LENZ Therapeutics and Graphite Bio Announce Merger Agreement

- Merger to create NASDAQ-listed, late clinical-stage biopharmaceutical company focused on advancing LENZ Therapeutics’ lead assets for the treatment of presbyopia
- Combined company expected to have approximately $225 million of cash or cash equivalents at close, including $53.5 million from a concurrent PIPE financing
- Companies to host joint webcast today, November 15, 2023 at 8:00 a.m. ET

SAN DIEGO & SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--LENZ Therapeutics, a late-stage biopharmaceutical company focused on developing and commercializing innovative therapies to improve vision, and Graphite Bio, Inc. (NASDAQ: GRPH) today announced that they have entered into a definitive merger agreement to combine the companies in an all-stock transaction. The lead programs of the combined company will address presbyopia, the inevitable loss of near vision that impacts the daily lives of nearly all people over the age of 45. The combined company is expected to trade on Nasdaq under the ticker symbol “LENZ.”

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20231115881807/en/

In connection with the merger, Graphite Bio has entered into a subscription agreement for a PIPE financing that is expected to close concurrently with the completion of the merger of $53.5 million, with a syndicate of healthcare investors led by LENZ’s existing investors and including participation from new investors. The merger is 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 the satisfaction of customary closing conditions.

With the cash expected from both companies at closing and the proceeds of the concurrent PIPE financing, the combined company is expected to have approximately $225 million of cash or cash equivalents. Graphite Bio is expected to contribute $115 million to the combined entity and expects to pay a dividend to Graphite Bio shareholders of approximately $60 million at the close of the transaction. Upon close, key healthcare investors in the combined company will include Versant Ventures, RA Capital Management, Alpha Wave Global, Point72, Samsara BioCapital, Sectoral Asset Management, RTW Investments and others. It is expected that the net proceeds from the merger and concurrent financing will allow the combined company to continue to build infrastructure and successfully commercialize LENZ’s lead product candidate, subject to successful completion of the ongoing Phase 3 trials, New Drug Application (NDA) submission and subsequent FDA approval.

“I am pleased to announce our merger with Graphite Bio, allowing us to create a publicly
traded company focused on the advancement of LENZ’s lead programs, LNZ100 and LNZ101 for the treatment of presbyopia. This pivotal change comes at an important time for the company as we gear up for the readout of the Phase 3 CLARITY trials in the second quarter of 2024,” said Eef Schimmelpennink, President and CEO of LENZ Therapeutics. “We believe that a once-daily pharmacological eye drop that can effectively and safely improve near vision throughout the full workday, without the need for reading glasses, will be a highly attractive commercial product with an estimated U.S. market opportunity in excess of $3 billion. We have assembled an executive team with extensive clinical, commercial and operational experience to commercialize such a product and become the category leader.”

“Graphite Bio ran a thorough and strategic process and we believe that this transaction represents the company’s commitment to delivering value to the Graphite stockholders,” said Kim Drapkin, CEO of Graphite Bio. “LENZ Therapeutics is strongly positioned with Phase 3 lead program, addressing a very large target market with near-term, high potential, value-inflecting milestones and a well-credentialed management team to lead the combined company.”

About LENZ Therapeutics’ Product Candidates

LENZ Therapeutics’ initial focus is the treatment of presbyopia. In the United States, the estimated population who suffer from this condition, known as presbyopes, is 128 million, almost four times the number of individuals suffering from dry eye disease and three times the number of individuals suffering from childhood myopia, macular degeneration, diabetic retinopathy and glaucoma combined. LENZ believes that a once-daily pharmacological eye drop that can effectively and safely improve near vision throughout the full workday, without the need for reading glasses, will be a highly attractive commercial product with an estimated U.S. market opportunity in excess of $3 billion.

LENZ’s product candidates, LNZ100 and LNZ101, are preservative-free, single-use, once-daily eye drops containing aceclidine and aceclidine plus brimonidine, respectively. These product candidates are differentiated based on rapid onset, degree and duration of near vision improvement, as well as their ability to be used across the full age range of presbyopes, from their mid-40s well into their mid-70s, as well as the broadest refractive range while avoiding blurry distance vision.

Aceclidine is a miotic, a small molecule that causes pupil contraction, creating a pinhole effect that improves near vision. Unlike other miotics, such as pilocarpine and carbachol, aceclidine’s mechanism of action (MOA) is pupil-selective, meaning it can reduce the pupil size below the desired 2 millimeters without overstimulating the ciliary muscles that can cause a myopic shift that can impair distance vision.

Aceclidine’s MOA was demonstrated in the Phase 2 INSIGHT trial (NCT05294328), where both LZN100 and LNZ101 achieved their primary endpoint of three-lines or greater near vision improvement without losing one or more lines in distance vision, with a responder rate of 71% (p<0.0001) and 56% (p<0.0001), respectively, compared to 6% for vehicle. Responders were able to read small text up-close without any visual aid, with both product candidates and demonstrated rapid onset with 73% (p<0.0001) and 62% (p<0.0001) having three-lines or greater improvement in near visual acuity within 30 minutes for LNZ100 and LNZ101, respectively, compared to 8% for vehicle, and sustained the statistically significant three-lines or greater improvement in near visual acuity over an extended duration of 10
hours post-treatment, the last measured timepoint. Both LNZ100 and LNZ101 were well-tolerated, with no serious drug-related adverse events. Additionally, their active ingredients have favorable tolerability profiles that have been well-established empirically as both aceclidine and brimonidine have been used as a treatment for glaucoma.

LENZ is currently conducting three Phase 3 multi-center, double-masked, randomized, active and vehicle-controlled, U.S.-based efficacy and safety trials for LNZ100 and LNZ101. To date, all sites are activated and the two six-week efficacy trials, CLARITY-1 and CLARITY-2, are fully enrolled and over 95% enrolled, respectively and the six-month safety trial, CLARITY-3, is fully enrolled. The CLARITY trials are enrolling participants ranging from 45 to 75 years old, the same age range used in the INSIGHT trial, with a refractive range of -4.0 diopters (D) spherical equivalent (SE) to +1.0D SE. Similar to the INSIGHT trial, the primary efficacy endpoint in the CLARITY-1 and CLARITY-2 trials is the percentage of subjects who achieve three-lines or greater improvement in near vision, but at three hours post-treatment rather than one hour post-treatment, comparing to brimonidine and vehicle, respectively.

LENZ expects to report Phase 3 topline results from the CLARITY trials in the second quarter of 2024 with a potential submission of an NDA for at least one product candidate in mid-2024. LENZ’s objective is to commercialize the approved product that will most effectively meet the needs of the widest range of presbyopes and best create loyalty and value based on an “all eyes, all day” brand mission.

About the Proposed Merger

Pre-merger Graphite Bio stockholders are expected to own approximately 35% of the combined company and pre-merger LENZ Therapeutics stockholders are expected to own approximately 65% of the combined company upon the closing of the merger, prior to the additional PIPE financing transaction. The percentage of the combined company that each company’s former stockholders are expected to own may be adjusted based on Graphite Bio’s net cash at closing.

The transaction has been unanimously approved by the Board of Directors of both companies and is expected to close in the first quarter of 2024, subject to customary closing conditions, including the approvals by the stockholders of each company.

Management and Organization

Following the merger, the combined company will be led by Eef Schimmelpennink, President and Chief Executive Officer of LENZ Therapeutics, and other members of the LENZ management team. Graphite Bio, Inc. will be renamed “LENZ Therapeutics, Inc.” and the corporate headquarters will be located in San Diego, CA. The merger agreement provides that the Board of Directors of the combined company will be composed of seven members, including five LENZ board members and two members selected by the Graphite Bio board.

Conference Call Information

The companies will host a webcast call and presentation to discuss the proposed transaction as well as LENZ’s pipeline assets today, November 15, 2023, at 8:00 a.m. ET. The live webcast can be accessed here and on the Graphite Bio website at www.graphitebio.com in
the Investors section or by calling 877-407-0898 or +1-201-689-8478. A replay of the webcast will be archived and available following the event.

Advisors

Leerink Partners is acting as exclusive financial advisor to Graphite Bio for the transaction and Goodwin Procter LLP is serving as its legal counsel. BofA Securities is serving as lead financial advisor to LENZ for the merger. Citi is also serving as financial advisor to LENZ for the merger. BofA Securities is serving as lead placement agent on the PIPE financing. Citi, Piper Sandler & Co. and William Blair & Company, L.L.C. are serving as co-placement agents for the PIPE financing. Latham & Watkins LLP is serving as legal counsel to the placement agents. Wilson Sonsini Goodrich & Rosati, P.C. is serving as legal counsel to LENZ.

About LENZ Therapeutics

LENZ Therapeutics is a late-stage biopharmaceutical company focused on developing and commercializing innovative therapies to improve vision. Its product candidates, LNZ100 and LNZ101, are preservative-free, single-use, once-daily, acetadine-based eye drops currently in Phase 3 clinical trials for the treatment of presbyopia. Presbyopia impacts an estimated 1.8 billion people globally and 128 million people in the United States. LENZ is headquartered in San Diego, California, and is backed by venture capital investors, including Versant Ventures, RA Capital Management, Alpha Wave Global, Point72, Samsara BioCapital, Sectoral Asset Management and RTW Investments. For more information, visit LENZ-Tx.com.

About Graphite Bio, Inc.

Graphite Bio, Inc. has historically been a clinical-stage, next-generation gene editing company. In February 2023, Graphite Bio announced its decision to discontinue the development of nulabeglogene autogedtemcel (“nula-cel”), Graphite Bio’s lead product candidate for sickle cell disease, and to initiate a process to explore and review a range of strategic alternatives focused on maximizing stockholder value from Graphite Bio’s product development assets and cash resources. For more information, please visit www.graphitebio.com.

Forward-Looking Statements

This communication contains “forward-looking statements” within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995, including but not limited to, express or implied statements regarding the structure, timing and completion of the proposed merger by and between Graphite Bio, Inc. (“Graphite”) and LENZ Therapeutics, Inc. (“LENZ”) (the “Merger”); the combined company’s listing on Nasdaq after the closing of the proposed Merger (the “Closing”); expectations regarding the ownership structure of the combined company; the anticipated timing of the Closing; the expected executive officers and directors of the combined company; expectations regarding the structure, timing and completion of a concurrent private financing, including investment amounts from investors, timing of closing, expected proceeds and impact on ownership structure; each company’s and the combined company’s expected cash position at the Closing and cash runway of the combined company following the Merger and private
financing; the future operations of the combined company, including commercialization activities, timing of launch, buildout of commercial infrastructure; the nature, strategy and focus of the combined company; the development and commercial potential and potential benefits of any product candidates of the combined company, including expectations around market exclusivity and IP protection; the location of the combined company’s corporate headquarters; anticipated clinical drug development activities and related timelines, including the expected timing for announcement of data and other clinical results and potential submission of a New Drug Application for one or more product candidates; and other statements that are not historical fact. All statements other than statements of historical fact contained in this communication are forward-looking statements. These forward-looking statements are made as of the date they were first issued, and were based on the then-current expectations, estimates, forecasts, and projections, as well as the beliefs and assumptions of management. There can be no assurance that future developments affecting Graphite, LENZ, the Merger or the concurrent private financing will be those that have been anticipated.

Forward-looking statements are subject to a number of risks and uncertainties, many of which involve factors or circumstances that are beyond Graphite’s control. Graphite’s actual results could differ materially from those stated or implied in forward-looking statements due to a number of factors, including but not limited to (i) the risk that the conditions to the Closing are not satisfied, including the failure to timely obtain stockholder approval for the transaction, if at all; (ii) uncertainties as to the timing of the consummation of the proposed Merger and the ability of each of Graphite and LENZ to consummate the proposed Merger; (iii) risks related to Graphite’s ability to manage its operating expenses and its expenses associated with the proposed Merger pending the Closing; (iv) risks related to the failure or delay in obtaining required approvals from any governmental or quasi-governmental entity necessary to consummate the proposed Merger; (v) the risk that as a result of adjustments to the exchange ratio, Graphite stockholders and LENZ stockholders could own more or less of the combined company than is currently anticipated; (vi) risks related to the market price of Graphite’s common stock relative to the value suggested by the exchange ratio; (vii) unexpected costs, charges or expenses resulting from the transaction; (viii) potential adverse reactions or changes to business relationships resulting from the announcement or completion of the proposed Merger; (ix) the uncertainties associated with LENZ’s product candidates, as well as risks associated with the clinical development and regulatory approval of product candidates, including potential delays in the completion of clinical trials; (x) risks related to the inability of the combined company to obtain sufficient additional capital to continue to advance these product candidates; (xi) uncertainties in obtaining successful clinical results for product candidates and unexpected costs that may result therefrom; (xii) risks related to the failure to realize any value from product candidates being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market; (xiii) risks associated with the possible failure to realize certain anticipated benefits of the proposed Merger, including with respect to future financial and operating results; (xiv) the risk that the private financing is not consummated upon the Closing; and (xv) the risk that Graphite stockholders receive more or less of the cash dividend than is currently anticipated, among others. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties. These and other risks and uncertainties are more fully described in periodic filings with the U.S. Securities and Exchange Commission (the “SEC”), including the factors described in the section titled “Risk Factors” in Graphite’s Annual
No Offer or Solicitation

This communication does not constitute an offer to sell or the solicitation of an offer to buy any securities nor a solicitation of any vote or approval with respect to the proposed transaction or otherwise. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the U.S. Securities Act of 1933, as amended, and otherwise in accordance with applicable law.

Additional Information and Where to Find It

This communication relates to the proposed Merger involving Graphite and Lenz and may be deemed to be solicitation material in respect of the proposed Merger. In connection with the proposed Merger, Graphite will file relevant materials with the SEC, including a registration statement on Form S-4 (the “Form S-4”) that will contain a proxy statement (the “Proxy Statement”) and prospectus. This communication is not a substitute for the Form S-4, the Proxy Statement or for any other document that Graphite may file with the SEC and send to Graphite’s shareholders in connection with the proposed Merger. BEFORE MAKING ANY VOTING DECISION, INVESTORS AND SECURITY HOLDERS OF GRAPHITE ARE URGED TO READ THE FORM S-4, THE PROXY STATEMENT AND OTHER DOCUMENTS FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT GRAPHITE, THE PROPOSED MERGER AND RELATED MATTERS.

Investors and security holders will be able to obtain free copies of the Form S-4, the Proxy Statement and other documents filed by Graphite with the SEC through the website maintained by the SEC at http://www.sec.gov. Copies of the documents filed by Graphite with the SEC will also be available free of charge on Graphite’s website at www.graphitebio.com, or by contacting Graphite’s Investor Relations at investors@graphitebio.com.

Participants in the Solicitation

Graphite, Lenz, and their respective directors and certain of their executive officers may be considered participants in the solicitation of proxies from Graphite’s shareholders with respect to the proposed Merger under the rules of the SEC. Information about the directors and executive officers of Graphite is set forth in its Annual Report on Form 10-K for the year...
ended December 31, 2022, which was filed with the SEC on March 20, 2023 and amended on April 27, 2023, subsequent Quarterly Reports on Form 10-Q and other documents that may be filed from time to time with the SEC. Additional information regarding the persons who may be deemed participants in the proxy solicitations and a description of their direct and indirect interests, by security holdings or otherwise, will also be included in the Form S-4, the Proxy Statement and other relevant materials to be filed with the SEC when they become available. You may obtain free copies of this document as described above.


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