Horizon Therapeutics plc
Viela Bio Acquisition Announcement
Conference Call
February 1, 2021

Tina Ventura
Senior Vice President, Investor Relations

Thank you, Shannon. Good morning, everyone, and thank you for joining us.

On the call with me today are:

- **Tim Walbert**, Chairman, President and Chief Executive Officer;
- **Paul Hoelscher**, Executive Vice President, Chief Financial Officer;
- **Andy Pasternak**, Executive Vice President, Chief Strategy Officer;
- **Karin Rosén,** Executive Vice President, Research & Development and Chief Scientific Officer; and
- **Liz Thompson**, Group Vice President, Clinical Development and External Search.

Tim will provide an overview of the strategic rationale for our acquisition of Viela Bio and a high-level review of the company, including their biologic medicine, UPLIZNA®. Karin will then provide an overview of Viela's pipeline assets and R&D expertise, followed by Paul, who will provide a brief financial overview and transaction details. After concluding remarks, we will take your questions. We have also posted a presentation on our website that you can use to follow along with this call.

As a reminder, during today's call we will be making certain forward-looking statements as noted on slide 3, as well as other factors outlined in our press release announcing the transaction, latest Form 10-Q, and any 8-Ks filed with the SEC (Securities and Exchange Commission).

You are cautioned not to place undue reliance on these forward-looking statements and Horizon disclaims any obligation to update such statements.

In addition, on today's conference call, non-GAAP financial measures will be used. Certain of these non-GAAP financial measures are reconciled with the comparable GAAP financial measures in our prior earnings press releases and other filings from today that are available on our investor website at www.horizontherapeutics.com.

I will now turn the call over to Tim.

Tim Walbert
Chairman, President and Chief Executive Officer

Thank you, Tina, and good morning, everyone.

We are very pleased this morning to announce our acquisition of Viela Bio, a biotechnology company with a deep, mid-stage biologics pipeline for autoimmune and severe inflammatory diseases, an experienced R&D team and UPLIZNA, a recently approved biologic medicine for a rare disease.

Before I discuss the benefits of the Viela transaction and how it aligns with our strategy, let me first provide a brief update on TEPEZZA® supply. As we first announced on December 17, due to government-mandated COVID-19 vaccine production orders, we are now in a short-term supply disruption with TEPEZZA that we expect could last through the first quarter of this year. We have made significant progress since our initial announcement, completing our first drug product manufacturing lot at increased scale. In line with our expectations, last week we submitted a pre-approval supplement with the data from this first lot. We also recently completed the second increased-scale drug product manufacturing lot. Between these two completed lots that are pending FDA approval, and the manufacturing capacity currently planned at Catalent, we expect that we would have sufficient supply to serve existing patients on therapy and be in a position to initiate treatment for new patients. In fact, if approved by the FDA, these two lots completed to date can provide enough supply for all prior TEPEZZA patients to resume and complete their therapy. We continue to make progress toward returning TEPEZZA to the market and hope to provide further updates on our fourth-quarter earnings call at the end of this month. This progress also reinforced our confidence in moving forward with this acquisition.

As we have discussed for the last several years, our strategic priority is to build a robust development-stage pipeline to drive the long-term value of Horizon. In May 2017, we began this process with the acquisition of teprotumumab, now TEPEZZA, which at the time was a Phase 3-ready candidate for Thyroid Eye Disease. We launched TEPEZZA a year ago after taking it through a very successful Phase 3 clinical program. We also acquired a Phase 2b-ready candidate, HZN-825, last April with the acquisition of Curzion Pharmaceuticals. It is an $LPAR_1$ antagonist, and we plan to initiate two pivotal trials with HZN-825 by the middle of this year – one for a rare form of scleroderma and one for interstitial lung diseases, with the first being IPF (idiopathic pulmonary fibrosis).

The acquisition of Viela significantly accelerates our strategy by adding a portfolio of novel pipeline medicines ranging from Phase 1 to Phase 3 in development; it expands the capabilities of our current strong R&D team; and it expands our commercial portfolio with UPLIZNA, an on-market biologic for a rare disease.

Looking at slide 5 … this transaction represents a significant step forward in our transformation to an innovation-driven, high-growth biotech company and gives us tremendous potential to further help patients, their caregivers and physicians by bringing to market medicines that truly serve unmet needs.

Viela adds a biologics pipeline with four candidates currently in nine development programs. Each of these molecules target central pathways that are implicated in a wide range of autoimmune diseases, providing many avenues for potential growth. TEPEZZA and KRYSTEXXA® will continue to be key drivers of our near-term growth with combined expected peak annual net sales of more than $4.5 billion.

Our plan is for the Viela candidates, along with HZN-825, to be additive to our growth drivers in the second half of the decade and beyond. We believe the three currently approved or clinical-stage Viela candidates each represents a more than $1-billion annual net sales opportunity, and we intend

to invest in expanding the indications being pursued for these candidates in order to realize their full potential.

The Viela portfolio is also highly complementary to our rare disease business and many of our therapeutic areas of focus, including rheumatology and nephrology. We will be pursuing global development and commercialization of this portfolio.

An additional benefit of the acquisition is that we will add additional R&D talent to our team. We have focused on significantly expanding our R&D leadership and scientific talent beginning in 2018 by adding a team with expertise across a broad range of therapeutic areas as well as rare diseases. Viela will enhance our early-stage translational capabilities as well as development expertise in autoimmune and severe inflammatory diseases. This will also allow us to continually innovate beyond what is included in our combined pipeline today.

Finally, Viela quickly accelerates our investment in R&D. We plan to significantly increase our R&D investment in 2021 into the low double digits as a percent of net sales, approaching levels of our profitable biotech peers.

On slide 6 is an overview of Viela, which is based in Gaithersburg, Maryland. It was founded in December 2017 through the acquisition of several molecules from the autoimmune and inflammatory disease portfolio of MedImmune, which was the legacy biologics division of AstraZeneca. The majority of the Viela team joined the company from MedImmune, where they had been instrumental in progressing their autoimmune disease portfolio.

In October 2019, Viela completed an initial public offering, and its key accomplishments include the FDA approval and launch of its lead candidate, UPLIZNA, in June of last year.

Viela has 170 employees, with about 60 of them in R&D. This will meaningfully augment our current R&D team of approximately 150 employees. We are committed long-term to maintaining and building upon the Viela presence in the Gaithersburg, Maryland area as well.

Lastly, the Viela R&D team – they bring significant talent. They bring extensive experience in early-stage pharmacology research and translational science to develop pipeline candidates with novel mechanisms from preclinical stages into the clinic. In addition, Viela's significant understanding of mechanisms and pathways that drive autoimmune diseases will allow Horizon to continuously innovate to develop new pipeline candidates – a crucial capability that we believe will serve us well in the years ahead. It's not easy to build a team with these capabilities, so bringing in this integrated, high-functioning team sets the stage for continued long-term growth.

Both Horizon and Viela bring key strengths that will help us drive growth – now, and over the long term. Horizon, with our proven track record of late-stage development and commercial execution, and Viela, with its early-stage research capabilities, development experience and a deep pipeline – we will leverage each company's unique strengths to reinforce Horizon's position as an innovation-driven, high-growth biotech – one with an even stronger ability to continuously innovate.

Slide 9 shows the combined pipeline of the two companies, with our current Horizon programs in purple and the Viela programs in pink. You can see that Viela adds significant breadth and depth across all stages of clinical development, with four candidates currently in nine development programs. In addition, these pipeline candidates are largely in disease areas where Horizon has late-stage development and commercial expertise, and they are highly complementary to our key therapeutic

areas. This acquisition also opens the door to attractive therapeutic areas and rare diseases where Horizon has not historically had a presence.

Given how well capitalized we are, we intend to explore the full potential of Viela's promising pipeline to maximize the potential of these molecules, including the pursuit of additional indications.

The Viela pipeline was validated with the FDA approval last June of its first commercial medicine, UPLIZNA. It is a humanized monoclonal antibody indicated for NMOSD, which is a rare, severe, autoimmune disease that attacks the optic nerve, spinal cord and brain stem. It is a devastating disease, where patients experience unpredictable attacks that can lead to permanent disability from blindness and paralysis. It is estimated that approximately 10,000 people in the U.S. are suffering from NMOSD, and UPLIZNA demonstrated strong efficacy, a favorable safety profile and has a convenient dosing regimen. Viela is also pursuing three additional potential indications for UPLIZNA, which Karin will discuss shortly.

With our strong set of commercial capabilities, deep experience and resources, we believe Horizon can maximize the potential of UPLIZNA using the comprehensive approach we've successfully used with our infused rare disease medicines, TEPEZZA and KRYSTEXXA. This includes our commercialization strategy that supports all stakeholders, including patients, their caregivers, physicians and payers. We also see opportunities to develop a robust clinical and medical affairs strategy to further educate the physician community on the use of UPLIZNA and drive clinical conviction. UPLIZNA also further diversifies our commercial portfolio. Upon closing, we will have 12 on-market medicines.

I'll now turn the call over to Karin.

Karin Rosén
Executive Vice President, Research & Development and Chief Scientific Officer

Thank you, Tim, and good morning, everyone.

This acquisition is transformational for the Horizon R&D organization. It expands our pipeline with four molecules currently in nine development programs from Phase 1 to Phase 3. It adds a talented team skilled in the development of medicines that treat autoimmune and inflammatory diseases, with important research and translational capabilities that will position us for growth now and in the future. With Viela, we are looking forward to building an even stronger R&D organization that maximizes the strengths of the combined teams. Our future prospects will be amplified by our very similar company cultures – cultures that put patients first – and we will be able to do so much more together for patients in the months and years ahead.

I will now review the Viela development platform for autoimmune diseases and their pipeline in more detail.

Moving to slide 12 … drug development in autoimmune diseases leverages individual compounds across multiple different indications based upon shared biologic and pathophysiologic processes. Mediating these central autoimmune pathways has the potential to treat multiple diseases. Viela is focused on understanding these critical pathways that drive autoimmune conditions, and then developing molecules that target them.

This is illustrated on the right side of slide 12, where the three later-stage Viela molecules modulate the central mechanisms of innate and adaptive immune responses which are activated in autoimmune diseases, each acting against distinct targets in these cascades.

In purple is the autoantibody pathway, which UPLIZNA targets. UPLIZNA is a humanized monoclonal antibody that works by binding to CD19, a cell surface molecule broadly expressed throughout the B cell development, including plasmablasts. UPLIZNA depletes B cells, and importantly, the pathogenic cells that produce autoantibodies.

Regarding the CD40/CD40 ligand co-stimulatory pathway, several autoimmune diseases are associated with the overactivation of this pathway. This is shown in orange. The CD40 ligand is expressed on activated T cells and stimulates B cells by binding with their CD40 receptor. VIB4920 is a fusion protein that binds to CD40 ligand, thereby disrupting this pathway and reducing autoantibody production.

And finally, with respect to the innate immunity pathway, plasmacytoid dendritic cells, or pDCs, play a critical role in autoimmune signaling, inflammation and associated tissue damage through cytokine production. VIB7734 is a human monoclonal antibody that binds to a unique cell surface receptor on pDCs called ILT7, thereby causing pDC depletion. Depleting these cells may interrupt the vicious cycle of inflammation that causes tissue damage in diseases such as lupus, dermatomyositis and a variety of other autoimmune conditions.

NMOSD is the first indication approved for UPLIZNA and Viela is also pursuing three additional indications with UPLIZNA, as shown on slide 13.

Myasthenia Gravis, or MG, is a chronic, rare, autoimmune neuromuscular disease that affects voluntary muscles, especially those that control the eyes, mouth, throat and limbs. In severe cases, respiratory muscles may be compromised. Viela initiated its Phase 3 trial in MG in the third quarter of last year to assess the safety and efficacy of UPLIZNA in this disease.

IgG4-related disease refers to a group of disorders marked by tumor-like swelling and fibrosis of affected organs, such as the pancreas, salivary glands and kidneys. It is primarily treated by rheumatologists, and rheumatology is one of our key therapeutic areas. The Phase 3 trial underway is assessing whether UPLIZNA can reduce flares in the absence of concomitant steroid treatment. Similar to many other autoimmune diseases, chronic steroid use is the current treatment approach, which unfortunately has a significant and toxic side-effect profile.

UPLIZNA is also being evaluated in a proof-of-concept trial in kidney transplant desensitization. However, given the at-risk patient population studied, this trial is currently paused due to COVID-19.

Moving to slide 14 and VIB4920, which is a CD40 ligand antagonist and is being studied by Viela in three potential indications: Sjögren's Syndrome, kidney transplant rejection and rheumatoid arthritis.

VIB4920 is in a Phase 2b trial for Sjögren's Syndrome, which is the second most common rheumatic disease after rheumatoid arthritis. It is a chronic, systemic autoimmune condition that impacts exocrine glands, including the salivary glands and tear glands. Inflammation and destruction of these glands lead to dry eye and dry mouth. In severe cases, the joints, lungs, skin, blood and kidneys may be also affected. There are currently no treatments approved for Sjögren's Syndrome. In these patients, both CD40 ligand and its receptor, CD40, are overexpressed in inflamed tissues. Targeting this pathway with VIB4920 may reduce inflammation and tissue damage.

There is also a Phase 2 trial in active rheumatoid arthritis patients. The primary objectives of this study are to better understand the pharmacodynamic and pharmacokinetic effects of VIB4920 and to further optimize its dosing regimen.

Viela is also conducting a small proof-of-concept study in kidney transplant rejection. The current standard of care to prevent transplant rejection involves a combination of various immunosuppressants and calcineurin inhibitors, the latter of which is associated with kidney toxicity. The objective of this trial is to evaluate if a combination of the immunosuppressant, belatacept, and 4920 can be as effective in preventing transplant rejection while reducing renal toxicity.

Moving now to VIB7734 … this is a human monoclonal antibody that has the potential to become a novel treatment for autoimmune diseases in which pDCs overproduce interferons and other types of cytokines and chemokines. This is one of the more exciting mechanisms we see in the Viela pipeline.

Systemic lupus erythematosus, or SLE, is a disease where pDCs play a key role. This is a systemic autoimmune disease where the body's immune system attacks a person's own tissues and organs. Inflammation caused by lupus can affect many different body systems — including joints, skin, kidneys, blood cells, brain, heart and lungs. Viela recently decided to move into a Phase 2 trial in SLE, after demonstrating encouraging results from their Phase 1b cutaneous lupus erythematosus trial, which were shared at the American College of Rheumatology medical meeting in November of last year. The data suggested that 7734 has the potential to meaningfully reduce skin lesions in lupus patients. The Phase 2 trial in SLE is expected to begin in the first half of this year. There remains significant unmet need with only 1 biologic approved and with substantial room for improvement in efficacy.

VIB7734 is also in Phase 1 development for COVID-19-related acute lung injury.

And finally, VIB1116 is expected to move into Phase 1 development in mid-2021 for autoimmune diseases, and we look forward to exploring the potential of this candidate.

In conclusion, Viela has built a strong portfolio of candidates which have the potential to address high unmet needs across autoimmune and severe inflammatory diseases. The Viela pipeline is an excellent fit with Horizon's existing R&D team and focus in biologics, autoimmune diseases, rheumatology and nephrology. Over the coming months, we will deploy the extensive experience of our combined team to pursue the full potential of each of these molecules.

With that, I will turn the call over to Paul.

Paul Hoelscher
Executive Vice President, Chief Financial Officer

Thanks, Karin.

As we announced in early January, we ended 2020 in a very strong financial position. Despite the challenging environment with COVID-19, 2020 was a stand-out year for Horizon. We achieved record full-year 2020 net sales and adjusted EBITDA, exceeding the high end of our guidance ranges of more than $2.14 billion and $940 million, respectively. This represents year-over-year growth of more than 65 percent for net sales and more than 95 percent for adjusted EBITDA.

This performance exemplifies our strength in commercial execution. We delivered on one of the best rare-disease-medicine launches in history with TEPEZZA, which finished last year with more than $800 million in net sales. KRYSTEXXA also ended the year above our expectations with more than $400 million in net sales.

This impressive performance resulted in a 2020 year-end cash balance of $2.08 billion. Our cash position is inclusive of the approximately $920 million in net proceeds we raised in our equity offering last August. At that time, we stated it was our priority to use the cash to fuel our strategy to acquire development-stage medicines, and Viela exemplifies this strategy in action. Beyond Viela, we will continue to evaluate additional acquisitions and licensing opportunities to further bolster our development pipeline.

Now, moving on to discuss the transaction details on slide 18 … under the terms of the definitive agreement, Horizon will acquire all of Viela's outstanding shares in an all-cash transaction valued at $53 per share. This results in a total acquisition value of $3.05 billion, or $2.67 billion net of Viela's cash and cash equivalents.

We currently plan to fund the transaction with $1.3 billion of new debt plus available cash on hand. Following the acquisition of Viela, our pro forma gross leverage ratio is expected to be about 2.8 times based on the high end of our 2020 adjusted EBITDA guidance range of greater than $940 million, and we expect our gross leverage ratio to be near our target of 2 times by the end of 2021.

We also recently discussed the addition of four new programs to the Horizon R&D pipeline, including two new KRYSTEXXA trials and two HZN-825 pivotal trials starting by mid-year. We anticipate that our new Horizon programs, along with continuing R&D and CMC (chemistry, manufacturing and controls) programs, will result in an approximate doubling of R&D dollar spend in 2021. In addition, the impact of adding Viela, including plans to further invest in Viela's pipeline programs, is expected to reduce Horizon's adjusted EBITDA by approximately $140 million in 2021. We expect our total R&D investment in 2021, including Viela programs, to increase to the low double-digits as a percent of net sales, approaching the level of profitable biotech peers, and reinforcing our position as an innovation-driven, biotech company. We expect to provide our total company 2021 guidance on our fourth-quarter conference call later this month.

The transaction has been unanimously approved by the Board of Directors of both companies. Stockholders holding 54 percent of the outstanding shares of Viela common stock have agreed to tender their shares in support of the transaction, and we plan to launch the tender offer within 10 business days. We expect the transaction to close by the end of the first quarter of 2021, subject to customary closing conditions and regulatory approvals.

I will now turn the call over to Tim for a brief summary.

Tim Walbert
Chairman, President and Chief Executive Officer

Thank you, Paul. In summary, the acquisition of Viela reinforces our position as an innovation-driven, high-growth biotech company.

Viela adds breadth and depth to our pipeline with four pipeline candidates currently in nine development programs. It also strengthens our R&D capabilities by adding a talented team with early-stage research and translational capabilities and deep scientific knowledge of autoimmune and severe inflammatory diseases. We believe the Viela portfolio can add more than $3 billion in peak annual net sales.

Together, we expect to create an even stronger Horizon R&D engine, providing us a greater opportunity to make a significant difference in the lives of more patients, as well as generate value for our shareholders.

We are more excited than ever about our prospects, given today's announcement in combination with the tremendous opportunity going forward with our two key growth drivers, TEPEZZA and KRYSTEXXA.

We will now open the call up for questions.

Tina Ventura
Senior Vice President, Investor Relations

Thank you, Shannon. That concludes our call this morning. A replay of this call and webcast will be available in approximately two hours. Thank you for joining us.