



Edited by **Massimo Colnago**
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The Fund

Onelife Fund is a long-only equity fund that invests in the biopharmaceutical sector. The target companies, mainly listed in the United States, research, develop, manufacture, and commercialize biotechnology drugs and treatments for the management and/or cure of various diseases. Companies are selected through a process of scientific analysis, assessment of therapeutic need, regulatory/competitive context, and financial sustainability.

Biotech Sector Update

The positive momentum for the sector continues, with the NBI index posting a strong +8.41% in the month. November proved to be a month of consolidation and selective growth for the biotech segment, supported by a mix of important regulatory approvals, strategic acquisitions, and clinical trial results.

M&A activity continues, as mentioned earlier, with another company (the eleventh since the start of the year) from the portfolio being acquired: **Mersana Therapeutics** has reached an agreement to be bought by Day One Biopharmaceuticals.

Arcellx lost 18% because Kelonia, a competing but unlisted company, drew great attention in November thanks to the first “first-in-human” data of its in vivo CAR-T against BCMA, which showed very positive responses in the first three treated patients. The market reacted enthusiastically, also because of the partnership with J&J, but strong doubts remain: the dataset is extremely preliminary, with very few patients and very short follow-up, so the reliability and durability of the responses are still unproven. Arcellx suffered a decline on the market due to the emergence of this potential competitor; we believe the reaction is excessive given the limited data available from Kelonia.

ADMA rose 26% thanks to growing revenues, improving margins, optimized production upon FDA approval, and an upward-revised outlook. The company is strengthening its position in the immunoglobulin /plasma-derived biologics segment.

Arrowhead gained 33% in a crucial month: the shift toward commercial stage with the approval of Redemphlo to reduce triglycerides in adults with FCS. Much attention is also focused on the phase 1/2a results of ARO-INHBE in obese adults expected by year-end, which could validate the RNAi approach to obesity treatment.

Jazz appreciated by 27%, confirming its transition from a company specialized in sleep disorder therapies (a pipeline it maintains) to a global oncology player with a diversified and ambitious portfolio. This month Jazz released positive phase 3 data with zanidatamab in gastroesophageal adenocarcinoma, potentially a turning point for the asset: if the regulatory submission succeeds, it could become a first-line standard of care for HER2+ gastroesophageal tumors, significantly expanding the market.

Madrigal, with Rezdiffra sales exceeding expectations, additional clinical data confirming its effectiveness, growth in the patient base, and the stock at an all-time high, is consolidating its role as a leader in MASH, rising 40%.

PTC Therapeutics +23%; quarterly results highlighted an excellent launch of Sephience for phenylketonuria, strengthening prospects of expanding beyond dystrophies. Another move in this direction is the upcoming meeting with the FDA toward year-end to discuss the design of the phase 3 study of votoplam in Huntington's disease, with a potential accelerated approval pathway.



Scholar Rock posted +43%, reacting well to the CRL received in October—remember, due to deficiencies attributable not to the company but to Novo Nordisk's fill & finish facility. The company reported the results of a Type A meeting with the FDA and reaffirmed its intention to complete the resubmission of apitegromab as soon as the issues at the Bloomington, Indiana site are resolved. Scholar Rock reiterated its intention to launch the product on the market during 2026.

Arcutis: the FDA has accepted the supplemental NDA to extend the indication of Zoryve for plaque psoriasis in children aged 2–5 years, with a PDUFA date of June 20, 2026. If approved, the therapy will become the first topical PDE-4 inhibitor indicated for psoriasis in children from age 2, significantly expanding the potential pediatric patient pool. The MUSE-4 study supporting this sNDA demonstrated a sustained efficacy and safety profile.

Bavarian Nordic (not in the portfolio). We sold the stock in September after it became the subject of a takeover bid. This month the consortium of funds that proposed the acquisition withdrew, and the stock price fell 21%. We know the company and its prospects well, and at these prices we are considering re-entering.

Cullinan, in addition to reorganizing its pipeline by suspending CLN-619 and CLN-617 to focus on CLN-049 and CLN-978 (both T-cell engagers), has begun the rolling submission to obtain accelerated approval of zipartinib in NSCLC with specific mutations. The stock appreciated 36%.

Mersana. Day One Biopharmaceuticals has offered USD 25 per share in cash to acquire the company. In addition, there is a CVR that may be worth up to USD 30.25. The stock gained about 200%. We are not selling because part of the CVR is relatively low-risk and expected to be realized in the short term.

Nuvation. The launch of Ibtrozi, approved in June, surprised with strong sales. +60%.

Savara announced it is in line with FDA requirements following the recent "refuse to file" (the FDA had refused to review the BLA in May due to CMC issues), having added another manufacturer to the application. They stated they will resubmit the BLA in December 2025. The stock rose 50%.

Urogen. Sales of Zusduri continue to gain momentum. Furthermore, the phase 3 study of UGN-103, conceived as an evolution of Zusduri, showed a complete response rate of 77.8%, consistent with previous results. As a result, the FDA has agreed that the data can support an NDA submission. In November the stock rose 50%.

Portfolio Activity

We are satisfied with the portfolio we hold. Although **Mersana** is being acquired, we prefer not to close the position because the CVRs granted at closing have very high value—USD 30.25 in addition to the cash payment of USD 25—of which at least USD 4 is payable in the short term. The only transaction of the month was increasing the investment in **Tempus AI** to bring it to EW.

Performance

Onelife Fund gained 10.12% in the month, outperforming the sector index (Nasdaq Biotech Index), which rose 8.41%. Year-to-date **Onelife Fund** is up 43.75%, outperforming the NBI (+34.97%) and ranking in the top 5 among peers.

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