



ASX ANNOUNCEMENT

8 September 2025

Successful TrialKey Observational Predictions

Align with 73% of Biotech Trial Outcomes – 1st Report shows average +76% with a high of +785% share price inflections

Pathkey.AI Ltd (ASX: PKY) ("Pathkey" or "the Company") today releases the first in a series of updates on the progress towards validating real-world performance of its TrialKey™ platform, which estimates the probability of clinical trials meeting primary endpoints.

Highlights:

- To check how TrialKey's predictive signals align with real outcomes, the Company studied 11 clinical programs that reported between 1 March and 29 July 2025¹. Eight (72.7%) met at least one primary endpoint. A simple hypothetical calculation: buy on the day TrialKey recorded the prediction, sell on results day – saw an average hypothetical share price return of +76%.
- **Abivax (NASDAQ: ABVX):** TrialKey Probability of Success (PoS) **83%** (91st percentile in ulcerative colitis (UC) Phase 3); shares up **~785%** during the Observation Window (refer to *Methodology summary* on page 5 for definition).
- **Mineralys Therapeutics (NASDAQ: MLYS):** PoS **71%** (86th percentile in resistant hypertension); shares up **55.8%** during the Observation Window.
- **Trevi Therapeutics (NASDAQ: TRVI):** PoS **44%** (64th percentile in refractory chronic cough); shares up **64.4%** during the Observation Window.
- **Nektar Therapeutics (NASDAQ: NKTR):** PoS **61%** (88th percentile in atopic dermatitis Phase 2b); shares up **59.8%** during the Observation Window.
- TrialKey is currently monitoring **20 additional NASDAQ- and ASX-listed companies** with predictions showing probabilities of success above the baseline for the specific indication and phase.

¹ The Company chose these programs because TrialKey flagged them as above average probability of success relative to competitors. These examples are observational; no trades were placed.



- TrialKey insights are being applied across **trial optimisation, insurance and biotech investing**. Pathkey has a partnership with **L39 Capital** to apply TrialKey data in L39's AI Biotech Fund which is **non-exclusive**.

What TrialKey does (and why it matters)

- **Purpose:** TrialKey uses AI to analyse decades of global clinical trial data and estimate a trial's **Probability of Success (PoS)** by reference to indication and phase. It identifies signals, **not guarantees**, of which trials sit, based on TrialKey's assessment, **meaningfully above peer baseline probabilities of success**.
- **How it works:** The platform analyses **500,000+ clinical trials**, capturing **1,500+ variables per trial** (trial design, protocol detail and compound features) to produce a calibrated PoS.

2025 spotlight observations

All of the below announcements are cross referenced in the Appendix.

- **Abivax (NASDAQ: ABVX)** — ulcerative colitis (UC), Phase 3
TrialKey PoS **83%** (assessed by TrialKey to be in the 91st percentile vs **nearest competitors** – refer to Methodology summary on page 5 for definition). Following positive progress in its pivotal UC program, ABVX share price rose **~785%** during the Observation Window.
- **Mineralys Therapeutics (NASDAQ: MLYS)** — Resistant hypertension, Phase 3
TrialKey PoS **71%** (assessed by TrialKey to be in the 86th percentile vs nearest assessed competitors). After Phase 3 data, MLYS share price rose **55.8%** during the Observation Window.
- **Trevi Therapeutics (NASDAQ: TRVI)** — Refractory chronic cough, Phase 2a
TrialKey PoS **44%** (64th percentile vs nearest assessed competitors). After positive Phase 2a data share price rose **64.4%** during the Observation Period.
- **Nektar Therapeutics (NASDAQ: NKTR)** — Atopic dermatitis, Phase 2b
TrialKey PoS **61%** (assessed by TrialKey to be in the 88th percentile vs nearest assessed competitors). After Phase 2b data share price rose **59.8%** during the Observation Period.

Table 1: TrialKey-Flagged **NASDAQ Biotechs** — Prediction Day to Results Day

Company	NASDAQ Ticker	Indication / Phase	TrialKey PoS & Percentile	Observation Date & Price (first trade)	Inflection Date & Price (last trade)	% Change	Met Endpoint(s)
Abivax	NASDAQ: ABVX	Ulcerative colitis – Phase 3	83% (91st pct)	8 Jul 2025 @ \$7.75	23 Jul 2025 @ \$68.60	785.20%	Met ⁱ
Trevi Therapeutics	NASDAQ: TRVI	Chronic cough – Phase 2a	44% (64th pct)	28 Feb 2025 @ \$4.50	10 Mar 2025 @ \$7.40	64.40%	Met ⁱⁱ
Nektar Therapeutics	NASDAQ: NKTR	Atopic dermatitis – Phase 2b	61% (88th pct)	17 Dec 2024 @ \$15.30	24 Jun 2025 @ \$24.45	59.80%	Met ⁱⁱⁱ
Mineralys Therapeutics	NASDAQ: MLYS	Resistant hypertension – Phase 3	71% (86th pct)	19 Feb 2025 @ \$9.60	10 Mar 2025 @ \$14.96	55.80%	Met ^{iv}
Cardiff Oncology	NASDAQ: CRDF	Hard-to-Treat Cancer – Phase 2	42% (75th pct)	6 May 2025 @ \$2.566	29 Jul 2025 @ \$2.08	-18.90%	Met ^v
AnaptysBio	NASDAQ: ANAB	Inflammatory diseases – Phase 2	38% (60th pct)	11 Feb 2025 @ \$12.38	12 Feb 2025 @ \$16.15	33.36%	Met ^{vi}
Veru	NASDAQ: VERU	Sarcopenic Obesity – Phase 2b	65% (58th pct)	6 May 2025 @ \$0.61	26 Jun 2025 @ \$0.675	10.70%	Met ^{vii}
Tourmaline Bio	NASDAQ: TRML	Systemic inflammation – Phase 2	57% (87th pct)	30 Apr 2025 @ \$16.10	20 May 2025 @ \$16.20	0.62%	Met ^{viii}
InflaRx	NASDAQ: IFRX	Pyoderma Gangrenosum – Phase 3	42.2% (rare, pct n/a)	30 Apr 2025 @ \$1.214	28 May 2025 @ \$0.850	-29.90%	Failed ^{ix}
Prothena	NASDAQ: PRTA	Amyloid Related Diseases – Phase 3	47% (pct n/a)	3 Apr 2025 @ \$10.31	24 May 2025 @ \$4.59	-55.50%	Failed ^x
Vor Biopharma	NASDAQ: VOR	AML – Phase 1/2	57% (73rd pct)	6 May 2025 @ \$0.63	8 May 2025 @ \$0.246 (Terminate d)	-61.00%	Terminated ^{xi}

Totals: trials observed **11** | **Met endpoint:** 8 | **Failed:** 2 | **Terminated:** 1 |

Average return: +**76.78%**



Pathkey.AI Executive Chairman, Saurabh Jain, said:

“These results show how powerful TrialKey can be when applied to the world's most challenging and consequential trials. Clinical programs with strong TrialKey scores are consistently proving their merit in the market. Each validation strengthens confidence in TrialKey, expands our dataset and enhances our ability to deliver insights to trial sponsors, CROs, insurers and investors worldwide.”.

Relationship with L39 Capital

Pathkey.AI has a partnership with **L39 Capital Pty Ltd** to apply TrialKey insights in L39's AI Biotech Fund. This partnership provides one commercial pathway for TrialKey and is **non-exclusive**; Pathkey retains full freedom to apply TrialKey across clinical trials, insurance and global life sciences markets.

Important Disclaimer

This release contains information generated by Pathkey.AI's TrialKey AI platform. The analysis is provided for the purpose of demonstrating the platform's predictive capability in relation to clinical trial outcomes and their potential impact on listed biotech/pharma companies. It is not intended, and should not be construed, as investment or financial advice. TrialKey estimates probabilities of trial success, not stock prices; market reactions are used here only as an external, observational proxy. Results are based on a small, early sample and may not repeat.

Pathkey.AI does not provide recommendations to buy, sell or hold securities, and accepts no responsibility for investment decisions made on the basis of this information. Investors should seek independent financial advice before making any investment decisions.

This announcement has been authorised for release by the Board of Pathkey.AI Ltd.

About Pathkey.AI

Pathkey.AI Limited (ASX: PKY) is an Australian technology company applying artificial intelligence to improve the efficiency, success, and transparency of clinical trials. Pathkey.AI's core platform, TrialKey, is an AI-powered decision-support tool that predicts the probability of success for clinical trials and helps sponsors optimise trial design and planning. The company is committed to transforming drug development by reducing risk, improving resource allocation and unlocking data-driven innovation across the life sciences sector.

Appendix

Methodology: Inclusion, Comparators, and Calculations

Inclusion rule: Programs are included in observed trials if, at the Observation Date, TrialKey's percentile vs closest assessed competitors is greater than 50%. Where a stable percentile is not available because the program is rare, inclusion requires a model probability of success of at least 40%.

Closest assessed competitors: for each program, we compare it with all trials we have on record for the same indication, or similar indications identified using ClinicalTrials.gov MeSH terms, in the same phase and for the same treatment type. This forms the comparison cohort used for percentiles.

Observation Date: The date on which the TrialKey prediction was documented.

Observation Window: The period starting on the Observation Date and ending on the Inflection Date.

Inflection Date and Price (ie. a hypothetical sell): The calendar date on which the trial result (efficacy readout) was first publicly announced; if a program was terminated, the termination-announcement date is used. The price recorded is the official exchange close on that date. "Last trade" refers to this hypothetical sell at the Inflection Date.

Returns and averages: Percent change is calculated as $(\text{Price as at the Inflection Date} - \text{Price at the Observation Date}) / \text{Price at the Observation Date}$. Average Per-Company return is the arithmetic mean of all per-name returns in the table, with a flat stake (i.e., this is not a trading track record).

Data treatment and exclusions: Prices are split-adjusted as per the listing venue. Returns are observational and hypothetical, use flat position sizing and exclude transaction costs, slippage, borrow fees, taxes and FX effects. Content is provided for model-validation context only; it is not investment advice and does not make forward-looking statements.

ⁱ <https://ir.abivax.com/news-releases/news-release-details/abivax-announces-positive-phase-3-results-both-abtect-8-week>

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- ⁱⁱ <https://www.nasdaq.com/press-release/trevi-therapeutics-announces-positive-topline-results-phase-2a-river-trial-haduvio>
- ⁱⁱⁱ <https://ir.nektar.com/news-releases/news-release-details/rezolve-ad-phase-2b-study-rezpegaldesleukin-meets-primary-and>
- ^{iv} <https://ir.mineralystx.com/news-events/press-releases/detail/60/mineralys-therapeutics-announces-positive-topline-results>
- ^v <https://investors.cardiffoncology.com/news-releases/news-release-details/cardiff-oncology-announces-positive-data-ongoing-randomized>
- ^{vi} <https://ir.anaptysbio.com/news-releases/news-release-details/anaptys-announces-rostilimab-achieved-positive-results-ra-phase>
- ^{vii} <https://ir.verupharma.com/news-events/press-releases/detail/236/veru-reports-positive-results-from-phase-2b-quality-and>
- ^{viii} <https://ir.tourmalinebio.com/news-releases/news-release-details/tourmaline-bio-announces-positive-topline-results-ongoing-phase>
- ^{ix} <https://www.inflarx.de/Home/Investors/Press-Releases/Press-Release~2025-05-InflaRx-Announces-Outcome-of-Interim-Analysis-for-Vilobelimab-Phase-3-Trial-in-Pyoderma-Gangrenosum~.html>
- ^x <https://ir.prothena.com/investors/press-releases/news-details/2025/Prothena-Announces-Phase-3-AFFIRM-AL-Clinical-Trial-for-Birtamimab-in-Patients-with-AL-Amyloidosis-Did-Not-Meet-Primary-Endpoint/default.aspx>
- ^{xi} <https://seekingalpha.com/news/4444540-vor-bio-plunges-as-it-winds-down-all-manufacturing-operations-reduces-95-of-workforce>