CLOSER LOOK

MEMORANDUM

## Painful Diabetic Peripheral Neuropathy (PDN) Competitive Landscape – January 27, 2026

**Executive Highlights**

- **The tables below include an overview of the painful diabetic peripheral neuropathy (PDN) landscape, to the best of our knowledge.** This condition impacts up to 50% of people with diabetes during their lifetime. In our sister organization dQ&A's patient panel, 21% of adults with type 2 diabetes and 13% of adults with type 1 diabetes have nerve damage, which underscores the substantial need for effective neuropathy treatments.
- **This list is divided into technological and pharmaceutical treatments,** but we acknowledge that there are other therapies that may not encompassed in these categories.
- **We will continuously update this list as needed,** but it is only up to date as noted above. The included timelines are based on publicly disclosed information as indicated in the "recent coverage" column. If you see an issue, please let us know.

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### Therapies

| Company | Candidate | Phase | Recent Coverage |
|---|---|---|---|
| **Applied Biologics** | APPB-429 gene therapy | Preclinical | ▪ APPB-429 is being developed to promote peripheral nerve regeneration and restoration of nerve function.<br>▪ Locally administered gene therapy intended to deliver regenerative and protective biological signals in affected lower extremities.<br>▪ Preclinical development program aims to identify the lead APPB-429 therapeutic construct and establish in vivo proof of concept. |
| **Daiichi Sankyo** | Oral α2δ ligand Tarlige | Approved | ▪ Approved in China for PDN in June 2024.<br>▪ In June 2024, results were published in *Pain and Therapy*.<br>▪ In May 2023, Daiichi Sankyo launched a disintegrating tablet formulation for Tarlige that dissolves on the tongue.<br>▪ In January 2023, China's regulatory agency accepted the filing for Tarlige in PDN.<br>▪ Expansion of indications for Tarlige as of March 2022 to include central neuropathic pain, in addition to its initial April 2019 indication for peripheral neuropathic pain in Japan. |
| **Vertex** | oral selective non-opioid NaV1.8 | Phase 3 | ▪ A second phase 3 DPN trial (n=734; NCT07231419) launched in November 2025, with completion expected in April 2027. |

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| | inhibitor suzetrigine (VX-548) | | ▪ The phase 3 trial (n=1,100; NCT06628908) for DPN continues to enroll participants and is expected to complete in May 2027.<br>▪ Approved by the FDA in January 2025 for moderate-to-severe acute pain.<br>▪ FDA granted suzetrigine Breakthrough Therapy designation for PDN – phase 3 program is on track to begin in 2H24.<br>▪ Vertex completed an end-of-phase 2 meeting with the FDA in April 2024.<br>▪ Vertex announced phase 2 results in December 2023.<br>▪ Three phase 3 studies of VX-548 (NCT05661734, NCT05558410, NCT05553366) for acute pain, abdominoplasty, and bunionectomy ongoing. |
| **Lexicon** | AAK1 inhibitor pilavapadin (LX9211) | Ready for phase 3 | ▪ As shared at JPM 2026, Lexicon is now seeking a partner to conduct phase 3 trials.<br>▪ Phase 2b PROGRESS trial results presented at EASD 2025, showing that all pilavapadin doses, including placebo, reduced average daily pain score from baseline through Week 8.<br>▪ Current phase 2b dose optimization study (PROGRESS) is ongoing, with completion expected in March 2025.<br>▪ In June 2024, phase 2 RELIEF-DPN 1 results of LX9211 for diabetic peripheral neuropathic pain published in *Diabetes Care.*<br>▪ In June 2023, late-stage trials in PDN proceeded following FDA feedback in May 2023.<br>▪ Phase 3 development and post-herpetic neuralgia based on phase 2 results from the RELIEF-DPN-1 study and the RELIEF-PHN-1 study, respectively.<br>▪ FDA fast track designation in DPN pain in December 2020. |
| **NeuroBo / MThera** | NB-01 | Ready for phase 3 | ▪ In July 2024, exclusive license agreement with MThera announced for the rights to phase 3-ready NB-01 for the treatment of PDN.<br>▪ In May 2019, poster presented at the NeuPSIG conference showing that NB-01 was well-tolerated in a phase 2a safety study evaluating the efficacy of NB-01 in reducing pain in PDN. |

## Technologies

| Company | Product | Recent Coverage |
|---|---|---|
| **Abbott** | Proclaim XR<br>Eterna | ▪ Eterna approved for use in chronic pain since in 2022.<br>▪ Proclaim XR approved for use in chronic pain in 2019. |
| **Boston Scientific** | WaveWriter Alpha | ▪ COMBO trial (n=89), published in March 2023, evaluated pain reduction without increased opioid use.<br>▪ Previously approved for chronic intractable pain of the trunk and/or limbs in December 2020. |

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| **DyAnys** | First Relief | ▪ FDA-approved for the treatment of PDN in July 2022. |
| **Medtronic** | Inceptiv<br>Intellis<br>Vanta | ▪ Inceptiv is FDA-approved for the treatment of PDN in April 2024.<br>▪ Inceptiv received CE-Mark approval in August; launched in Europe on 3Q23.<br>▪ Inceptiv submitted for FDA approval in 3Q22.<br>▪ Intellis rechargeable neurostimulator and Vanta recharge-free neurostimulator FDA-approved for the treatment of chronic pain associated with PDN in January 2022. |
| **Nevro** | HFX-iQ<br>HFX | ▪ Acquired by medical device company Globus Medical in February 2025.<br>▪ FDA clears HFX iQ with HFX AdaptivAI – a personalized pain management platform that will power their existing HFX iQ SCS system – in September 2024.<br>▪ Enrollment in PDN sensory study is currently paused to allow for interim primary endpoint analysis.<br>▪ In August 2023, Nevro announced publication of 24-month outcomes from SENZA-PDN study.<br>▪ PDN-SENSORY study (n=143) launched in April 2023 for PDN, with completion expected in August 2026<br>▪ In January 2023, Nevro entered limited launch of "HFX-IQ."<br>▪ HFX spinal cord stimulator approved for treatment of PDN in July 2021. |

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