



Neurogene and Neoleukin Announce Definitive Merger Agreement

July 18, 2023

- *Proposed merger to create Nasdaq-listed biotech company focused on advancing Neurogene's differentiated portfolio of genetic medicines for complex neurological diseases*
- *Combined company is expected to have a cash balance of approximately \$200 million at close, including approximately \$95 million from concurrent private financing by Neurogene's new and existing investors*
- *Cash expected to fund combined company into 2H:26 and through multiple catalysts, including preliminary data in 4Q:24 and additional data in 2H:25 from a Phase 1/2 clinical trial in Rett syndrome*
- *Companies to host conference call today at 8:30 am ET*

NEW YORK and SEATTLE, July 18, 2023 (GLOBE NEWSWIRE) -- Neurogene Inc., a clinical-stage company founded to bring life-changing genetic medicines to patients and families affected by rare neurological diseases, and Neoleukin Therapeutics, Inc. (NASDAQ:NLTX) today announced that they have entered into a definitive merger agreement to combine the companies in an all-stock transaction. The combined company will focus on advancing Neurogene's pipeline of differentiated genetic medicines, including NGN-401, a clinical-stage product for Rett syndrome, which uses novel gene regulation technology for a potential best-in-class profile. Upon completion of the merger, which is subject to approval by Neurogene and Neoleukin stockholders, the combined company is expected to operate under the name Neurogene Inc. and trade on the Nasdaq Capital Market under the ticker symbol "NGNE".

In connection with the merger, Neurogene announced an oversubscribed \$95 million private financing led by new and existing healthcare-dedicated specialist and mutual fund institutional investors, including participation from Great Point Partners, EcoR1 Capital, Redmile Group, Samsara BioCapital, Janus Henderson Investors, funds and accounts managed by Blackrock, Casdin Capital, Avidity Partners, Arrowmark Partners, Cormorant Asset Management, Alexandria Venture Investments, and a healthcare investment fund.

With the cash from both companies at closing and the proceeds of the concurrent private financing, the combined company is expected to have approximately \$200 million of cash or cash equivalents immediately following the closing. The cash resources are intended to be used to advance Neurogene's pipeline through multiple clinical milestones and are expected to fund operations into the second half of 2026. The merger and concurrent private financing are expected to close in the fourth quarter of 2023, subject to stockholder approval of both companies, the effectiveness of a registration statement to be filed with the U.S. Securities and Exchange Commission to register the securities to be issued in connection with the merger and concurrent financing, and the satisfaction of customary closing conditions.

"We are excited to announce our planned merger with Neoleukin, which we believe is a transformative step forward in our mission to bring life-changing genetic medicines to the patients and families impacted by devastating neurological diseases," said Rachel McMinn, Ph.D., Founder and Chief Executive Officer of Neurogene. "This transaction is expected to bolster our ability to progress our differentiated pipeline, including our clinical-stage program in Rett syndrome which contains our novel, proprietary EXACT technology. We believe EXACT represents a meaningful technological advance for the gene therapy field, allowing us to develop therapeutic product candidates for complex diseases with attractive market opportunities not addressable with conventional gene therapy. This capital will also support our internal manufacturing capabilities, which we expect will continue to provide significant financial and strategic flexibility. With cash on hand at the close of this transaction expected to fund operations into the second half of 2026, we believe we are well positioned to successfully execute beyond multiple anticipated clinical inflection points for both Rett syndrome and Batten disease, and advance our discovery stage pipeline."

"This merger with Neurogene reflects the continued commitment of our management team and Board of Directors to deliver value to stockholders and, importantly, meaningfully improve patients' lives," said Donna Cochener, Interim Chief Executive Officer and General Counsel of Neoleukin. "Neurogene has an innovative genetic medicines portfolio, in-house product design and manufacturing capabilities, an impressive management team, and will be well positioned to deliver multiple data readouts in the next 18 to 24 months. We are grateful to our current and former employees who contributed to Neoleukin's efforts and look forward to the combined company's continued progress and success."

About Neurogene's Portfolio and EXACT Gene Regulation Platform

Neurogene's internally manufactured portfolio of purposefully designed therapies aims to address several key limitations of conventional gene therapies, including variable gene expression, safety limitations, and inefficient gene delivery.

The company's novel and proprietary Expression Attenuation via Construct Tuning (EXACT) gene regulation platform technology is a self-contained transgene regulation platform that can be tuned to deliver a desired level of transgene expression within a narrow range, potentially avoiding transgene related toxicities associated with conventional gene therapy. EXACT is compatible with viral and non-viral delivery platforms.

Neurogene's clinical-stage portfolio includes:

NGN-401: NGN-401 is an investigational AAV9 gene therapy being developed as a one-time treatment for Rett syndrome. It is the first candidate to deliver the full-length human MECP2 gene under the control of Neurogene's EXACT technology. Embedding EXACT technology into NGN-401 is an important advancement in gene therapy for Rett syndrome, specifically because the disorder requires a treatment approach that enables targeted levels of MECP2 transgene expression without causing toxic effects associated with conventional gene therapy. Rett syndrome is a debilitating, X-linked, neurodevelopmental disorder with significant unmet medical need, and one of the most common genetic causes of developmental and

intellectual impairment in females.

The robust preclinical data package for NGN-401 provides evidence of a potentially compelling efficacy and safety profile in Rett syndrome. The company's Investigational New Drug (IND) application was cleared by the U.S. Food and Drug Administration in January 2023. In the U.S., NGN-401 has received Orphan Drug Designation, Rare Pediatric Disease Designation, and Fast Track designation. Neurogene plans to commence dosing in a Phase 1/2 trial ([NCT05898620](#)) designed to assess the safety, tolerability, and efficacy of a single dose of NGN-401 in female pediatric patients with Rett syndrome in the second half of 2023, with preliminary data expected in the fourth quarter of 2024 from the first cohort of patients, and additional expected data in the second half of 2025 from an expanded set of patients.

NGN-101: NGN-101 is being developed as a one-time treatment for both ocular and neurological manifestations of CLN5 Batten disease using AAV9 to deliver the gene encoding CLN5, which is deficient in children with the disease. Batten disease is a family of rare neurodegenerative diseases caused by pathogenic changes in one of a series of genes that results in the accumulation of toxic deposits across multiple organ systems. CLN5 Batten disease is a rare, pediatric-onset and rapidly progressive condition caused by a pathogenic mutation in the CLN5 gene, leading to loss of function. It is characterized by loss of vision, seizures, and progressive decline in intellectual and motor capabilities beginning in childhood leading to substantial impairments and early mortality.

In preclinical studies, NGN-101 has demonstrated the potential to slow or halt the key features of disease progression, including associated vision and motor declines. NGN-101 has received Orphan Drug Designation by U.S. and European regulatory agencies and is currently being evaluated in a Phase 1/2 clinical trial in children with CLN5 Batten disease ([NCT05228145](#)). Preliminary data is expected in the second half of 2024.

In addition to these two clinical-stage programs, Neurogene is also advancing a discovery-stage candidate that will expand its pipeline into an additional area of high unmet need. Neurogene expects to initiate a clinical study of this candidate in 2025.

About the Proposed Merger

Under the terms of the merger agreement, Neoleukin will issue to pre-merger Neurogene stockholders shares of Neoleukin common stock as merger consideration in exchange for the cancellation of shares of capital stock of Neurogene, and Neurogene will become a wholly owned subsidiary of Neoleukin. Pre-merger Neoleukin stockholders are expected to own approximately 16% of the combined company and pre-merger Neurogene stockholders (including those purchasing Neurogene shares in the concurrent private financing discussed above) are expected to own approximately 84% of the combined company. The percentage of the combined company that pre-merger Neurogene stockholders and pre-merger Neoleukin stockholders will own as of the close of the proposed transaction is subject to certain adjustments as described in the merger agreement, including the amount of Neoleukin's net cash at closing. In connection with the closing of the proposed transactions, Neoleukin stockholders will also be issued contingent value rights representing the right to receive certain payments from proceeds received by the combined company, if any, related to Neoleukin's pre-transaction legacy assets or from savings realized by the combined company, if any, related to the reduction of Neoleukin's legacy lease obligations.

Upon closing of the proposed transaction, Neoleukin Therapeutics, Inc., will be renamed Neurogene Inc. The combined company will be led by Rachel McMinn, Ph.D., Founder and Chief Executive Officer of Neurogene, and other members of the Neurogene management team. The combined company's Board of Directors will be comprised of five board members selected by Neurogene and two members selected by Neoleukin. The transaction has been unanimously approved by the Board of Directors of each company and is expected to close in the fourth quarter of 2023, subject to customary closing conditions, including the approval of the transaction by the stockholders of each company.

TD Cowen is serving as exclusive financial advisor to Neurogene. TD Cowen and Stifel are serving as placement agents on Neurogene's planned concurrent private financing. Gibson Dunn & Crutcher LLP is serving as legal counsel to Neurogene and Cooley LLP is serving as legal counsel to the placement agents. Leerink Partners is serving as the exclusive financial advisor to Neoleukin. Fenwick & West LLP is serving as legal counsel to Neoleukin.

Conference Call Information

Neurogene and Neoleukin will host a conference call today, July 18, 2023, at 8:30 am E.T. to discuss the proposed merger. The live webcast can be accessed by visiting <https://edge.media-server.com/mmc/p/q3vx354g>. To access the event via phone, please register to receive a unique dial-in and PIN number using the following link:

<https://register.vevent.com/register/BI3014e8ea8bec4d9cbdf9a68a0b5c78ec>

A replay of the webcast will be available for a limited time following the event on the Events & Presentations section of Neoleukin's website at <https://investor.neoleukin.com/events> and on the News section of Neurogene's website at <https://www.neurogene.com/news/>.

About Neurogene

The mission of Neurogene is to turn devastating neurological diseases into treatable conditions to improve the lives of patients and families impacted by these rare diseases. Neurogene is developing novel approaches and treatments to address the limitations of conventional gene therapy in central nervous system disorders. This includes selecting a delivery approach to maximize distribution to target tissues and by designing products to maximize potency and purity for an optimized efficacy and safety profile. The company's novel and proprietary EXACT gene regulation platform technology allows for the delivery of therapeutic levels while limiting transgene toxicity associated with conventional gene therapy. For more information, visit www.neurogene.com.

About Neoleukin

Neoleukin is a biopharmaceutical company creating next generation immunotherapies for cancer, inflammation and autoimmunity using *de novo* protein design technology. Neoleukin uses sophisticated computational methods to design proteins that demonstrate specific pharmaceutical properties that provide potentially superior therapeutic benefit over native proteins. For more information, please visit the Neoleukin website: www.neoleukin.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements (including within the meaning of Section 21E of the Securities Exchange Act of 1934, as

amended, and Section 27A of the Securities Act of 1933, as amended (Securities Act) concerning Neurogene, Neoleukin, the proposed transactions and other matters. These statements may discuss goals, intentions and expectations as to future plans, trends, events, results of operations or financial condition, or otherwise, based on current expectations and beliefs of the management of Neoleukin and Neurogene, as well as assumptions made by, and information currently available to, management of Neoleukin and Neurogene. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as “may,” “will,” “should,” “would,” “expect,” “anticipate,” “plan,” “likely,” “believe,” “estimate,” “project,” “intend,” and other similar expressions or the negative or plural of these words, or other similar expressions that are predictions or indicate future events or prospects, although not all forward-looking statements contain these words. Statements that are not historical facts are forward-looking statements. Forward-looking statements in this communication include, but are not limited to, expectations regarding the proposed merger and financing transactions; the potential benefits and results of such transactions; the sufficiency of the combined company’s capital resources; the combined company’s cash runway; the expected timing of the closing of the proposed transactions; statements regarding the potential and timing of, and expectations regarding, Neurogene’s programs, including NGN-101, NGN-401 and its research stage opportunities; statements by Neoleukin’s Interim Chief Executive Officer and General Counsel; and statements by Neurogene’s Founder and Chief Executive Officer. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: the limited operating history of each company; the significant net losses incurred since inception of each company; the ability to raise additional capital to finance operations; the ability to advance product candidates through preclinical and clinical development; the ability to obtain regulatory approval for, and ultimately commercialize, Neurogene’s product candidates; the outcome of preclinical testing and early clinical trials for Neurogene’s product candidates, including the ability of those trials to satisfy relevant governmental or regulatory requirements; Neurogene’s limited experience in designing clinical trials and lack of experience in conducting clinical trials; the ability to identify and pivot to other programs, product candidates, or indications that may be more profitable or successful than Neurogene’s current product candidates; expectations regarding the market and potential for Neurogene’s current product candidates; the substantial competition Neurogene faces in discovering, developing, or commercializing products; the negative impacts of the COVID-19 pandemic on operations, including ongoing and planned clinical trials and ongoing and planned preclinical studies; the ability to attract, hire, and retain skilled executive officers and employees; the ability of Neoleukin or Neurogene to protect their respective intellectual property and proprietary technologies; reliance on third parties, contract manufacturers, and contract research organizations; the risk that the conditions to the closing of the proposed transactions are not satisfied, including the failure to obtain stockholder approval for the proposed transactions from both Neoleukin and Neurogene’s stockholders or to complete the transactions in a timely manner or at all; uncertainties as to the timing of the consummation of the proposed transactions and the ability of each of the parties to consummate the proposed transactions; risks related to Neoleukin’s continued listing on the Nasdaq Capital Market until closing of the proposed transactions; risks related to Neoleukin’s and Neurogene’s ability to correctly estimate their respective operating expenses and expenses associated with the proposed transactions, as well as uncertainties regarding the impact any delay in the closing would have on the anticipated cash resources of the combined company upon closing and other events and unanticipated spending and costs that could reduce the combined company’s cash resources; the occurrence of any event, change or other circumstance or condition that could give rise to the termination of the merger agreement or the financing transaction; competitive responses to the proposed transactions; unexpected costs, charges or expenses resulting from the proposed transactions; the outcome of any legal proceedings that may be instituted against Neoleukin, Neurogene or any of their respective directors or officers related to the merger, the financing transaction, or the proposed transactions contemplated thereby; potential adverse reactions of changes to business relationships resulting from the announcement or completion of the proposed transactions; the effect of the announcement or pendency of the transactions on Neoleukin’s or Neurogene’s business relationships, operating results and business generally; the expected trading of the combined company’s stock on Nasdaq Capital Market under the ticker symbol “NGNE” and the combined company’s ability to remain listed following the proposed transactions; and legislative, regulatory, political and economic developments and general market conditions. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors included in Neoleukin’s most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K filed with the SEC, the registration statement on Form S-4 to be filed with the SEC by Neoleukin, as well as risk factors associated with companies, such as Neurogene, that operate in the biopharma industry. There can be no assurance that the conditions of the proposed transactions will be satisfied or that future developments affecting Neurogene, Neoleukin or the proposed transactions will be those that have been anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond Neurogene and Neoleukin’s control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. Nothing in this press release should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that the contemplated results of any such forward-looking statements will be achieved. Forward-looking statements in this press release speak only as of the day they are made and are qualified in their entirety by reference to the cautionary statements herein. Except as required by applicable law, Neoleukin and Neurogene undertake no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise.

This press release contains hyperlinks to information that is not deemed to be incorporated by reference into this press release.

No Offer or Solicitation

This press release and the information contained herein is not intended to and does not constitute (i) a solicitation of a proxy, consent or approval with respect to any securities or in respect of the proposed transactions or (ii) an offer to sell or the solicitation of an offer to subscribe for or buy or an invitation to purchase or subscribe for any securities pursuant to the proposed transactions or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law. No offer of securities shall be made except by means of a prospectus meeting the requirements of the Securities Act of 1933, as amended, or an exemption therefrom.

Subject to certain exceptions to be approved by the relevant regulators or certain facts to be ascertained, the public offer will not be made directly or indirectly, in or into any jurisdiction where to do so would constitute a violation of the laws of such jurisdiction, or by use of the mails or by any means or instrumentality (including without limitation, facsimile transmission, telephone and the internet) of interstate or foreign commerce, or any facility of a national securities exchange, of any such jurisdiction.

NEITHER THE SEC NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THE SECURITIES OR DETERMINED IF THIS PRESS RELEASE IS TRUTHFUL OR COMPLETE.

Important Additional Information About the Proposed Transactions Will be Filed with the SEC

This press release is not a substitute for the registration statement or for any other document that Neoleukin may file with the SEC in connection with the proposed transactions. In connection with the proposed transactions, Neoleukin intends to file relevant materials with the SEC, including a registration statement on Form S-4 that will contain a proxy statement/prospectus of Neoleukin. NEOLEUKIN URGES INVESTORS AND STOCKHOLDERS TO READ THE REGISTRATION STATEMENT, PROXY STATEMENT/PROSPECTUS AND ANY OTHER RELEVANT DOCUMENTS THAT MAY BE FILED WITH THE SEC, AS WELL AS ANY AMENDMENTS OR SUPPLEMENTS TO THESE DOCUMENTS, CAREFULLY AND IN THEIR ENTIRETY IF AND WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT NEOLEUKIN, NEUROGENE, THE PROPOSED TRANSACTIONS AND RELATED MATTERS. Investors and stockholders will be able to obtain free copies of the proxy statement/prospectus and other documents filed by Neoleukin with the SEC (when they become available) through the website maintained by the SEC at www.sec.gov. In addition, investors and stockholders should note that Neoleukin communicates with investors and the public using its website (www.neoleukin.com), the investor relations website (<https://investors.neoleukin.com/>) where anyone will be able to obtain free copies of the proxy statement/prospectus and other documents filed by Neoleukin with the SEC and stockholders are urged to read the proxy statement/prospectus and the other relevant materials when they become available before making any voting or investment decision with respect to the proposed transactions.

Participants in the Solicitation

Neoleukin, Neurogene and their respective directors and executive officers may be considered participants in the solicitation of proxies in connection with the proposed transaction. Information about Neoleukin's directors and executive officers is included in Neoleukin's most recent Annual Report on Form 10-K, including any information incorporated therein by reference, as filed with the SEC, and the proxy statement for Neoleukin's 2023 annual meeting of stockholders, filed with the SEC on April 27, 2023. Additional information regarding the persons who may be deemed participants in the solicitation of proxies will be included in the proxy statement/prospectus relating to the proposed transaction when it is filed with the SEC. These documents can be obtained free of charge from the sources indicated above.

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Source: Neoleukin Therapeutics, Inc.