Biogen Completes Acquisition of Alcyone Therapeutics

November 14, 2025

CAMBRIDGE, Mass., Nov. 14, 2025 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) has completed the acquisition of Alcyone Therapeutics, a clinical-stage biotechnology company known for its innovative CNS therapy delivery solutions, such as the ThecaFlex DRx™ drug delivery system.

ThecaFlex DRx™ is an investigational implantable device designed to provide an alternative to repeat lumbar punctures in chronic intrathecal administration of medicines, which could ease both patient experience and accessibility for a broader population of people living with neurologic disorders.

ThecaFlex DRx™ has been in development since 2019, with thePIERRE and PIERRE-PK clinical studies for nusinersen currently underway. Nusinersen is currently marketed under the brand name SPINRAZA® and is indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients. Biogen plans to introduce the new drug delivery system for SPINRAZA in early 2028, contingent upon the successful completion of clinical trials and regulatory approval.

“The ThecaFlex DRx™ allows us to merge Biogen’s cutting-edge biopharmaceutical innovation with advanced medical device technology to strengthen Biogen’s portfolio and expand our expertise in pioneering new delivery methods,” said Lisa Shafer, Head of CMC Development, Product Delivery Solutions at Biogen. “This acquisition affirms our continued commitment to drug delivery solutions with the potential to enhance the patient experience and enable greater accessibility to Biogen’s therapies.”

About The ThecaFlex DRx™ System
The ThecaFlex DRx™ System (ThecaFlex), a technology within Alcyone’s Falcon™ Delivery Platform, is an investigational implantable intrathecal (IT) catheter, catheter fixation device and subcutaneous port system designed to provide access to the cerebrospinal fluid (CSF) for the infusion of therapies by IT bolus administration. Lumbar puncture (LP) is the current standard of care approach to delivering therapeutics into the CSF. ThecaFlex is designed to be an alternative to repeated LP. ThecaFlex has received a CE Mark in Europe and IDE (Investigational Device Exemption) from the U.S. Food and Drug Administration (FDA) to conduct a clinical investigation but has not yet been approved for commercial use by FDA. In addition, ThecaFlex has received Breakthrough Device Designation from FDA.

About SPINRAZA
SPINRAZA (nusinersen) 12mg/5 mL injection is approved in more than 71 countries to treat infants, children and adults with spinal muscular atrophy (SMA). As a foundation of care in SMA, more than 14,000 individuals have been treated with SPINRAZA worldwide.[1]

SPINRAZA has shown efficacy across ages and SMA types with a well-established safety profile based on data in patients treated up to 10 years,[2,3] combined with unsurpassed real-world experience. The most common adverse events observed in clinical studies were respiratory infection, fever, constipation, headache, vomiting and back pain. Laboratory tests can monitor for renal toxicity and coagulation abnormalities, including acute severe low platelet counts, which have been observed after administration of some ASOs.

Biogen licensed the global rights to develop, manufacture and commercialize SPINRAZA from Ionis Pharmaceuticals, Inc. (Nasdaq: IONS). Please click here for Important Safety Information and full Prescribing Information for SPINRAZA in the U.S. or visit your respective country’s product website.

The high dose regimen of SPINRAZA (nusinersen) was recently approved in Japan and is actively under review by the European Medicines Agency (EMA) and other global regulators. The high dose regimen of nusinersen is currently under review with the U.S. Food and Drug Administration (FDA) with a decision expected by April 3, 2026.

About Biogen
Founded in 1978, Biogen is a leading biotechnology company that pioneers innovative science to deliver new medicines to transform patient’s lives and to create value for shareholders and our communities. We apply deep understanding of human biology and leverage different modalities to advance first-in-class treatments or therapies that deliver superior outcomes. Our approach is to take bold risks, balanced with return on investment to deliver long-term growth.

The company routinely posts information that may be important to investors on its website at www.biogen.com. Follow Biogen on social media – Facebook, LinkedIn, X, YouTube.

Safe Harbor
This press release contains forward-looking statements, relating to: our acquisition of Alcyone Therapeutics; the anticipated and potential benefits of the transaction, including the potential to strengthen our portfolio, expand expertise in pioneering delivery methods and enable accessibility to therapies; the potential to enhance patient experiences; our strategy and plans; potential of, and expectations for, the development of ThecaFlex DRx™, nusinersen and our other commercial business and pipeline programs, including the timing for potential availability of a new delivery system for SPINRAZA; clinical development programs, clinical trials, and data readouts and presentations; regulatory discussions, submissions, filings, and approvals; the potential benefits, safety, and efficacy of our products and investigational therapies; and our future financial and operating results. These forward-looking statements may be accompanied by such words as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “forecast,” “goal,” “guidance,” “hope,” “intend,” “may,” “objective,” “outlook,” “plan,” “possible,” “potential,” “predict,” “project,” “prospect,” “should,” “target,” “will,” “would” or the negative of these words or other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements.

Given their forward-looking nature, these statements involve substantial risks and uncertainties that may be based on inaccurate assumptions and could cause actual results to differ materially from those reflected in such statements. These forward-looking statements are based on management’s current beliefs and assumptions and on information currently available to management. Given their nature, we cannot assure that any outcome expressed in these forward-looking statements will be realized in whole or in part.

We caution that these statements are subject to risks and uncertainties, many of which are outside of our control and could cause future events or results to differ materially from those stated or implied in this press release, including, among others, factors relating to: our substantial dependence on revenue from our products and other payments under licensing, collaboration, acquisition or divestiture agreements; uncertainty of long-term success in developing, licensing, or acquiring other product candidates or additional indications for existing products; expectations, plans, prospects and timing of actions relating to product approvals, approvals of additional indications for our existing products, sales, pricing, growth, reimbursement and launch of our marketed and pipeline products; the potential impact of increased product competition in the biopharmaceutical and healthcare industry, as well as any other markets in which we compete, including increased competition from new originator therapies, generics, prodrugs and biosimilars of existing products and products approved under abbreviated regulatory pathways; our ability to effectively implement our corporate strategy; the successful execution of our strategic and growth initiatives, including acquisitions; the drivers for growing our business; difficulties in obtaining and maintaining adequate coverage, pricing, and reimbursement for our products; the drivers for growing our business, including our dependence on collaborators and other third parties for the development, regulatory approval, and commercialization of products and other aspects of our business, which are outside of our full control; risks associated with current and potential future healthcare reforms; risks related to commercialization of biosimilars, which is subject to such risks related to our reliance on third-parties, intellectual property, competitive and market challenges and regulatory compliance; failure to obtain, protect, and enforce our data, intellectual property, and other proprietary rights and the risks and uncertainties relating to intellectual property claims and challenges; the risk that positive results in a clinical trial may not be replicated in subsequent or confirmatory trials or success in early stage clinical trials may not be predictive of results in later stage or large scale clinical trials or trials in other potential indications; risks associated with clinical trials, including our ability to adequately manage clinical activities, unexpected concerns that may arise from additional data or analysis obtained during clinical trials, regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates; the occurrence of adverse safety events, restrictions on use with our products, or product liability claims; risks relating to technology, including our incorporation of new technologies such as artificial intelligence into some of our processes; risks related to use of information technology systems and potential impacts of any breakdowns, interruptions, invasions, corruptions, data breaches, destructions and/or other cybersecurity incidents of our systems or those of connected and/or third-party systems; problems with our manufacturing capacity, including our ability to manufacture products efficiently or adequately address global bulk supply risks; risks relating to management, personnel and other organizational changes, including our ability to attracting, retaining and motivating qualified individuals; risks related to the failure to comply with current and new legal and regulatory requirements, including judicial decisions, accounting standards, and tariff or trade restrictions; the risks of doing business internationally, including geopolitical tensions, acts of war and large-scale crises; risks relating to investment in our manufacturing capacity; risks relating to the distribution and sale by third parties of counterfeit or unfit versions of our products; risks relating to the use of social media for our business, results of operations and financial condition; fluctuations in our operating results; risks related to investment in properties; risks relating to access to capital and credit markets to finance our present and future operations and business initiatives and obtain funding for such activities on favorable terms; risks related to indebtedness; the market, interest, and credit risks associated with our investment portfolio; risks relating to share repurchase programs; change in control provisions in certain of our collaboration agreements; fluctuations in our effective tax rate and obligations in various jurisdictions in which we are subject to taxation; environmental risks; and any other risks and uncertainties that are described in other reports we have filed with the U.S. Securities and Exchange Commission.

These statements speak only as of the date of this press release and are based on information and estimates available to us at this time. Should known or unknown risks or uncertainties materialize or should underlying assumptions prove inaccurate, actual results could vary materially from past results and those anticipated, estimated or projected. Investors are cautioned not to put undue reliance on forward-looking statements. A further list and description of risks, uncertainties and other matters can be found in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024 and in our subsequent reports on Form 10-Q and Form 10-K, in each case including in the sections thereof captioned “Note Regarding Forward-Looking Statements” and “Item 1A. Risk Factors,” and in our subsequent reports on Form 8-K. Except as required by law, we do not undertake any obligation to publicly update any forward-looking statements whether as a result of any new information, future events, changed circumstances or otherwise.

References:

1. Based on commercial patients, early access patients, and clinical trial participants through December 31, 2022.
2. Core Data sheet, Version 13, October 2021. SPINRAZA. Biogen Inc, Cambridge, MA.
3. Finkle et al. Cure SMA 2024. “Final Safety and Efficacy Data From the SHINE Study in Participants With Infantile-Onset and Later-Onset SMA.”

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