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Portfolio Re-Evaluation – August 2025

Portfolio Overview & Strategy

We are focused on micro-cap biotech/medtech positions with near- to mid-term catalysts, aiming to maximize **alpha** (market-beating returns). After deep research into recent developments, we will **realign the portfolio** to concentrate on the most promising opportunities. This involves **locking in profits** on stocks that have run up and reallocating capital to new high-upside catalysts, while maintaining core holdings with strong theses. All trades and stops are detailed below. *(Current cash available: $4.64; will increase upon planned sales.)*

Holdings Re-Evaluation

ABEO – Abeona Therapeutics (Gene Therapy Launch) – Continue to Hold

Thesis: Abeona's RDEB gene therapy *ZEVASKYN* is now FDA-approved (April 2025) and launching in 3Q'25 [1] [2]. They monetized the Priority Review Voucher for $155M, bolstering cash to $226M (June 30) [3] [4] – enough for >2 years of operations **before** counting any ZEVASKYN sales [3] [5]. Early launch indicators are **very positive**: first patient treatment is on track for Q3, with strong patient interest (dozens identified) and 100% insurance approvals so far [6] [7]. Management even projects profitability by 1H'26 [3] [8], reflecting high expected pricing and demand for this one-time therapy.
Catalysts: Initial commercial uptake in 2H'25 – e.g. news of first patient treated (imminent in Q3) and Q4 earnings revealing early sales – could drive further upside. The **Lancet** just published Abeona's pivotal data, boosting visibility [9] [10].
Risks: Launch execution and patient uptake are key; any delays in treating patients or reimbursement hurdles could weigh on the stock. However, with broad payer coverage already secured (United Healthcare and others covering ~60% of RDEB lives) [7] [11], this risk is moderated.
Position: *Hold.* We have a profitable position (stock ~$7.15 as of 8/15, vs. our $5.77 entry) [12] [13] and will **continue to hold for the 3Q–4Q launch ramp**. To protect gains, we will raise the stop-loss from $4.90 to **$6.00** (just below the ~$6.30–$6.56 consolidation range pre-Q2) [14] [15]. This allows ample room for volatility while ensuring we lock in at least a small profit if the stock pulls back. No changes to position size.

ACTU – Actuate Therapeutics (Pancreatic Cancer *Moonshot*) – Sell to Reallocate

Thesis Review: Actuate's **GSK-3β inhibitor** (elraglusib) showed *impressive Phase 2 results* in first-line metastatic pancreatic cancer. Patients on therapy had **nearly double 1-year survival** (43.6% vs 22.5%) and significantly longer median OS (9.3 vs 7.2 months) [16] [17]. These data met primary endpoints and were statistically significant (p=0.002) [16], pointing to a potential breakthrough in a very lethal cancer. If these results are replicated in Phase 3, the value inflection could be enormous. Actuate plans to seek FDA **Breakthrough Therapy** designation and discuss Phase 3 with the FDA in 2025 [18] [19].
Recent Developments: The stock has **appreciated strongly** since our entry – now ~$8.22 (8/14 close) vs. our $5.75 cost [20], a ~43% gain. This rise reflects optimism around the Phase 2 data and possibly the recent financing that extended its cash runway. In late June, Actuate raised ~$4.7M in a private placement [21] [22]

and added $2.1M via an equity facility [23], easing immediate cash concerns. However, total cash (~$10M) still likely only funds <1 year of ops – *further capital or a partnership will be needed* for Phase 3. A routine shelf registration was just filed (Aug 7) [24], indicating they are prepared to issue more shares if needed.

Catalysts/Risks: We expect a **FDA Breakthrough** decision possibly in the coming months (could be a catalyst if granted). A partnership or larger financing could also come by Q4. However, absent near-term news, the stock could languish or fall on dilution fears. The *binary risk* here is longer-term – if no partner emerges, dilution could significantly pressure shares. Given the recent run-up, the **risk/reward is less compelling short-term**.

Position: *Sell.* We will **lock in profits** on ACTU and free up ~$49 in cash (6 shares × ~$8.17 expected). This is a risk-management move: while we remain intrigued by Actuate's drug, our priority is to redeploy capital into catalysts with more immediate payoff. We can *revisit ACTU* ahead of any Breakthrough or partnership news. *(If ACTU dips or new info arises, we'll consider re-entry; for now, focus on nearer-term alpha).*

ESPR – Esperion Therapeutics (Cholesterol Drug Turnaround) – Sell (for now)

Thesis Review: Esperion is executing a turnaround with its cholesterol-lowering drugs **Nexletol/Nexlizet (bempedoic acid)**. U.S. product sales are growing rapidly (+42% YoY in Q2 to $40.3M) [25] [26] thanks to positive CV outcomes data and expanded insurance coverage. Total Q2 revenue hit $82.4M (+12% YoY), beating estimates by ~30% [27] [28] – and Esperion even achieved its *first quarter of operating income* (~$15M) [26]. Critically, Esperion resolved its dispute with Daiichi Sankyo Europe in Jan 2024, securing $125M (with $100M paid upfront) [29]. This settlement boosted cash (Q2 cash $86M [30]) and removed the overhang regarding milestone payments. Management now guides for potential **sustainable profitability by 2026** [31] [32], aided by international expansion (e.g. an **Otsuka partnership** targeting up to $120M in milestones) [32] and ongoing U.S. growth (scripts +20% QoQ). A **Japan approval** decision (via partner Otsuka) is expected in H2'25 – another catalyst for modest milestones and sales.

Recent Stock Performance: Despite improving fundamentals, ESPR stock remains depressed; it *popped ~10%* to ~$1.63 on Q2's earnings beat [33], but is still near $1.60 (far below 52-week high of $3.94) [33]. The heavy debt (debt-to-capital 67% [34]) and the long runway to profitability likely keep investors cautious. We originally entered at $1.91, and shares have yet to reclaim that level.

Position: *Sell.* Esperion's story is improving, but it's a **slow-burn turnaround** with no major price-moving events expected in the immediate term (the next inflection may be if quarterly sales continue beating estimates, or the Japan approval late-year). Given our tiny position (2 shares) and the need to concentrate capital into higher-upside trades, we'll **exit ESPR** now (around ~$1.63) and monitor from the sidelines [33]. This frees ~$3.20. *We remain positive on Esperion's long-term prospects (profitability in 2026 would be transformative), and may re-enter in the future once nearer catalysts emerge.*

ATYR – aTyr Pharma (Pulmonary Sarcoidosis Phase 3) – Hold (High-Risk, High-Reward)

Thesis: aTyr's lead drug **efzofitimod** is a novel immunomodulator for pulmonary sarcoidosis, a serious inflammatory lung disease (form of interstitial lung disease) with high unmet need. The Phase 3 EFZO-FIT trial (n=264) *has fully enrolled* and **top-line results are due in mid-September 2025** [35] [36] – a potential game-changer for the company. Prior data are encouraging: a 37-patient Phase 1b/2 study showed efzofitimod *significantly reduced steroid requirements* and improved symptoms vs placebo over 24 weeks, without safety issues. This gives reason for optimism heading into Phase 3. aTyr also has a strong balance sheet (~$83M cash) to support operations into 2026, mitigating financing risk in the near term.

Catalyst: Phase 3 readout (Sept 2025) – If positive, ATYR's stock could **skyrocket** (pulmonary sarcoidosis has no FDA-approved biologic; efzofitimod could become a first-in-class therapy). We'd expect partnering or

acquisition interest as well, given the rare disease focus. Conversely, a trial failure would be devastating (shares could plummet >50%). This is a classic **binary event**.

Position: *Hold (small position).* We initiated ATYR as a *high-risk/high-reward bet* and will **maintain our 8 shares** into the data readout. The position is deliberately small (~$40 cost basis) to limit downside. Our stop-loss is set at **$4.20** (about 17% below our $5.09 entry) – although realistically if the trial fails, the stock may gap well below $4.20 and the stop won't prevent a loss. If the **data are positive**, we will reassess quickly (could take profits on the surge or continue to hold for further upside, depending on the strength of results). *Bottom line: we accept the binary risk here in pursuit of outsized alpha.*

New Positions to Enhance Alpha

After exiting ACTU and ESPR, we will deploy the freed capital (~$42) into two compelling micro-cap opportunities:

IINN – Inspira Technologies (Respiratory Device Turnaround) – Buy

About: Inspira is an Israeli med-tech company developing advanced extracorporeal respiratory support devices. Its FDA-cleared **ART100** system is a portable heart-lung bypass device (for oxygenating blood) that can be used in ECMO procedures and acute respiratory failure. After years of R&D, Inspira is now transitioning into **commercial revenue generation**.

Thesis: A recent *breakthrough sale* validates Inspira's technology and kickstarts its turnaround. In July, the company **secured a $22.5 million binding purchase order** for ART100 from an overseas partner – a huge deal relative to Inspira's size (market cap ~$31M) [24] [37]. The buyer is a private company with strong government and hospital ties, and **full payment is due in 2025** [38] [39]. This order not only brings immediate revenue (likely starting in 2H'25 deliveries) but also signals market demand. Indeed, Inspira reports it is in *advanced negotiations with additional healthcare and government entities* worldwide and expects **more deals soon** [39] [40]. They have already begun onboarding and logistics for the big order, and even **expanded production capacity** to meet anticipated demand (including a potential European government contract) [37] [41]. Essentially, Inspira is at an inflection point from pre-revenue to commercial scale-up.

Catalysts: - **Further contract announcements:** Management hints at discussions with a foreign government to integrate ART100 into a national emergency infrastructure, and a European authority for ART100 deployment [37]. Any such deal could be announced in the coming weeks/months, likely boosting the stock.

- **Product expansion:** Development of the next-gen ART500 system (designed for partial respiratory support with patients awake) and a non-invasive blood sensor (HYLA) is ongoing [42]. Regulatory milestones or partnerships on these could add value, though primary focus is ART100 rollout.

- **Financial turnaround:** Recognition of the $22.5M order in revenue (starting late 2025) will be a dramatic shift for financials. Analyst coverage has reacted – SeeThruEquity recently **raised their price target to $3 (from $2)** on this order news [43]. Achieving Nasdaq compliance (bid >$1) removed delisting risk [44].

Risks: As a micro-cap, Inspira faces **financing risk** – it filed a shelf registration to allow future capital raises [24] [45]. Dilution is a possibility if they need funds to fulfill large orders or ramp up production (though the $22.5M incoming cash may reduce immediate need). Execution risk exists in delivering the product at scale and turning orders into long-term recurring sales. Also, any delays in the big order or failure to secure

follow-on contracts would hurt momentum.
Action: *Buy.* We will **initiate a position in IINN** to capitalize on its turnaround momentum.

- **Buy Order – Monday, Aug 18, 2025:** Buy **10 shares of IINN** at a limit price of **$1.25** (good for the day). The stock last traded around $1.20 [46], so this limit gives a little buffer to ensure execution.
- **Stop-Loss:** Set an initial stop at **$1.00** (just below Nasdaq's $1 compliance level, and ~17% downside). This matches the technical support around $1 (also the stop suggested in our prior thesis). We want to limit risk in case of any negative surprises or dilution.

AXGN – Axogen, Inc. (Nerve Repair FDA Catalyst) – Buy

About: Axogen is the leader in peripheral nerve repair products. Their flagship **Avance Nerve Graft** is an off-the-shelf processed human nerve allograft used by surgeons to bridge nerve gaps. Until now, Avance has been marketed under a special regulatory program; Axogen pursued a full FDA approval to solidify its status. The company also sells complementary surgical products (nerve protectors, connectors, etc.), and has a global sales network in place. Importantly, Axogen is a **revenue-generating** company (expected ~$219M in 2025 sales) and near breakeven profitability [47] [48].

Thesis: We see a very favorable risk/reward into Avance's FDA decision: - **PDUFA Catalyst (Sep 5, 2025):** The FDA's decision on Avance's Biologics License Application (BLA) is due by Sept 5 [49] [50]. We expect approval, given Avance's long track record of clinical use (over 50,000 Avance grafts have been implanted under prior regulatory agreements) and the fact that Axogen completed all required FDA inspections and meetings with no red flags [50]. If approved, Avance will be the **first FDA-approved nerve graft** and should receive **12-year biologic exclusivity** [51] – a *huge moat* against any competitors [52] [53]. FDA approval also likely accelerates hospital adoption and insurer reimbursement for Avance. This is a classic "binary" catalyst, but odds appear high in Axogen's favor. - **Financial Momentum:** Axogen's base business is performing well. Q2 2025 revenue grew 18.3% YoY to $56.7M, beating estimates [54], and gross margin is a strong ~74% [55] [56]. They even reported **$0.12 EPS (non-GAAP)**, doubling analyst estimates [57]. Management raised 2025 revenue guidance to +17% ($219M) on anticipated Avance approval boost [47] [48], and believes they will be **net cash flow positive in 2025** [48]. In short, this isn't a cash-burning biotech – it's an operating med-tech with growing sales, which limits downside if approval is delayed. - **Market Opportunity:** Peripheral nerve repair is a significant market (hundreds of thousands of nerve repair procedures annually). Avance graft offers an alternative to autografting (which requires an extra surgery to harvest a nerve). Axogen's products address various nerve injury scenarios (extremities, breast reconstruction, oral/maxillofacial, etc. [58] [59]). With FDA approval, Axogen can more aggressively market Avance and potentially expand indications. The company is already expanding reimbursement coverage (10 million more lives covered in 2025) [60], which should drive adoption post-approval. **Catalysts:** The **FDA decision** is the main catalyst (Sep 5). If positive, expect a jump in stock price and heavy news flow (approval PR, analyst upgrades, etc.). In the longer run, quarterly earnings in late 2025 will show the impact of approval (perhaps guidance raise, new surgeon customers, etc.). Axogen is also conducting new clinical studies (e.g. a comparative study for Avance in specific injuries) which could broaden labels, though that's further out [61]. **Risks:** A *negative FDA decision* (delay or denial) is the primary risk – that would likely crash the stock (Axogen would have to cease marketing Avance or meet additional FDA requirements). However, given the extensive dialogue with FDA and completion of inspections, this seems unlikely. Another risk is that the stock has rallied into the event (recent price ~$15, up from ~$13 pre-Q2) [62] [63] – so some good news is priced in. If approval comes with unexpected restrictions (e.g. limited labeling or safety warnings), the stock might not jump much. Nonetheless, the downside of an approval scenario is limited, and the upside of a clear approval (with

exclusivity) could be significant as investor confidence rises. **Action:** *Buy.* We want exposure before the PDUFA date.

- **Buy Order – Monday, Aug 18, 2025:** Buy **2 shares of AXGN** at a limit price of **$15.10** (good for day). The stock is ~$15.00 [63] ; we set a slightly higher limit to account for any small gap up.
- **Stop-Loss:** Initially **$12.00** (20% below purchase). This is a wide stop given the binary event – it's mainly to guard against any pre-decision volatility or a mild negative surprise. *(In a full FDA approval scenario, we may raise the stop to protect gains; in a rejection scenario, the stop won't help much due to an overnight gap, but position size (2 shares) limits our absolute risk.)*
- **Plan:** Intend to *hold through the FDA decision*. If approval, likely continue to hold at least through year-end 2025 to capture operational upside. If not approved, re-evaluate based on FDA feedback (we'd likely cut the loss).

Trade Execution Plan (Orders for Week of Aug 18, 2025)

1. **Sell *Actuate Therapeutics (ACTU)* – Aug 18, 2025:** Place a **limit sell** for *all 6 shares* at **$8.00** (GTC/DAY). This locks in our ~40% gain [20] while ensuring we don't sell below recent market price ($8.22 last close [64]). *Rationale:* Taking profit and freeing capital for better opportunities.
2. **Sell *Esperion (ESPR)* – Aug 18, 2025:** Place a **limit sell** for *all 2 shares* at **$1.60** (DAY). This is around our stop level and just below the ~$1.63 pre-market price post-earnings [33] , to ensure execution. *Rationale:* Redirect funds to nearer-term catalysts; minimal impact on portfolio performance.
3. **Buy *Inspira Tech (IINN)* – Aug 18, 2025:** Place a **limit buy** for *10 shares* at **$1.25** (DAY). If filled, immediately set a **stop-loss** at **$1.00**. *Rationale:* Initiating position for upcoming contract catalysts, with defined risk (stop ~20% lower).
4. **Buy *Axogen (AXGN)* – Aug 18, 2025:** Place a **limit buy** for *2 shares* at **$15.10** (DAY). If filled, set a **stop-loss** at **$12.00** (≈20% drawdown protection). *Rationale:* Positioning ahead of Sept 5 FDA decision; stop in place for risk management.
5. **Adjust Stop *Abeona (ABEO)* –** Raise stop-loss from $4.90 to **$6.00** on our 4 shares. *Rationale:* Lock in a no-loss floor now that ABEO has run to $7+, while still giving it room to fluctuate during the early launch phase. [14] [15]

All orders are to be placed at the market open on Monday (8/18/2025). Sell orders (ACTU, ESPR) should execute and free up funds before buy orders trigger. We will monitor execution – if the sell orders **fail** (e.g. if price gaps down below limits and doesn't recover), the buy orders won't be executed due to insufficient cash. In that case, we'd reassess (possibly adjust limit or forgo a purchase).

Updated Portfolio Thesis Summary (Post-Trade)

ABEO (Abeona Therapeutics) – *Gene therapy launch.* **Thesis:** First-and-only one-time treatment for RDEB; FDA-approved and launching Q3'25. $155M PRV sale funds launch; strong early demand and payer coverage. **Catalyst:** First patient treated (Q3), initial sales reported in Q4'25. **Risk:** Launch execution. **Position:** *Hold.* (Stop raised to $6.00).

IINN (Inspira Tech) – *Respiratory device turnaround.* **Thesis:** $22.5M order for ART100 validates product; more contracts (including gov't deals) likely in pipeline [39] [40] . Transitioning to revenue phase. **Catalysts:**

New deal announcements; 2H'25 product deliveries. **Risk:** Possible dilution (shelf filed) [24] or order delays. **Position:** *Buy new position.* (Stop $1.00).

AXGN (Axogen) – *Nerve repair FDA bet.* **Thesis:** Established nerve repair leader with growing sales; Avance graft FDA decision 9/5/25 could grant 12-yr exclusivity [51] and boost growth. **Catalyst:** PDUFA Sep 5, 2025 (BLA approval likely) [50] . **Risk:** Binary FDA outcome. **Position:** *Buy (hold through PDUFA).* (Stop $12.00).

ATYR (aTyr Pharma) – *Pulmonary sarcoidosis Phase 3.* **Thesis:** Efzofitimod Phase 3 data mid-Sept 2025; prior data positive in reducing steroids. Huge upside if success in high-unmet-need disease. **Catalyst:** Top-line results ~Sept 15, 2025 [35] . **Risk:** Trial could fail (binary). **Position:** *Hold small position.* (Stop $4.20).

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