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Portfolio Evaluation and Recommendations (July 18, 2025)

Portfolio Performance: As of July 18, the portfolio's total equity stands at **$116.41**, reflecting an **approximately +16% return** since inception – significantly outperforming the Russell 2000 index in the same period. This strong performance has been driven by savvy selections in small-cap biotech/medtech stocks that realized key catalysts. Below we evaluate each current holding and provide action recommendations (Buy/Sell/Hold) based on recent developments and future outlook.

Abeona Therapeutics (ABEO) – HOLD (Continue to Hold)

Overview: Abeona is a gene therapy company that achieved a major milestone in April 2025 with FDA approval of **ZEVASKYN™ (prademagene zamikeracel)**, the first autologous cell-based gene therapy for recessive dystrophic epidermolysis bullosa (RDEB) [1]. The company capitalized on this approval by selling its Priority Review Voucher (PRV) for **$155 million**, boosting its **cash reserves to ~$225 million as of June 30, 2025** [2]. This windfall gives Abeona **over two years of operating capital** and negates near-term dilution risk [3]. Abeona plans to treat the **first commercial patient in Q3 2025** and projects to reach **profitability by early 2026** [4].

Recent Developments: With ZEVASKYN's launch underway (treatment centers being established [5]), Abeona is transitioning to a commercial-stage company. The **PRV sale proceeds** ensure the company can **fully fund the product launch and pipeline work** ("robust financial flexibility, ensuring over two years of operating capital…prior to accounting for ZEVASKYN sales" according to the CFO) [3]. Additionally, Abeona is monetizing its AAV gene therapy platform – e.g. **licensing its AAV204 capsid** to Beacon Therapeutics for ophthalmic uses, which provided an upfront payment plus potential milestones/royalties [6]. This validates Abeona's platform value beyond its lead product.

Outlook: Abeona's **cash-rich position** and impending **revenue generation in Q3 2025** make its outlook positive. With **no immediate need for fundraising**, management can focus on executing the **ZEVASKYN launch** and advancing its pipeline of gene therapies for ophthalmic diseases [7] [8]. The **RDEB market** is small but high-value (no current treatments), and Abeona's therapy could command significant pricing, supporting the profitability timeline. Given the stock's ~15% rise since June 30 (from $5.68 to $6.59), much good news is priced in, but **further upside is possible** as sales ramp up and additional centers come online. **We recommend HOLDING ABEO** to participate in the company's growth, as it remains reasonably valued relative to its ~$225M cash and first-in-class therapy. Risks to monitor are the **launch execution** (insurance reimbursement and patient uptake) and any unexpected competition or manufacturing hurdles. At this juncture, however, Abeona's fundamentals are strong and justify maintaining the position.

Catalysts Ahead: Initial **sales updates in late 2025**, any partnership deals for ex-U.S. rights or pipeline assets, and **progress in its AAV ophthalmology programs** (which could bring milestone payments) are potential upside catalysts. We will watch for Q3 earnings reports to gauge **ZEVASKYN's early uptake**.

Candel Therapeutics (CADL) – SELL (Take Profits)

Overview: Candel is a clinical-stage immunotherapy company developing oncolytic viral treatments for cancer. Its lead candidate **CAN-2409** (an adenovirus-based gene therapy) showed **positive Phase 3 results in localized prostate cancer**, significantly improving **disease-free survival (DFS)** by 30% vs placebo (HR 0.70, p=0.0155) [9]. These impressive results – first announced in late 2024 and presented at ASCO 2025 – mark the **first successful Phase 3 in localized prostate cancer in decades** [10]. Candel is now preparing for a **Biologics License Application (BLA) submission for CAN-2409**, though notably this is **anticipated in Q4 2026** [11] [12], indicating a long road before potential FDA approval and commercialization.

Recent Developments: In the past month, Candel's stock surged from ~$5 to ~$6.7 (current) – a ~33% gain – driven by a couple of key events. On June 24, Candel announced a **$15 million direct equity offering at $4.67/share** to strengthen its balance sheet for pre-commercialization of CAN-2409 [13] [14]. The participation of existing healthcare investors and insiders in that financing signaled confidence, and the cash will fund **launch readiness and the BLA filing process** (which is a costly, multi-year endeavor) [11]. Subsequently, effective June 30, Candel was **added to multiple Russell small-cap value indexes** as part of the 2025 reconstitution [15]. Inclusion in the **Russell 2000/2500 and Value indexes** likely brought additional institutional buying. Management noted these index inclusions come as Candel enters a "**transformative period**" preparing for regulatory submission and commercialization of CAN-2409 in intermediate-to-high-risk prostate cancer [16].

While Candel's **fundamentals have improved** (successful Phase 3, ~$15M cash infusion, index visibility), the next catalysts (BLA filing, FDA decision) are distant. The **BLA submission is not expected until late 2026** [11], meaning approval (if all goes well) and any revenue would be at least 2+ years away. Candel will likely continue burning cash on multiple ongoing trials (they also have earlier-stage assets like CAN-3110 in brain cancer [17]), and **further fundraising** might be needed before 2026. The stock's recent rally has priced in much of the Phase 3 success.

Recommendation: Given the **substantial gain (+~33%) in a short period** and the lack of near-term catalysts, we recommend **selling CADL to lock in profits**. The stock's momentum could cool in the coming months as the excitement of the Phase 3 data and index addition fades. Moreover, at ~$6.74, CADL trades above levels of the recent financing – taking profit here is prudent, as the company transitions into the long process of regulatory filings. We see better opportunities to redeploy this capital into stocks with nearer-term upsides (see the ACTU recommendation below). **Sell CADL** and monitor from the sidelines for now. (We would reconsider an entry in the future if valuations become attractive ahead of a major catalyst such as a partnership or FDA filing.)

Azitra, Inc. (AZTR) – HOLD (Speculative Hold for Upcoming Data)

Overview: Azitra is a micro-cap biotech focused on **precision dermatology**, using engineered probiotic bacteria to treat skin diseases. Its lead program **ATR-12** is a topical live biotherapeutic for **Netherton syndrome**, a rare genetic skin disorder with no approved treatments [18]. Azitra is currently conducting a Phase 1b trial in adult Netherton patients and expects to report **topline results by year-end 2025** [19] [20]. The company also has **ATR-04** in Phase 1/2 development for **EGFR inhibitor-associated rash**, a side effect in cancer patients on EGFR-targeted therapies [21]. Notably, Azitra presented on ATR-04 at ASCO 2025,

highlighting the importance of this program for an unmet dermatologic need affecting ~150k cancer patients annually [21]. The FDA has granted **Fast Track designation** to ATR-04 for EGFRi rash [22].

Recent Developments: Azitra's stock has been roughly flat-to-down (currently $0.23, slightly below our $0.25 cost basis). The company has, however, hit some **operational milestones**: In June, Azitra **reported initial safety data from the Phase 1b ATR-12 trial, which was "promising"** – no serious adverse issues in the first patients [23]. This clears the way for completing the trial and obtaining efficacy readouts. Azitra also secured an **equity purchase agreement for up to $20M** with an investor (Alumni Capital LP) and raised a small ~$2.2M via offerings in Q1 [24] [25]. While the current **cash on hand was very low (~$3.2M as of 3/31/2025)** [26], these financing arrangements aim to fund the pipeline through the upcoming data releases. The trade-off is potential dilution via that $20M facility (which could put pressure on the share price if utilized heavily at current low prices).

Outlook: Azitra remains **high-risk, high-reward**. On one hand, **Netherton syndrome** is an *ultra-orphan* disease with significant unmet need – positive Phase 1b results (even in a small trial) could quickly validate ATR-12 and make Azitra an attractive acquisition or partner target given no competition in this niche. Management is optimistic that ATR-12 could be "life-changing" for patients if it shows efficacy [27]. On the other hand, Azitra's **financial position is very tight**, and it will almost certainly need to draw on the $20M equity line (diluting shareholders) to continue operations. The next major inflection is the **Phase 1b topline by end of 2025**, which is several months away.

Recommendation: We recommend **HOLDING AZTR** for now **only for investors with a high risk tolerance**, as the position is small and the potential upside from positive data is significant. Selling now would lock in a minor loss, whereas **holding through the data could yield a large payoff** if ATR-12 shows clear efficacy (the stock could rally on that news given the tiny market cap ~$4M [28]). However, be mindful that this is a speculative position. We do **not advise committing new capital** to AZTR at this time (and our portfolio will refrain from averaging down) because of the dilution overhang and execution risk. We'll keep a close eye on any interim updates. **HOLD AZTR** for the anticipated **year-end 2025 data readout**, which will be the make-or-break moment for this stock.

Inspira Technologies (IINN) – HOLD/Accumulate (High-Conviction Hold; Add on Dips)

Overview: Inspira Technologies is a med-tech company in the **advanced respiratory support** space. It has developed the **INSPIRA ART™ line** of devices – *ART100*, an FDA-cleared extracorporeal oxygenation system (approved for cardiopulmonary bypass in the U.S., and for ECMO use outside the U.S.), and *ART500*, a next-gen system in development aimed at oxygenating patients without invasive mechanical ventilation [29] [30]. After a challenging 2024, Inspira is now **commercial-stage** with real revenue on the horizon.

Recent Developments: In July 2025, Inspira achieved a transformative milestone: it **secured a binding purchase order of** $22.5 million **for its ART100 system** [31]. This is a huge order relative to the company's size (market cap was ~$20–40M), effectively launching Inspira into its "full-scale revenue generation" phase [32]. The order comes from a strategic partner outside the U.S. and **full payment is due within 2025** [33], which will greatly bolster Inspira's finances. The first clinical deployments of ART100 in top U.S. hospitals – proving the device in real-world use – helped catalyze this deal [34]. Moreover, management indicates this is

likely *just the beginning*: they are in **advanced talks with additional healthcare and government entities for further agreements**, expecting more commercial deals in the near term [35].

In tandem with this commercial progress, Inspira addressed a critical stock issue: it **regained compliance with Nasdaq's $1 minimum bid price** in mid-July, after trading above $1 for 10 consecutive days [36] [37]. This removes the delisting risk that had been looming when the stock was under $1. The share price strength reflects growing investor confidence due to the recent successes: per the company, **"the past few weeks have marked a transformative shift"** with the large order, manufacturing expansion, and government partnership pathway [38]. Notably, Inspira's CEO highlighted a new **government-focused strategy** for national-scale adoption, building on these milestones [39]. In short, Inspira has transitioned from an R&D outfit to a **revenue-generating commercial company** with global expansion plans.

Outlook: We are bullish on IINN's trajectory. The $22.5M order (to be delivered and paid in 2025) not only brings in substantial cash, but also **validates the market demand** for Inspira's ART devices [32]. If the company successfully fulfills this order, it could lead to follow-on orders and serve as a case study to win business from other hospitals and even militaries (for portable ECMO use, etc.). Inspira is also developing the ART500 for less invasive support; any progress or FDA clearances there would open an even larger market. With Nasdaq compliance regained, the stock is accessible to more investors, and the removal of that overhang is positive [40] [41]. One should watch for **execution risks** – delivering such a large order on time and scaling up manufacturing is a new challenge for the company. However, Inspira has expanded its production capacity in preparation [42] [43], and the fact that the customer is paying upfront in 2025 suggests confidence in delivery.

Recommendation: HOLD IINN for further upside. We have strong conviction in this name given its recent momentum and **would even consider adding on any pullbacks**, as the pipeline of potential news is rich (e.g. announcement of *additional orders or partnerships* could come at any time). Our portfolio's position (20 shares at $1.50) is currently just slightly down (~-6%), but with the fundamentals drastically improved, we foresee the stock trending upward as revenues materialize. We will maintain the current holding and look to ride the growth. In summary, **continue to HOLD IINN**, and be alert for opportunities to **accumulate** if the market undervalues the company's progress.

New Position: Actuate Therapeutics (ACTU) – BUY

Rationale for Addition: We are deploying the proceeds from the Candel sale into **Actuate Therapeutics (ACTU)**, a small-cap biotech that we believe has **strong near-term upside potential**. Actuate is developing **elraglusib**, a novel GSK-3β inhibitor, for difficult cancers. In June 2025, Actuate announced **impressive Phase 2 results in first-line metastatic pancreatic cancer** – a notoriously hard-to-treat cancer. In a 170-patient randomized trial, adding elraglusib to standard chemo **significantly improved overall survival: median OS 10.1 months vs 7.2 months for chemo alone**, a **37% reduction in risk of death**, effectively **doubling one-year survival from 22% to 44%** [44] [45]. These are remarkable efficacy signals in pancreatic cancer, and they were highlighted in an oral presentation at ASCO 2025 and by oncology KOLs as a meaningful breakthrough [46]. The safety profile was also favorable (no major added toxicity) [47].

Actuate's data not only validates its drug mechanism (there were also immune biomarker improvements noted with elraglusib [48]), but also **positions the company for a potential pivotal trial and partnership**. We view Actuate as an attractive **short-to-mid term trade** because:

- The **Phase 2 success is likely to attract larger oncology companies** looking for pipeline assets in pancreatic cancer. Actuate could secure a *lucrative partnership or even be an acquisition target* in the coming quarters.
- Actuate's stock has momentum and visibility: it was recently **added to the Russell 3000 and 2000 indexes** in late June [49], similar to Candel, which can increase institutional ownership.
- With a market cap around ~$120M, the stock doesn't fully reflect the potential value of a new pancreatic cancer therapy (a multi-billion dollar market). There is room for upside as investors appreciate the data and as Actuate moves toward Phase 3.
- Importantly, Actuate appears well-funded for now (it completed an IPO last year and hasn't indicated immediate cash issues), allowing it to advance elraglusib into the next trial.

Action: BUY ACTU. We will initiate a position in Actuate using the freed cash from selling CADL. Based on the July 18 closing price (~$6.14), we plan to purchase **6 shares of ACTU** (approximately $36 investment). This will diversify our biotech holdings into a company with a **late-stage asset and significant catalyst** potential. We set ACTU with a **Buy** rating, aiming to hold through possible near-term catalysts such as any **partnership announcements, Fast Track designation by FDA, or the start of a Phase 3 trial** – all of which could drive the stock higher. We will monitor Actuate's news flow closely and re-evaluate after a strong move or if fundamental circumstances change.

Summary of Recommended Actions (July 18, 2025)

- **Sell *Candel Therapeutics (CADL)* – SELL to lock in +33% profit.** The stock has run up on good news that is now priced in, and no major catalysts are expected until 2026 [11]. We will liquidate the 5 shares of CADL at ~$6.74 each (≈$33.7 total).
- **Buy *Actuate Therapeutics (ACTU)* – NEW BUY.** Using the CADL proceeds (and available cash $2.32), purchase ~6 shares of ACTU around $6.00 each. This initiates a position in a promising biotech with positive Phase 2 cancer results [44] and potential short-term upside.
- **Hold *Abeona Therapeutics (ABEO)* – HOLD.** Maintain our 6 shares. Abeona's strong cash position and imminent product launch support continued holding [4] [1]. We expect further value realization as ZEVASKYN sales ramp up.
- **Hold *Azitra (AZTR)* – HOLD (Speculative).** Keep our 55 shares of AZTR. Despite current slight loss, the upcoming Phase 1b data in Netherton syndrome (due Q4 2025) is a high-impact catalyst worth waiting for [19]. (No additional buying due to risk level, but hold existing stake.)
- **Hold *Inspira Technologies (IINN)* – HOLD/Accumulating.** Retain our 20 shares. Inspira's $22.5M order and Nasdaq compliance mark a turning point [31] [40]. We will hold for anticipated further contracts and consider adding on dips as confidence grows.

By executing these moves, the portfolio will be rebalanced into 5 holdings (ABEO, AZTR, IINN, ACTU, plus a small cash reserve). This strategy locks in gains from Candel and reallocates capital into Actuate, while continuing to support our high-conviction positions. We believe these adjustments position the portfolio well for the next phase, with exposure to both **revenue-generating stories (ABEO, IINN)** and **upcoming**

clinical catalysts (AZTR, ACTU). We will continue to monitor all developments and will adjust our strategy as needed based on news or price movements.

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- Abeona Therapeutics – FDA approval of gene therapy for RDEB [1]
- Abeona/Beacon deal – validation of AAV capsid tech [6]
- Candel Therapeutics – Russell index inclusion and CAN-2409 BLA timeline [16] [11]
- Candel Therapeutics – Positive Phase 3 DFS improvement in prostate cancer [9]
- Candel Therapeutics – $15M fundraise for launch readiness [11] [13]
- Azitra – Pipeline milestones (ATR-12 Netherton data timelines) [19] [20]
- Azitra – Q1 financials (cash $3.2M) [26] and funding agreements [24]
- Azitra – Initial safety data reported (June 17, 2025) [23]
- Inspira Technologies – $22.5M purchase order details [31] [32]
- Inspira Technologies – Nasdaq compliance regained, citing $22.5M order and milestones [40] [37]
- Actuate Therapeutics – Phase 2 pancreatic cancer success (survival benefit) [44]
- Actuate Therapeutics – Russell 2000/3000 index inclusion (June 2025) [49]

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