Neil Archer â?? EVP International, Madrigal

> We achieved what 24 companies before us could not â?? the first approved treatment for MASH.

22.09.2025

Tags:

Switzerland, Madrigal, Global, MASH, Hepatology, Strategy, Clinical Trials, Internationalisation

Neil Archer, Executive Vice President International at Madrigal, discusses the companyâ??s pioneering role in treating MASH (Metabolic Dysfunction-Associated Steatohepatitis), a progressive liver disease with no prior approved therapies. He shares insights on Madrigalâ??s breakthrough first-in-class treatment, the challenges of launching an entirely new therapeutic category, and the bold international expansion strategy being led from Switzerland. With over USD 200 million in quarterly U.S. revenues and strong momentum in Europe, Archer outlines how Madrigal is shaping the future of liver care on a global scale.

Could you begin by providing our international readership with an overview of Madrigal, including the companyâ??s mission, your breakthrough asset, and the disease it treats?

Madrigal represents a compelling case study in pharmaceutical perseverance and strategic focus. The organisation maintains a singular, unwavering commitment: leading the global fight against MASH, commonly known as fatty liver disease.

This therapeutic area has historically served as a pharmaceutical graveyard, analogous to Alzheimerâ??s disease or sepsisâ??domains where countless organisations have invested billions in research and development with minimal meaningful breakthroughs. Specifically, within MASH, approximately 24 companies preceding Madrigal failed to achieve regulatory success. Several advanced compounds through Phase III clinical studies, yet none have succeeded in bringing a registered therapeutic product to market.

Our achievement with our liver-directed treatment represents the complexity inherent to pioneering a novel disease treatment and the challenges of being first-to-market. The assetâ??s development story is quite remarkable: it originated as a compound that had been deprioritised within a larger pharmaceutical organisationâ??s pipeline. Dr Becky Taub, one of our founders and a brilliant scientist with exceptional single-minded passion, recognised the compoundâ??s potential and founded Madrigal around this asset. Through extraordinary determination and strategic vision, she successfully extracted the compound from the original developer and advanced it through the complete development pathway, from laboratory bench through Phase III clinical trials to regulatory approval. First in the US market and subsequently in Europe.

To understand the significance of this breakthrough, it is essential to comprehend MASH as a disease.

The disease progression follows a structured fibrosis staging system, rated F0 through F4. Clinically, MASH manifests as progressive stiffening and scarring of hepatic tissue, diagnosed commonly using elastography, utilising sound wave technology to measure liver stiffness through tissue reflection patterns. The most severe stage, F4, represents cirrhosis, a critical condition familiar to many, often requiring liver transplantation and potentially progressing to fatal complications.

Our treatment has secured regulatory approval for F2 and F3 stages, moderate to advanced hepatic fibrosis. Patients at these stages face up to a seventeen-fold increased risk of liver-related mortality, with potentially rapid disease progression. The primary clinical objective in developing MASH therapeutics involves halting or reversing fibrosis and scarring progression, which our asset has demonstrated conclusively in pivotal clinical studies.

The condition is predominantly lifestyle-related, often associated with obesity, necessitating comprehensive lifestyle interventions. However, despite increasing global awareness of healthy living and weight management, MASH prevalence continues rising, clearly indicating the critical need for targeted hepatic therapies addressing underlying pathophysiology.

You joined Madrigal nine months ago from major multinationals like Eli Lilly to establish international operations from Switzerland. What motivated this transition, and what strategic objectives drive your international expansion?

The transition represents a purposeful move that leverages my entire pharmaceutical career. Each previous experience has equipped me for this role. There is not a day that I do not draw upon learnings from previous organisations. However, the contrast is profound. Every entrepreneurial clichÃ© proves accurate, from personally maintaining office equipment to resolving technical challenges, whilst simultaneously being the most challenging and rewarding professional experience of my career.

Not every pharmaceutical organisation would pursue global product rollout at our scale. When I joined, Madrigal employed approximately four hundred individuals globally, and I served as the first full-time employee outside the US market specifically tasked with establishing international operations. This decision reflects recognition of the substantial unmet medical need globally. We are literally pioneering a new therapeutic category, with no competitors, no established treatment paradigms. This presents an extraordinary opportunity from both a human and commercial perspective: making meaningful differences for a previously untreatable condition whilst leveraging significant opportunities for shareholders and the patients we serve.

Given the absence of precedents in MASH treatment, how are you structuring your international rollout strategy, and how receptive have stakeholders been to your pioneering efforts?

The absence of established playbooks became immediately apparent through early discussions with European payers. A senior payer representative explicitly stated: â??We understand MASH and recognise the unmet need. However, you must establish the agenda as pioneers. We support your efforts, but cannot provide comparative frameworks.â?•

This realisation crystallised our mandate: we are not merely launching a new medicine but creating an entire disease category, encompassing public awareness, diagnostic pathways, and treatment protocols. Our country-by-country approach involves collaboration with four key stakeholder groups: patient organisations, who demonstrate exceptional activity and effectiveness in this therapeutic space; the clinical community, with whom we have maintained excellent collaboration throughout clinical development and launch preparation; the payer community, recognising that hepatic diseases impose substantial healthcare system burdens, leading to constructive dialogue regarding optimal value delivery; and governmental stakeholders, acknowledging MASH as a serious disease requiring greater attention as populations live longer and health systems face ongoing challenges.

The stakeholder response has been remarkably positive and unanimous. Every stakeholder group demonstrates strong support for Madrigalâ??s mission. This partly reflects recognition of our tenacity and persistence in a therapeutic area where significantly larger, better-resourced organisations had previously failed due to development complexity.

Germany represents our primary initial focus, as it typically serves as the first European launch market, permitting commercialisation prior to securing pricing and reimbursement agreements, whilst other markets require completing these processes before launch, potentially requiring up to one year or more. We have also established smaller leadership teams across the UK, France, Italy, and Spain, taking individualised country approaches, whilst considering distribution partnerships for smaller markets, including Central Eastern Europe, Israel, and Middle Eastern territories.

With US revenues exceeding 200 million USD per quarter now, what are your European market expectations, and how are you approaching the challenge of building diagnostic infrastructure and awareness for this new therapeutic category?

We approach market assessment through patient-centric rather than population-centric metrics. Whilst headlines may suggest five percent of the global population have MASH, responsible marketing focuses on patients who will derive maximum benefit from our treatmentâ??s therapeutic profile.

Our analysis concentrates on patients with formal F2 or F3 diagnoses under active hepatologist or gastroenterologist management, recognising significant leakage between actual disease prevalence and formal diagnosis rates. In the US, approximately 19,000 patients were on treatment at the end of the first twelve months in the market from an eligible pool of 315.000 formally diagnosed patients under specialist care, from millions with the underlying condition.

Across European countries, this patient population translates to approximately 350 to 370 thousand patients. This represents our initial addressable patient population for collaboration with prescribing specialists. Revenue translation will depend on individual country reimbursement and pricing negotiations and subsequent launch plans.

Regarding diagnostic infrastructure, patients require a formal F2-F3 MASH diagnosis to qualify for Madrigalâ??s treatment. Reliable diagnosis utilises VCTE (Vibration-Controlled Transient Elastography) soundwave elastography, available in multiple versions with reasonably good accessibility. However, systematic MASH diagnostic implementation has been inconsistent, primarily due to the historical absence of therapeutic options post-diagnosis.

Following US approval, we have observed increasingly systematic, predictable diagnostic pathways as clinical communities recognise available therapeutic intervention. European markets, having anticipated treatment availability during our EMA review process, have similarly developed more systematic diagnostic approaches, though implementation varies by country. Diagnostic infrastructure expansion will not constitute an immediate strategic priority, as sufficient diagnosed F2-F3 patients under specialist care currently exist to fully utilise our implementation capacity.

What philosophy guides your talent acquisition, and why was Switzerland chosen for this global expansion?

The team we have assembled demonstrates characteristics which differ in some respects from traditional large pharmaceutical organisations. Some large pharma professionals transition successfully, whilst others find the less structured environment challenging. Our teamâ??s defining characteristic is exceptional passion and implementation urgency. I recall a meeting in the early part of 2025, the first time we had recruited enough of a critical mass to call ourselves â??a team.â?• Approximately twenty attendees were present, and most hadnâ??t officially started with the company. They were participating voluntarily during personal time, unable to wait for the official commencement, such was their passion to begin preparing for approval and launch.

We require experienced professionals capable of immediate impact. Traditional European launch preparation typically begins twenty-four months pre-approval; we had nine months, realistically six, requiring individuals who could execute immediately without extensive onboarding. The collaborative approach has been remarkable, initially learning extensively from US operations, which achieved one of the most successful speciality pharmaceutical launches in industry history. Team members must remain open to external learning whilst maintaining flexible boundaries. Success requires a willingness to transcend traditional roles and focus on execution.

Switzerland was selected because it has long served as a global biopharma epicentre, alongside the US East and West Coast regions. This became immediately apparent during my first Zug visit in November, when I coincidentally attended a social mixer following an R&D-focused CEO presentation. The networking event revealed how many industry professionals I recognised from two decades of prior experience, illustrating Switzerlandâ??s central role in attracting pharmaceutical talent.

The local talent pool represents a significant advantage, with exceptional professionals accessible within a fifteen-minute drive. Additionally, Zug Canton demonstrates exceptional cooperation and understanding of our business model, recognising mutual success opportunities. Their welcoming approach and collaborative support have exceeded expectations, creating positive experiences that generate further industry recommendations.

Looking forward three years to 2028, what achievements would you want to highlight?

By 2028, we will have established definitive leadership in the treatment of MASH. I hope we will no longer be alone in this therapeutic space, with our success enabling other treatment options to reach the market, ultimately benefiting patients with this condition. However, our asset and Madrigal should be recognised as the foundational platform upon which all subsequent MASH therapeutic developments have been built.

If the MAESTRO-NASH-OUTCOMES study in later-stage MASH demonstrates positive results, we will be addressing another patient population equal in size to our current treatment group, representing substantial patient impact through expanded therapeutic access.

After nine months in this role, what key insights could you share with others considering similar entrepreneurial transitions?

Completely abandon preconceptions about operational boundaries and maintain absolute openness to learning. Despite arriving with extensive large pharmaceutical experience, I quickly realised how much I still could learn about earlier stage, breakthrough pharmaceutical operations.

An entirely different ecosystem exists, populated by professionals with diverse expertise across various industry segments and business functions, providing invaluable support when undertaking not merely a new role, but a completely new therapeutic area within a fundamentally different organisational structure. Maintaining openness to new approaches and continuous learning is essential.

This represents arguably the most exciting opportunity currently available in our industry, a truly unique prospect with substantial future potential. The MASH therapeutic category is just beginning its development, and there is much more innovation to come.

See more interviews