT	\$649m	17%	27%
May 27	Singular Genomics Systems	In vitro diagnostics	\$258m	5%	25%
Feb 11	Talis Biomedical	In vitro diagnostics	\$254m	7%	-31%
Feb 5	Lucira Health	In vitro diagnostics	\$176m	6%	-61%

*All listings on the Nasdaq, except Signify on the NYSE.  
Source: Evaluate Medtech, company websites.*





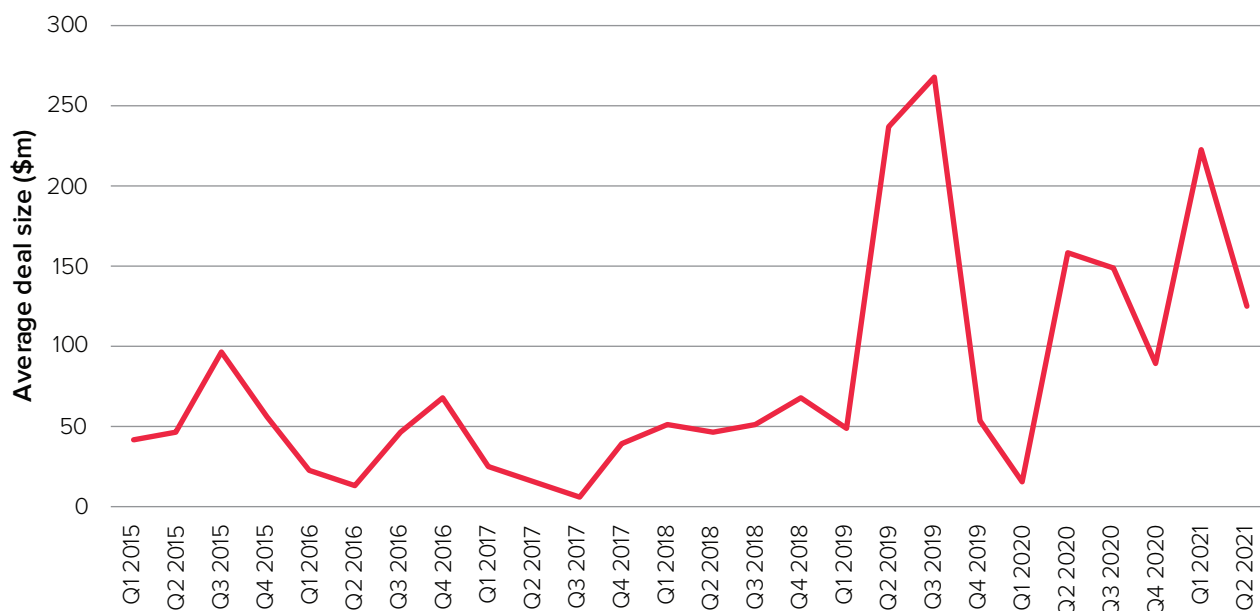
What is intriguing is how poorly some of this year's diagnostics flotations have done once on the stock market.

Lucira launched an upsized offering in early February at \$17, and soon hit a high of \$37, but shed value rapidly after that, becoming the worst-performing market debutante of the first half. It is likely that the falling demand for Covid-19 testing in the US is at least partly to blame for Lucira's disappointing showing – something that would also help explain Talis Biomedical's 31% share price fall.

The overall message for device makers wishing to float appears to be: go big or go home. All but one of the medtech deals raised at least \$100m. And, even excluding Ortho-Clinical's megadeal, the next largest medtech IPO – Signify Health's \$649m offering on the NYSE – dwarfed biotech's biggest.

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#### Average Medtech IPO size 2015-2021



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A more detailed analysis of these data can be found here:

[Floating medtechs go big or go home](#)



## The FDA takes its foot off the pedal

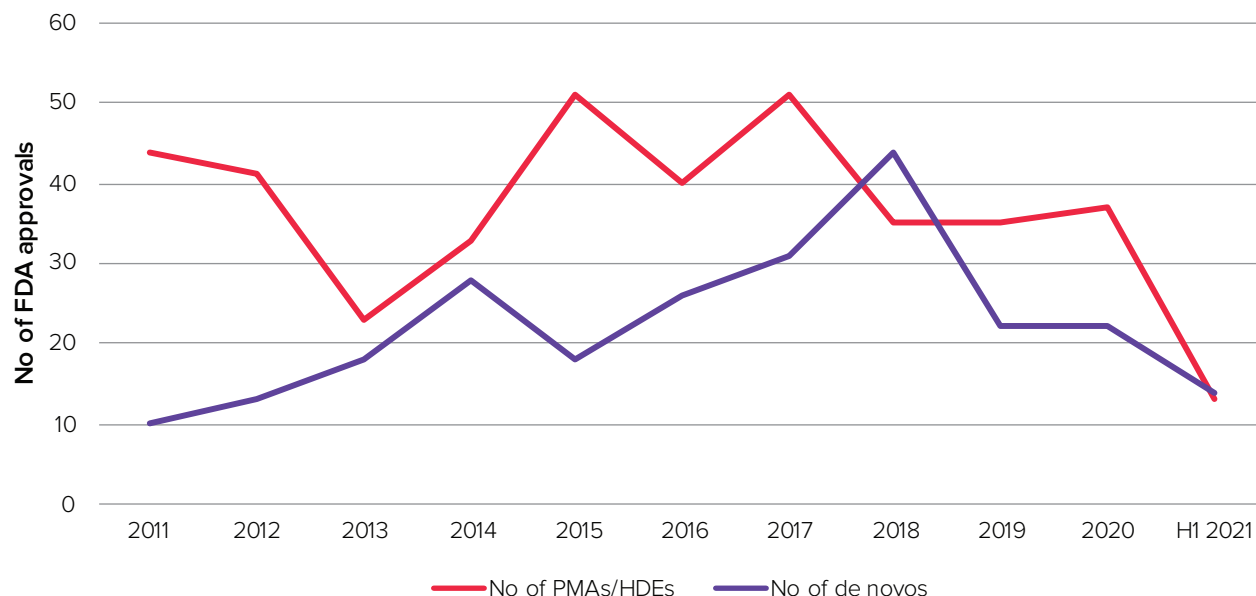
Last year the FDA kept up a scorching pace of medical device approvals in tandem with rushing Covid-19 diagnostics, and other devices necessary to aid with the pandemic, to market via emergency authorisations.

Now it seems that burnout might have hit the agency. During the first six months of 2021 the FDA awarded just 12 first-time premarket approvals and one humanitarian device exemption. If this rate is maintained throughout the second half this year will see the fewest high-risk devices reach the US market since 2013.

A different trend is apparent when it comes to low-risk novel devices. With 14 de novo 510(k) clearances awarded in the first half of 2021 the full-year total could end up higher than that for 2020 or the year before.

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### Medtech approvals over the last decade





In fairness, the agency had warned that a slowdown might be coming. In April Jeff Shuren and William Maisel of the FDA's Center for Devices and Radiological Health (CDRH) wrote that the unprecedented Covid-19-related workload has put a significant strain on the CDRH's resources, particularly within the office that deals with in vitro diagnostics submissions.

Mr Shuren and Mr Maisel added that there was a backlog of non-Covid-19 files pending review, and said that the CDRH expected delays in meeting review timelines for some of these submissions.

In fact, while fewer devices seem to be getting approved, the speed at which the agency is reviewing those that do get the nod is very respectable. The high-risk innovative devices, which must go through either the PMA or HDE routes, received approval in just over a year, on average, while the low-risk products were faster still.

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## H1 2021's approvals by therapy area

Evaluate Medtech classification	Number of PMAs/ HDEs	Avg approval time (mths)	Number of de novos	Avg approval time (mths)
Anaesthesia & respiratory	-	-	1	10.5
Cardiology	5	10.9	4	13.2
Ear, nose & throat	1	15.0	1	12.9
Gastroenterology	-	-	1	7.0
General & plastic surgery	-	-	1	22.4
In vitro diagnostics	3	16.7	1	9.9
Neurology	-	-	2	7.3
Ophthalmics	1	11.1	1	10.2
Orthopaedics	1	7.6	-	-
Physical medicine	-	-	2	10.2
Radiology	2	10.1	-	-
<b>Total</b>	<b>13</b>	<b>-</b>	<b>14</b>	<b>-</b>
<b>Average</b>	<b>-</b>	<b>12.2</b>	<b>-</b>	<b>11.5</b>

Source: Evaluate Medtech, FDA



The impact of Covid-19 can be seen in the types of product receiving approval. In previous periods, the most approvals have almost always gone to in vitro diagnostics – but not this time. Only four assays were given the agency’s blessing, as the diagnostics wing of the regulator concentrated on evaluating Covid-19 tests via the emergency us authorisation pathway.

One of the few diagnostics approvals is particularly notable. The French firm Biomérieux obtained de novo clearance of its Biofire Respiratory Panel 2.1, which tests for a range of bacterial and viral pathogens including the virus that causes Covid-19 – the first time a Covid-19 test has received a formal approval, rather than an emergency authorisation.

Since this kind of authorisation lapses after the state of emergency in the US is lifted, the move shows Biomérieux is looking beyond the end of the pandemic. It is highly likely that other diagnostics groups will also seek clearance or approval for their Covid-19 tests.

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A more detailed analysis of these data can be found here:

[The FDA takes its foot off the pedal](#)



## Outlook

The first half of 2021 showed a sector recovering from the pandemic doldrums. The second half ought to see this continue, though there could be one potential brake on growth on the regulatory side.

In terms of M&A, the picture is fairly rosy, with more than \$10bn-worth of deals announced in January alone. 2021 had the strongest first quarter for device maker deal-making since 2016. Since then, the pace has slowed somewhat, but deals worth \$11.6bn remain open.

Many medtechs, particularly Covid-19 diagnostics makers, are sitting on considerable cash piles and looking to spend, so it seems likely that by the end of the year 2021 will have seen a pretty healthy sum spent on acquiring innovative healthcare tech.

No retrenchment in private financings is likely, either. Private medtechs can tap vast amounts of cash with relative ease, aided by increased participation by non-traditional venture funders, such as corporate VCs whose coffers are swollen with cash reaped during the pandemic, and players such as family offices and hedge funds.

With the public markets continuing to show enthusiasm, the buoyant IPO scene is also likely to continue for the next few months at least. In combination with the sudden explosion of special purpose acquisition companies looking for device makers and digital health groups to buy, the opportunities for exits are expanding, further spurring venture investors.

One uncertainty for the medtech industry in the back half of the year will be the FDA's possible behaviour. The appointment of a new permanent commissioner could mean the pace of approvals picks up again – or it could go the other way, with more thorough scrutiny, particularly of higher-risk devices, driving approvals down.

The latter would be alarming for the medtech sector. If companies cannot get their products to market in a reasonable timeframe even the most generous investors and buyers will wonder whether their cash might not be better spent elsewhere.



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