Halozyme

95

Company Overview

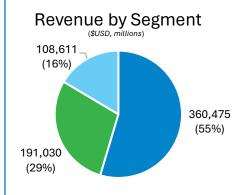
Halozyme Therapeutics Inc. is a biotechnology company founded in 1998. HALO's main revenue driver is their proprietary enzyme rHuPH20, which is used to facilitate bulk fluid flow in subcutaneous ("SC") injections delivery of drugs and fluids. They license ENHANZE, the technology of rHuPH20, to other companies such as Roche, Pfizer, and Eli Lilly. Patent royalties make up the bulk of their revenues at 55% with product sales following at 29%. Halozyme's ENHANZE patent will expire in Europe this year and will last till 2027 in the US, but they have outlined expected royalty terms for co-formulation patents. Revenues from ENHANZE products are expected to continue past 2030 for all wave 1-3 products. The only drug expected to affect revenue in 2027 is Darzalex SC with a 50% reduced royalty rate out till 2033. While the 2027 expiration could cause a patent cliff, wave 3 product royalties go out till early 2040. The product sales segment breakdown is 43% bulk 2HuPH20 sales, 38% Proprietary Products, and the rest Device Partnered Partners. Within Proprietary Products, the key product is the XYOSTED which is a SC, once weekly testosterone enanthate injection used in testosterone replacement therapy (TRT). XYOSTED has an expected \$100M in sales for 2023 and CAGR is projected at 25% for the next 5 years. In 2022, Halozyme acquired Antares Pharma for \$960 million to add drug injection technology to its product portfolio. This acquisition has allowed for XYOSTED, TLANDO, and several other products to be growth drivers beyond 2027.

Key Pipeline highlights

The ATRS–1902 is the only proprietary product candidate in the pipeline and it doesn't use the ENHANZE technology. The program is currently in stage 3 and was granted the Fast Track designation by the FDA after positive results from Phase 1. This medication would fall under the auto-injector category and be used in the endocrinology market. Several serious diseases can lead to acute adrenal deficiency (Addison's Disease) such as Cancer or Tuberculosis. Another key drug in their pipeline is Atezolizumab or TECENTRIQ SC as its product name. This product is a partnership with Roche and is currently in field testing after a successful phase 3. The drug has already been approved in the UK and is awaiting expected approval in 2024. The final key drug in the pipeline is the Efgartigimod or VYVGART. This product is a collaboration with Argenx and has already been approved by the FDA for the treatment of gMG. I have included it in the pipeline as it is waiting for approval for use in adults with CIDP. TECENTRIQ SC and VYVGART are the leading products in the wave 3 product mix. Refer to the chart on the next page to see the royalty terms of the drugs mentioned above.

Market Trend - Testosterone

Halozyme is projecting XYOSTED to be one of the main revenue drives moving forward. When most people hear the word "testosterone," negative connotations of steroids come to mind but there are countless benefits when used properly. Normal testosterone levels are 300 - 1000 ng/dL for males and 15 - 70 ng/dL for females and TRT is used to supplement when needed. If one's testosterone levels are too low, this can cause countless negative side effects such as depression, muscle loss, insomnia, infertility, bone loss, slowed metabolism, and cholesterol problems. 40% of men over 45 and 40% of obese men have levels below 300 ng/dL (hypogonadism). Several men outside these demographics are being prescribed testosterone, even those who are not hypogonadal in hopes of "optimizing" their testosterone levels. While less common, several women are hypogonadal and could benefit from TRT in lower doses. TRT treatment is typically done for the remainder of someone's life once they start due to it shutting down their natural production of testosterone. Drugs like Enclomiphene exist that help restart natural testosterone production, but it isn't as effective for older patients, it doesn't always work, and users typically don't want to stop taking it due to the positive effects. When testosterone is compared to Ozempic it is much more effective since there is a significant amount of muscle loss due to high user caloric deficits. With testosterone, there is a much greater rate of muscle retention and body fat percentage loss. Ozempic is primarily used by women whereas testosterone could be dubbed as the male alternative. The main driver of Ozempic's success, beyond its effectiveness in losing weight, was its support from famous figures like Elon Musk and Oprah Winfrey. While TRT has seen some celebrity support, it is relatively unknown to a broader audience. The TRT market size is \$2.01 billion and its CAGR is 2.9% but this could change given a strong public backing.





Key Info

Ticker: HALO Rev: \$660M Price: \$34.92 R&D: \$77M Mkt Cap: \$4.61B FCF: \$352M

Pipeline

ATRS 1902 – Adrenal Deficiency (NDA filed end of 2022)

Rybrevant – Lung Cancer (Stage 3, expected US launch in 2025) Nivolumab – Kidney Cancer (Stage 3)

HyQvia – CIDP (expected EU Approval Feb 2024) ACU193 – Alzheimer's (Initiate Phase 1 mid-2024)

Atezolizumab – Lung Cancer (expected FDA Approval Mid 2024) Efgartigimod – CIDP (Estimated PDUFA date mid 2024) Opdualag – Melanoma (Phase 3)

Competitors (Mkt Cap)

ACADIA	4.25B
(Alkermes	4.51B
Madrigal	4.28B
4	





4.71B



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95

BUY Theses

Halozyme's royalty-based business model allows for low costs and strong cash flow margins at \$352 million for LTM. The company is expecting consistent growth with a \$1.6 billion revenue projection for 2028, which is double its current year projected revenue. **EBITDA** margins at 72-74% projected for 2028 compared to 51-52% for 2023. The margin projections could increase from wave 4 & 5 product royalties. The consistently strong margins provide opportunities for M&A.

HALO Anticipated Royalty Terms



Effective positioning post-2027

There are 5 products currently contributing to Halozyme's royalty revenue in the US and this is expected to go to 9 in 2025. The company is expecting co-formulation patents (filled during clinical trials and they extend patent expiration) to allow royalty revenues to continue past the ENHANZE expiration. All products in Wave 1 & 2 have been granted a co-formulation patent extending their royalty termination dates till 2030. As mentioned earlier, VYVGART and TENTRIQ SC will be key products for their wave 3 product mix and both have royalty terms until 2040. The purchase of Antares was a step towards auto-injectors and away from ENHANZE while marking their first steps to acquisition growth post-2027. Patents are pending for their HVAI injector technology that allows for delivery of up to 10 ml in less than 30 seconds. The company has effectively shifted from a single technology to a dual technology company, combining the power of ENHANZE with its SC injection technology. This combination will allow for future partnerships long past the patent expiration. An example of this was the product DARZALEX SC, which was a partnership with Janssen that allows for reduced treatment times from 3-5 hour IV drips to a 3-5 minute injection for patients with Multiple Myeloma. Forming partnerships that leverage both technologies allows them to grow far past their current patent cliffs.

Revenue from Increased Subcutaneous Testosterone Injections

Halozyme is currently projecting the XYOSTED for a 25% CAGR, but I believe this to be an underestimate. Testosterone will be a major new headline in the near future and the question will be, which method is best? There are several types of testosterone, but the XYOSTED is composed of testosterone enanthate which is by far the best form of the hormone with a lower side effect profile and moderate duration. The XYOSTED works similarly to Ozempic, where it comes in a pen-shaped object and is injected subcutaneously into the stomach. This is the only subcutaneous testosterone injection that has been FDA-approved for once-a-week use. Compared to alternatives, this technology is by far the easiest and most effective in terms of effectiveness ratio to side effects. Intramuscular injections are currently the most common way of using testosterone, but this is much more difficult and prone to side effects. XYOSTED may soon replace IM injections as the main method to use testosterone for its convenience and appeal to the average man. As an example of the company's ability to see where the market is heading, they have terminated their license with Lipocine to sell TLANDO, an oral testosterone pill. While these pills may be beneficial to people starting TRT, almost no one continues with long-term use due to unpredictably involving metabolization and the inconvenience of swallowing two large pills each day. XYOSTED is a much better alternative and would have eventually cannibalized TLANDO if it had been kept in the product mix.

Common Testosterone Administration Options

*Grey boxes represent options offered by Halozyme

Topicals

Topicals are rubbed on the skin, typically the arms.
Risks include contamination and cancer if put on the wrong areas such as breast tissue.

IM Injection

Intramuscular injections require large needles inserted deep into muscle tissue. Can cause pain and bumps under the skin which is why is usually applied to the glutes.

SC Injection

Subcutaneous Injections are the best way to inject testosterone. It is easy and has lower side effects relative to alternative methods.

Orals

Certain testosterone esters can be liver-toxic if broken down in the liver. TLANDO is broken down in the intestine and avoids this issue.

Typically, unpredictable and requires swallowing large pills every day.

Patch

Applied to the skin similar to a nicotine patch. It is relatively safe but is inconvenient and has a lot of restrictions around when and where to use it.



