Biogen to Acquire Alcyone Therapeutics, Expanding Drug Delivery Solution Portfolio for Key Product and Pipeline Candidates

September 18, 2025

- Biogen to drive end-to-end development and commercialization of ThecaFlex DRx™, an investigational implantable device for intrathecal delivery of antisense oligonucleotides (ASOs)
- ThecaFlex DRx™ has the potential to be a new, convenient way to administer medicines to patients living with neurological disorders.

CAMBRIDGE, Mass., Sept. 18, 2025 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) announced the company has entered into a definitive agreement to acquire Massachusetts-based Alcyone Therapeutics. As part of an existing partnership with Alcyone Therapeutics, the companies are advancing ThecaFlex DRx™, an implantable subcutaneous port and catheter device being investigated for the intrathecal delivery of antisense oligonucleotides (ASOs). ThecaFlex DRx™ is 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.

Biogen will drive end-to-end development, manufacturing and commercialization of ThecaFlex DRx™. Upon closing, Alcyone employees who will join Biogen will be integrated into the company's product delivery solutions team, building upon the existing portfolio and expertise in drug-device combination products. The ThecaFlex DRx™ System is initially being evaluated with SPINRAZA® (nusinersen) in patients with spinal muscular atrophy, which will inform pathways for Biogen's broader portfolio of investigational therapies.

"For nearly three decades, Biogen has pioneered ASO development, and we are committed to continuing to improve patient experience and ease of administration," said Nicole Murphy, Head of Pharmaceutical Operations and Technology at Biogen. "We believe the acquisition of Alcyone Therapeutics offers a strategic opportunity to both expand the company's capabilities and enhance the value proposition of our medicines by offering a meaningful, patient-centered solution."

"Alcyone has been a pioneer in precision CNS delivery. With ThecaFlex DRx™, following our productive partnership with Biogen, we now have the opportunity to further deliver what could be the first truly patient-centered, chronic intrathecal delivery option for these important therapies," said PJ Anand, Founder, President, and Chief Executive Officer of Alcyone Therapeutics. "We believe Biogen's deep expertise in ASOs and its proven track record in advancing drug delivery innovations make it the ideal partner to bring this technology forward."

Biogen and Alcyone Therapeutics have collaborated since 2023 on the development of ThecaFlex DRx™, 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.

Alcyone Therapeutics is based in Lowell, Massachusetts. ThecaFlex DRx™ has been in development since 2019 and is manufactured locally.

Financial Details and Terms of the Transaction
Under the terms of the agreement, Biogen has agreed to acquire Alcyone Therapeutics for an upfront cash payment of $85M plus certain milestones payable related to the development and regulatory approval of ThecaFlex DRx™ with nusinersen and additional pipeline products, securing all rights to ThecaFlex DRx™. It is expected Biogen will account for this transaction as the acquisition of an asset and substantially all of the value of the upfront payment will be recorded by the company as Acquired in-process research and development, upfront and milestone expense in the fourth quarter of 2025. The transaction is subject to customary closing conditions.

With the acquisition, Biogen expects to oversee the end-to-end development, manufacturing and commercialization of ThecaFlex DRx™, while Alcyone's remaining therapeutic assets along with its Falcon™ precision intra-cerebrospinal fluid (CSF) drug transport modeling, and intraparenchymal delivery will be divested into a new independent company, Neela Therapeutics, Inc. The transaction will include a convertible debt financing in Neela Therapeutics, Inc. from existing investors, including Biogen.

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 is an antisense oligonucleotide (ASO) that targets the underlying cause of motor neuron loss by continuously increasing the amount of full-length survival motor neuron (SMN) protein produced in the body.[2] It is administered directly into the central nervous system, where motor neurons reside, to deliver treatment where the disease starts.[2]

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,[3,4] 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.

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.

About Alcyone Therapeutics
Alcyone Therapeutics is a clinical-stage biotechnology company committed to transforming pediatric care through a diversified portfolio of precision CNS therapeutics and dosing platforms. The Company is advancing a therapeutic pipeline in collaboration with Nationwide Children's Hospital (AWRI) focused on severe pediatric neurological diseases. Alcyone's lead programs include miRNA sponge for X chromosome reactivation to treat X-linked genetic disorders, including Rett syndrome and a clinical-stage gene therapy for CLN3 Batten disease and a follow-on pipeline that includes EPH-101, targeting Ephrin pathway to address neurodegeneration. Alcyone's proprietary Falcon ^{TM} precision intra-cerebrospinal fluid (CSF) drug transport modeling and delivery platform technology incorporates deep knowledge of CSF dynamics, artificial intelligence, computational modeling, and bioengineering. This comprehensive approach allows for the optimization of central nervous system (CNS) dosing and delivery to better target the pathophysiology and anatomy specific to various neurological diseases. For more information, visit www.alcyonetx.com.

Biogen Safe Harbor
This press release contains forward-looking statements, relating to: Biogen's agreement to acquire Alcyone Therapeutics; the anticipated and potential benefits of the potential transaction, including the potential to expand our capabilities and enhance the value proposition of our medicines; our strategy and plans; costs and other expected financial impacts of the proposed transaction; potential of, and expectations for, the development of ThecaFlex DRx™ and Biogen's other commercial business and pipeline programs, including nusinersen (marketed as 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 and our collaboration partners' 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.
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3. Core Data sheet, Version 13, October 2021. SPINRAZA. Biogen Inc, Cambridge, MA.
4. 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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