06-May-2025

Halozyme Therapeutics, Inc. (HALO)

Q1 2025 Earnings Call

Copyright © 2001-2025 FactSet CallStreet, LLC

CORPORATE PARTICIPANTS

Tram Bui
Vice President-Investor Relations and Corporate Communications, Halozyme Therapeutics, Inc.

Helen I. Torley
President, Chief Executive Officer & Director, Halozyme Therapeutics, Inc.

Nicole LaBrosse
Chief Financial Officer, Halozyme Therapeutics, Inc.

OTHER PARTICIPANTS

Sadia Rahman
Analyst, Wells Fargo Securities LLC

Sean Laaman
Analyst, Morgan Stanley Australia Ltd.

Michael DiFiore
Analyst, Evercore ISI

Mitchell S. Kapoor
Analyst, H. C. Wainwright & Co. LLC

Brendan Smith
Analyst, TD Securities (USA) LLC

David Risinger
Analyst, Leerink Partners LLC

MANAGEMENT DISCUSSION SECTION

Operator: Good afternoon. My name is Beri, and I will be your conference operator today. At this time, I would like to welcome everyone to Halozyme's First Quarter 2025 Financial and Operating Results Conference Call. All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question-and-answer session. [Operator Instructions] Please note this event is being recorded.

I will now turn the call over to Tram Bui, Halozyme's Vice President of Investor Relations and Corporate Communications. Please go ahead.

Tram Bui
Vice President-Investor Relations and Corporate Communications, Halozyme Therapeutics, Inc.

Thank you, Operator. Good afternoon, and welcome to our first quarter 2025 financial and operating results conference call. In addition to the press release issued today after the market closed, you could find a supplementary slide presentation that will be referenced during today's call in the Investor Relations section of our website.

Leading the call will be Dr. Helen Torley, Halozyme's President and Chief Executive Officer, who will provide an update on our business; and Nicole LaBrosse, our Chief Financial Officer, who will review our financial results as well as our outlook.

On today's call, we will be making forward-looking statements as outlined on slide 2. I would also refer you to our SEC filings for a full list of risks and uncertainties. During the call, both GAAP and non-GAAP financial measures

Copyright © 2001-2025 FactSet CallStreet, LLC

will be discussed. Certain non-GAAP or adjusted financial measures are reconciled with the comparable GAAP financial measures in our earnings press release and slide presentation.

I will now turn the call over to Dr. Helen Torley.

Helen I. Torley

President, Chief Executive Officer & Director, Halozyme Therapeutics, Inc.

Good afternoon, everyone, and thank you for joining us today. It really has been a tremendous start to 2025. Before I describe the many events and successes in the first quarter, let me begin by thanking the many shareholders and sell-side analysts who participated in our investor feedback interviews earlier this year. We really appreciate your feedback and it has been invaluable. Your feedback helped us understand more granularly the role that we are playing in different investor portfolios and we're very pleased to be considered your consistent stock grower. Not surprisingly, each of you recognized our leadership in drug delivery for biologics and how this foundation can be expanded to additional areas of drug delivery.

All investors agreed on key themes about Halozyme. For example, no investor wants Halozyme to invest in drug development binary risks. We agree. All investors want to make sure that we maximize the organic growth represented by ENHANZE and our auto-injectors by fully investing where there are opportunities. Again, we agree. And later this year, we will settle an update about potential new ENHANZE uses and the opportunity. All investors encourage us to also seek to grow inorganically through M&A. While opinions differed about the exact destination for our M&A, all investors want us to remain disciplined about our net leverage and we listen to your feedback.

With this in mind, I am pleased to reiterate our strategy. Our goal, said simply, is to grow organically and through serial acquisitions, excelling in licensing, disruptive drug delivery platform technologies that improve the patient treatment experience and result in better outcomes. With the strategy, we aim to deliver strong and durable revenue and EBITDA growth well into the next decade. We will achieve this performance by continuing to focus first and foremost on organic growth.

We will continue to invest in and grow ENHANZE and our auto-injector businesses, where we are absolutely the best positioned company to capitalize on the growing pharma and patient priority for at-home patient delivered treatment.

We will also seek to grow inorganically through M&A. Our focus here is on identifying new drug delivery platforms, where the business model results in long durable revenue streams, such as through royalties, and where we see the opportunity to license to multiple pharma partners. We heard you in leverage and we will be seeking deals that can be accomplished without the need for a significant increase in net debt to EBITDA leverage. And we heard how much our share buybacks are appreciated by our investors given the high IRR they have delivered. I am pleased to announce that we're planning to continue this in 2025, announcing today the plan to repurchase $250 million in shares.

Let me now move to the Q1 performance, beginning on slide 3. And here's how I'd like to think about our business, our performance and our future. Firstly, we have three blockbusters that are driving our current growth. We'll go into more detail on those in a moment. Secondly, we have 11 new growth catalysts that have either just happened or will happen in the next months. These catalysts will drive our growth for multiple years to come. And thirdly, we have several products in our development pipeline, plus our auto-injector technology that will drive additional future growth. As an example, today, we are pleased to announce our very first high-volume auto-injector agreement.

Copyright © 2001-2025 FactSet CallStreet, LLC

Petitioner Merck, Ex. 1086, p. 3
Merck Sharp & Dohme LLC v. Halozyme Inc.
IPR2026-00314

Turning now to slide 4, let me briefly highlight the strong first quarter results. Total revenue increased 35% year-over-year to $265 million, with royalty revenue increasing by 39% to a $168 million, primarily driven by the three blockbusters DARZALEX subcutaneous, Phesgo and VYVGART Hytrulo.

Adjusted EBITDA increased to $162 million and non-GAAP EPS increased to $1.11, both representing approximately 40% year-over-year growth.

Net income also grew an impressive 54% in the quarter to $118 million.

Let me now expand on the three blockbusters that are key revenue drivers and that are projected to keep growing for years to come, DARZALEX FASPRO, Phesgo and VYVGART Hytrulo.

I'll begin with DARZALEX shown on slide 5. In the first quarter, Johnson & Johnson reported another strong quarter of growth for DARZALEX, which increased 22% year-over-year on an operational basis to $3.2 billion. The growth was primarily driven by continued share gains of approximately 3 points across all lines of therapy and approximately 5 points in the frontline setting, as well as through market growth.

DARZALEX subcutaneous with ENHANZE, which is marketed as DARZALEX FASPRO in the United States, accounts for approximately 95% of all DARZALEX sales in the United States and commands a similarly high proportion of share in the major ex-US markets. And DARZALEX continues to set the standard in multiple myeloma treatment. With Johnson & Johnson's commitment to its clinical advancement continuing to solidify its role as the backbone of treatment across front- and second-line patients.

Moving now to the first of the 11 new growth catalysts, which is the recent European approval of a DARZALEX-based quadruplet regimen for patients with newly diagnosed multiple myeloma regardless of transplant eligibility, further supports near-term growth, and the analyst estimates for DARZALEX to reach $17 billion in sales in 2028, with the subcutaneous formulation driving this growth and the vast majority of the sales. We predict royalties in DARZALEX subcutaneous through 2032.

Let me move now to slide 6, and Roche's Phesgo, which is a combined therapy of Perjeta, Herceptin and ENHANZE. Phesgo continues to demonstrate strong adoption and commercial success. In the first quarter, Phesgo was the number one growth driver in Roche's pharmaceutical portfolio, with sales increasing 52% to approximately $675 million, with strong performance in international regions. Our second new growth catalyst is Phesgo gaining National Reimbursement Drug Listing in China, with Roche commenting on their Q1 call that the growth in China is accelerating noticeably following the listing, which happened earlier this year.

Conversion from Perjeta to Phesgo is ongoing, reaching 47% in the 58 launch countries in the first quarter, with expectations for conversion to reach more than 50% across global markets in 2025. In April of 2025, the CHMP recommendation in Europe to expand the Phesgo label to allow administration outside of a clinical setting is our third growth catalyst. Availability of this option will deliver on patient preference for at-home administration. We see this also as an important step in freeing up cancer care capacity in the clinical settings.

Sales of Phesgo are projected to reach approximately $3.3 billion by 2028, entirely from the ENHANZE-enabled subcutaneous formulation, where we earn a mid-single digit royalty on net sales through 2030. The product's strong growth and broad geographic uptake underscore the commercial success possible with ENHANZE-enabled therapies.

Copyright © 2001-2025 FactSet CallStreet, LLC

Let me now move to argenx's VYVGART and VYVGART Hytrulo, which is the subcutaneous version enabled by ENHANZE. These are shown on slide 7. Today, VYVGART Hytrulo is approved for two indications in the United States, generalized myasthenia gravis and chronic inflammatory demyelinating polyneuropathy. And for one indication, generalized myasthenia gravis in Europe. In the United States, VYVGART Hytrulo with ENHANZE has played a pivotal role in adding new prescribers and new patients in the first approved indication generalized myasthenia gravis reaching patients earlier in the treatment paradigm and accessing new to brand patients.

Moving now to the second approved US indication CIDP, VYVGART Hytrulo was approved as a subcutaneous-only treatment recently in September of 2024. argenx has reported initial strong demand from patients and physicians, highlighting the unmet need for safe and effective treatment alternatives. As reported in February of 2025, more than 1,000 CIDP patients were in therapy. For CIDP, argenx has stated that they have attained favorable or highly favorable coverage for 90% of US lives. They further commented that their recent sales force expansion has contributed to deeper community reach, noting that 25% of prescribers for CIDP are new to VYVGART. In Europe, VYVGART Hytrulo was approved for generalized myasthenia gravis in November of 2023. VYVGART total sales reached $2.2 billion in 2024, with continued strong growth, especially of VYVGART Hytrulo projected in 2025.

Turning now to slide 8, I'll comment on the growth catalysts number five, six and seven. In April of 2025, the FDA approved the new option for patients to self-inject argenex's VYVGART Hytrulo prefilled syringe, which contains the same VYVGART which is co-formulated with ENHANZE as is in the vial, and where Halozyme received the same mid-single digit royalty on net sales. This FDA approval of the prefilled syringe is our fifth new growth catalyst.

The VYVGART Hytrulo prefilled syringe is approved as a 20 to 30 second subcutaneous injection, which is administered by a patient, a caregiver or a healthcare professional and will contribute to VYVGART Hytrulo's strong growth trajectory for 2025 and beyond.

The prefilled syringe also received a positive recommendation in Europe for use in generalized myasthenia gravis patients in February of this year. This is projected to result in approval in the second quarter of 2025 and is our sixth growth catalyst. In April of 2025, argenx received a positive opinion for VYVGART Hytrulo from the CHMP in Europe for the indication of chronic inflammatory demyelinating polyneuropathy, with approval expected to occur mid-year 2025, following the CHMP opinion. This new indication, which we expect to be for a vial and for the prefilled syringe, will significantly expand the opportunity and add new growth. And this is our seventh new growth catalyst in 2025.

VYVGART is just starting its journey of innovation. As you will see on slide 9, argenx has multiple active subcutaneous programs in development with ENHANZE, including for ocular myasthenia gravis and for thyroid eye disease, which will further fuel the revenue growth. With Halozyme earning royalties through the early 2040s, VYVGART Hytrulo represents one of the most significant and durable contributors to our long-term financial performance.

Continued to expand on new growth catalysts, I'll now move to slide 10 and the four additional recently launched products that are just warming up and are at the start of what promise to be exciting launches. Let me begin with OCREVUS ZUNOVO with ENHANCE, which was approved last year for multiple sclerosis as an approximately 10-minute subcutaneous injection. This compares with multiple hours that is typically required for the intravenous administration.

Copyright © 2001-2025 FactSet CallStreet, LLC

Importantly, and the eight new growth catalyst Roche recently reported that OCREVUS ZUNOVO received its permanent J-code in the US on April 1, which they stated will help accelerate uptake in the second half of 2025. Outside the United States, work continues to gain that all important reimbursement in each country. Roche reported that 50% of patients who started on OCREVUS ZUNOVO were naïve to the brand, providing Roche with confidence that ZUNOVO will open up new patient populations to OCREVUS and not simply cannibalize existing share. Roche believes that OCREVUS ZUNOVO could represent an incremental approximately $2 billion opportunity for the brand through this expansion, resulting in an approximately $10 billion analyst projection for IV and subcutaneous OCREVUS in 2028. OCREVUS ZUNOVO is projected to earn Halozyme royalties at its full mid-single digit rate until 2030 and at a step-down rate until at least 2034.

I'll move now to Roche's TECENTRIQ HYBREZA with ENHANZE, which gained FDA and EMA approval in 2024. The approvals work for all of the intravenous indications offering patients the convenience of an approximately 7-minute subcutaneous injection. With a permanent J-code in place and work continuing to gain reimbursement in all countries, the strategy is to convert IV TECENTRIQ patients to TECENTRIQ HYBREZA. Halozyme will earn royalties on TECENTRIQ HYBREZA at the full mid-single digit rate until the 2040s.

Moving now to Bristol Myers Squibb OPDIVO QVANTIG, the subcutaneous formulation of nivolumab with ENHANZE, which was granted FDA approval at the end of 2024 in the United States. BMS is focused on continuing to increase breadth of prescribing in both the community and academic settings and the permanent J-code, our ninth new growth catalyst is expected on July 1. The J-code is expected to drive adoption of the subcutaneous formulation in the second half of the year. BMS recently commented that they're receiving promising early feedback from practices and patients on the subcutaneous formulation, which is a 3-to-5-minute subcutaneous injection, uses predominantly happening in the community setting and is occurring across multiple tumor types.

In April of 2025, BMS announced the positive CHMP opinion for OPDIVO subcutaneous with ENHANZE, representing our 10th new growth catalyst. We anticipate European approval in mid-2025.

I'll move now to subcutaneous RYBREVANT, which is Johnson & Johnson's innovative EGFR C-MET inhibitor. Johnson & Johnson gained European approval of subcutaneous RYBREVANT co-formulated with ENHANZE in April of 2025, for use in combination with lazertinib in the first line treatment of adult patients with advanced EGFR mutated non-small cell lung cancer. Subcutaneous RYBREVANT represents a more convenient, patient-friendly formulation reducing administration time from multiple hours required for the IV to just 5 minutes for the subcutaneous. Importantly, there is a five-fold reduction in infusion related reactions compared to the IV formulation. Work is now underway to gain reimbursement for subcutaneous RYBREVANT in each country. And our 11th new growth catalyst is the potential US approval of RYBREVANT subcutaneous. J&J has continued to work on gaining this approval in 2025.

I wanted to also highlight recent data on RYBREVANT. Very excitingly, the results of the Phase 3 MARIPOSA trial were presented at the European Lung Cancer Congress in March of 2025. The combination of RYBREVANT and lazertinib significantly reduced the risk of death by 25% versus Tagrisso, which is considered by many to be the current standard of care in patients with newly diagnosed EGFR mutated non-small cell lung cancer. With a projected improvement projected of more than 12 months survival benefit over this current standard of care, this is certainly a potentially important advance for patients with this type of cancer, where only 20% of patients survive beyond five years today.

Copyright © 2001-2025 FactSet CallStreet, LLC

With our now 10 launched products, which are shown on slide 11, we remain on track to deliver over $1 billion in royalty revenue in 2027, with all products continue to generate royalties to at least 2030 and many expected to continue to the 2040s.

I'll move now to slide 12 and to some highlights on our pipeline that represent potential new growth drivers, the royalty revenues of which are not included in our multi-year guidance. During the first quarter, Acumen reported top-line results for sabirnetug subcutaneous with ENHANZE for Alzheimer's disease, which support further clinical development for the subcutaneous formulation with ENHANZE.

ViiV also reported positive Phase 2 data for N6LS subcutaneous with ENHANZE in combination with cabotegravir. The study demonstrated the promise of an every four-month treatment in combination with cabotegravir. This is another terrific example of how ENHANZE can support a more extended dosing interval, reducing the treatment burden for patients. And we were also very hard at work during the quarter, continuing discussions with several companies and entering into discussions with multiple new companies with regard to new deals.

I'm pleased to announce that we have signed our first development agreement with the current ENHANZE partner for development of our high-volume auto-injector. The majority of the ongoing discussions continue to focus on ENHANZE alone and ENHANZE with the high volume auto-injector, if the volume is between 2 to 10 mLs. I can update that we are progressing through the multi-step review and decision-making committees in several of these discussions.

And turning to our small volume auto-injector business, I'm pleased to say that one of our current partners is progressing now to test the small volume auto-injector in a Phase 1 study. There has not been a time in Halozyme history when we have been in such a strong position in terms of having 10 de-risked, proven, approved subcutaneous products with 11 recent or soon to happen events that are catalysts to expand opportunity, adoption and growth. The underlying continued strength of DARZALEX subcutaneous, Phesgo and VYVGART Hytrulo plus these new growth catalysts have resulted in the increased 2025 guidance, which Nicole will review in a moment after she discusses our first quarter results in more detail. Nicole.

Nicole LaBrosse

Chief Financial Officer, Halozyme Therapeutics, Inc.

Thank you, Helen. The first quarter of 2025 represented a strong start to the year, and we're excited to raise our full-year expectations based on these strong results. We grew revenue by 35% with EBITDA growth of 40% as we continued to drive leverage on our high margin royalty revenue, contributing a $153 million in free cash flow in the quarter.

Let me start on slide 13. In the first quarter, we completed the $250 million ASR announced in December of 2024. Since 2019, we have repurchased $1.55 billion of shares, which is on average $250 million each year at an average price of $33.72. Due to the strong performance to-date, we are announcing an additional $250 million of share repurchases to be executed during the remainder of the year. As Helen mentioned, we continue to evaluate M&A opportunities to complement our organic growth expectations.

Let me now turn to our detailed first quarter results on slide 14. Revenue grew 35% to $264.9 million, compared to $195.9 million in the prior year period. This includes higher-than-expected revenue in all categories. Royalty revenue of $168.2 million increased by 39% from a $120.6 million in the prior year and was higher than our original expectations. The continued commercial success of subcutaneous DARZALEX and Phesgo and the

Copyright © 2001-2025 FactSet CallStreet, LLC

Petitioner Merck, Ex. 1086, p. 7
Merck Sharp & Dohme LLC v. Halozyme Inc.
IPR2026-00314

robust growth of VYVGART Hytrulo exceeded our expectations for the quarter, driving an increase in our full-year guidance.

Product sales of $78 million increased by 33%, from $58.6 million in the prior-year period, mainly driven by higher API sales than originally estimated due to an increase in partner orders. We have an increase in partner orders in later quarters of 2025, which is also a driver of the increase in our full-year guidance. Collaboration revenue of $18.6 million, an increase of 12% from $16.7 million in the prior year period was also higher than expected due to the achievement of a VYVGART Hytrulo sales milestone one quarter earlier than originally projected.

Research and development expenses were $14.8 million compared to $19.1 million in the prior year period. The decrease was primarily due to lower compensation expense driven by resource optimization and improved labor allocations to COGS and the timing of planned investments in ENHANZE related to the development of our new high yield rHuPH20 manufacturing process.

Selling, general and administrative expenses were $42.4 million in the quarter, up from $35.1 million in the prior year period, primarily due to increased compensation expense and consulting and professional service fees.

Adjusted EBITDA increased 40% to $162 million from a $115.7 million last year. GAAP diluted earnings per share was $0.93 and non-GAAP diluted earnings per share was $1.11. This is compared with GAAP diluted earnings per share of $0.60 and non-GAAP diluted earnings per share of $0.79 in the first quarter of 2024.

We continue to maintain a strong balance sheet with cash, cash equivalents and marketable securities of $747.9 million on March 31, 2025, compared to $596.1 million on December 31, 2024. The increase was primarily a result of cash generated from operations. Our net debt position was $777 million, with a net leverage ratio of 1 time.

As a result of our strong first quarter performance, we are raising our guidance, as you can see on slide 15. We now expect total revenue of $1.2 billion to $1.28 billion representing year-over-year growth of 18% to 26%, driven by increased projections in all three revenue categories, royalties, product sales and collaboration revenue. Royalty revenues of $750 million to $785 million, representing year-over-year growth of 31% to 37%. We continue to expect VYVGART Hytrulo with ENHANZE to be the largest royalty dollar growth driver. Product sales of $340 million to $365 million, driven by higher partner demand for our rHuPH20 in the year. Collaboration revenue of a $110 million to $130 million driven by the EU approval of RYBREVANT SC in April, for which a milestone will be recognized in the second quarter.

Adjusted EBITDA of between $790 million to $840 million, representing year-over-year growth of 25% to 33%, reflecting high margin royalty growth coupled with flat operating expenses from our continued focus on operational efficiency. And non-GAAP diluted EPS of $5.30 to $5.70, representing year-over-year growth of 25% to 35%, which does not include the impact of future share repurchases, including the $250 million announced today.

As you refine your models, I'd like to reiterate the following. While we achieved a VYVGART Hytrulo milestone one quarter earlier than expected in the first quarter, we continue to expect collaboration revenues for the year to be more weighted in the second half of 2025. We continue to expect product sales to be weighted in the second half of the year with the second quarter flat with the first quarter. For royalties, we continue expect quarterly sequential growth for the remaining quarters in the year.

With that, I'll now turn the call back over to Helen.

Copyright © 2001-2025 FactSet CallStreet, LLC

Helen I. Torley
President, Chief Executive Officer & Director, Halozyme Therapeutics, Inc.

Thank you, Nicole. Our strong first quarter performance, particularly of DARZALEX subcutaneous, Phesgo and VYVGART Hytrulo, plus our 11 new growth catalysts, gave us the confidence to raise the full year 2025 financial guidance ranges. With 10 products now approved and launched in at least one major region, we have durable revenue streams that will continue to support our conviction in the future success of Halozyme.

Our robust pipeline, along with our ability to defend our intellectual property, further strengthens our confidence in delivering sustainable growth and profitability well into the future. This is an incredibly exciting time of growth for Halozyme and this would not have been possible without our terrific partners and our dedicated and expert Halozyme team. And I'd like to say a sincere thank you to everybody who has contributed.

Operator, with that, we are now ready to open the call for questions. Thank you.

QUESTION AND ANSWER SECTION

Operator: [Operator Instructions] Your first question comes from the line of Mohit Bansal with Wells Fargo. Your line is open.

Sadia Rahman
Analyst, Wells Fargo Securities LLC

Q

Hi. Sorry about that, I was on mute. Hi, this is Sadia Rahman on for Mohit. Thanks for taking the questions. So, on the IP case with Merck, I had a question about that. Can you comment on the expected timelines for the PGR decisions and what action you could take if the PGR goes in Merck's favor?

Helen I. Torley
President, Chief Executive Officer & Director, Halozyme Therapeutics, Inc.

A

Yeah. Thanks for that. With regard to the PGR, the first decision by the Patent Office on institution will be in early June. And if there is institution, that will mean that the case will be reviewed about 12 months from them. They also can decide not to pick up the case, in which case it would not proceed.

Sadia Rahman
Analyst, Wells Fargo Securities LLC

Q

Got it. And just related to that, is there a possibility that, that PGR case and your patent infringement lawsuit could be tied together? Or is that not possible due to logistical reasons?

Helen I. Torley
President, Chief Executive Officer & Director, Halozyme Therapeutics, Inc.

A

Again, not logistical, but two very different approaches that are going on there. Obviously, the PGR, we consider to be frankly a little bit of a side show. PGR tend to be filed when companies are concerned that they are infringing and they seek to invalidate the patents. We feel very confident in our ability to prevail in those PGRs. And even if they were to win one or two of the PGR, because there are several place, we do not believe that will have any impact at all on our infringement case, where we have multiple additional claims that are not subject to

Copyright © 2001-2025 FactSet CallStreet, LLC

the PGR that are the basis of that infringement case. So, two very separate things. The most important one is actually the actual lawsuit that we filed. I'd keep your attention on that one.

Sadia Rahman
Analyst, Wells Fargo Securities LLC

Q

Got it. Thanks so much.

Operator: Your next question comes from the line of Sean Laaman with Morgan Stanley. Your line is open.

Sean Laaman
Analyst, Morgan Stanley Australia Ltd.

Q

Thank you, operator. Hello, Helen. Hope you're well and congratulations on a nice set of numbers. What's the [indiscernible] (00:31:04) number today and you've upgraded guidance. But there was, say, one particular area of strength that surprised you during the quarter and is driving the upgrade or is it more broad-based?

Helen I. Torley
President, Chief Executive Officer & Director, Halozyme Therapeutics, Inc.

A

Yeah. I will say it's our three blockbuster products that have been performing for us for the last several years and frankly are expected to continue to have this excellent performance. So, it's across the board with DARZALEX subcutaneous, Phesgo and also with VYVGART Hytrulo. And so, one of the other things we mentioned, not just the royalties, but we achieved a milestone on VYVGART Hytrulo, one quarter earlier than we had anticipated as well. And that was a commercial sales attainment milestone. So, they are just continuing to perform very, very well, Sean. Behind them, are obviously excited about the other four launch products that are really just at the very beginning. But just based on the performance comments from the partners and our estimates, we're going to continue to see strong growth from all of those products for many years to come.

Sean Laaman
Analyst, Morgan Stanley Australia Ltd.

Q

Great. Thank you. And on the small volume auto-injector, when might you'd be in a position to tell us who the partner is? And how do the economics of that deal compare to the high-volume auto-injector partnerships? And when do you ultimately see commercialization might be a reality?

Helen I. Torley
President, Chief Executive Officer & Director, Halozyme Therapeutics, Inc.

A

Yeah. With regard to when that might become public, that really will be the partner who will be in control of that. I would take an estimate and guess that when it enters clinical studies that it might be public, that it's our small volume auto-injector, but for competitive reasons, we're seeing again that our partners don't want to be signaling to their competition exactly what they're doing to continue to evolve their product offering and differentiate it for patients.

The small volume and the high-volume auto-injector agreements are both development agreements, Sean. They really lay out exactly how we will work together to create a auto-injector for use in clinical development. We have yet to move forward to the commercial licensing – supply agreement, sorry, where the actual financial terms will be there.

Copyright © 2001-2025 FactSet CallStreet, LLC

Petitioner Merck, Ex. 1086, p. 10
Merck Sharp & Dohme LLC v. Halozyme Inc.
IPR2026-00314

But I would expect in both instances what you're going to see is going to be where we have a price per device that is based on the cost of manufacturing and the time it takes us to manufacture and some cost plus benefit for, for Halozyme. But more to come on that later. We're just incredibly excited that we're now moving forward with two of our partners to be using and testing our auto-injectors in the future in their clinical studies.

Sean Laaman
Analyst, Morgan Stanley Australia Ltd.

Q

Great. Thank you, Helen. That's all I have for now.

Helen I. Torley
President, Chief Executive Officer & Director, Halozyme Therapeutics, Inc.

A

Thanks, Sean.

Operator: Your next question comes from the line of Michael DiFiore with Evercore ISI. Your line is open.

Michael DiFiore
Analyst, Evercore ISI

Q

Thanks a lot. Hey, guys. Thanks for taking my question and congrats on all the continued progress. Two question from me, centering on the Merck, Halozyme litigation. Number one, do you guys see AstraZeneca's Alteogen deal as evidence that large pharma companies are willing to accept patent litigation risk rather than to sign ENHANZE deals? And if so, how do you counter that narrative?

Second question is have any ENHANZE partners paused new target add-ons or renegotiations while they watch this litigation play out? And if so, how material could that be to long-term growth? Thank you.

Helen I. Torley
President, Chief Executive Officer & Director, Halozyme Therapeutics, Inc.

A

Yeah, I'll tackle the second one first, Mike. And no, we have not heard from any partner who is a firm partner or even conversations we're having with potential future partners where anything has been paused to evaluate the outcome of the Merck litigation. And I don't expect that really to happen at all. I think – it's very clear ENHANZE is seen as the market leader here, where the most de-risked, the most validated with the million patients treated. And, and I can say that for all of the people who are looking at Hyaluronidase, including all of the ones who have signed deals with Alteogen, all of them have come to Halozyme first and perhaps found that the target they were intending or wanting to use it for was not available. And I think we're going to continue to see that pattern.

With regard to your specific question on, on AstraZeneca, again, I don't want to speculate on what AstraZeneca is thinking with regard to the litigation, but I'll come back to the comment I made a moment ago. All of the people that have moved forward with the deal with Alteogen have actually discussed specific targets with Halozyme that were taken by other of our current partners. And I think, again, that is the trend that we have seen to date.

Michael DiFiore
Analyst, Evercore ISI

Q

Okay. Very helpful. Thank you.

Operator: Your next question comes from the line of Jessica Fye with JPMorgan. Your line is open.

Copyright © 2001-2025 FactSet CallStreet, LLC

Q

Hello, this is [ph] Adam (00:36:26) on for Jess. Thank you for taking our question. I just wanted to ask, how are you thinking about the implications of the Enhertu frontline breast cancer data for Phesgo sales and royalties? Thank you.

Helen I. Torley
President, Chief Executive Officer & Director, Halozyme Therapeutics, Inc.

A

Yeah, obviously, we're keeping a close watch on that. What we are seeing with Phesgo is with the great long-term data and there's more long-term data, as you know, that's going to be coming out on Phesgo this year as well, together with the very convenient patient administration in just 5 to 7 minutes for it. We believe that the Phesgo is going to continue to demonstrate this very strong market adoption and uptake where there is incredibly high patient satisfaction for it. So, not just the clinical benefits, the administration benefits, but also the patient satisfaction. So, we're not concerned with regard to the Enhertu data that will be emerging.

Delighted to see the strong uptake continues for Phesgo. We mentioned on the call 47% share now in the 58 launch markets expected to get to more than 50% this year. And we've seen with our products that when a patient has moved to the subcu version of the products, they tend to be very sticky. So, we are projecting continued strong growth of Phesgo for multiple years to come.

Operator: Your next question comes from the line of Mitchell Kapoor with H.C. Wainwright. Your line is open.

Mitchell S. Kapoor
Analyst, H. C. Wainwright & Co. LLC

Q

Hey, everyone. Thanks for taking the question. Wanted to ask a little bit about your views in the future of the changing proportion of the mix of royalty revenues as your pipeline evolves. Just kind of trying to understand when we could get to more even proportions versus the three blockbusters serving as the heavy weights for the royalty revenues.

Helen I. Torley
President, Chief Executive Officer & Director, Halozyme Therapeutics, Inc.

A

All right. And, it's when you have such great products, Mitch, it's an embarrassment of riches. And we do expect several of our products that are currently just starting, their launch trajectory to also be meaningful contributors. There was a time where people were very focused on DARZALEX and it having a very large proportion of our sales. It will continue to be a very important contributor to us for many years to come. But products like VYVGART Hytrulo, Phesgo, OCREVUS, others are going to be very important contributors as well.

I think Nicole mentioned that this year the larger dollar growth is actually VYVGART Hytrulo, which shows you how our portfolio is broadening. So, we're going to have multiple very high impact blockbusters like DARZALEX and then frankly, by the end of this year, next year. Let me see if Nicole would add anything to that.

Nicole LaBrosse
Chief Financial Officer, Halozyme Therapeutics, Inc.

A

Yeah. And we don't break out our royalties by products, but we have shared, the buckets as we think about our royalty projections. We shared DARZALEX and Phesgo in total the contribution that they're expected to have in the long term and then the next wave of our products, so comparing it to DARZALEX and Phesgo, having a $20

Copyright © 2001-2025 FactSet CallStreet, LLC

billion market opportunity in 2028 and then looking at the next wave of our products in totality, having a $35 billion market opportunity in 2028, I think that gives you that good sense for how over the next few years those products will start contributing very meaningfully and taking up a good proportion of our royalty revenue.

Mitchell S. Kapoor
Analyst, H. C. Wainwright & Co. LLC

Q

Thank you. That's very helpful. And one more from me, just talking about the M&A activity and the expectations for future activity in that space. Could you talk a little bit about what you're looking for in your next BD deal there and how that contrasts with your strategy with Evotec? And then if you could just talk about timing on when you would like to execute on one of those transactions? Is there kind of a timeline for that and kind of size larger or smaller multiple smaller ones, any clarity around those particular aspects of the M&A strategy?

Helen I. Torley
President, Chief Executive Officer & Director, Halozyme Therapeutics, Inc.

A

Yeah. Thanks, Mitch. Well, with regard to M&A, we're very focused on seeking to find opportunities in, in the drug delivery space where there platform technologies that can result in long durable revenues, including and particularly for royalties. Obviously, we like that model. But I will say we are not in a hurry to do it and we're going to be carefully evaluating and being thoughtful as we've always been to identify something that we believe would be needed and required by multiple pharma companies and result in a very positive contribution to Halozyme's long-term growth.

So, think drug delivery, think licensing business, that is where we are evaluating today. No specific timeline. And as we're still evaluating, Mitch, it'd be premature to comment on the size but it – so I can't comment on that at this period of time. So, that's where we're going to be focused and we're excited to try to create new platforms and create just great businesses like ENHANZE and that we've done so successfully with that.

Mitchell S. Kapoor
Analyst, H. C. Wainwright & Co. LLC

Q

Great. Thank you all very much for taking the questions.

Operator: [Operator Instructions] Your next question comes from the line of Brendan Smith with TD Cohen. Your line is open.

Brendan Smith
Analyst, TD Securities (USA) LLC

Q

Great. Thanks for taking the question, guys, and congrats on all the great update. Maybe just another one kind of regarding the litigation with KEYTRUDA, just kind of in [ph] point long-term (00:42:42). Can you just confirm first that whatever the outcome for your litigation against Merck that the decision will have no impact on your actual core ENHANZE business? And then on the flipside, kind of the same question regarding the PDR2 from Merck or is the one from them a little bit more targeted to ENHANZE itself, just trying to kind of understand the relative potential impact down the line?

Helen I. Torley
President, Chief Executive Officer & Director, Halozyme Therapeutics, Inc.

A

That's great, Brendan. And to be very clear, what is going on in the MDASE, which is a separate and distinct set of patents from ENHANZE, will have absolutely no impact whatsoever on our ENHANZE business, our guidance

Copyright © 2001-2025 FactSet CallStreet, LLC

that we provided or our future growth of ENHANZE. Think of the MDASE as future upside opportunity. That has been identified as we are finding that companies are infringing our intellectual property and we're seeking to have those companies take licenses from us.

So that's it bottom line with regard to what would happen, so specifically with the outcome of the PGRs, yes, absolutely no impact on our ENHANZE business. And same with the infringement case, no impact on the ENHANZE business or potential upside if we were to win either a license with Merck or when compensatory damages as we are seeking in the litigation, so two very distinct things where MDASE is just potential upside coming from great innovation and inventions that Halozyme has created over the years.

Brendan Smith
Analyst, TD Securities (USA) LLC

Q

Got it. Okay, great. Thank you. And then maybe just a quick one on tariffs. We do get a lot of questions about this, can you just speak really quickly to how we should be thinking about the potential impact of pharma and maybe EU tariffs? And if you've had any conversations with any of your partners about them, I guess particularly relevant for DARZALEX and VYVGART, just given their global footprint. Thank you.

Helen I. Torley
President, Chief Executive Officer & Director, Halozyme Therapeutics, Inc.

A

Yeah, I'll start with Halozyme's manufacturing, where we've been very deliberate ourselves in establishing our manufacturing in the United States. And we also have been seeking to assure we can source all or virtually all of our components of materials needed in the United States too. And so, I can confirm that from the Halozyme point of view for the products we produce in our API, there is a very, very limited exposure to the currently imposed tariffs and any small impact is already contemplated in our guidance.

With regard to the pharma tariffs, I can say that based on our agreements, if the pharma tariffs were implemented for products being imported into the US, Halozyme will not see or should not see any impact on our royalty revenues. And so, it's based on our agreements and based on what we're aware of with regard to the manufacturing of our partner products and importantly also US distribution and how that works. So, we should not see any impact that with regard to tariffs.

Brendan Smith
Analyst, TD Securities (USA) LLC

Q

All right. Great. Thank you.

Operator: And your next question comes from the line of David Risinger with Leerink Partners. Your line is open.

David Risinger
Analyst, Leerink Partners LLC

Q

Thanks very much and congrats, Helen, and team on the very strong financial progress. I have two questions. The first is with respect to external acquisitions, are you also considering broadening your royalty streams by considering acquiring royalty companies? And then with respect to potential new customer deals, could you just talk about the gating factors for new business announcements? For example, are some customers awaiting FDA guidance – or sorry CMS guidance for IRA negotiations in coming months for 2028 under the new administration? Thanks very much.

Copyright © 2001-2025 FactSet CallStreet, LLC

Petitioner Merck, Ex. 1086, p. 14
Merck Sharp & Dohme LLC v. Halozyme Inc.
IPR2026-00314

Helen I. Torley
President, Chief Executive Officer & Director, Halozyme Therapeutics, Inc.

A

All right. So, with regard to external acquisitions, David, I mentioned that we really are focused on creating new platform businesses that can result in durable long revenue streams, such as we have created for ENHANZE. And so, I think drug delivery platforms as being our primary focus in terms of where we are evaluating opportunities today.

On the new customer deals and specifically for ENHANZE, the – and I've talked about this before, what we do see in companies is there is a multi-step review process and then a multi-step decision process. And so, really what we're doing at the moment is working through that process in each company where each company has a slightly different process. Now you do get to the end of it, as we've seen very nicely, by announcing our small volume auto-injector deal last quarter with the high volume one. And we are in several discussions going through that process on ENHANZE.

So, it simply is more a question of getting through the internal decision-making processes in the pharma and biotech companies that will result in an ENHANZE deal. And I remain confident we will sign a deal on ENHANZE this year.

It's been interesting on CMS and people are waiting the IRA. I would not say that's a gate at all. It just is a question of interest to see whether the CMS will continue to recognize that a product that is two active ingredients is a separate drug from the single ingredients. And so, if anything, that might bring us some additional new opportunities, David, but it hasn't been holding anyone back waiting to see that, that is confirmed. Much more focus on the strong differentiation that ENHANZE is able to bring for their patients and their mission for improving the patient treatment experience.

David Risinger
Analyst, Leerink Partners LLC

Q

Got it. Thank you.

Helen I. Torley
President, Chief Executive Officer & Director, Halozyme Therapeutics, Inc.

A

Thanks very much.

Operator: And there are no further questions at this time. This does conclude today's conference call. You may now disconnect.

Copyright © 2001-2025 FactSet CallStreet, LLC

Petitioner Merck, Ex. 1086, p. 15
Merck Sharp & Dohme LLC v. Halozyme Inc.
IPR2026-00314

Disclaimer
The information herein is based on sources we believe to be reliable but is not guaranteed by us and does not purport to be a complete or error-free statement or summary of the available data. As such, we do not warrant, endorse or guarantee the completeness, accuracy, integrity, or timeliness of the information. You must evaluate, and bear all risks associated with, the use of any information provided hereunder, including any reliance on the accuracy, completeness, safety or usefulness of such information. This information is not intended to be used as the primary basis of investment decisions. It should not be construed as advice designed to meet the particular investment needs of any investor. This report is published solely for information purposes, and is not to be construed as financial or other advice or as an offer to sell or the solicitation of an offer to buy any security in any state where such an offer or solicitation would be illegal. Any information expressed herein on this date is subject to change without notice. Any opinions or assertions contained in this information do not represent the opinions or beliefs of FactSet CallStreet, LLC. FactSet CallStreet, LLC, or one or more of its employees, including the writer of this report, may have a position in any of the securities discussed herein.

THE INFORMATION PROVIDED TO YOU HEREUNDER IS PROVIDED "AS IS," AND TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, FactSet CallStreet, LLC AND ITS LICENSORS, BUSINESS ASSOCIATES AND SUPPLIERS DISCLAIM ALL WARRANTIES WITH RESPECT TO THE SAME, EXPRESS, IMPLIED AND STATUTORY, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, ACCURACY, COMPLETENESS, AND NON-INFRINGEMENT. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, NEITHER FACTSET CALLSTREET, LLC NOR ITS OFFICERS, MEMBERS, DIRECTORS, PARTNERS, AFFILIATES, BUSINESS ASSOCIATES, LICENSORS OR SUPPLIERS WILL BE LIABLE FOR ANY INDIRECT, INCIDENTAL, SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, INCLUDING WITHOUT LIMITATION DAMAGES FOR LOST PROFITS OR REVENUES, GOODWILL, WORK STOPPAGE, SECURITY BREACHES, VIRUSES, COMPUTER FAILURE OR MALFUNCTION, USE, DATA OR OTHER INTANGIBLE LOSSES OR COMMERCIAL DAMAGES, EVEN IF ANY OF SUCH PARTIES IS ADVISED OF THE POSSIBILITY OF SUCH LOSSES, ARISING UNDER OR IN CONNECTION WITH THE INFORMATION PROVIDED HEREIN OR ANY OTHER SUBJECT MATTER HEREOF.

The contents and appearance of this report are Copyrighted FactSet CallStreet, LLC 2025 CallStreet and FactSet CallStreet, LLC are trademarks and service marks of FactSet CallStreet, LLC. All other trademarks mentioned are trademarks of their respective companies. All rights reserved.

Petitioner Merck, Ex. 1086, p. 16
Merck Sharp & Dohme LLC v. Halozyme Inc.
IPR2026-00314