BIOPHARMAWATCH RESEARCH · NOVEMBER 2026

The Biotech Anatomy 2026

What every readout, FDA decision, pipeline asset and specialist-fund position since 2021 says about each disease area and drug type

1,640
data readouts from 394 companies

373
first FDA decisions on new drugs, 2021 to 2026

15,697
pipeline assets by disease and drug type

$137B
held by 45 specialist biotech funds (13F, Q2 2026)

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biopharmawatch.com · Data as of 4 Nov 2026 · Not investment advice

Ten things the data says that the headlines do not

Each finding is one slide in this report, with its sample size and its source

01 **91% / 47%**
of readouts are called positive by the company / of those, the share where the stock rose

02 **44% vs 24%**
CRL rate on a new drug's first FDA decision: first-time sponsors vs experienced ones

03 **59%**
of biologics from first-time sponsors drew a CRL (13 of 22); small molecules 40%

04 **33% vs 8%**
of Phase 2 programmes reached Phase 3: immunology vs gastrointestinal

05 **60%**
of biotechs sold stock within a week of a 60%+ jump on data, most the same day (a random week: 1.8%)

06 **3.6x**
growth in specialist-fund money in metabolic and endocrine names since 2021, against 1.3x for the whole book

07 **$12.4B**
of specialist-fund stock left through 24 takeouts in a year; Lilly and Merck bought three holdings each

08 **37% vs 36%**
of CRLs vs approvals where specialist funds had cut the stock the quarter before: no warning in 13Fs

09 **29% vs 7%**
of oncology vs rare-disease biotechs trade below their cash

10 **78% vs 24%**
of active programmes held by big pharma: infectious disease vs rare disease

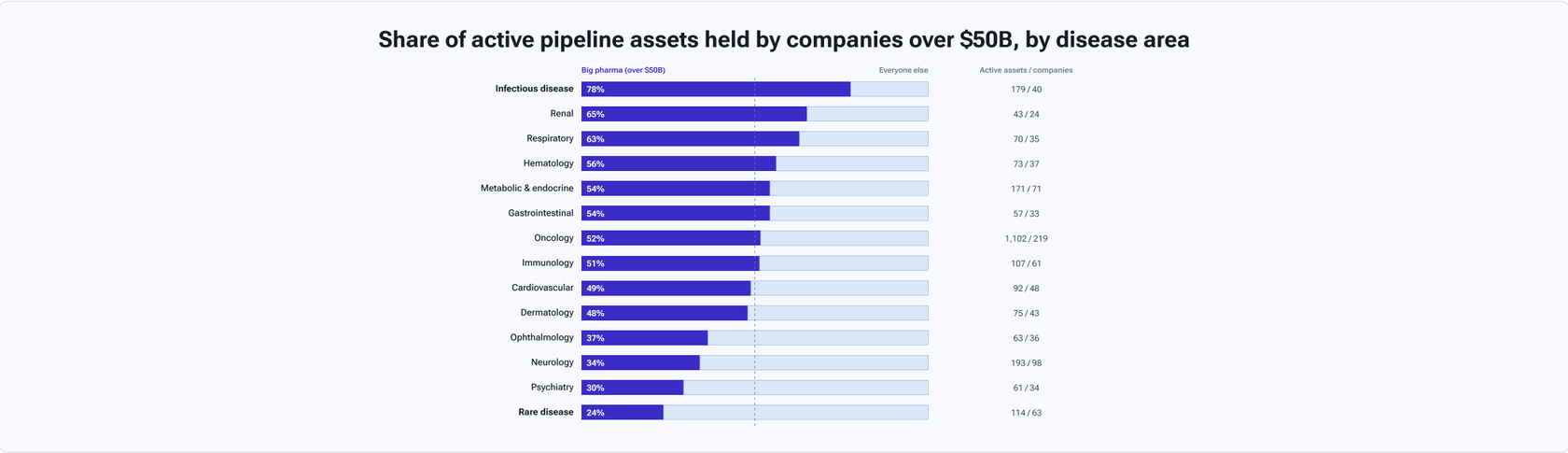
- The pattern that repeats: **what a company says and what the market pays are two different things**, and the gap depends on the disease and the drug type.

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Source: SEC filings, company releases and BiopharmaWatch data

Big pharma holds 78% of infectious-disease programmes, but only 24% in rare disease

Rare disease, psychiatry, neurology and ophthalmology are biotech ground: companies under $50B hold two-thirds or more of active programmes



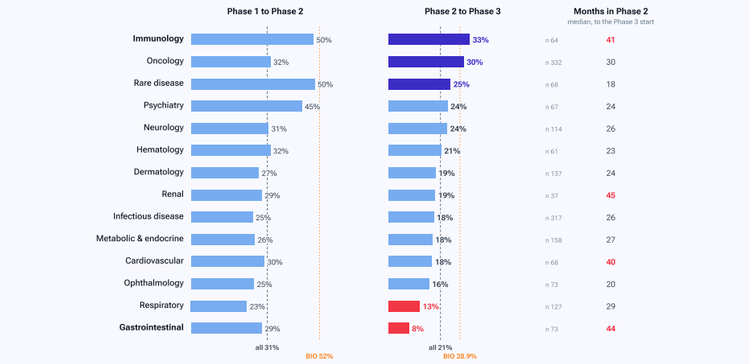
- Infectious disease is a big-pharma market: **GSK** $GSK alone runs 40 active programmes, mostly vaccines.
- Oncology is the most crowded and the most fragmented: **1,102 active assets** across 219 companies. Outside big pharma, 532 assets sit with 201 biotechs, and the top five hold only 18%.
- Respiratory (63%) and renal (65%) look like infectious disease: a few large owners, few independent biotechs.

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Source: SEC filings, company releases and BiopharmaWatch data

Phase 2 splits disease areas: 33% of immunology programmes reach Phase 3, 8% in GI

Programmes that entered a phase in 2012 to 2020, followed for at least four years. Across all areas 31% moved from Phase 1 to 2 and 21% from Phase 2 to 3



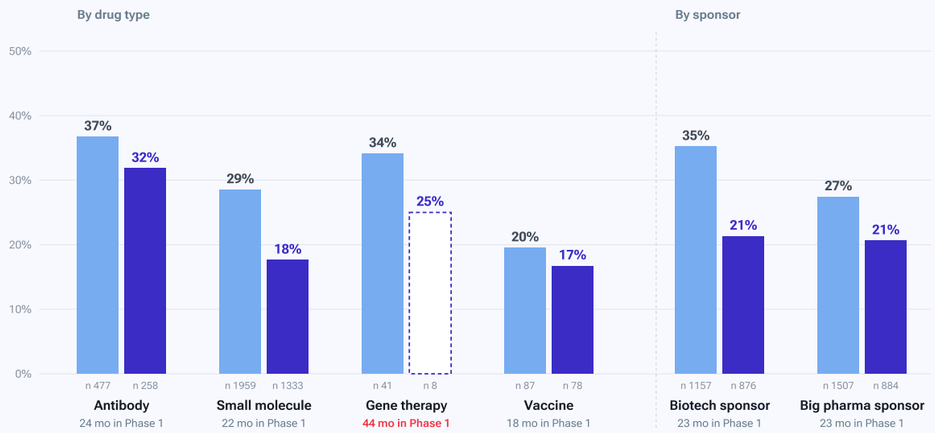
- Oncology is crowded and still advances well: **30%** of Phase 2 programmes reached Phase 3, second only to immunology.
- Gastrointestinal, respiratory and ophthalmology stall at Phase 2. Gastrointestinal programmes that did advance spent a median **44 months** in Phase 2.
- Immunology advanced most often: **33%** of its Phase 2 programmes reached Phase 3, against BIO's industry benchmark in orange.

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Source: SEC filings, company releases and BiopharmaWatch data

Antibodies reach Phase 3 from Phase 2 almost twice as often as small molecules: 32% vs 18%

Biotechs carry Phase 1 programmes forward more often than big pharma (35% vs 27%), but by Phase 2 both land at 21%



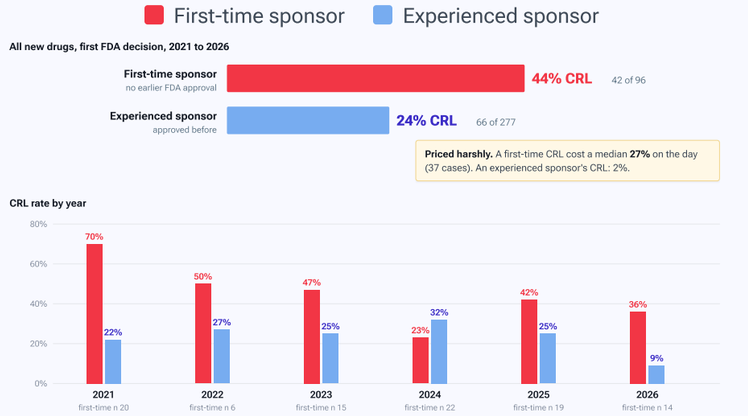
- An antibody usually starts from a target the field already understands, with fewer off-target surprises. It shows: **82 of 258** antibody Phase 2 programmes reached Phase 3, against 235 of 1,333 small molecules.
- Big pharma prunes early: it starts more Phase 1 programmes and drops more of them. A biotech with one or two drugs keeps going.
- Gene therapy is slow before it is risky: a median **44 months** in Phase 1, twice the 22 months of a small molecule. Vaccines advance least often (20% from Phase 1).

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Source: SEC filings, company releases and BiopharmaWatch data

First-time FDA sponsors get a CRL nearly twice as often as experienced ones

Since 2021, 44% of first FDA decisions on new drugs from companies with no prior approval were CRLs, against 24% for experienced sponsors



- Across the **first FDA decision on 373 new drugs** since 2021, **42 of 96** first-time sponsors got a CRL, against 66 of 277 experienced ones.
- The gap held in five of six years (2024 was the exception). An FDA-commissioned review of 2002 to 2004 found the same: first-cycle approval of 30% for first-timers vs 51%.
- The biggest one-day losses on a first-time CRL:
  - **Galera** $GRTX **-86%**
  - **Applied** $APLT **-80%**
  - **Replimune Group** $REPL **-73%**
  - **BeyondSpring** $BYSI **-65%**

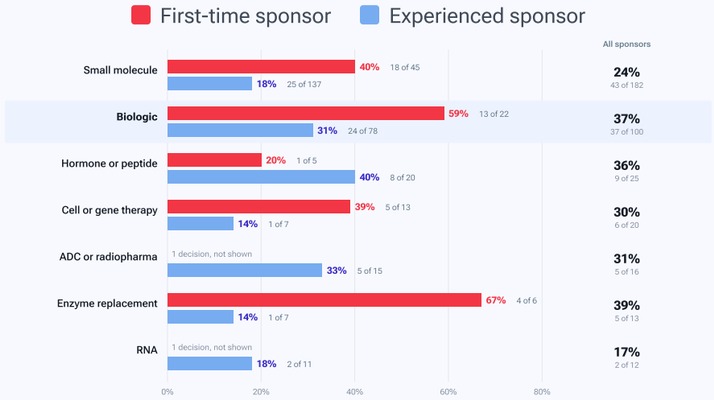
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Source: SEC filings, company releases and BiopharmaWatch data

Biologics from first-time sponsors drew a CRL 59% of the time. Small molecules: 40%

The drug type matters as much as the sponsor: experienced companies still got a CRL on 31% of biologics, against 18% of small molecules

CRL rate on the first FDA decision, by drug type and sponsor experience, 2021 to 2026



- A biologic is approved with its factory: the FDA inspects the plant before it licenses the product. A first-time sponsor usually depends on a contract manufacturer it has never filed with.
- **13 of 22** first-time biologics got a CRL, against 18 of 45 first-time small molecules. Experienced sponsors show the same gap: 31% vs 18%.
- RNA drugs were the cleanest: **2 CRLs in 12** decisions, nearly all from experienced sponsors. First-time enzyme replacement: 4 of 6.

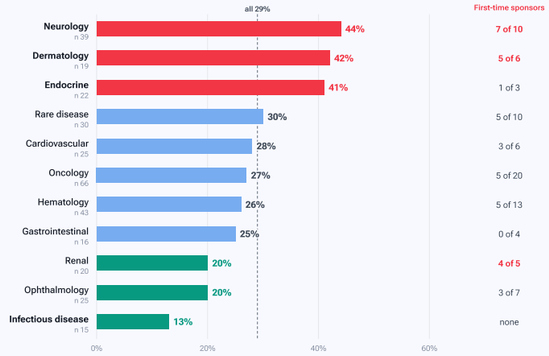
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Source: SEC filings, company releases and BiopharmaWatch data

Neurology drugs got a first-try CRL 44% of the time, three times infectious disease

Infectious disease: 13%. Neurology, dermatology and endocrine sit above 40%; oncology, with the FDA's most-used fast lanes, sits near the average

CRL rate on the first FDA decision for a new drug, by disease area, 2021 to 2026



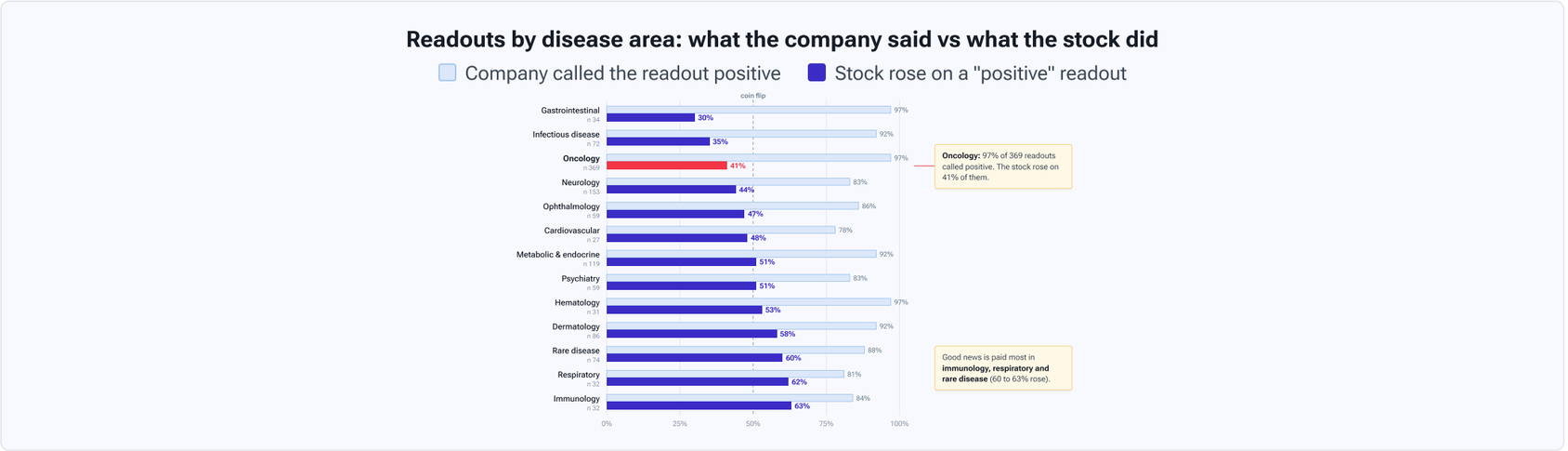
- Neurology endpoints are scales and symptoms, not tumour size or viral load. **17 of 39** neurology drugs got a CRL, and first-time sponsors 7 of 10.
- Oncology: **18 of 66** (27%). Real-time review and accelerated approval let sponsors fix problems before the clock starts.
- Renal looks safe overall (20%), but 4 of its 5 first-time sponsors got a CRL. Small samples: read the n next to each bar.

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Source: SEC filings, company releases and BiopharmaWatch data

Biotechs call 91% of their readouts positive. The stock rose on fewer than half of them

Across 1,640 readouts from 394 companies since mid-2021, the stock rose on 47% of "positive" days; oncology was among the weakest at 41%



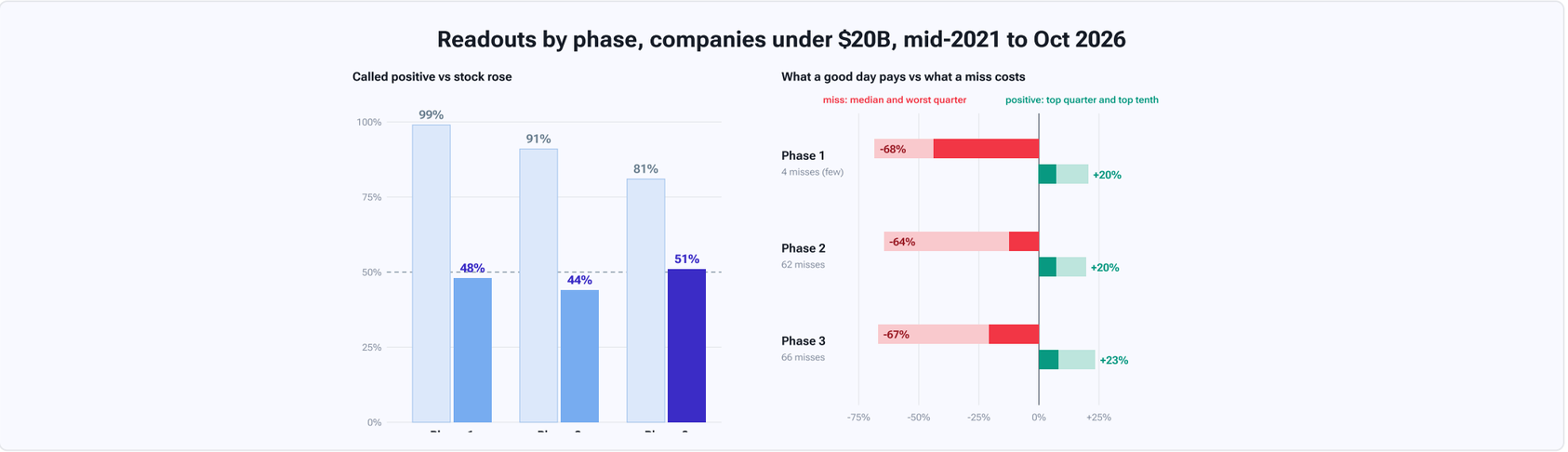
- Companies called **1,499 of 1,640** readouts positive. The median stock move on those days was **-0.6%**, and 9.3% of them fell 20% or more.
- The label is the company's; the verdict is the market's. **Viking** $VKTX called its oral VK2735 Phase 2 positive on 19 Aug 2025. The stock fell 39%.
- A real miss costs more than a win pays: the median negative readout lost **16%**, a Phase 3 miss **21%** (66 cases).

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Source: SEC filings, company releases and BiopharmaWatch data

99% of Phase 1 readouts are called positive. The stock rose on 48%

Phase 3 is the only stage where good news lifts the stock more often than not (51%), and its worst quarter of misses lost 67% or more



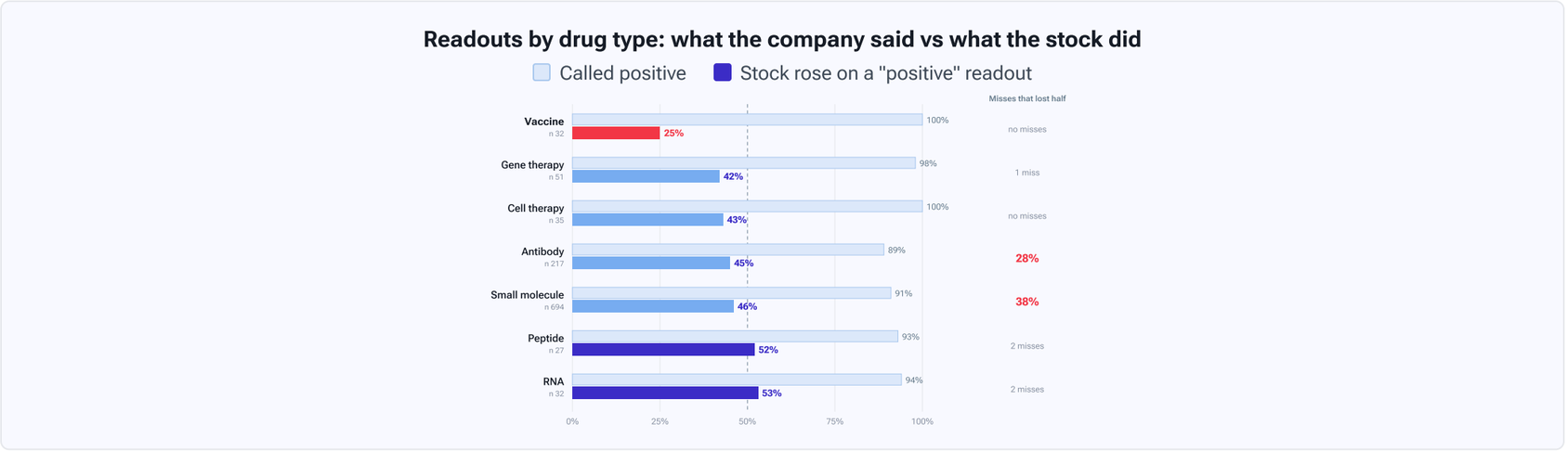
- Phase 1 is a safety study, so almost every release reads as good news: **440 of 444**. The stock rose on 48% of them.
- The payoff is lopsided at every phase. A positive Phase 3 day in the top tenth gains **23% or more**; a Phase 3 miss has a one-in-three chance of halving the stock (33% lost 50% or more).
- This is why biotechs trade like options into data: many small wins are priced in already, and the loss on a miss is several times the gain on a win.

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Source: SEC filings, company releases and BiopharmaWatch data

Every vaccine readout was called positive. The stock rose on 8 of 32

Gene and cell therapy: 98 to 100% called positive, 42% rose. RNA and peptide drugs are the only types where good news lifted the stock more often than not



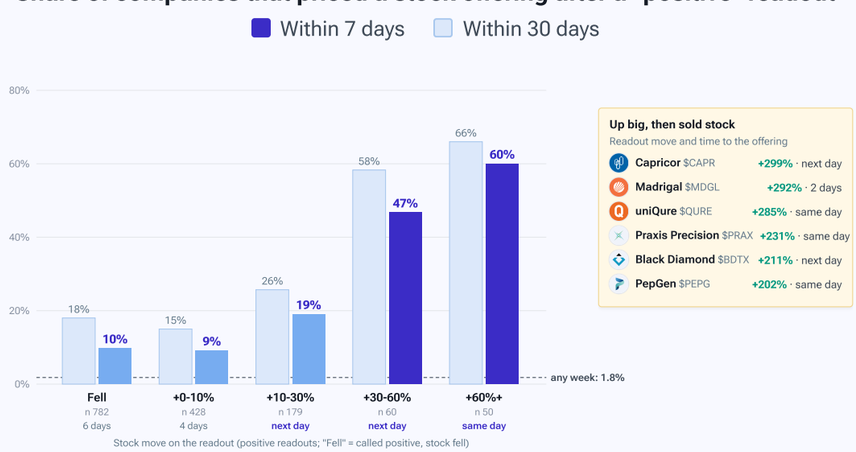
- Companies almost never call a gene- or cell-therapy readout negative: **1 negative in 51** gene-therapy readouts, none in cell therapy. The market does the grading.
- When a small molecule misses, it misses hard: **38%** of small-molecule misses lost half the company's value, against 28% for antibodies.
- Samples outside small molecules and antibodies are small (27 to 51 readouts). Treat them as direction, not precision.

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Source: SEC filings, company releases and BiopharmaWatch data

After a 60%+ jump on data, 60% of biotechs sold stock within a week, most the same day

In a random week the chance of an offering is 1.8%. After a 30 to 60% jump it is 47%, more than 25 times higher



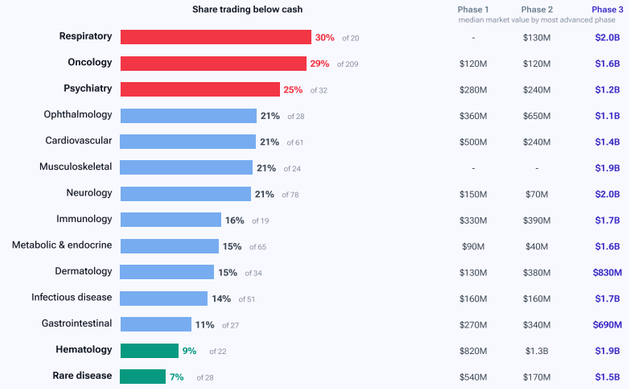
- The median gap after a 60%+ jump is **zero days**: the deal is lined up before the data and priced that evening. Investors who buy the morning after often buy next to new stock.
- Even readouts the market did not like led to raises: **9.7%** within a week, five times the base rate. A company that needs cash raises on whatever news it has.
- Small gains (+0 to 10%) rarely trigger a raise (9.1% in a week). The bigger the jump, the faster the supply.

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Source: SEC filings, company releases and BiopharmaWatch data

29% of oncology biotechs trade below their cash. In rare disease, 7%

And the market pays almost nothing for reaching Phase 2: in oncology the median Phase 1 and Phase 2 company are both worth about $120M; Phase 3, $1.6B



- **61 of 209** oncology companies are valued below the cash and securities on their latest 10-Q. Oncology is also the most crowded field (slide 2).
- Rare disease has the fewest below-cash names, and it is where buyers came this year: Soleno (Neurocrine), KalVista (Chiesi) and Astria (BioCryst).
- Value appears at Phase 3, not before: the median Phase 3 company is worth **$1.2B to $2.0B** in most areas, roughly ten times a Phase 1 or Phase 2 company.

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Source: SEC filings, company releases and BiopharmaWatch data

Specialist biotech funds have put 3.6 times more money into metabolic disease since 2021

$4.9B to $17.6B in metabolic and endocrine names, while their whole book grew 1.3x, from $106B to $137B



- **45 specialist funds**, among them Baker Bros, RA Capital, RTW, Perceptive and Avoro, held **$137B** of US-listed stock in their Q2 2026 13Fs.
- Metabolic money now spans obesity (Structure, MBX, Kailera), MASH (Madrigal) and rare endocrine (Ascendis, Rhythm). **Respiratory (3.4x) and dermatology (3.0x)** came next.
- Oncology is still the biggest bet at **$44B** but grew only 1.4x. Ophthalmology and infectious disease are flat.

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Source: SEC 13F filings and BiopharmaWatch data

The funds' biggest exits of the past year were takeouts: 24 companies, $12.4B of their stock

19 different buyers. Lilly and Merck took three of the funds' holdings each, Sanofi two

Specialist-fund holdings that left the 13Fs through an acquisition, Q2 2025 to Q2 2026

Company	Bought by	Funds' stake at their last 13F	Funds
Centessa $CNTA	Lilly	$1.69B	16
Merus $MRUS	Genmab	$1.62B	13
Cidara $CDTX	Merck	$1.37B	10
Arcellx $ACLX	Gilead	$1.06B	4
Akero $AKRO	Novo Nordisk	$0.96B	19
Verona $VRNA	Merck	$0.88B	6
Apellis $APLS	Biogen	$0.86B	5
Terns $TERN	Merck	$0.82B	12
89bio $ETNB	Roche	$0.55B	5
KalVista $KALV	Chiesi	$0.50B	12
RAPT $RAPT	GSK	$0.40B	14
Dynavax Technologies $DVAX	Sanofi	$0.27B	3
Metsera $MTSR	Pfizer	$0.25B	4
Tourmaline $TRML	Novartis	$0.21B	3
Soleno $SLNO	Neurocrine	$0.21B	11
iTeos $ITOS	Concentra	$0.16B	5

- **Akero** $AKRO was the most widely held: **19 of 45** funds held it at the last quarter-end before Novo Nordisk agreed to buy it.
- Buyers paid for late-stage, single-disease stories: MASH and obesity (Akero, 89bio, Metsera), sleep (Centessa, Avadel), respiratory and HAE (Verona, KalVista, Astria).
- Takeout cash is recycled fast: the same quarter's biggest new buys were companies the funds did not hold a quarter earlier (slide 16).

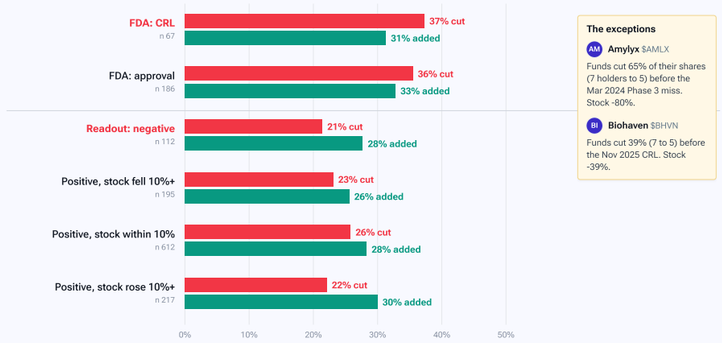
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Source: SEC 13F filings and BiopharmaWatch data

Funds did not see it coming: they cut before 37% of CRLs and 36% of approvals

Before failed readouts they cut 21% of the time; before readouts that jumped 10% or more, 22%. The 13F trail gives no edge in either direction

Change in specialist funds' shares in the quarter before the event (cut or add of 10% or more)



- Across **1,389 events**, the share of cuts is flat across good and bad outcomes.
- That fits how these funds work: they size into binary events with a view, and a 13F is up to 135 days old when it is read. It shows what they own, not what they know.
- Copying a fund's 13F is a way to find names worth researching, not a signal about the next readout or PDUFA date.

Source: SEC 13F filings and BiopharmaWatch data

The funds' biggest Q2 2026 buys were brand-new positions: Parabilis, Kailera, Hemab

$0.97B went into Parabilis from 9 funds at once. The two most widely held names are Revolution Medicines and Cogent, with 19 funds each

Biggest net buying, Q2 2026

change in the funds' combined position, at the quarter-end price

Parabilis $PBLS	**+$969M** 9 funds, all new
Kailera $KLRA	**+$776M** 5 funds, all new
Hemab $COAG	**+$559M** 7 funds, all new
Alnylam $ALNY	**+$346M** 7 funds hold, 2 new
Genmab $GMAB	**+$287M** 4 funds hold, 0 new
CG Oncology $CGON	**+$247M** 9 funds hold, 1 new
Avalo $AVTX	**+$243M** 18 funds hold, 7 new
Oruka $ORKA	**+$241M** 14 funds hold, 2 new

Most widely held, Q2 2026

number of the 45 funds holding the stock

Revolution $RVMD	**19 funds** $41.9B value
Cogent $COGT	**19 funds** $5.3B value
Avalo $AVTX	**18 funds** $380M value
Dianthus $DNTH	**18 funds** $4.6B value
Abivax $ABVX	**17 funds** $7.7B value
Definium $DFTX	**15 funds** $4.3B value
Disc Medicine $IRON	**15 funds** $3.2B value
Enliven $ELVN	**15 funds** $3.3B value

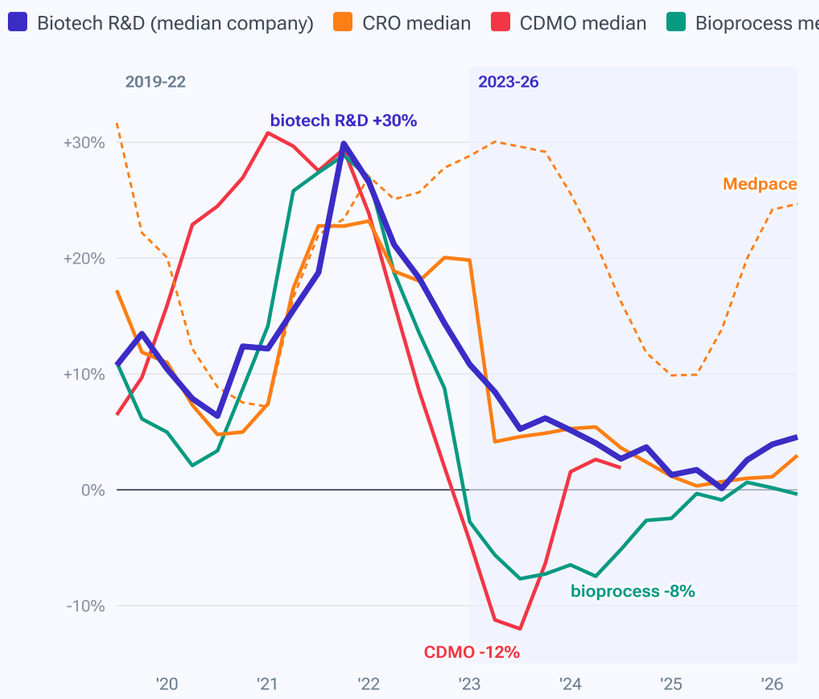
- New money concentrated: **9 funds** opened Parabilis together, 5 opened Kailera and 7 opened Hemab in the same quarter.
- The crowded names are oncology precision drugs (Revolution, Cogent, Enliven) and immunology (Dianthus, Abivax).
- A name held by 15 to 19 specialist funds has many informed holders and few marginal buyers left. That matters when it reports.

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Source: SEC 13F filings and BiopharmaWatch data

The biotech supply chain moves with R&D. None of it leads

13 CRO, CDMO and bioprocess companies peaked with biotech R&D in 2021 and slowed with it. A lead that looked real in 2019-22 did not hold in 2023-26



	Revenue growth	Same-quarter r 2019-22 → 2023-26	3-qtr lead r 2019-22 → 2023-26
CROS			
Medpace $MEDP	+25%	0.29 → **0.80**	0.64 → **0.28**
IQVIA $IQV	+8%	0.74 → **-0.02**	-0.31 → **-0.58**
ICON $ICLR	+3%	0.86 → **0.87**	0.32 → **0.56**
Charles River $CRL	-1%	0.41 → n/a	-0.32 → n/a
Fortrea $FTRE	-2%	n/a → **0.20**	n/a → **-0.80**
CDMO AND FILL-FINISH			
West $WST	+12%	0.52 → **-0.21**	-0.58 → **-0.63**
Emergent $EBS	-10%	-0.41 → **-0.23**	-0.67 → **0.65**
Catalent $CTLT	acquired	0.22 → **-0.44**	-0.52 → n/a
BIOPROCESS SUPPLIERS			
Repligen $RGEN	+15%	0.72 → **-0.36**	-0.37 → **-0.90**
Bio-Rad $BIO	+1%	0.26 → **-0.32**	-0.72 → **-0.80**
Bio-Techne $TECH	0%	0.83 → **-0.09**	-0.21 → **0.26**
Avantor $AVTR	-2%	0.67 → **-0.32**	-0.38 → **-0.79**
Maravai $MRVI	-3%	n/a → **-0.23**	-0.34 → **-0.82**

- Before 2023 the same-quarter link was strong: IQVIA 0.74, ICON 0.86, Repligen 0.72, Bio-Techne 0.83. Since then only **ICON (0.87) and Medpace (0.80)** still move with biotech R&D. No lead held up: Medpace's 3-quarter lead fell from 0.64 to 0.28, and the two that rose (ICON, Emergent) were weak or negative before 2023.
- Manufacturing had the deeper bust: the bioprocess median went from **+29% to -8%** and CDMOs to -12% as COVID-era stock was used up. Biotech R&D never shrank: its low was +0.1%.
- Medpace is the outlier at **+25%** against a CRO median of +3%. Its 2026 rebound is its own, not the sector's.

Source: SEC filings, company releases and BiopharmaWatch data