

MIND CLUB

BIOTECH BRIEF

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Biotech & Pharma Intelligence

SIGNAL > NOISE · IMPLICATIONS > HEADLINES · PRIMARY SOURCES > COMMENTARY

THIS EDITION

FDA approves a drug that may spare rectal surgery

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FDA GAVE ACCELERATED APPROVAL TO A DRUG THAT MAY LET SOME RECTAL CANCER PATIENTS SKIP SURGERY.

It rests on a single-arm Phase 2. Pharma also paid up for RNA and ADCs.

XBI · 10.19 147.86 1W -2.3% · 1M -5.7% YTD +21.3%	IBB · 10.19 204.06 1W -0.1% · 1M -0.2% YTD +20.9%	UST 10-YEAR 5.15% UP 6BP ON THE DAY 2Y 4.77% · 2S10S +38BP	BIOTECH IPOS YTD 27 ~\$8.4B RAISED M&A ~\$204.6B YTD
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Market figures as of the 10.19 close: XBI and IBB closes from Robinhood market data; Treasury yields from the U.S. Treasury daily par yield curve (10.19); IPO and M&A counts from BioBucks (10.19 and 10.18). SPY, IWM, fed funds and the VIX print in 01 Markets & outlook. Facts only, not a view on any security.

VERIFICATION AT A GLANCE

CLAIM CHECK 4 1 match · 3 partial · 0 mismatch	CALENDAR DATES 22/24 confirmed at the source	REGISTRY WATCH 48 trials · 0 changes · 8 flags	OPEN CALLS 9 none resolved today · next grade 10.30	CORRECTIONS 17 none new · see 16
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THE FIVE-MINUTE READ

THREE THAT MATTER · ONE DATE · ONE OPEN QUESTION

#	WHAT HAPPENED	SO WHAT · OUR ANALYSIS	PRIORITY · SOURCES	PAGE
01	FDA granted accelerated approval to Jemperli for untreated dMMR or MSI-H stage II and III rectal cancer. In AZUR-1, 47% of 116 centrally reviewed patients had a 12-month complete response.	For a small, defined group, treatment may start with one drug instead of surgery and radiation. Lasting benefit still has to be confirmed.	MUST READ GOV REG CO	08
02	Merck KGaA agreed to buy Silence Therapeutics for about \$1.3B in cash. The prize is divesiran, a Phase 2 siRNA for polycythemia vera.	A big buyer paid a 130% premium for a company led by one mid-stage siRNA. One deal is a price point for the modality, not a re-rating of it.	MUST READ CO REG	08
03	Roche licensed Hansoh's ADCs for \$400M upfront and more than \$15B in potential milestones. The programs are preclinical.	Pharma still pays real cash for Chinese ADC engines, but the headline is mostly milestones.	MUST READ CO PRESS	09
+ Also today. 04 Rapport's RAP-219 beat placebo in bipolar mania by 3.1 points (p=0.045). 05 EyePoint's LUCIA missed in wet AMD; it is cutting about 53% of staff.				09
DATE	One date to hold. Mon 10.26: FDA goal date for GSK's bepirovirsen in chronic hepatitis B, confirmed by GSK on 04.28 (Priority Review, Breakthrough Therapy). With no voucher disclosed, it tests FDA's standard priority clock.			24
OPEN	The open question. How many AZUR-1 patients keep the organ for years? FDA reports two different measures, 47% of 116 with a 12-month response and "almost three-fourths" free of surgery, radiotherapy or chemotherapy at over two years; neither answers it. Longer follow-up after the 11.02.2026 primary completion should.			23



HOW TO READ THIS BRIEF

MUST READ understand today. **KNOW IT** secondary. **SCAN** awareness only. **VERIFIED** means a primary source was checked, **CLAIM** means a company statement, and **ANALYSIS** means our interpretation. The red boxes are the **red team**: the strongest case against the implication just drawn.

Source badges show what each item rests on: **REG** trial registry **GOV** agency or government **PEER** peer-reviewed journal **PRE** preprint, not peer-reviewed **CO** company or organizer release **DATA** curated scientific database **PRESS** journalism.

Claim Check verdicts compare a headline with the registered protocol: **MATCH** **PARTIAL** **MISMATCH**. A verdict says what differs, never why; late changes can be perfectly legitimate.

READING PRIORITY INDEX

MUST READ	Jemperi in rectal cancer · Merck KGaA and Silence · Roche and Hansoh ADCs · Rates and the 30/60/90 outlook
KNOW IT	RAP-219 in bipolar mania · EyePoint LUCIA and restructuring · Emvistegrist in ulcerative colitis · Disc's \$350M offering · TriGemX SPAC and PIPE · Lycia IPO terms · Lilly and METiS · Target Evidence Card: TARP y8
SCAN	Ambrose and AM-Pharma · CorMedix sNDA priority review · Novartis ends a Fabhalta lupus study · Roche pauses German investment · Preprint Radar · Registry Watch

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MARKETS & OUTLOOK

Small biotech rose 2.5% on Monday, a day with a takeover and two Phase 3 wins, while the 10-year rose back to 5.15%. One day doesn't undo last week's 6.2% drop.

BENCHMARK	10.19 CLOSE	DAY	1W	1M	YTD	READ
XBI (equal-weight biotech)	147.86	+2.5%	-2.3%	-5.7%	+21.3%	Disc (+39%) and Veradermics (+12%) among the day's gainers
IBB (cap-weight biotech)	204.06	+1.0%	-0.1%	-0.2%	+20.9%	Flat over the month
XLV (health care)	175.65	-0.6%	n.a.	n.a.	n.a.	Large-cap health care slipped as small biotech rose
SPY	766.48	+0.4%	n.a.	n.a.	n.a.	Steady
IWM	271.28	+0.3%	n.a.	n.a.	n.a.	Small caps lagged XBI

Price returns from Robinhood daily data: day vs 10.16, 1W vs 10.12, 1M vs 09.18, YTD vs 12.31.2025. n.a. = not pulled this edition. Stock moves are 10.19 closes vs 10.16 closes.

Rates & macro

Fed funds target	3.75 to 4.00%	Raised 25bp in September
UST 2Y / 10Y	4.77% / 5.15%	10.16: 4.74% / 5.09%
Next FOMC	10.27 to 10.28	About eight in ten odds of a hold, CME FedWatch as reported by Forbes (10.19)
VIX	18.44	19.99 on 10.16
This week	No CPI	September CPI came out 10.14; GDP and PCE 10.29

Biotech capital, YTD

IPOs	27 / ~\$8.4B	BioBucks, 10.19
M&A	73 / ~\$204.6B	BioBucks, 10.18; before Silence
PDBB tally, \$5M+	693 / \$75.6B	US 451 · rest of world 242
IPO queue	Lycia	Terms set 10.20: 14.7M shares at \$16 to \$18
Follow-on	Disc \$350M	Proposed 10.19 after the close; not priced as of this edition

Sources: U.S. Treasury daily par yield curve (10.19) [GOV](#); Federal Reserve, open market operations [GOV](#); Forbes citing CME FedWatch (10.19) [PRESS](#); Robinhood market data; BioBucks IPO and M&A trackers [PRESS](#); IPOscoop (10.20) [PRESS](#); Disc release (10.19) [CO](#); Mind Club financing tally.

WHY BIOTECH ROSE WHILE YIELDS ROSE

Last week XBI fell as the 10-year fell. On Monday the reverse happened: the 10-year rose 6bp to 5.15% and XBI gained 2.5%. Monday's biggest movers rose on company news, including Disc's Phase 3, so this looks like stock-specific buying rather than a macro turn. Prices alone can't prove that. The Fed is in its blackout before the 10.28 decision, so the next macro signals are data and the meeting itself. [ANALYSIS](#)



2026 CAPITAL SCORECARD

One new financing reached the tally, TriGemX's \$160M PIPE (expected to fund at the merger's closing, targeted for Q1 2027). Disc's \$350M offering and Lycia's IPO wait for pricing.

CHANNEL	2026 YTD	AS OF	READ
IPOs	27 · ~\$8.4B	10.19	BioBucks count. Lycia set terms on 10.20 for about \$250M at the midpoint; it counts when it prices.
IPOs, PDBB tally	US 26 · \$7.4B	10.20	Rest of world adds 17 IPOs and \$2.2B, mostly in Hong Kong.
Venture, PDBB tally	US 180 · \$13.6B	10.20	Rest of world adds 162 rounds and \$10.9B. No new round of \$5M or more in this window.
Follow-ons, PIPEs & RM	US 245 · \$37.7B	10.20	PDBB tally, the largest channel by far; TriGemX's de-SPAC PIPE is today's addition.
M&A (context)	73 · ~\$204.6B	10.18	BioBucks headline values, which can include contingent payments. Before Merck KGaA's ~\$1.3B Silence deal.

Sources: BioBucks IPO and M&A trackers (10.18 to 10.19) [PRESS](#); IPOscoop (10.20) [PRESS](#); Mind Club financing tally (693 financings of \$5M or more, \$75.6B), updated this edition. Counts differ by source and scope and are shown as reported, not reconciled. Capital: +1 deal, USD 160.0M; nothing corrected, removed or held.

RED TEAM

A quiet tally day can mislead. Disc alone may add \$350M once it prices, and Lycia about \$250M, so the week's total could look very different by Friday. Counting only priced deals keeps the tally honest, but it lags the market by a day or two. [ANALYSIS](#)



WHERE THE MONEY WENT

US money still runs through follow-ons and PIPEs; outside the US, venture rounds carry most of it.

United States 451 FINANCINGS · \$58.7B

THERAPEUTIC AREA	IPOS	VENTURE ROUNDS	FOLLOW-ONS, PIPES & RM	TOTAL
Oncology	\$1.7B	\$3.0B	\$12.0B	\$16.7B
Immunology & inflammation	\$1.2B	\$2.6B	\$9.7B	\$13.5B
Neuroscience & pain	\$600M	\$1.2B	\$5.6B	\$7.4B
Rare & genetic	\$1.0B	\$1.1B	\$3.7B	\$5.8B
Cardiovascular & renal	\$1.2B	\$428M	\$2.1B	\$3.7B
Obesity & metabolic	\$706M	\$979M	\$1.6B	\$3.3B
Other	\$448M	\$1.6B	\$1.1B	\$3.2B
AI & platform	\$400M	\$1.1B	\$300M	\$1.8B
Infectious disease & vaccines	.	\$428M	\$1.3B	\$1.7B
Ophthalmology	\$150M	\$1.1B	\$262M	\$1.5B
TOTAL	\$7.4B	\$13.6B	\$37.7B	\$58.7B

Rest of world 242 FINANCINGS · \$16.8B

EUROPE 91 · CHINA & HK 90 · KOREA 22 · AUSTRALIA & NZ 11 · CANADA 8 · JAPAN 8 · OTHER 12

THERAPEUTIC AREA	IPOS	VENTURE ROUNDS	FOLLOW-ONS, PIPES & RM	TOTAL
Oncology	\$574M	\$3.0B	\$2.1B	\$5.7B
AI & platform	\$270M	\$4.1B	\$92M	\$4.4B
Rare & genetic	.	\$847M	\$574M	\$1.4B
Immunology & inflammation	\$351M	\$782M	\$224M	\$1.4B
Cardiovascular & renal	\$534M	\$422M	\$28M	\$984M
Neuroscience & pain	.	\$798M	\$168M	\$966M
Other	\$205M	\$197M	\$325M	\$728M
Infectious disease & vaccines	\$227M	\$144M	\$145M	\$516M
Obesity & metabolic	.	\$282M	\$121M	\$403M
Ophthalmology	\$42M	\$288M	\$5M	\$335M
TOTAL	\$2.2B	\$10.9B	\$3.8B	\$16.8B

LESS  MORE

One scale across both tables: channel columns together, totals separately.

Coverage: 693 disclosed 2026 financings of \$5M or more, \$75.6B in total. US means raised on a US exchange or, for private rounds, by a US-headquartered company. Rest of world covers money raised on non-US exchanges or, for private rounds, by companies headquartered outside the US: mainly mainland China and Hong Kong, Europe, South Korea, Japan, Australia and Canada. A US company raising on a non-US exchange counts as rest of world. Base gross upfront new money; excludes debt, standalone convertibles, at-the-market sales, grants, unexercised warrants and money raised before 2026. Sourced deal by deal in the Mind Club financing tally. US is close to complete; read rest of world as directional. Therapeutic area by lead program.



THE NEXT 30, 60 AND 90 DAYS

No change to our odds. Monday's bounce came from company news, and the 10-year moved the other way.

HORIZON	WHAT DECIDES IT	BASE CASE	TELL TO WATCH
30 days to ~11.19	Kidney Week 10.22 to 10.25 · ESMO 10.23 to 10.27 · bepirovirsen goal date 10.26 · FOMC 10.27 to 10.28 · GDP and PCE 10.29 · big pharma Q3 (Roche 10.22; Novartis 10.27; Merck, Lilly, BMS, Gilead 10.29) · mitapivat SCD 11.01 (a Sunday) · midterms 11.03 · AASLD 11.05 to 11.09	Choppy. October has been mixed for XBI (up in 10 of 20 years, median -0.2%). Our base case is no rate change on 10.28; reported hold odds are about eight in ten.	Whether XBI holds Monday's gain without more deal news. Whether reported hike odds stay below 30%.
60 days to ~12.19	ACR 11.06 to 11.11 · ObesityWeek 11.14 · ivonescimab goal date 11.14 · BBP-418 goal date 11.27 · IRA 2028 prices by 11.30 · FOMC with dots 12.08 to 12.09 · ASH 12.12 to 12.15	XBI rose in 14 of the last 20 Novembers (median +4.1%), a small sample and not a forecast. Pharma Q3 commentary on pricing, tariffs and BD appetite may matter more than earnings per share.	Whether more takeovers land at large premiums. Whether companies keep pairing data with a raise, as Disc did.
90 days to ~01.18	Tax-loss selling · pre-JPM deal season (JPM opens 01.11.2027) · December dots	Pharma is still buying mostly by license and option, with selective cash takeovers like Silence.	December dots. Any \$5B+ biopharma acquisition (call 09).

SCENARIO (90D)	OUR ODDS	PATH	IMPLICATION
Bull	20% (20%)	The Fed skips October and December, inflation cools, the 10Y falls back toward 4.75%, and M&A picks up into JPM.	Rates path is the main variable for long-duration names
Base	50% (50%)	At most one more hike by December, the 10Y holds 5.0 to 5.4%, and steady licensing plus conference catalysts support companies with data.	Dispersion between funded and unfunded names
Bear	30% (30%)	Inflation stays hot, two more hikes come, the 10Y breaks above 5.5%, and the IPO window shuts again.	Rates and financing risk for small and mid caps; more reverse mergers and wind-downs

Prior odds in brackets (10.19). Seasonality: our calculation from XBI monthly closes, October and November 2006 to 2025 (20 years each), price only, from Robinhood data, as printed 10.19. Scenario odds are our judgment, not market-implied. What changed since yesterday: XBI rose 2.5% on company news while the 10-year rose 6bp. That's one day against last week's 6.2% drop (10.09 to 10.16 closes), so we hold the odds. **FORECAST**

RED TEAM

A 130% takeover premium and a \$350M follow-on the same day hint that risk appetite for de-risked assets is healthier than last week's tape suggested. If so, our bear case leans too hard on rates. The counter is that one premium deal says more about the buyer's view of one drug than about the market. **ANALYSIS**



FIVE THINGS TO KNOW

01 FDA gave Jemperli accelerated approval for rectal cancer that may not need surgery

MUST READ

WHAT HAPPENED

On 10.19 FDA granted accelerated approval to GSK's Jemperli (dostarlimab) alone for adults with previously untreated stage II or III locally advanced rectal cancer that is mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H). The basis is AZUR-1 (NCT05723562), a single-arm Phase 2 in 154 patients. FDA's approval notice gives the primary measure: 47% of 116 centrally reviewed patients had a complete clinical response that lasted 12 months; investigators put it at 68% of 144. FDA's notice doesn't say why the other 38 of 154 weren't assessable. **VERIFIED**

FDA's press announcement adds that after a median follow-up of more than two years, "almost three-fourths of patients had not needed surgery, radiotherapy or chemotherapy." FDA says this is the 11th approval reviewed under the Commissioner's National Priority Voucher pilot. FDA's notice says it came 4 months ahead of the goal date. **VERIFIED**

WHY IT MATTERS

The label rests on sustained complete response, not on surgery, so keeping the organ becomes the aim of treatment. For a small, biomarker-defined group, treatment may start with one immunotherapy instead of chemoradiation and surgery. It also shows the voucher pilot moving a supplemental indication quickly, which matters for any sponsor weighing whether to apply. **ANALYSIS**

WHAT WE'RE WATCHING

Confirmatory requirements, which FDA's notice doesn't spell out; the registered primary's completion on 11.02.2026; 24- and 36-month response data; and how quickly testing for dMMR at diagnosis spreads, since the label depends on it.

CLAIM CHECK **PARTIAL** AZUR-1 (NCT05723562) registers sustained complete clinical response at 12 months by central review, at 18 months, N=154. FDA's notice reports that measure in 116 evaluable patients (47%); the press announcement leads with a different measure, freedom from surgery, radiotherapy or chemotherapy (almost three-fourths).

RED TEAM

Single-arm data can't show the drug beats standard care; it shows many patients avoided it. The 47% and "almost three-fourths" figures measure different things, and the gap is wide enough to matter to a patient deciding against surgery. Two years is short for rectal cancer, where regrowth can come later, and watch-and-wait needs intense surveillance that not every center can run. **ANALYSIS**

SOURCE · [FDA PRESS ANNOUNCEMENT \(10.19\)](#) **GOV** · [FDA APPROVAL NOTICE \(10.19\)](#) **GOV** · [GSK RELEASE \(10.19\)](#) **CO** · [NCT05723562](#) **REG**

02 Merck KGaA pays about \$1.3B for an siRNA in a blood cancer **MUST READ**

WHAT HAPPENED

Merck KGaA, Darmstadt, Germany agreed on 10.19 to acquire Silence Therapeutics for \$20.00 in cash per American Depositary Share, an equity value of about \$1.3B and an enterprise value of about \$1.1B. The price is a 130% premium to the 10.16 close and 82% to the 30-day average. It's a UK scheme of arrangement that needs shareholder, High Court and regulatory approvals, and closing is expected in Q1 2027. **VERIFIED**

The main asset is divesiran, a wholly owned siRNA against TMPRSS6 for polycythemia vera, which Silence calls potentially best in class on Phase 2 data. Merck KGaA plans to speed it into Phase 3. **CLAIM**



WHY IT MATTERS

It's a cash takeover of an RNAi company led by one mid-stage asset in a rare blood cancer, by a buyer that isn't an RNA specialist. One cash takeover suggests siRNA can now be bought outright, not only licensed; one deal isn't a trend. Divesiran works by raising hepcidin to restrain red cell production, an approach that competes with phlebotomy and with hepcidin mimetics already further along. [ANALYSIS](#)

WHAT WE'RE WATCHING

The scheme document and vote timetable; whether Merck KGaA names a Phase 3 design and start date; and how the hepcidin-mimetic competition reads out first.

RED TEAM

A big premium on a thinly traded ADS says more about how cheap the stock had become than about siRNA's value. Divesiran's Phase 2 is the only randomized evidence, and the first hepcidin-pathway drug to market will set the bar it must clear. One acquirer's conviction is a price point, not a sector call. [ANALYSIS](#)

SOURCE · [SILENCE RELEASE \(10.19\)](#) [CO](#) · [SEC FILING, DEFA14A EXHIBIT \(10.19\)](#) [CO](#) · [NCT05499013](#) [REG](#) · [FIERCE BIOTECH \(10.19\)](#) [PRESS](#)

03 Roche returns to Hansoh for ADCs with \$400M upfront [MUST READ](#)

WHAT HAPPENED

Hansoh Pharma licensed Roche worldwide rights outside mainland China, Hong Kong, Macau and Taiwan to two preclinical antibody-drug conjugates and to multiple programs on targets Roche will propose. Hansoh receives \$400M upfront and \$110M on the first anniversary, and potentially more than \$15B in development, regulatory and commercial milestones, plus tiered royalties. Hansoh runs development through global Phase 1a and may opt into up to two programs outside its territory. [VERIFIED](#)

WHY IT MATTERS

\$400M upfront plus \$110M due in a year is a large commitment for programs that haven't reached people. Roche is paying for an ADC engine and Hansoh's speed to first-in-human, not for clinical data. It also lands as China weighs curbs on foreign acquisitions of critical biopharma platforms. [ANALYSIS](#)

WHAT WE'RE WATCHING

Which targets Roche picks, how fast the first programs reach Phase 1a, and whether China's proposed rules touch licensing as well as acquisitions.

RED TEAM

The \$15B figure is almost all milestones on unnamed assets and is close to meaningless as a valuation. ADC differentiation is narrowing as linkers and payloads converge, so Roche may be buying capacity more than science. If Beijing tightens platform transfers, structures like this could get slower or costlier. [ANALYSIS](#)

SOURCE · [HANSOH RELEASE \(10.19\)](#) [CO](#) · [FIERCE BIOTECH \(10.19\)](#) [PRESS](#) · [FIERCE BIOTECH, CHINA PLATFORM RULES](#) [PRESS](#)

04 A new kind of glutamate drug beat placebo in acute mania, narrowly [KNOW IT](#)

WHAT HAPPENED

Rapport Therapeutics reported on 10.20 that RAP-219, a negative modulator of AMPA receptors that carry the TARP γ8 subunit, improved Young Mania Rating Scale scores by 3.1 points more than placebo at week 3 in 253 hospitalized adults with bipolar I mania (p=0.045). Scores fell 15.4 points on drug and 12.3 on placebo. Severity on CGI-BP improved 0.4 points more (p=0.024). [CLAIM](#)



Adverse events were similar overall (51.6% vs 52.8%), with more agitation (16.7% vs 9.4%) and nausea (5.6% vs 1.6%) on drug; 3.2% vs 0.8% stopped for side effects, and there were no serious adverse events. Rapport plans an end-of-Phase 2 meeting in Q1 2027 and two Phase 3s from the second half of 2027. [CLAIM](#)

WHY IT MATTERS

Rapport calls it the first new mechanism for bipolar mania in decades; we found no earlier randomized result for a TARP γ 8-selective drug in psychiatry. The mechanism aims to damp overactive forebrain circuits without the sedation that limits antipsychotics. A drug already in Phase 3 for focal seizures now has a second possible indication. [ANALYSIS](#)

WHAT WE'RE WATCHING

The full dataset with effect size and response rates, how agitation was distributed, and whether FDA accepts this trial toward a program.

CLAIM CHECK [MATCH](#) NCT07046494 registers YMRS change from baseline to week 3, N=253; the release reports that endpoint at that timepoint in 253 patients.

RED TEAM

p=0.045 on a 3.1-point gap is a thin margin. Approved antimanic drugs have often shown larger separations in trials of similar length, and the placebo-adjusted gap was still widening at the last visit. More agitation on drug in a mania trial is worth a close look. One Phase 2 supports a Phase 3, not a new standard. [ANALYSIS](#)

SOURCE · [RAPPORT RELEASE \(10.20\)](#) [CO](#) · [NCT07046494](#) [REG](#)

05 EyePoint's wet AMD implant missed; it is cutting about 53% of staff [KNOW IT](#)

WHAT HAPPENED

EyePoint said on 10.19 that LUCIA, its second Phase 3 of DURAVYU (vorolanib in a sustained-release insert) given every 24 weeks against aflibercept 2 mg every 8 weeks in wet AMD, did not show statistical non-inferiority on best corrected visual acuity at weeks 52 and 56. The release gives no visual acuity numbers. It reports a 38% cut in treatment burden. [CLAIM](#)

The company is ending its wet AMD Phase 3 work early, cutting about 53% of positions and focusing on diabetic macular edema, with Phase 3 readouts in Q4 2027. It had about \$118M in cash and investments at 09.30. [CLAIM](#)

WHY IT MATTERS

Durability was the whole pitch for tyrosine kinase inhibitor inserts in the retina. A miss on vision against the standard injection suggests fewer shots may not be enough if vision can't be shown to hold, and it may raise the bar for other long-acting programs. [ANALYSIS](#)

WHAT WE'RE WATCHING

The full visual acuity data and non-inferiority margin, how the first Phase 3 (LUGANO) compares, and whether other sustained-delivery programs change their trial designs.

CLAIM CHECK [PARTIAL](#) NCT06683742 registers average change in BCVA at weeks 52 and 56, the endpoint the release reports as missed. The registry lists 400 participants; the release says 475.

RED TEAM

Without the BCVA difference and margin, we can't tell a near miss from a clear failure. A 38% burden reduction may still matter to some patients and payers. DME is a different disease with different dynamics, so this miss doesn't settle the DME program. [ANALYSIS](#)

SOURCE · [EYEPOINT LUCIA RELEASE \(10.19\)](#) [CO](#) · [EYEPOINT PRIORITIZATION RELEASE \(10.19\)](#) [CO](#) · [NCT06683742](#) [REG](#)



BRIGHT SPOT

A French team profiled 423 newly diagnosed myeloma tumors in Nature Medicine and built a model that predicted, with an area under the curve of 0.77, which patients would clear detectable disease after four-drug induction. Key findings held up across three outside cohorts totaling 1,451 cases. It's a step toward choosing who needs more therapy early, though the model still needs testing in practice. VERIFIED [MAGRANGEAS ET AL., NAT MED \(10.19\),](#)

[VIA PUBMED](#)

[PEER](#)





FIVE TALKING POINTS

- 01 The Jemperli label may change what "cure" means for a small group of rectal cancers: FDA approved it on **sustained complete response** rather than survival, which may make keeping the organ an accepted goal.
- 02 Merck KGaA paid cash for one Phase 2 siRNA in a rare blood cancer. One deal isn't a shift from licensing to buying, but it is **a price point for RNAi**.
- 03 Roche's Hansoh deal shows **China's ADC engines still command real cash**, \$510M near-term for preclinical programs, even as Beijing weighs limits on platform transfers.
- 04 RAP-219 makes **subunit-selective glutamate drugs** a psychiatry story as well as an epilepsy story, but a $p=0.045$ result is a reason for Phase 3, not for confidence.
- 05 EyePoint's miss is a reminder that in the retina, **durability needs vision to match**: fewer injections may not count for much if vision can't be shown to match the standard.



CLAIM CHECK

We pulled the ClinicalTrials.gov record for four of the window's readouts. One matches; three are partial, on the reported measure, a single reported dose and enrollment.

READOUT	WHAT THE REGISTRY SAYS	WHAT THE HEADLINE SAYS	VERDICT
Dostarlimab · GSK AZUR-1 · NCT05723562	Sustained complete clinical response for 12 months by central review, at 18 months. N=154. Primary completion 11.02.2026.	FDA notice: 47% of 116 centrally reviewed. FDA press: almost three-fourths avoided surgery, radiotherapy or chemotherapy	PARTIAL
RAP-219 · Rapport Phase 2 · NCT07046494	YMRS change, baseline to week 3. N=253. Primary completion 08.05.2026.	3.1-point gap vs placebo at week 3 (p=0.045), N=253	MATCH
Emvistegrast · Gilead SWIFT · NCT06290934	Clinical response at week 12 (modified Mayo). N=228. Primary completion 03.04.2026.	66% vs 37% clinical response at week 12 on 200 mg (39 of 59 vs 22 of 60); 238 in the safety set; the 75 mg and 25 mg arms not disclosed	PARTIAL
DURAVYU · EyePoint LUCIA · NCT06683742	Average BCVA change at weeks 52 and 56 vs aflibercept. N=400. Primary completion 10.2026.	Missed non-inferiority on BCVA; N=475; no BCVA numbers	PARTIAL

Registry records pulled from ClinicalTrials.gov on 10.20.2026 **REG**. Headline figures from FDA (10.19) and company releases (10.19 to 10.20). What a verdict means: Match, the headline reports the registered primary at the registered timepoint and N within 10%. Partial, it leads with another measure or a subgroup, the registry is stale, or N differs by more than 10%. Mismatch, the registered primary isn't what the headline reports.

RED TEAM

Registries lag, and enrollment fields often go stale after a trial closes, which may explain LUCIA's gap. FDA's press figure for Jemperli is a different measure, reported openly next to the registered one in FDA's own notice; the gap is emphasis, not concealment. Gilead's release itself prints two different counts for the top-dose responders (33 and 39 of 59); only 39 of 59 matches the 66% it reports, so we use that. **ANALYSIS**



M&A, BD & LICENSING

BUYER / PARTNER	SELLER / LICENSOR	ASSET / MOA	AREA · STAGE	UPFRONT	TOTAL	
Merck KGaA	Silence Therapeutics	Divesiran, TMRSS6 siRNA	Polycythemia vera · Phase 2	~\$1.3B equity	~\$1.1B EV	MUST
Roche	Hansoh Pharma	ADCs: 2 preclinical plus Roche-chosen targets	Oncology · preclinical	\$400M (+\$110M yr 1)	>\$15B	MUST
Eli Lilly	METiS TechBio (Hong Kong)	Tissue-targeted lipid nanoparticles for RNA	Platform · discovery	low double-digit \$M*	~\$1.1B*	KNOW
TCGX Acquisition (SPAC)	TriGemX Bio	Elismetrep, oral TRPM8 blocker	Acute migraine · Phase 3	\$160M PIPE	~\$600M equity	KNOW
Ambrose Healthcare	AM-Pharma (Netherlands)	Ilofotase alfa, recombinant alkaline phosphatase	Hypophosphatasia · Phase 2-ready (100% share purchase)	n.d.	up to €161M	SCAN

* As reported by TechNode Global and Endpoints; the upfront wasn't disclosed exactly. n.d. = not disclosed. Silence: Silence release and SEC DEFA14A exhibits (10.19) **CO**. Hansoh: Hansoh release (10.19) **CO**. TriGemX: TCGX 8-K exhibit 99.1 (10.19) **CO**. AM-Pharma: Ambrose release, GlobeNewswire (10.20, 02:00 ET) **CO**. Release times for Silence, Hansoh and METiS weren't printed on their pages; Hansoh's and METiS's may fall in Asian hours on 10.19.

What pharma is willing to pay for

Two ends of the spectrum in one day. Merck KGaA paid a full takeover premium for a company led by one Phase 2 siRNA headed for Phase 3; Roche paid \$510M near-term for ADC programs that haven't reached people, betting on an engine. Lilly's METiS deal is the cheap option in between: a small upfront for delivery technology that could take RNA beyond the liver. The common thread is RNA and conjugates, the two modalities where delivery is the bottleneck. **ANALYSIS**

RED TEAM

One acquisition and two licenses are a busy Monday, not a trend. The Hansoh and METiS headline values are mostly milestones that may never be paid, and the SPAC's \$600M equity value assumes no redemptions from a trust that is only about \$86M. Read the cash, not the biobucks. **ANALYSIS**



FINANCING & CAPITAL MARKETS

COMPANY	AMOUNT	STRUCTURE	STAGE	INVESTORS / BANKS	IMPLICATION	
Disc Medicine	\$350M	proposed	Underwritten offering, common and pre-funded warrants; \$52.5M option	Phase 3 met (EPP)	Jefferies, Leerink, Morgan Stanley, Cantor	Raising the same day as data, after a 39% gain. Not priced as of this edition, so not in the tally.
TriGemX Bio	\$160M	PIPE with SPAC merger (TCGX); about \$86M more in trust if not redeemed	Phase 3 (migraine)	TCGX, Viking Global, ADAR1, BVF, Samsara, Vianti and others	Specialist investors, several of whom (TCGX, Viking) co-led TriGemX's \$94M round in early October, backing a late-stage asset through a SPAC. Counted in the tally (PIPE only), as announced; expected to fund at closing, targeted for Q1 2027.	
Lycia Therapeutics	~\$250M	at midpoint	IPO terms: 14.7M shares at \$16 to \$18	Phase 1 (IgE degrader)	Jefferies, TD Securities, Evercore ISI, Guggenheim, LifeSci Capital	The IPO window stays open for platforms with early clinical data. Counts when it prices.

Disc release, GlobeNewswire (10.19, 16:01 ET) **CO**; TCGX 8-K exhibit 99.1 (10.19) **CO**; IPOscoop and Investing.com (10.20) **PRESS**. City Therapeutics closed its upsized \$230.0M IPO on 10.19, including the full option; it priced on 10.15 and was counted then. Nouscom's \$135M Series D (10.19, 02:00 ET) went into the tally in Edition 024.

CAPITAL MARKETS TEMPERATURE: WARM FOR DATA

Disc launched a \$350M raise within hours of its Phase 3 and a 39% gain, Lycia set terms for a \$250M IPO, and specialist funds agreed to a \$160M PIPE for a Phase 3 migraine asset, tied to a merger close expected in Q1 2027. Money is there for companies with fresh data (Disc) and for late-stage assets whose first Phase 3 readout is still a way off (TriGemX, mid-2027). That's consistent with last week's IPOs (City, lambic) and doesn't yet tell us whether earlier-stage companies can raise. **ANALYSIS**

RED TEAM

A raise launched into a spike says more about management's timing than about investors' appetite until it prices; the discount and final size will tell. SPAC PIPEs often come with redemptions that shrink the cash. And one IPO setting terms is not one pricing. **ANALYSIS**



CLINICAL READOUTS

DRUG · COMPANY	MOA	INDICATION · TRIAL	N	RESULT	VERDICT	CLAIM CHECK
Dostarlimab · GSK	PD-1 antibody	dMMR/MSI-H rectal · Ph2 AZUR-1	154	cCR12 47% of 116 (central review)	Approved (accelerated)	PARTIAL
RAP-219 · Rapport	TARP γ8 AMPA receptor NAM	Bipolar I mania · Ph2	253	YMRS -3.1 vs placebo, p=0.045	Positive Phase 2 (company topline)	MATCH
Emvistegraft · Gilead	Oral α4β7 integrin blocker	Ulcerative colitis · Ph2 SWIFT	238 (safety); 119 compared	Response 66% vs 37%; remission 31% vs 8% (nominal p)	Positive Phase 2 (nominal p)	PARTIAL
DURAVYU · EyePoint	VEGFR TKI insert	Wet AMD · Ph3 LUCIA	475	Missed BCVA non-inferiority; burden -38%	Failure on primary	PARTIAL

Company releases (10.19 to 10.20) **CO**; FDA (10.19) **GOV**; ClinicalTrials.gov records pulled 10.20 **REG**. Gilead's SWIFT data were presented at UEG Week on 10.19 and reported before our Monday edition's build; Edition 024 didn't cover them.

Emvistegraft (SWIFT) **KNOW IT**

Result. At week 12, 66% (39 of 59) on 200 mg once daily had a clinical response against 37% (22 of 60) on placebo; clinical remission was 31% vs 8%, and endoscopic improvement 39% vs 12%. All p-values are nominal. **CLAIM**

Comparator. Placebo; Entyvio comparisons in the press are across trials. **Safety.** Adverse events 36% vs 37%; serious events 2% vs 0, none judged related. **CLAIM**

Interpretation. An oral form of a validated gut-selective mechanism looks active at Phase 2. **ANALYSIS** **Remaining question.** Whether the effect holds in a Phase 3 (planned for 2027) and in patients who failed biologics.

SOURCE · GILEAD STATEMENT (10.19) **CO** · NCT06290934 **REG**

RAP-219 and DURAVYU **KNOW IT**

Both are in 04. For RAP-219, statistical significance is thin and clinical significance is unclear without response and remission rates; separation grew from 0.9 points at week 1 to 3.1 at week 3. For DURAVYU, the release gives no BCVA difference or margin, so the size of the miss is unknown. **ANALYSIS**

Also noted **SCAN**

Novartis stopped a Phase 2 study of Fabhalta in lupus nephritis and said there were no efficacy or safety concerns behind the decision (10.19, as reported by Fierce). XBiotech said its Phase 2 in refractory colorectal cancer met a prespecified efficacy criterion; we couldn't retrieve the numbers. **CLAIM**

RED TEAM

Three of four readouts rest on company releases without full data. The one with a regulator's numbers, Jemperli, is single-arm. A positive day for readouts can still be a thin day for evidence: the strongest comparative result here, emvistegraft, uses nominal p-values from a dose-ranging Phase 2. **ANALYSIS**



NOVEL BIOLOGY & TARGET WATCH

Target Evidence Card: TARP γ 8 (CACNG8)

CACNG8 has no human genetic evidence for bipolar disorder in Open Targets. One company runs every active interventional trial on the target, two of them in Phase 3 for focal seizures.



HUMAN GENETICS

None found

No evidence identified for bipolar disorder (MONDO_0004985): its 0.11 direct score is clinical only, from gabapentin trials mapped to the calcium channel complex. No genetic association for epilepsy either. Direction not established.

MECHANISM

AMPA subunit

Auxiliary subunit that regulates the trafficking and gating of AMPA-type glutamate receptors. Class from UniProt (Q8WXS5); ChEMBL has no curated mechanism for RAP-219, which isn't in ChEMBL.

HOW CROWDED

4

active interventional trials aimed at TARP γ 8 alone on ClinicalTrials.gov (recruiting or active, not recruiting; all diseases; drug as background or comparator excluded), all of RAP-219: bipolar mania Phase 2, a focal epilepsy extension and two focal seizure Phase 3s. Phase 3 count: 2 (Phase 2/3 counted with Phase 3; none).

THE BAR

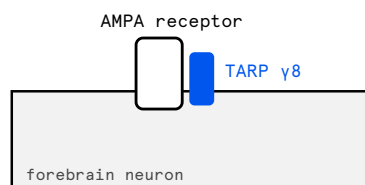
0

FDA-approved products, including biosimilars: none aimed at TARP γ 8 (originators 0, biosimilars 0). Perampanel, a non-selective AMPA receptor blocker, is approved for epilepsy and isn't counted.

HOW IT WORKS

Think of TARP γ 8 as a volume knob fitted to glutamate receptors mostly in the forebrain. The drug tries to turn that knob down a little, where mania and seizures may start, while leaving the rest of the brain alone.

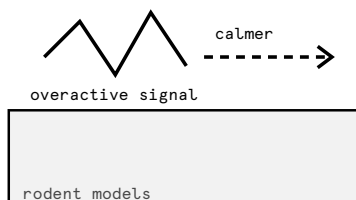
1 · THE KNOB



TARP γ 8 is a partner protein that sets how AMPA receptors open. A human PET study shows it is high in the hippocampus and low in the cerebellum.

DEMONSTRATED

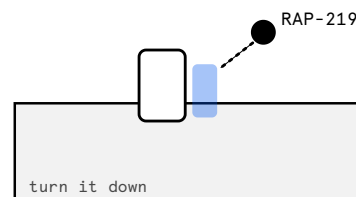
2 · TOO LOUD



In rodents, γ 8-selective blockers stopped seizures without the motor problems seen with broad AMPA blockers. That's animal data, not people.

SUGGESTIVE

3 · WHAT THE DRUG TRIES



Rapport says RAP-219 selectively dampens γ 8-linked receptors. In its Phase 2, mania scores fell 3.1 points more than on placebo; the trial result is in people, and the selectivity claim rests on the company.

COMPANY CLAIM

Solid: seen in people (any design, including genetic association). Dashed: animals or cells. Dotted: hypothesis or company claim. Line style shows where a step was seen, not proof.

EVIDENCE LADDER

DEMONSTRATED	TARP γ 8 is an AMPA receptor auxiliary subunit, and a human PET ligand shows it concentrated in hippocampus and cortex and low in cerebellum and brainstem.
SUGGESTIVE	γ 8-selective blockers are anticonvulsant in rodents without motor impairment; company-reported Phase 2 data show a 3.1-point YMRS gain in mania and, in a 30-patient open-label focal epilepsy study without a control group, company-reported reductions in device-recorded long episodes (the registered primary) and in clinical seizures against each patient's own baseline.
SPECULATIVE	That the selectivity holds in people at doses that treat mania, and that the effect is large enough to compete with existing antimanic drugs.

Who's running. Rapport alone in the clinic, with RAP-219 in two Phase 3s for focal seizures (FOCUS 1 and 2), a Phase 2 extension in focal epilepsy and the bipolar Phase 2, which has reported topline data but is still listed as active, not recruiting. Lilly's LY3130481 and Janssen's JNJ-55511118 series stayed preclinical as far as the registry shows. No peer-reviewed human efficacy paper on RAP-219 was found.

VERIFIED

V1 · 10.20.2026
First published, Edition 025

NEXT RE-PULL
On next lead mention or after 90 days



Open Targets Platform: CACNG8 target record and direct associations, release 26.09, 10.20.2026 [DATA](#). ChEMBL v34 target and compound search, 10.20.2026 [DATA](#). UniProt Q8WXS5 [DATA](#). ClinicalTrials.gov, interventional, 10.20.2026: [NCT07046494](#), [NCT07219407](#), [NCT07563881](#), [NCT07594119](#), [NCT06377930](#) (completed) [REG](#). Kato et al., [Nat Med, 2016](#) (forebrain-selective AMPA antagonism, rodents) [PEER](#). Koole et al., [Eur J Nucl Med Mol Imaging, 2025](#) (human PET distribution) [PEER](#). Rapport releases (10.20.2026; 11.06.2025) [CO](#).

BLUE TEAM · THE CASE

TARP γ8 offers a way to quiet forebrain glutamate signaling while sparing the cerebellum, which human PET imaging supports. Rodent studies showed seizure control without the motor effects of broad AMPA blockers. Rapport says RAP-219's randomized Phase 2 met its registered primary in mania, with similar overall adverse event rates. If the Phase 3s in focal seizures and a larger mania trial confirm the effect, one target could serve two diseases.

[ANALYSIS](#)

RED TEAM · THE CATCH

No human genetics tie CACNG8 to bipolar disorder or epilepsy, so the case rests on pharmacology. The mania gain was 3.1 points at $p=0.045$, agitation was higher on drug, and RAP-219's selectivity in people is company-reported. A single sponsor runs every active trial, so there's no independent replication. The seizure data so far come from a 30-patient open-label study. [ANALYSIS](#)



POLICY & REGULATORY WATCH

ITEM	STATUS	WHAT HAPPENED	WHAT IT COULD MEAN
Jemperli, rectal cancer	ENACTED	Accelerated approval 10.19 on AZUR-1; Priority Review and Breakthrough Therapy; 11th approval under the National Priority Voucher pilot, per FDA.	The voucher pilot is producing approvals at a steady clip, including supplemental indications. Confirmatory terms will show how FDA handles single-arm organ-preservation data.
Rezzayo sNDA (CorMedix, Mundipharma)	UNDER REVIEW	FDA accepted with Priority Review an sNDA for rezafungin as prophylaxis of invasive fungal disease after allogeneic stem cell transplant; goal date Q1 2027 (10.19).	A label expansion for an approved antifungal; no exact date given.
FDA leadership	POLITICAL	Kyle Diamantas remains Acting Commissioner; FDA quoted him on the Jemperli approval. No Senate vote on a nominee is expected before the midterms, as reported.	Policy continuity through the voucher and rare disease programs, for now.
Rare Disease Framework	PROPOSED	Hybrid public meeting set for 10.28, 1 to 5 pm ET, at FDA's White Oak campus in Silver Spring, per FDA's Federal Register notice (public meeting and request for comments; comments due 12.11); announced 10.14.	A request for input on rare disease evidence standards, not guidance; nothing binding yet.
China platform rules	PROPOSED	China is weighing export bans or limits on about 40 technologies including biomedicine, and reportedly curbs on foreign acquisitions of critical biopharma platforms (10.16).	Could slow or reshape licensing deals like Roche and Hansoh's. Proposed, not in force.
Roche and Germany	POLITICAL	Roche paused future investments in Germany over health care cost cuts, as reported by Fierce Pharma (10.19).	Pharma is using investment as leverage in European pricing debates.

FDA press announcement and approval notice (10.19) **GOV**; CorMedix release (10.19, 07:30 ET) **CO**; BioPharma Dive (10.15), Medical Daily (10.01), The Star (10.16), Fierce Biotech and Fierce Pharma **PRESS**. No new CMS, MFN, tariff or PBM action was found in the window. We didn't check NMPA or PMDA in depth.

RED TEAM

The voucher pilot's count of approvals is FDA's own framing; we can't yet compare its review times with standard priority review on like-for-like applications. Faster approvals on single-arm data shift more of the evidence burden to confirmatory studies, which have a mixed record of finishing on time. **ANALYSIS**



PATTERN RECOGNITION

EMERGING PATTERN

Pharma may be paying for delivery and conjugate engines as well as molecules.

EVIDENCE

Lilly and METiS (10.19), Roche and Hansoh (10.19), and Roche and Rona (ALK7 RNAi) in recent weeks.

POTENTIAL IMPLICATION

The scarce asset may be a way to get a payload to the right tissue. Three deals are a thread to watch, not yet a trend.

ANALYSIS



WHAT MAY BE UNDERESTIMATED

A The testing step behind organ preservation

The Jemperli label applies only to dMMR or MSI-H tumors identified by an FDA-authorized test. If tumors aren't tested at diagnosis, before chemoradiation starts, eligible patients may miss the option. The uptake question may be pathology workflow more than the drug. ANALYSIS

B Retina's durability case got harder to make

EyePoint's miss is a reminder that sustained-delivery wet AMD programs must show vision holds against standard injections, not just fewer injections. Without the BCVA numbers, how much it affects other programs is unclear.

ANALYSIS



WHERE THIS BRIEF COULD BE WRONG

The edition's biggest conclusion is that Jemperli's approval may make organ preservation an accepted goal of treatment. Here's the strongest case against it, and what would decide.

RED TEAM

Base case. A single-arm Phase 2 that treated 154 patients, with sustained 12-month complete responses in 47% of the 116 who could be assessed by central review, and most patients avoiding surgery at two years, earned accelerated approval for a defined biomarker group. **ANALYSIS**

Counter-case. Accelerated approval is conditional. If longer follow-up shows late regrowth, or confirmatory work stalls, the label could narrow. The different FDA figures (47% vs almost three-fourths) suggest the measure of success is still being defined.

What would settle it. AZUR-1's registered primary at completion (11.02.2026), 24- and 36-month data, and the confirmatory requirements.

CONSENSUS IMPLICATION	STRONGEST COUNTER-CASE	WHAT WOULD SETTLE IT
Jemperli sets organ preservation as a goal	Single-arm, two years of follow-up, two different success measures	Registered primary at completion; 36-month data
siRNA is now a buyable modality	One acquisition at a premium on a cheap stock	More cash takeovers of RNAi companies at Phase 2
China's ADC engines command cash	Milestones dominate; Beijing may restrict platform transfers	Final Chinese rules; Roche's first Phase 1a starts
RAP-219 opens a psychiatry path for TARP γ8	p=0.045, more agitation, no human genetics, single sponsor	Full data; a larger, replicated mania trial
Monday's bounce was stock-specific	It may be the start of a rebound in risk appetite	XBI through the 10.28 FOMC without more deal news

BLIND SPOT CHECK

Three of five lead items rest on company releases without full data. We couldn't find exact release times for Silence, Hansoh and METiS, so some may fall just before our window. Disc's offering hadn't priced by our build.

ClinicalTrials.gov last-update dates couldn't be retrieved, so stale-record flags rest on status and dates. ESMO abstracts aren't public yet. NEJM and Nature article pages wouldn't load, so the journal sweep relied on PubMed.

NMPA, PMDA and EMA weren't checked in depth, and no October CRL turned up, which may be a coverage gap rather than a signal.



VERIFIED CATALYST CALENDAR

Twenty-two of 24 dates confirmed at the source. ESMO, Kidney Week, the FOMC and two weekend FDA goal dates fall inside two weeks.

DATE	EVENT	CONFIRMED AT
Tue 10.20	Post-trial hearing, AnaptysBio v. GSK/Tesaro over Jemperli	COMPANY
Wed 10.21	Abbott Q3 results	COMPANY
Wed 10.21	IDWeek 2026, Washington, DC	ORGANIZER
10.21 to 10.24	NASPGHAN annual meeting, San Diego	AGGREGATOR
Thu 10.22	Roche Q3 sales, before the Swiss open	COMPANY
Thu 10.22	ASN Kidney Week, Denver (to 10.25)	ORGANIZER
Fri 10.23	ESMO Congress 2026, Madrid (to 10.27)	COMPANY
Fri 10.23	Novartis investor call on remibrutinib in MS, 6:30 pm ET	COMPANY
Sat 10.24	Goal date: Joenja (leniolisib) sNDA, APDS ages 4 to 11 (a Saturday; FDA may act earlier)	COMPANY
Sun 10.25	ESMO orals: OSE Combi-TED and Nouscom NOUS-209	COMPANY
Mon 10.26	Goal date: bepirovirsen, chronic hepatitis B (GSK; priority review)	COMPANY
Tue 10.27	Novartis Q3 results	COMPANY
Tue 10.27	FOMC; statement 2:00 pm ET on 10.28	FED
Wed 10.28	FDA public meeting, Rare Disease Framework Initiative, Silver Spring	AGGREGATOR
Thu 10.29	Merck Q3 call, 9:00 am ET	COMPANY
Thu 10.29	Lilly Q3 results, call 10:00 am ET	COMPANY
Thu 10.29	BMS Q3 results	COMPANY
Thu 10.29	Gilead Q3 results, after the close	COMPANY
Thu 10.29	FDA action expected: Ilumya (tildrakizumab), psoriatic arthritis (Sun Pharma)	COMPANY
Thu 10.29	Q3 GDP advance estimate and September PCE, 8:30 am ET	BEA
Fri 10.30	AbbVie and Regeneron Q3 results, before the open	COMPANY
Fri 10.30	FDA DODAC: atropine 0.01% for pediatric myopia (Sydnexis)	FDA
Sun 11.01	Goal date: mitapivat sNDA, sickle cell disease, based on data in patients 16 and older, filed under the accelerated approval pathway (Agiros; priority review; a Sunday, so FDA may act earlier)	COMPANY
Mon 11.02	Vertex Q3 results, after the close; AZUR-1 registered primary completion	COMPANY

Sources were opened 10.19 to 10.20 and every weekday checked against the 2026 calendar. "Aggregator" means we found no primary confirmation today; treat that date as likely, not certain. FDA doesn't publish PDUFA dates, so goal dates come from sponsor releases or filings. Dates listed only by aggregators and contradicted or unconfirmed by sponsors (a Humacyte 10.22 goal date and an Ionis BIIB080 10.26 date) are left out.



REGISTRY WATCH

All 48 watchlist trials pulled; no field changed since 10.19. Eight records have passed their primary completion dates without a status change or posted results.

TRIAL	STATUS	PRIMARY COMPLETION	FLAG (BOLD) OR NOTE
LIBREXIA-STROKE	Active, not recruiting	10.15.2026	Primary completion passed
Tilrekimig AD Phase 2	Recruiting	10.19.2026	Still recruiting at primary completion
ALOFT-IPF	Unchanged	10.06.2026	Topline out 10.12; no results posted
MAXPIRe	Unchanged	09.2026	Primary completion passed
ARISE	Unchanged	08.2026	Primary completion passed
ZP9830 Phase 1	Recruiting	08.2026	Still recruiting past primary completion
MRT-8102	Unchanged	07.2026	Primary completion passed
BMF-650	Unchanged	05.2026	Primary completion passed
COURAGE	Unchanged	n/a	Study completion date 10.21.2026

ClinicalTrials.gov, pulled 10.20.2026 **REG**; diffed field by field against the 10.19 snapshot (status, enrollment, primary outcome, dates, phase): no changes, no additions, no removals. Last-update-posted dates couldn't be retrieved, so flags rest on status and dates. Full table on Fridays.



PREPRINT RADAR

Three preprints from 10.16 to 10.19. None is peer-reviewed, so read them as early signals.

Base editing corrected a kidney disease mutation in human tubuloids [PRE]

A Charité team corrected the UMOD p.Cys170Tyr variant behind a dominant tubulointerstitial kidney disease, with A-to-G conversion of up to 83.4%, and restored uromodulin trafficking in cell lines and human kidney tubuloids. Four mutation-agnostic ways to switch off the faulty gene reached 44.1% to 71.9% on target. It's all cells and organoids, with no delivery or animal data yet. [CLAIM]

BIORXIV · [10.64898/2026.10.15.758759](https://doi.org/10.64898/2026.10.15.758759) (10.16)

A long-studied heart risk locus may act through an RNA in blood vessel cells [PRE]

Karolinska researchers mapped the 9p21.3 coronary disease locus in primary human vascular cells and point to the long noncoding RNA MIR31HG as an effector in endothelium; turning on the lead enhancer raised MIR31HG, and depleting it was associated with endothelial activation. Small donor numbers and cell work only, so the link to heart attacks is still inferred. [CLAIM]

MEDRXIV · [10.64898/2026.10.15.26365688](https://doi.org/10.64898/2026.10.15.26365688) (10.19)

Belzutifan's adjuvant kidney cancer benefit may be front-loaded [PRE]

Reconstructing patient data from published curves, a Kaohsiung group estimates the disease-free survival hazard ratio for belzutifan plus pembrolizumab at 0.55 (95% CI 0.43 to 0.71) before month 12 and 1.16 (0.87 to 1.54) after, in LITESPARK-022, by central review. The later window is post hoc, rests on data reconstructed from published curves with short follow-up, and its interval includes no difference, so it raises a question rather than answering it. [ANALYSIS]

MEDRXIV · [10.64898/2026.10.14.26365591](https://doi.org/10.64898/2026.10.14.26365591) (10.16)

Preprint-to-journal tracker: all 17 tracked preprints re-checked 10.20.2026; none has a published journal DOI yet. These three join the tracker. bioRxiv and medRxiv APIs [PRE].



PUBLIC CALLS LEDGER

Nine open calls. None resolved since yesterday; the next full grade is 10.30.

#	CALL (RESOLVES YES OR NO)	BY	OUR ODDS	STATUS
06	FDA approves GSK's bepirovirsen for chronic hepatitis B	10.26	75%	OPEN
07	The Fed raises rates at the 10.27 to 10.28 FOMC	10.28	20%	OPEN
04	The 10-year Treasury closes below 5.00% on any day	10.31	35%	OPEN
05	uniQure announces FDA acceptance of the AMT-130 BLA	11.02	60%	OPEN
08	Sanofi duvakitug HS Phase 2b (NCT07812116) shows Recruiting on ClinicalTrials.gov	11.15	70%	OPEN
12	FDA approves BridgeBio's BBP-418 for limb-girdle muscular dystrophy 2I/R9	11.27	60%	OPEN
10	CMS publishes negotiated maximum fair prices for the 15 drugs selected for 2028 (IRA third cycle)	11.30	90%	OPEN
15	Viking's SUNRISE 1 Phase 3 of oral VK2735 (NCT07868835) shows Recruiting on ClinicalTrials.gov	11.30	55%	OPEN
09	A biopharma acquisition of \$5B or more is announced	12.31	80%	OPEN

Running Brier score 0.0668 on seven resolved calls (as of 10.19). Merck KGaA's Silence deal (about \$1.3B) doesn't resolve call 09. The 10-year closed at 5.15% on 10.19, so call 04 stays open. Calls cover scientific, regulatory and macro events only, never share prices.



ASK MIND CLUB AND CORRECTIONS

Reader questions are answered in the Sunday edition. No new correction today.

CORRECTIONS LOG

EDITION	WHAT WE GOT WRONG	WHAT IT SHOULD SAY	FIXED
012 (our correction of 10.07)	Our 10.07 correction to Edition 012's Target Evidence Card for LRRK2 gave the Open Targets genetic association score for Parkinson's disease as 0.93, with 0.88 overall.	Those figures appear to include indirect evidence. On the direct basis our Target Evidence Cards use, Open Targets scores LRRK2 at 0.82 for Parkinson's disease and 0.76 overall (release 26.09, checked 10.16.2026), the values Edition 012 first printed. LRRK2's genetic link to Parkinson's is unchanged.	10.19
018	Section 02 said Alaunos's 10.13 release on completing its acquisition of Velaris gave no price, structure or concurrent financing.	Alaunos's 10.13 release reports a private placement of Series C non-voting convertible preferred stock, led by Fairmount, with gross proceeds of approximately \$350 million. The PDBB tally now counts it.	10.14
014	A RED TEAM box on the atezolizumab (ATOMIC) approval said neoadjuvant checkpoint blockade, as in NICHE-2, may move treatment before surgery and shrink the adjuvant market, without saying what kind of study NICHE-2 was.	Clarification: NICHE-2 was a single-arm Phase 2 of nivolumab plus ipilimumab given before surgery in resectable, locally advanced dMMR colon cancer (NEJM, 2024). It shows the timing of treatment could move, not that it has.	10.13
013 to 018	Section 02 listed Candid via Rallybio (\$505M) among reverse mergers with the largest concurrent financings, and the PDBB tally and heat map counted it as a 2026 financing.	Candid terminated its Rallybio merger on 05.03.2026 to be acquired by UCB (Rallybio 8-K, 05.04.2026), so the merger never closed and its concurrent financing is not counted. The tally now holds 467 financings and \$66.4B.	10.13
013	Section 01 said Gilead and Amgen each rose about 2.6% on 10.07.	Amgen rose 2.6% and Gilead 1.8% on 10.07, per Robinhood daily closes.	10.09
013	Sections 01 and 02 said BioBucks' venture tracker title and body differ (\$24.4B vs \$24.9B).	The tracker's title gives \$24.9B and \$24.4B appears nowhere on the page; 193 rounds and about \$24.9B were right.	10.09
013	Section 02 listed reverse-merger financings as Candid via Rallybio \$506M and Avere via NextCure \$500M.	Candid's concurrent financing was \$505M. Avere's totaled \$820M across two placements (\$320M, then \$500M), so it ranks first.	10.09
013	Sections 01 and 04 quoted the FOMC minutes as most participants judging a further hike "likely appropriate by year end."	The minutes say most participants assessed that another increase "would likely be appropriate by year end." The meaning was right; the quotation wasn't verbatim.	10.09
013	Item 05 dated Bayer's Kerendia sNDA acceptance release 10.07.	Bayer's release went out on 10.08.2026 (2:30 am EDT), still inside the window.	10.09
013	Section 10 said the GLOBE Part B final rule starts 04.01.2027.	Implementation begins 01.01.2027 with a voluntary reporting quarter; the five-year performance period starts 04.01.2027.	10.09
013	The Verified Catalyst Calendar marked Abbott's 10.21 Q3 results as Aggregator and counted 16 of 19 dates confirmed.	Abbott's own 09.30 release confirms Wednesday 10.21 before the open, so 17 of 19 dates were confirmed at the source.	10.09
013	Claim Check gave ATSN-201's LIGHTHOUSE registry primary as DLTs and adverse events only.	That is the Parts A and B primary. The registry (NCT05878860) also lists a Part C primary: the share of patients with a microperimetry gain of 7 dB or more at week 52. The Partial verdict stands.	10.09
012	Section 07 dated J&J's Delaware injunction blocking a Simponi (golimumab) biosimilar to 10.02.	The preliminary injunction order is dated 09.30.2026, with a \$98.8M bond; the defendants filed a notice of appeal on 10.01.	10.07



EDITION	WHAT WE GOT WRONG	WHAT IT SHOULD SAY	FIXED
012	Claim Check (02B) and Clinical readouts (05) put "no safety concerns" in quotation marks for Kariya's KP405, as if from its source.	The source, NeurologyLive's MDS report, contains no such phrase; it says the study was not designed or powered for efficacy. KP405's registered primary endpoints are safety measures, and no safety finding was quoted.	10.07
012	Sections 03 and 06 reported Kura Oncology's launch of Caspian Therapeutics, to develop the menin inhibitor KO-7246 for beta-cell regeneration, as news from the 10.06 to 10.07 window, with financing terms not disclosed and a Phase 1 planned.	Caspian launched on 09.09.2026 with a \$50M Series A, in which Kura holds about 49%. The only news in the window was a 10.07 notice of an investor webcast on 10.13. KO-7246 is in IND-enabling work, with no Phase 1 date announced.	10.07
012	The Target Evidence Card for LRRK2 (section 06) gave the Open Targets genetic association score for Parkinson's disease as 0.82, with an overall score of 0.76.	Open Targets scores LRRK2 at 0.93 for genetic association with Parkinson's disease (MONDO_0005180) and 0.88 overall, re-pulled on 10.07.2026. The late-onset (0.94, overall 0.84) and young-onset (0.32) scores were right.	10.07
009	The Verified Catalyst Calendar listed a 10.10 FDA goal date for ifinatamab deruxtecan in previously treated extensive-stage small cell lung cancer, marked as confirmed by the company.	Merck and Daiichi Sankyo voluntarily withdrew that BLA on 09.25.2026, so there was no 10.10 goal date. Edition 007 had it right; Edition 009 relied on an outdated release.	10.05



SOURCES

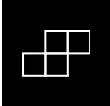
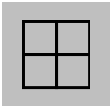
1. [FDA press announcement, Jemperli in rectal cancer \(10.19\)](#) **GOV**
2. [FDA approval notice, dostarlimab \(10.19\)](#) **GOV**
3. [GSK release, Jemperli approval \(10.19\)](#) **CO**
4. [Silence Therapeutics release \(10.19\)](#) **CO**
5. [Silence DEFA14A exhibit 99.8, SEC \(10.19\)](#) **CO**
6. [Fierce Biotech, Merck KGaA and Silence \(10.19\)](#) **PRESS**
7. [Hansoh Pharma release, Roche license \(10.19\)](#) **CO**
8. [Fierce Biotech, Roche and Hansoh \(10.19\)](#) **PRESS**
9. [Fierce Biotech, China platform rules](#) **PRESS**
0. [The Star, China export restrictions \(10.16\)](#) **PRESS**
1. [Rapport release, RAP-219 Phase 2 \(10.20\)](#) **CO**
2. [EyePoint release, LUCIA topline \(10.19\)](#) **CO**
3. [EyePoint release, strategic prioritization \(10.19\)](#) **CO**
4. [Gilead statement, SWIFT \(10.19\)](#) **CO**
5. [Disc Medicine release, proposed offering \(10.19\)](#) **CO**
6. [TCGX Acquisition 8-K exhibit 99.1, TriGemX \(10.19\)](#) **CO**
7. [Fierce Biotech, TriGemX SPAC \(10.19\)](#) **PRESS**
8. [IPOScoop, Lycia IPO terms \(10.20\)](#) **PRESS**
9. [TechNode Global, METIS and Lilly \(10.20\)](#) **PRESS**
0. [Ambrose Healthcare release, AM-Pharma \(10.20\)](#) **CO**
1. [CorMedix release, Rezzayo sNDA \(10.19\)](#) **CO**
2. [BioPharma Dive, Rare Disease Framework \(10.15\)](#) **PRESS**
3. [Magrangeas et al., Nature Medicine \(10.19\), via PubMed](#) **PEER**
4. [Kato et al., Nature Medicine \(2016\)](#) **PEER**
5. [Koole et al., Eur J Nucl Med Mol Imaging \(2025\)](#) **PEER**
6. [Open Targets Platform, CACNG8 \(release 26.09\)](#) **DATA**
7. [UniProt Q8WXS5, CACNG8](#) **DATA**
8. [ClinicalTrials.gov NCT05723562 \(AZUR-1\)](#) **REG**
9. [ClinicalTrials.gov NCT07046494 \(RAP-219 mania\)](#) **REG**
0. [ClinicalTrials.gov NCT06290934 \(SWIFT\)](#) **REG**
1. [ClinicalTrials.gov NCT06683742 \(LUCIA\)](#) **REG**
2. [ClinicalTrials.gov NCT05499013 \(divesiran\)](#) **REG**
3. [U.S. Treasury, daily par yield curve \(10.19\)](#) **GOV**
4. [Federal Reserve, open market operations](#) **GOV**
5. [Forbes, citing CME FedWatch \(10.19\)](#) **PRESS**
6. [BioBucks IPO tracker \(10.19\)](#) **PRESS**
7. [BioBucks M&A tracker \(10.18\)](#) **PRESS**
8. [bioRxiv 10.64898/2026.10.15.758759](#) **PRE**
9. [medRxiv 10.64898/2026.10.15.26365688](#) **PRE**
0. [medRxiv 10.64898/2026.10.14.26365591](#) **PRE**
1. [GSK release, bupirovirsen priority review \(04.28\)](#) **CO**
2. [Pharming 6-K, leniolisib goal date](#) **CO**
3. [Agiros release, mitapivat goal date \(07.07\)](#) **CO**
4. [Roche investor update, Q3 date \(10.15\)](#) **CO**
5. [Novartis investor event calendar](#) **CO**
6. [Merck Q3 call notice \(10.01\)](#) **CO**



7. [Gilead Q3 date \(10.15\)](#) CO
8. [AbbVie Q3 call notice \(10.01\)](#) CO
9. [Vertex Q3 date](#) CO
0. [Federal Reserve, October 2026 calendar](#) GOV
1. [BEA release schedule](#) GOV

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