

Portfolio Re-evaluation – Catalyst-Focused Microcap Strategy

Our microcap portfolio remains centered on upcoming catalysts and high-conviction theses. Below we revisit each holding with the latest developments, adjust risk management as needed, and deploy the remaining cash into a new catalyst play. The goal is **maximizing alpha** while actively managing downside risk.

ABEO – Abeona Therapeutics (Gene Therapy Launch Play)

Update: Abeona's gene therapy **ZEVASKYN™ (prademagene zamikeracel)** for RDEB was FDA-approved in April and is now launching as the **first and only autologous cell-based gene therapy** for this ultra-rare skin disease ¹ ². Abeona monetized its FDA-awarded Priority Review Voucher for **\$155 million**, boosting cash to ~\$225 million (June 30) and securing 2+ years of runway ³ ⁴. The **first patient treatments are slated for Q3 2025**, with **profitability projected by early 2026** ⁵. Abeona is rapidly activating Qualified Treatment Centers (QTCs) – e.g. Stanford and Lurie Children's in Chicago – to administer ZEVASKYN ⁶ ².

Thesis Check: Our thesis of *"first-mover advantage in a rare disease with premium pricing"* remains solid. ZEVASKYN offers a unique one-time surgical treatment (gene-modified skin graft) that achieved meaningful wound healing with a **single application** ⁷ ². This contrasts with the competing topical gene therapy (Krystal's Vyjuvek) which requires weekly applications ⁸. ZEVASKYN's one-and-done approach and Abeona's comprehensive patient support (Abeona Assist™) should drive uptake in eligible RDEB patients ⁹ ¹⁰. With no direct *approved* competitors for one-time treatments, Abeona can command premium pricing, and the **PRV sale cash cushions launch execution risk**.

Risk/Reward: Downside is low given ZEVASKYN is already approved and the company is well-capitalized ¹¹ ⁵. Near-term risk is mainly execution: the pace of patient onboarding and reimbursement. We'll monitor initial uptake as QTCs come online. Upside comes from revenue ramp into 2026+ and potential early profitability. **No change** to our position – we continue to **HOLD ABEO** through the launch ramp. Stop-loss not emphasized here due to fundamental strength and cash buffer; we would reassess only if launch metrics severely disappoint in coming quarters.

IINN – Inspira Technologies (MedTech Turnaround)

Update: Inspira has transformed from a struggling penny stock into a revenue-generating medtech with **bullish momentum**. In July, the company secured a **\$22.5 million binding purchase order** for its FDA-cleared INSPIRA ART100 respiratory system ¹² – a **"major commercial inflection point"** marking the shift to full-scale revenue generation ¹³. The order (from an international partner with government ties) will be paid in full this year ¹⁴, validating product-market fit. Inspira also regained Nasdaq compliance on July 18 by lifting its share price back above \$1 ¹⁵. Management reports advanced talks with additional healthcare

and government customers for more deals ¹⁶, and has **scaled up production capacity** in anticipation of a potential European government order ¹⁷ ¹⁸.

Thesis Check: The catalyst of the \$22.5M order and compliance regain panned out, confirming our thesis. The large order **"opened the door to... the next wave of global deployments"**, per the CEO ¹⁹ ¹⁶. Inspira's ART100 (an ECMO/cardio-pulmonary bypass device) now has proven **clinical use in top U.S. hospitals** and a path to integrate into emergency preparedness programs ²⁰ ²¹. We're optimistic about follow-on contracts – for example, management's June update hinted at **advanced negotiations with a European government** ¹⁷ ¹⁸ and the company is positioning as a "strategic public health supplier" globally ²² ²³.

Risk/Reward: We realized some profits earlier and hold a core position. Upside drivers include additional orders (government adoption could be a game-changer) and the development of next-gen systems (ART500) and sensors (HYLA) ²⁴. Downside risks: any delay in executing the big order or dilution (they filed a routine shelf F-3, though clarified it's standard practice ²⁵). We'll **HOLD IINN**, aiming to ride further contract wins. **Risk management:** To protect gains, we set a **stop-loss at \$1.00** (the Nasdaq compliance threshold). This ensures we exit if momentum reverses significantly, while giving the stock room to fluctuate above the dollar mark.

AXGN – Axogen (FDA Catalyst in Nerve Repair)

Update: Axogen is approaching a binary catalyst: **FDA's decision on the Avance® Nerve Graft BLA by September 5, 2025 (PDUFA date)** ²⁶. Recent performance suggests growing confidence. **Q2 2025 revenue jumped 18.3% YoY** to \$56.7M, beating estimates, with double-digit growth across all nerve repair markets ²⁷. Gross margin hit 74% ²⁷ and adjusted EPS turned positive (\$0.12 vs \$0.06 est.) ²⁸. Axogen even raised full-year revenue guidance to ≥17% growth (≥\$219M in 2025) and expects to be **net cash flow positive for the year** ²⁹ ³⁰. Crucially, the BLA review appears on track: late-cycle FDA meetings and inspections are complete, and if approved, Avance will be the **first biologically processed nerve allograft with full approval**, granting **12 years of exclusivity** ³¹ ³². Axogen has expanded reimbursement – over 55% of insured Americans now have coverage for its nerve repair products ³³ – which should accelerate adoption post-approval.

Thesis Check: We viewed this as an asymmetric bet on FDA approval. That thesis remains *intact* and arguably strengthened by Axogen's strong execution. Even **if approval were denied**, Axogen's existing business (nerve conduit, allografts under current regulatory allowance) has shown resilience – 18% sales growth and near-breakeven operations ²⁷ ²⁸ – which would help limit downside. However, the latest signals point toward approval: management **"completed late-cycle review"** with FDA with no red flags disclosed ³¹. Approval would cement Axogen's leadership in peripheral nerve repair and likely spur a breakout in the stock, given the high barrier to entry (exclusivity + established surgeon network).

Risk/Reward: This is a *moderate risk, high reward* scenario. A positive FDA decision could re-rate AXGN significantly higher (securing its graft as standard of care), whereas a negative outcome could cut the stock (though we expect Axogen would appeal or refocus on other products, leveraging its strong commercial base). We will **HOLD AXGN through the PDUFA**. No pre-emptive stop is set – we accept binary risk on this position. If the decision is negative, we will reassess swiftly (likely exit, as the thesis would shift); if positive, we may add on initial strength *up to our micro-cap size limit*, given the new growth runway (we note AXGN's market cap might exceed \$300M on success, so **no adding thereafter** per our micro-cap discipline).

ESPR – Esperion Therapeutics (Cholesterol Drug Turnaround)

Update: Esperion's turnaround is progressing, driven by increasing sales of its cholesterol-lowering drugs **NEXLETOL® (bempedoic acid)** and **NEXLIZET®**. **U.S. net product revenue grew 41% year-over-year in Q1 2025** ³⁴ and **42% in Q2 2025** (reaching \$40.3M in Q2) ³⁵ ³⁶. Total revenue for Q2 was \$82.4M (+12% YoY) ³⁵, reflecting continued royalty and milestone contributions. The overhang with Daiichi Sankyo Europe was resolved: Esperion **settled the dispute** over European milestones – securing **\$125M** (with \$100M paid in Jan 2024 and \$25M after an EMA decision) ³⁷ ³⁸. This bolstered the balance sheet; Esperion ended Q1 2025 with **\$114.6M cash** ³⁹ and expects cash runway into 2026. Critically, the settlement also expanded the partnership (DSE took over EU supply and will collaborate on a triple combo pill) ⁴⁰ ⁴¹, aligning Daiichi's interests with Esperion's going forward.

Operationally, Esperion is capitalizing on the landmark CLEAR Outcomes data for bempedoic acid (which showed reduced CV events). The drug earned a **Level 1a recommendation in new ACS/ACC guidelines** ⁴², boosting its credibility. Esperion surpassed **1 million prescriptions** in the U.S. ⁴³ and is pushing on statin-intolerance awareness (30% of lipid patients) to grow its niche ⁴⁴ ⁴⁵. They also have upcoming catalysts: **Japan approval** (partner Otsuka expects regulatory approval and pricing in H2 2025) ⁴⁶ which could bring milestone payments to Esperion, and **Canada approvals** in late 2025 ⁴⁷. Meanwhile, R&D isn't ignored – Esperion introduced a new preclinical program for primary sclerosing cholangitis (diversifying their pipeline) ⁴⁸ ⁴⁹.

Thesis Check: Our thesis was a “commercial-stage biotech with improving sales and multiple shots on goal.” That holds true. U.S. sales are climbing (>40% YoY) ³⁴, and Esperion is moving toward potential profitability by **Q1 2026** ⁵⁰ if trends hold. The Daiichi saga outcome, while netting less than the hoped \$300M, was positive in that Esperion got meaningful capital and eliminated legal uncertainty ³⁷ ⁴¹. With ~\$82M quarterly revenue and controlled expenses (Q1 net loss narrowed to \$20M; Q2 likely similar magnitude), the path to breakeven is visible.

Risk/Reward: As a commercial small-cap, ESPR is less binary than our other biotechs, but risks include the need for further cash by 2026 if profitability slips, and competition in cholesterol therapy (PCSK9 inhibitors, etc., though bempedoic acid has the advantage for statin-intolerant patients). Upside drivers are **continued sales growth** (CLEAR Outcomes data could boost usage in broader populations), potential **partnerships** (ex-U.S. or for the combo pill), and general sector re-rating if they achieve profitability. We see multi-bagger potential from current ~\$200M range if bempedoic acid becomes a standard add-on therapy. We will **HOLD ESPR** as a rare *commercial-stage* name in our catalyst portfolio. No hard stop-loss – the stock is volatile, but we'll monitor fundamentals; a break of trend (e.g., U.S. sales stalling or cash falling below 1-year runway) would prompt re-evaluation.

ACTU – Actuate Therapeutics (High-Risk Oncology Moonshot)

Update: Actuate's bet on **elraglusib (GSK-3β inhibitor)** for pancreatic cancer is showing extraordinary promise. The **Phase 2 trial (first-line metastatic pancreatic cancer)** met its primary endpoint, with **median overall survival (mOS) 10.1 months vs 7.2 months** for standard chemo (GnP) – a **37% reduction in risk of death (HR=0.63, p=0.01)** ⁵¹ ⁵². Notably, the **12-month survival doubled (44.1% vs 22.3%)** ⁵². These robust results, presented at ASCO in late May, were followed by additional subgroup analyses in June: patients who received ≥1 cycle of therapy had mOS 12.5 vs 8.5 months (HR=0.57) ⁵³ ⁵⁴, and even those

with liver metastases saw dramatic gains (2.5× one-year survival) ⁵³ ⁵⁵ . In short, elraglusib combined with chemo appears to meaningfully extend survival in one of the toughest cancers – a **potential game-changer** in metastatic pancreatic ductal adenocarcinoma.

⁵⁶ ⁵⁷ *Kaplan-Meier overall survival curves from Actuate's Phase 2 trial: elraglusib + chemo (blue) vs chemo alone (red) show a clear separation* ⁵² . *Elraglusib cut the risk of death by ~37% and nearly doubled 1-year survival* ⁵² .

Actuate is now leveraging these results: they plan to seek **FDA Breakthrough Therapy Designation** and meet regulators in H2 2025 on the path to registration ⁵⁸ ⁵⁹ . They also initiated a collaboration with **Incyte** and UPMC on a new trial adding Incyte's PD-1 inhibitor to elraglusib (a sign larger players are paying attention) ⁶⁰ ⁶¹ . On the financial side, Actuate addressed near-term liquidity by raising **\$4.7M in June via a private placement** ⁶² . The deal was done at \$7.00/share with warrants at \$7 that could bring another \$4.7M upon a future FDA milestone (e.g. Breakthrough designation) ⁶² ⁶³ . One new investor now owns ~50%, indicating high insider conviction ⁶⁴ . Even after this infusion, **going-concern risk persists** – Q1 cash was only \$3.9M ⁶⁵ and, by management's admission, more capital is needed beyond Q2 2025 to continue operations ⁶⁶ . However, the data strength improves chances of either a bigger raise at higher prices or partnering with a pharma for Phase 3.

Thesis Check: Our thesis was a *"high-risk, high-reward oncology play with standout survival data."* The data **exceeded expectations**, validating the drug's mechanism and our conviction. This is precisely the kind of result that can eventually lead to a multi-bagger outcome (if Phase 3 confirms it, Actuate could be a buyout target or independently worth many times its current microcap valuation). The presence of **key opinion leaders** (lead PI from Northwestern) praising the result ⁶⁷ and involvement of Incyte in trials lend credibility. That said, Actuate remains *very risky*: it has no approved products and very limited cash. The going-concern warning is a stark reminder that **dilution is likely** (the recent raise itself heavily diluted shares at a \$14M pre-money valuation). This is why we instituted a strict stop-loss initially.

Risk/Reward: Upside could be **astronomical** if elraglusib becomes a new cornerstone in pancreatic cancer (a multi-billion market with dire need). Near-term upside catalysts: possible **Breakthrough Therapy** designation or fast-track (the warrant structure suggests we might hear news on this within months), start of a pivotal Phase 3 (perhaps with a partner to fund it), or even an acquisition by a larger oncology company. Downside: a cash crunch or trial setback. Given the volatility, we **maintain our hard stop-loss** – we will exit if ACTU's price falls **20% below our cost basis**, to cap tail-risk. (*If currently \$7.30, stop ~\$5.84 as an example.*) We already trimmed some profits after the ASCO spike. For now, we **HOLD a modest position in ACTU**, letting this winner run but with a short leash. This balanced approach lets us capture further upside while guarding against a sudden collapse if financing or other news disappoints.

New Buy – ATYR – aTyr Pharma (Pulmonary Sarcoidosis Phase 3)

Catalyst: We are initiating a position in aTyr Pharma, a microcap (~\$200M) with a near-term binary catalyst: **Phase 3 trial results due in mid-September 2025** for its lead drug *efzofitimod* in pulmonary sarcoidosis ⁶⁸ ⁶⁹ . Sarcoidosis is an inflammatory lung disease (a form of interstitial lung disease) often treated with steroids; no targeted biologic is approved. Efzofitimod, an immunomodulator targeting neuropilin-2, aims to reduce steroid use while improving symptoms. The **EFZO-FIT Phase 3** enrolled 268 patients across 85 centers ⁷⁰ , measuring reduction in steroid dose at 48 weeks as the primary endpoint (with lung function and symptom scores secondary) ⁷¹ . Phase 2 data were encouraging – patients on efzofitimod showed

steroid-sparing and clinical improvements – hence FDA granted it **Orphan Drug** and Fast Track status earlier. If Phase 3 is positive, aTyr plans to file for approval in 2026, making efzofitimod potentially *the first steroid-sparing therapy for pulmonary sarcoidosis*.

Thesis: This setup resembles Axogen's: a late-stage readout with asymmetric payoff. We see *moderate to high probability of success* given prior data and the trial design (forced steroid taper in all arms sets a low bar for showing a benefit if efzofitimod truly helps patients maintain stability off steroids). The commercial opportunity in sarcoidosis ILD is significant (thousands of patients with chronic disease needing better options). aTyr also benefits from a **partnership with Kyorin (Japan)**, which could bring milestone payments on success, and it's exploring efzofitimod in other ILDs like systemic sclerosis-ILD (interim data showed promising biomarker and skin improvements ⁷² ⁷³). Notably, **aTyr's cash position is \$83M (Q2 2025)**, and they project **runway for 1 year beyond Phase 3 readout** ⁷⁴, reducing immediate financing risk. This cash buffer and pipeline depth (multiple ILD indications) help moderate the downside if the sarcoidosis trial disappoints – the company wouldn't be bankrupt, and the drug could still be tested in other indications.

Risk/Reward: As with any Phase 3, the result could be negative or only modestly positive. If efzofitimod fails to beat placebo in steroid reduction or safety issues arise, ATYR shares could drop >50%. However, if it meets primary and key secondary endpoints, ATYR could rerate dramatically – peak sales estimates for sarcoidosis are in the ~\$500M-\$1B range, which would justify a multi-fold increase in market cap. Moreover, we might see strategic interest (partners or acquisition) given efzofitimod's platform potential in ILDs. On balance, the **risk/reward is attractive** for a small position using leftover cash.

Trade Details: On Aug 8, 2025, using \$45.36 cash, we BUY 12 shares of ATYR at ~\$3.78 (market) for a total ~\$45. We set an initial stop-loss at \$3.00, about 20% below the current price. This limits risk on a failed trial (we'd reassess fundamentally if results are bad, but at that point the thesis is broken). If the trial is positive, we may add on the news (as long as market cap remains < \$300M at our entry).

Bottom Line: Our portfolio remains concentrated in catalyst-rich microcaps, each with a clear path to price inflection:

- **ABEO:** Launch of first-in-class gene therapy for RDEB; well-funded and executing rollout ⁵ ⁷⁵. *Holding* (long-term growth story just beginning).
- **IINN:** Major \$22.5M device order validates commercial traction ¹²; regained compliance and pursuing global deals. *Holding*, with stop at \$1 to lock gains.
- **AXGN:** FDA approval decision by Sep 5 – potential game-changer with 12-year exclusivity ³¹. *Holding through binary event*.
- **ESPR:** Bempedoic acid sales up >40% YoY ³⁴; cash runway into 2026 ³⁹ and profitability in sight. *Holding* for turnaround upside.
- **ACTU:** Phase 2 success in pancreatic cancer (median OS +3-4 months) ⁵² ⁵⁴ shows multi-bagger potential; but tiny cap with high cash needs. *Holding small position*, tight stop-loss to manage risk.

- **ATYR (new):** Phase 3 sarcoidosis readout mid-Sept 2025 ⁷⁶ – **added** as a speculative catalyst play with high upside if positive.

All positions are actively monitored. By next week, we expect to refine theses based on any new developments (e.g. FDA news, launch updates). This balanced, catalyst-driven approach – with disciplined stops and position sizing – keeps us focused on our sole goal: **generating alpha**.

Portfolio Thesis Summary (for quick reference):

- **ABEO (Abeona)** – *Gene therapy launch*. **Thesis:** Monetized PRV funds launch; first-and-only one-time RDEB therapy can command premium pricing ¹¹ ⁷. **Catalyst:** Initial sales in 2H'25. **Risk:** Launch execution. *Continue to Hold*.
- **IINN (Inspira)** – *Respiratory device turnaround*. **Thesis:** \$22.5M order proves demand ¹²; more contracts (gov't, global) likely. **Catalysts:** New deals, product expansions. **Risk:** Dilution (shelf filed) or order delays. *Hold; Stop \$1.00*.
- **AXGN (Axogen)** – *Nerve repair FDA bet*. **Thesis:** Established revenue base + near-breakeven; if Avance graft wins approval (Sep 5), unlocks exclusivity and growth ³¹. **Catalyst:** FDA decision 9/5/25. **Risk:** Binary FDA outcome. *Hold through PDUFA*.
- **ESPR (Esperion)** – *Cholesterol drug turnaround*. **Thesis:** U.S. sales +42% YoY ³⁶, EU dispute settled ³⁷; runway into 2026, aiming profitability 2026. **Catalysts:** Continued sales growth; Japan approval H2'25. **Risk:** Needs to hit sales trajectory to avoid financing in 2025/26. *Hold*.
- **ACTU (Actuate)** – *Moonshot oncology*. **Thesis:** Phase 2 pancreatic data nearly doubled 1-yr survival ⁵²; huge value inflection if replicated. **Catalysts:** FDA Breakthrough decision; partnership. **Risk:** Cash (~\$5M) < 1 year need ⁶⁵, dilution ahead. *Hold small; Stop ~20%*.
- **ATYR (aTyr)** – *New buy: ILD Phase 3*. **Thesis:** Efszofitimod Phase 3 in sarcoidosis, high unmet need; prior data positive, \$83M cash ⁷⁴. **Catalyst:** Top-line mid-Sept 2025 ⁶⁸. **Risk:** Trial could fail; binary outcome. *Buy small position; Stop \$3.00*.

¹ ³ ⁴ ⁵ ¹¹ Abeona Therapeutics® Closes Sale of Rare Pediatric Disease Priority Review Voucher for \$155 Million :: Abeona Therapeutics Inc. (ABEO)

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⁸ [PDF] Vyjuvek (beremagene geperpavec-svdt)

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