Insmed Presents Positive Patient-Reported Outcomes and Microbiologic Data from Phase 3 ARISE Study Of ARIKAYCE® (Amikacin Liposome Inhalation Suspension) in Patients with NTM Lung Disease Caused by MAC at American Thoracic Society 2024 International Conference Plenary Session

—Patients Treated with ARIKAYCE Plus Macrolide-Based Background Regimen Had Meaningfully Greater Improvements in Respiratory Symptoms vs. Macrolide-Based Background Regimen Alone, As Measured By the QOL-B Respiratory Domain Instrument—

—QOL-B Respiratory Domain Scores for ARIKAYCE Patients Showed Improvement Through Month 6 and Continued to Improve Through Month 7 (1 Month Off Treatment), While Improvements in the Comparator Arm Plateaued After Month 3 and Worsened After Month 6—

—Microbiologic Data Presented Showed Patients in the ARIKAYCE-treated Arm Had Numerically Greater Rates of Culture Conversion By Month 6, and Nominally Statistically Significantly Higher Rates By Month 7, With Earlier Time to First Culture Conversion vs. Comparator Arm—

—No Study Patients Developed MAC with Resistance to ARIKAYCE or Macrolides—

BRIDGEWATER, N.J., May 20, 2024 /PRNewswire/ -- Insmed Incorporated (Nasdaq: INSM), a global biopharmaceutical company on a mission to transform the lives of patients with serious and rare diseases, today announced that late-breaking data from the ARISE study of ARIKAYCE® (amikacin liposome inhalation suspension) were presented at the American Thoracic Society (ATS) 2024 International Conference in San Diego. Data from ARISE evaluating patients with newly diagnosed or recurrent nontuberculous mycobacterial (NTM) lung infection caused by *Mycobacterium avium* complex (MAC) who had not received antibiotics for their current infection were presented in an oral session and during the ATS Breaking News session "Clinical Trial Results in Pulmonary Medicine."

"The inclusion of late-breaking ARISE data in both a plenary and in two oral sessions at ATS highlights the importance of these study results for the NTM community and the exciting potential for ARIKAYCE to reach a broader population of people living with MAC lung disease," said Martina Flammer, M.D., M.B.A., Chief Medical Officer of Insmed. "Additionally, the ATS congress is an important opportunity for us to share our continued efforts to bring new therapies to patients with serious pulmonary diseases. We are pleased to be presenting seven additional abstracts during the congress, including data on our investigational medicine brensocatib, as well as studies that deepen our understanding of bronchiectasis and pulmonary hypertension."

As previously announced, data from ARISE demonstrated that the Quality of Life-Bronchiectasis (QOL-B) respiratory domain may be an effective patient-reported outcome (PRO) tool in patients with MAC lung disease. The ARISE study was designed to help support the validation of a PRO tool to be used in ENCORE, the ongoing Phase 3b registrational study evaluating the efficacy and safety of an ARIKAYCE-based regimen in patients with newly diagnosed or recurrent MAC lung disease who have not received antibiotics for their current infection.

In ARISE, ARIKAYCE-treated patients performed better than those in the comparator arm (a macrolide-based multi-drug regimen) as measured by the QOL-B instrument, with 43.8% of patients achieving an improvement in QOL-B respiratory score above or equal to the estimated meaningful within-subject score difference of 14.8, compared with 33.3% of patients in the comparator arm. While the study was not powered to show a statistically significant difference between treatment arms, a strong trend toward significance was observed for improvement from baseline at Month 7 (least-squares mean change from baseline 12.24 vs. 7.76, p=0.1073).

New data presented showed that patients in the ARIKAYCE treatment arm experienced continued improvement in QOL-B

scores to Month 7, which included one month off treatment (observed mean QOL-B score change from baseline: 14.1). In contrast, in patients randomized to the comparator arm, QOL-B scores plateaued between Month 3 and Month 6 and worsened after stopping treatment at Month 6 through Month 7 (observed mean QOL-B score change from baseline: 6.9).

In a separate abstract presented, microbiologic evaluation of sputum samples showed that a greater proportion of patients treated with the ARIKAYCE plus macrolide-based background regimen achieved culture conversion by Month 6 versus patients in the comparator arm (80.6% vs. 63.9%, p=0.0712). Patients in the ARIKAYCE arm also achieved nominally statistically significantly higher culture conversion rates at Month 7 versus patients in the comparator arm (78.8% vs. 47.1%, p=0.0010) with culture conversion more likely to persist by Month 7.

Of those patients who achieved culture conversion by Month 6, more patients in the ARIKAYCE arm achieved culture conversion by Month 1 versus the comparator arm (74.3% vs. 46.7%, respectively) and median time to first culture conversion event was 1.0 month in the ARIKAYCE arm and 2.0 months in the comparator arm. Notably, no patients in this study developed a MAC isolate with resistance to ARIKAYCE and/or macrolide.

"These findings are very important given that NTM lung disease is a challenging and complex disease to treat with limited therapeutic options. Based on the positive results from ARISE, I look forward to seeing the results from the ongoing Phase 3 registrational study ENCORE and the impact they may have on the NTM patient community," said lead study investigator Charles Daley, M.D., Chief of the Division of Mycobacterial and Respiratory Infections at National Jewish Health.

The discontinuation rate of ARIKAYCE or the placebo used in the comparator arm was 22.9% in the ARIKAYCE arm and 7.8% in the comparator arm. Study completion rates were 91.7% in the ARIKAYCE arm and 94.1% in the comparator arm. No new safety signals were observed in the ARIKAYCE arm, and the safety profile in general was as expected in both treatment arms. Treatment-emergent adverse events (TEAEs) were reported by 91.7% of patients in the ARIKAYCE arm and 80.4% of patients in the comparator arm. The most common TEAEs were dysphonia (41.7% for the ARIKAYCE arm vs. 3.9% for the comparator arm), cough (27.1% vs. 7.8%), diarrhea (27.1% vs. 25.5%), and COVID-19 (12.5% vs. 9.8%). Of the treatment-emergent serious adverse events observed in the trial, none were determined to be related to ARIKAYCE and none were deemed related to COVID-19.

In addition to the ARISE results, the following Insmed abstracts are being presented at ATS from across the Company's respiratory portfolio, expanding the understanding of serious and rare pulmonary diseases:

- Incremental Burden of Pulmonary Hypertension Among Patients With Connective Tissue Disease-related Interstitial Lung Disease in the Real-world Setting
- Incremental Burden of Pulmonary Hypertension Among Patients With Non-Connective Tissue Disease-related Interstitial Lung Disease in the Real-world Setting
- Treprostinil Palmitil Conversion Sites in the Lung
- Incidence and Prevalence of Non-Cystic Fibrosis Bronchiectasis inJapan
- A Phase 1 Study of Brensocatib Following a Single Oral Administration in Subjects With or Without Renal Impairment
- Association Between Exacerbation Burden and Comorbidities Among Patients With Non-Cystic Fibrosis Bronchiectasis Over 1 Year
- Novel Anti-Inflammatory and Immunomodulatory Effects of the Dipeptidyl Peptidase-1 Inhibitor Brensocatib: A Post-Hoc Analysis of the WILLOW Trial

About the ARISE & ENCORE Clinical Trial Program
ARIKAYCE was granted accelerated approval by the FDA in September of 2018 for the treatment of MAC lung disease as part of a combination antibacterial drug regimen for adult patients who have limited or no alternative treatment options. It is the first and only therapy approved in the U.S. for the treatment of MAC lung disease. The ARISE and ENCORE clinical trial program is intended to fulfill the FDA's post-marketing requirement to allow for full approval of ARIKAYCE in the U.S. and to support a supplemental new drug application for the use of ARIKAYCE as a treatment for patients with a MAC lung infection.

ARISE was a global, randomized, double-blind, placebo-controlled, Phase3b study in adult patients with newly diagnosed or recurrent MAC lung disease who had not received antibiotics for their current infection that aimed to generate evidence demonstrating the domain specification, reliability, validity, and responsiveness of PRO-based scores. Patients were randomized 1:1 to receive ARIKAYCE plus background regimen or placebo plus background regimen once daily for six months. Patients then discontinued all study treatments and remained in the trial for one month for the continued assessment of PRO endpoints. The study enrolled 99 patients.

The ongoing ENCORE trial is a randomized, double-blind, placebo-controlled, Phase3b study to evaluate the efficacy and safety of an ARIKAYCE-based regimen in patients with newly diagnosed or recurrent MAC lung disease who have not started antibiotics. Patients are randomized 1:1 to receive ARIKAYCE plus background regimen or placebo plus background regimen once daily for 12 months. Patients will then discontinue all study treatments and remain in the trial for three months for the assessment of durability of culture conversion. The primary endpoint is change from Baseline to Month 13 in respiratory symptom score. The key secondary endpoint is the proportion of patients achieving durable culture conversion at Month 15.

About ARIKAYCE

ARIKAYCE is approved in the United States as ARIKAYCE® (amikacin liposome inhalation suspension), in Europe as ARIKAYCE® Liposomal 590 mg Nebuliser Dispersion, and in Japan as ARIKAYCE® inhalation 590 mg (amikacin sulfate inhalation drug product). Current international treatment guidelines recommend the use of ARIKAYCE for appropriate patients. ARIKAYCE is a novel, inhaled, once-daily formulation of amikacin, an established antibiotic that was historically administered intravenously and associated with severe toxicity to hearing, balance, and kidney function. Insmed's proprietary PULMOVANCE® liposomal technology enables the delivery of amikacin directly to the lungs, where liposomal amikacin is taken up by lung macrophages where the infection resides, while limiting systemic exposure. ARIKAYCE is administered once daily using the Lamira® Nebulizer System manufactured by PARI Pharma GmbH (PARI).

About PARI Pharma and the Lamira® Nebulizer System

ARIKAYCE is delivered by a novel inhalation device, the Lamira® Nebulizer System, developed by PARI. Lamira® is a quiet, portable nebulizer that enables efficient aerosolization of ARIKAYCE via a vibrating, perforated membrane. Based on PARI's 100-year history working with aerosols, PARI is dedicated to advancing inhalation therapies by developing innovative delivery platforms to improve patient care.

About Brensocatib

Brensocatib is a small molecule, oral, reversible inhibitor of dipeptidyl peptidase 1 (DPP1) being developed by Insmed for the treatment of patients with bronchiectasis, CRSsNP, and other neutrophil-mediated diseases. DPP1 is an enzyme responsible for activating neutrophil serine proteases (NSPs), such as neutrophil elastase, in neutrophils when they are formed in the bone marrow. Neutrophils are the most common type of white blood cell and play an essential role in pathogen destruction and inflammatory mediation. In chronic inflammatory lung diseases, neutrophils accumulate in the airways and result in excessive active NSPs that cause lung destruction and inflammation. Brensocatib may decrease the damaging effects of inflammatory diseases such as bronchiectasis by inhibiting DPP1 and its activation of NSPs. Brensocatib is an investigational drug product that has not been approved for any indication in any jurisdiction.

IMPORTANT SAFETY INFORMATION AND BOXED WARNING FOR ARIKAYCE IN THE U.S.

WARNING: RISK OF INCREASED RESPIRATORY ADVERSE REACTIONS

ARIKAYCE has been associated with an increased risk of respiratory adverse reactions, including hypersensitivity pneumonitis, hemoptysis, bronchospasm, and exacerbation of underlying pulmonary disease that have led to hospitalizations in some cases.

Hypersensitivity Pneumonitis has been reported with the use of ARIKAYCE in the clinical trials. Hypersensitivity pneumonitis (reported as allergic alveolitis, pneumonitis, interstitial lung disease, allergic reaction to ARIKAYCE) was reported at a higher frequency in patients treated with ARIKAYCE plus background regimen (3.1%) compared to patients treated with a background regimen alone (0%). Most patients with hypersensitivity pneumonitis discontinued treatment with ARIKAYCE and received treatment with corticosteroids. If hypersensitivity pneumonitis occurs, discontinue ARIKAYCE and manage patients as medically appropriate.

Hemoptysis has been reported with the use of ARIKAYCE in the clinical trials. Hemoptysis was reported at a higher frequency in patients treated with ARIKAYCE plus background regimen (17.9%) compared to patients treated with a background regimen alone (12.5%). If hemoptysis occurs, manage patients as medically appropriate.

Bronchospasm has been reported with the use of ARIKAYCE in the clinical trials. Bronchospasm (reported as asthma, bronchial hyperreactivity, bronchospasm, dyspnea, dyspnea exertional, prolonged expiration, throat tightness, wheezing) was reported at a higher frequency in patients treated with ARIKAYCE plus background regimen (28.7%) compared to patients treated with a background regimen alone (10.7%). If bronchospasm occurs during the use of ARIKAYCE, treat patients as medically appropriate.

Exacerbations of underlying pulmonary disease has been reported with the use of ARIKAYCE in the clinical trials. Exacerbations of underlying pulmonary disease (reported as chronic obstructive pulmonary disease (COPD), infective exacerbation of COPD, infective exacerbation of bronchiectasis) have been reported at a higher frequency in patients treated with ARIKAYCE plus background regimen (14.8%) compared to patients treated with background regimen alone (9.8%). If exacerbations of underlying pulmonary disease occur during the use of ARIKAYCE, treat patients as medically appropriate.

Anaphylaxis and Hypersensitivity Reactions: Serious and potentially life-threatening hypersensitivity reactions, including anaphylaxis, have been reported in patients taking ARIKAYCE. Signs and symptoms include acute onset of skin and mucosal tissue hypersensitivity reactions (hives, itching, flushing, swollen lips/tongue/uvula), respiratory difficulty (shortness of breath, wheezing, stridor, cough), gastrointestinal symptoms (nausea, vomiting, diarrhea, crampy abdominal pain), and cardiovascular signs and symptoms of anaphylaxis (tachycardia, low blood pressure, syncope, incontinence, dizziness). Before therapy with ARIKAYCE is instituted, evaluate for previous hypersensitivity reactions to aminoglycosides. If anaphylaxis or a hypersensitivity

reaction occurs, discontinue ARIKAYCE and institute appropriate supportive measures.

Ototoxicity has been reported with the use of ARIKAYCE in the clinical trials. Ototoxicity (including deafness, dizziness, presyncope, tinnitus, and vertigo) were reported with a higher frequency in patients treated with ARIKAYCE plus background regimen (17%) compared to patients treated with background regimen alone (9.8%). This was primarily driven by tinnitus (7.6% in ARIKAYCE plus background regimen vs 0.9% in the background regimen alone arm) and dizziness (6.3% in ARIKAYCE plus background regimen vs 2.7% in the background regimen alone arm). Closely monitor patients with known or suspected auditory or vestibular dysfunction during treatment with ARIKAYCE. If ototoxicity occurs, manage patients as medically appropriate, including potentially discontinuing ARIKAYCE.

Nephrotoxicity was observed during the clinical trials of ARIKAYCE in patients with MAC lung disease but not at a higher frequency than background regimen alone. Nephrotoxicity has been associated with the aminoglycosides. Close monitoring of patients with known or suspected renal dysfunction may be needed when prescribing ARIKAYCE.

Neuromuscular Blockade: Patients with neuromuscular disorders were not enrolled in ARIKAYCE clinical trials. Patients with known or suspected neuromuscular disorders, such as myasthenia gravis, should be closely monitored since aminoglycosides may aggravate muscle weakness by blocking the release of acetylcholine at neuromuscular junctions.

Embryo-Fetal Toxicity: Aminoglycosides can cause fetal harm when administered to a pregnant woman. Aminoglycosides, including ARIKAYCE, may be associated with total, irreversible, bilateral congenital deafness in pediatric patients exposed *in utero*. Patients who use ARIKAYCE during pregnancy, or become pregnant while taking ARIKAYCE should be apprised of the potential hazard to the fetus.

Contraindications: ARIKAYCE is contraindicated in patients with known hypersensitivity to any aminoglycoside.

Most Common Adverse Reactions: The most common adverse reactions in Trial 1 at an incidence ≥5% for patients using ARIKAYCE plus background regimen compared to patients treated with background regimen alone were dysphonia (47% vs 1%), cough (39% vs 17%), bronchospasm (29% vs 11%), hemoptysis (18% vs 13%), ototoxicity (17% vs 10%), upper airway irritation (17% vs 2%), musculoskeletal pain (17% vs 8%), fatigue and asthenia (16% vs 10%), exacerbation of underlying pulmonary disease (15% vs 10%), diarrhea (13% vs 5%), nausea (12% vs 4%), pneumonia (10% vs 8%), headache (10% vs 5%), pyrexia (7% vs 5%), vomiting (7% vs 4%), rash (6% vs 2%), decreased weight (6% vs 1%), change in sputum (5% vs 1%), and chest discomfort (5% vs 3%).

Drug Interactions: Avoid concomitant use of ARIKAYCE with medications associated with neurotoxicity, nephrotoxicity, and ototoxicity. Some diuretics can enhance aminoglycoside toxicity by altering aminoglycoside concentrations in serum and tissue. Avoid concomitant use of ARIKAYCE with ethacrynic acid, furosemide, urea, or intravenous mannitol.

Overdosage: Adverse reactions specifically associated with overdose of ARIKAYCE have not been identified. Acute toxicity should be treated with immediate withdrawal of ARIKAYCE, and baseline tests of renal function should be undertaken. Hemodialysis may be helpful in removing amikacin from the body. In all cases of suspected overdosage, physicians should contact the Regional Poison Control Center for information about effective treatment.

U.S. INDICATION

LIMITED POPULATION: ARIKAYCE® is indicated in adults, who have limited or no alternative treatment options, for the treatment of *Mycobacterium avium* complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy. As only limited clinical safety and effectiveness data for ARIKAYCE are currently available, reserve ARIKAYCE for use in adults who have limited or no alternative treatment options. This drug is indicated for use in a limited and specific population of patients.

This indication is approved under accelerated approval based on achieving sputum culture conversion (defined as 3 consecutive negative monthly sputum cultures) by Month 6. Clinical benefit has not yet been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Limitation of Use: ARIKAYCE has only been studied in patients with refractory MAC lung disease defined as patients who did not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy. The use of ARIKAYCE is not recommended for patients with non-refractory MAC lung disease.

Patients are encouraged to report negative side effects of prescription drugs to the FDA. Visit **www.fda.gov/medwatch**, or call 1-800-FDA-1088. You can also call the Company at 1-844-4-INSMED.

Please see Full Prescribing Information.

About Insmed

Insmed Incorporated is a global biopharmaceutical company on a mission to transform the lives of patients with serious and rare diseases. Insmed's first commercial product is a first-in-disease therapy approved in the United States, Europe, and Japan to treat a chronic, debilitating lung disease. The Company is progressing a robust pipeline of investigational therapies targeting areas of serious unmet need, including neutrophil-mediated inflammatory diseases and rare pulmonary disorders. Insmed is also advancing an early-stage research engine encompassing a wide range of technologies and modalities, including artificial intelligence-driven protein engineering, gene therapy, and protein manufacturing. Insmed is headquartered in Bridgewater, New Jersey, with additional offices and research locations throughoutthe United States, Europe, and Japan. Visit www.insmed.com to learn more.

Forward-looking Statements
This press release contains forward-looking statements that involve substantial risks and uncertainties. "Forward-looking statements," as that term is defined in the Private Securities Litigation Reform Act of 1995, are statements that are not historical facts and involve a number of risks and uncertainties. Words herein such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "intends," "potential," "continues," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) may identify forward-looking statements.

The forward-looking statements in this press release are based upon the Company's current expectations and beliefs, and involve known and unknown risks, uncertainties and other factors, which may cause the Company's actual results, performance and achievements and the timing of certain events to differ materially from the results, performance, achievements or timings discussed, projected, anticipated or indicated in any forward-looking statements. Such risks, uncertainties and other factors include, among others, the following: failure to continue to successfully commercialize ARIKAYCE, our only approved product, in the US, Europe or Japan (amikacin liposome inhalation suspension, Liposomal 590 mg Nebuliser Dispersion, and amikacin sulfate inhalation drug product, respectively), or to maintain US, European or Japanese approval for ARIKAYCE; uncertainties or changes in the degree of market acceptance of ARIKAYCE by physicians, patients, third-party payors and others in the healthcare community; our inability to obtain full approval of ARIKAYCE from the FDA, including the risk that we will not successfully or in a timely manner validate a patient reported outcome (PRO) tool and complete the confirmatory post-marketing clinical trial required for full approval of ARIKAYCE; inability of us, PARI or our other third-party manufacturers to comply with regulatory requirements related to ARIKAYCE or Lamira®; our inability to obtain and maintain adequate reimbursement from government or third-party payors for ARIKAYCE or acceptable prices for ARIKAYCE; development of unexpected safety or efficacy concerns related to ARIKAYCE, brensocatib, TPIP or our other product candidates; inaccuracies in our estimates of the size of the potential markets for ARIKAYCE, brensocatib, TPIP or our other product candidates or in data we have used to identify physicians, expected rates of patient uptake, duration of expected treatment, or expected patient adherence or discontinuation rates; the risks and uncertainties associated with, and the perceived benefits of, our secured senior loan with certain funds managed by Pharmakon and our royalty financing with OrbiMed Royalty & Credit Opportunities IV, LP, including our ability to maintain compliance with the covenants in the agreements for the senior secured loan and royalty financing and the impact of the restrictions on our operations under these agreements; our inability to create or maintain an effective direct sales and marketing infrastructure or to partner with third parties that offer such an infrastructure for distribution of ARIKAYCE or any of our product candidates that are approved in the future; failure to obtain regulatory approval to expand ARIKAYCE's indication to a broader patient population; risk that brensocatib or TPIP does not prove to be effective or safe for patients in ongoing and future clinical studies, including, for brensocatib, the ASPEN study; risk that our competitors may obtain orphan drug exclusivity for a product that is essentially the same as a product we are developing for a particular indication; failure to successfully predict the time and cost of development, regulatory approval and commercialization for novel gene therapy products; failure to successfully conduct future clinical trials for ARIKAYCE, brensocatib, TPIP and our other product candidates and our potential inability to enroll or retain sufficient patients to conduct and complete the trials or generate data necessary for regulatory approval of our product candidates or to permit the use of ARIKAYCE in the broader population of patients with MAC lung disease, among other things; risks that our clinical studies will be delayed, that serious side effects will be identified during drug development, or that any protocol amendments submitted will be rejected; risks that interim or partial data sets are not representative of a complete or larger data set or that blinded data will not be predictive of unblinded data; failure to obtain, or delays in obtaining, regulatory approvals for ARIKAYCE outside the US, Europe or Japan, or for our product candidates in the US, Europe, Japan or other markets, including separate regulatory approval for Lamira® in each market and for each usage; failure of third parties on which we are dependent to manufacture sufficient quantities of ARIKAYCE or our product candidates for commercial or clinical needs, to conduct our clinical trials, or to comply with our agreements or laws and regulations that impact our business or agreements with us; our inability to attract and retain key personnel or to effectively manage our growth; our inability to successfully integrate our recent acquisitions and appropriately manage the amount of management's time and attention devoted to integration activities; risks that our acquired technologies, products and product candidates are not commercially successful; inability to adapt to our highly competitive and changing environment; inability to access, upgrade or expand our technology systems or difficulties in updating our existing technology or developing or implementing new technology; risk that we are unable to maintain our significant customers; risk that government healthcare reform materially increases our costs and damages our financial condition; business or economic disruptions due to catastrophes or other events, including natural disasters or public health crises; risk that our current and potential future use of artificial intelligence and machine learning may not be successful; deterioration in general economic conditions in the US, Europe, Japan and globally, including the effect of prolonged periods of inflation, affecting us, our suppliers, third-party service providers and potential partners; inability to adequately protect our intellectual property rights or prevent disclosure of our trade secrets and

other proprietary information and costs associated with litigation or other proceedings related to such matters; restrictions or other obligations imposed on us by agreements related to ARIKAYCE or our product candidates, including our license agreements with PARI and AstraZeneca AB, and failure to comply with our obligations under such agreements; the cost and potential reputational damage resulting from litigation to which we are or may become a party, including product liability claims; risk that our operations are subject to a material disruption in the event of a cybersecurity attack or issue; our limited experience operating internationally; changes in laws and regulations applicable to our business, including any pricing reform and laws that impact our ability to utilize certain third parties in the research, development or manufacture of our product candidates, and failure to comply with such laws and regulations; our history of operating losses, and the possibility that we never achieve or maintain profitability; goodwill impairment charges affecting our results of operations and financial condition; inability to repay our existing indebtedness and uncertainties with respect to our ability to access future capital; and delays in the execution of plans to build out an additional third-party manufacturing facility approved by the appropriate regulatory authorities and unexpected expenses associated with those plans.

The Company may not actually achieve the results, plans, intentions or expectations indicated by the Company's forward-looking statements because, by their nature, forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. For additional information about the risks and uncertainties that may affect the Company's business, please see the factors discussed in Item 1A, "Risk Factors," in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 and any subsequent Company filings with the Securities and Exchange Commission (SEC).

The Company cautions readers not to place undue reliance on any such forward-looking statements, which speak only as of the date of this press release. The Company disclaims any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

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