Insmed Reports Fourth-Quarter and Full-Year 2023 Financial Results and Provides Business Update

—Topline Data from the Phase 3 ASPEN Trial of Brensocatib in Adult Patients with Bronchiectasis Remain on Track to Read Out in the Latter Part of Second-Quarter 2024—

—Enrollment in the Phase 2 Study of TPIP in Patients with PH-ILD Completed in November 2023; Topline Data Expected in Second-Quarter 2024 Ahead of the ASPEN Readout—

—Company Ends 2023 With $780 Million of Cash, Cash Equivalents, and Marketable Securities, Providing Runway Beyond the Expected ASPEN Readout—

— ARIKAYCE® (amikacin liposome inhalation suspension) Total Revenue of $83.7 Million for Fourth-Quarter and $305.2 Million for Full-Year 2023, Reflecting 24% Annual Growth and Exceeding the Upper End of Full-Year 2023 Guidance Range—

—Company Reiterates Sales Guidance for 2024 Global ARIKAYCE Revenues in the Range of $340 Million to $360 Million, Reflecting Double-Digit Growth Compared to 2023—

BRIDGEWATER, N.J., Feb. 22, 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 reported financial results for the fourth quarter and full year ended December 31, 2023 and provided a business update.

"Insmed continued to deliver strong performance in 2023, demonstrating commercial success evidenced by ARIKAYCE revenues that exceeded the upper end of our 2023 sales guidance range," said Will Lewis, Chair and Chief Executive Officer of Insmed. "The positive ARISE data announced in September 2023, followed by encouraging blinded TPIP data shortly thereafter, marked the beginning of a transformative period of clinical catalysts for the Company. This series of meaningful data readouts from our mid- to late-stage pipeline is expected to continue uninterrupted in the months ahead, with topline results from the PH-ILD and ASPEN trials expected in quick succession in the second quarter. We believe these near-term data readouts have the potential to fundamentally change the trajectory for our company and the patients we serve."

Recent Pillar Highlights

Pillar 1: ARIKAYCE

- ARIKAYCE global revenue grew 24% in 2023 compared to 2022, reflecting continued strong growth in the U.S., Japan, and Europe.
- Insmed received encouraging written feedback in December 2023 from the U.S. Food and Drug Administration (FDA) on the patient-reported outcome data produced in the Phase 3 ARISE study. The Company expects to meet with the FDA in the coming months to gain additional insights and guidance, from which it will finalize its statistical plan for the Phase 3 ENCORE study.
- As previously communicated in January 2024, the Company achieved its original target enrollment goal of 250 patients in the ENCORE trial in patients with newly diagnosed or recurrent nontuberculous mycobacterial lung infection caused by *Mycobacterium avium* complex (MAC) who had not started antibiotics. Enrollment in the trial remains open.
- The Data Safety Monitoring Committee for the ENCORE study held its third safety review meeting in November 2023 and recommended that the study continue as planned.
- Consistent with the Company's expectations, the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan recently confirmed that it would not consider a label expansion for ARIKAYCE based on data from the ARISE study alone due to (i) the lack of Japanese subjects in that study; (ii) the absence of what PMDA considers a sufficiently long treatment exposure (12 months); and (iii) the absence of resulting evidence of culture conversion the PMDA considers durable (15 months). The ongoing ENCORE trial is designed to satisfy the PMDA's remaining regulatory requirements, including the enrollment of Japanese patients, sufficient treatment exposure, and an endpoint for durable culture conversion.
- The Company continues to expect topline data for ENCORE in 2025.

Pillar 2: Brensocatib

- Insmed continues to expect topline data from the Phase 3 ASPEN study of brensocatib in patients with non-cystic fibrosis bronchiectasis in the latter part of the second quarter of 2024.
- If ASPEN is successful and regulatory approval is obtained, the Company anticipates a launch in bronchiectasis in the U.S. in mid-2025, followed by launches in Europe and Japan in the first half of 2026. Insmed continues to advance its launch readiness activities in preparation for these potential launches.
- The Data Safety Monitoring Committee for the ASPEN study held its fifth and final meeting in November 2023. No safety signals were identified, and the Committee recommended that the trial continue as planned.
- The Company is currently enrolling patients in the Phase 2b BiRCh trial of brensocatib in patients with chronic rhinosinusitis

without nasal polyps (CRSsNP).
- The Company expects to initiate a Phase 2 study of brensocatib in patients with hidradenitis suppurativa (HS) in the second half of 2024, pending positive results from the ASPEN study.

Pillar 3: TPIP

- In October 2023, Insmed announced encouraging blended and blinded data from two ongoing Phase 2 studies of treprostinil palmitil inhalation powder (TPIP) in pulmonary hypertension associated with interstitial lung disease (PH-ILD) and pulmonary arterial hypertension (PAH).
- The Company completed enrollment of 39 patients in the Phase 2 safety study in PH-ILD in November 2023, exceeding its initial enrollment target of 32 patients. Topline data from the study are anticipated in advance of Phase 3 ASPEN data in the second quarter of 2024.
- Enrollment remains ongoing in the Phase 2 study in PAH. Insmed anticipates sharing updated blinded data from approximately 40 patients in the PAH study at the same time topline results from the PH-ILD study become available in the second quarter of 2024. Topline results from the Phase 2 PAH study continue to be expected in 2025.
- Insmed has submitted a protocol amendment to the FDA and other regulatory authorities for the open-label extension of the Phase 2 PAH study. This amendment, if approved, would allow investigators to continue to increase the dose of TPIP up to a maximum of 1,280 micrograms once daily.

Pillar 4: Early-Stage Research

- Insmed's early-stage research efforts include more than 30 identified pre-clinical programs in development, all of which have the potential to become first-in-class or best-in-class therapies.
- The Company continues to anticipate the totality of its early-stage research programs will comprise less than 20% of overall annual spend.

Fourth-Quarter and Full-Year 2023 Financial Results

- Total revenue for the fourth quarter ended December 31, 2023, was $83.7 million, reflecting 41% growth compared to total revenue of $59.3 million for the fourth quarter of 2022. Total revenue for the full-year 2023 was $305.2 million, compared to total revenue of $245.4 million for the full-year 2022, reflecting 24% year-over-year growth.
- Total revenue for the full-year 2023 was comprised of ARIKAYCE net sales of $224.2 million in the U.S., $65.7 million in Japan, and $15.3 million in Europe and rest of world. Full-year 2023 sales demonstrated year-over-year growth of 21% in the U.S. and 16% in Japan, reflecting continued strong growth trends for ARIKAYCE in these regions.
- Cost of product revenues (excluding amortization of intangibles) was $18.4 million for the fourth quarter of 2023, compared to $13.1 million for the fourth quarter of 2022, primarily reflecting the increase in sales volumes. For the full-year 2023, cost of product revenues (excluding amortization of intangibles) was $65.6 million compared to $55.1 million for the full-year 2022.
- Research and development (R&D) expenses were $137.0 million for the fourth quarter of 2023, compared to $124.8 million for the fourth quarter of 2022. For the full-year 2023, R&D expenses were $571.0 million compared to $397.5 million in 2022, reflecting one-time, non-cash asset acquisition costs and the continued investment in Insmed's early and mid- to late-stage pipeline programs, including increases in headcount to support those existing and acquired programs.
- Selling, general and administrative (SG&A) expenses for the fourth quarter of 2023 were $89.5 million, compared to $73.5 million for the fourth quarter of 2022. For the full-year 2023, SG&A expenses were $344.5 million, compared to $265.8 million for the full-year 2022. The year-over-year increase in SG&A expenses resulted primarily from commercial readiness activities for brensocatib and an increase in headcount.
- For the fourth-quarter 2023, Insmed reported a net loss of $186.1 million, or $1.28 per share, compared to a net loss of $160.1 million, or $1.21 per share, for the fourth-quarter 2022. For the full-year 2023, Insmed reported a net loss of $749.6 million, or $5.34 per share, compared to a net loss of $481.5 million, or $3.91 per share, for the full-year 2022.

Balance Sheet, Financial Guidance, and Planned Investments

- As of December 31, 2023, Insmed had cash, cash equivalents, and marketable securities totaling $780.4 million.
- Insmed is reiterating its sales guidance for full-year 2024 global ARIKAYCE revenues in the range of $340 million to $360 million, representing 15% year-over-year growth at the midpoint compared to 2023.
- Insmed continues to anticipate that over 80% of total annual expenditures will be on its mid- to late-stage and commercial programs (ARIKAYCE, brensocatib, and TPIP), and that less than 20% of overall spend will be on its early-stage research programs, reflecting the Company's historical approach to spending.
- The Company plans to continue to invest in the following key activities in 2024:

  (i) commercialization and expansion of ARIKAYCE globally;

  (ii) advancement of brensocatib, including the Phase 3 ASPEN study in patients with bronchiectasis, and commercial launch readiness activities, the ongoing Phase 2 trial in patients with CRSsNP, and the Phase 2 program in HS to be initiated in the second half of the year if the ASPEN result is positive;

  (iii) advancement of the clinical trial program for ARIKAYCE, which is intended to satisfy the post-marketing requirement for full approval of its current indication and potentially support label expansion to include all patients with a MAC lung infection;

  (iv) advancement of its Phase 2 clinical development programs for TPIP; and

  (v) development of its early-stage research programs.

Conference Call

Insmed will host a conference call beginning today at 8:30 AM Eastern Time. Shareholders and other interested parties may participate in the conference call by dialing (888) 210-2654 (U.S. and international) and referencing access code 7862189. The call

will also be webcast live on the Company's website at **www.insmed.com**.

A replay of the conference call will be accessible approximately 1 hour after its completion through March 23, 2024, by dialing (800) 770-2030 (U.S. and international) and referencing access code 7862189. A webcast of the call will also be archived for 90 days under the Investor Relations section of the Company's website at **www.insmed.com**.

INSMED INCORPORATED
Consolidated Statements of Net Loss
(in thousands, except per share data)
(unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	**2022**	**2023**	**2022**
Product revenues, net	$ 83,693	$ 59,300	$ 305,208	$ 245,358
Operating expenses:				
Cost of product revenues (excluding amortization of intangible assets)	18,443	13,069	65,573	55,126
Research and development	137,029	124,763	571,011	397,518
Selling, general and administrative	89,530	73,479	344,501	265,784
Amortization of intangible assets	1,263	1,264	5,052	5,053
Change in fair value of deferred and contingent consideration liabilities	15,700	(1,800)	28,697	(20,802)
Total operating expenses	261,965	210,775	1,014,834	702,679
Operating loss	(178,272)	(151,475)	(709,626)	(457,321)
Investment income	9,853	8,318	42,132	11,081
Interest expense	(20,784)	(16,445)	(81,694)	(26,446)
Change in fair value of interest rate swap	1,970	(1,526)	320	(1,526)
Other income (expense), net	2,170	1,130	1,856	(5,939)
Loss before income taxes	(185,063)	(159,998)	(747,012)	(480,151)
Provision for income taxes	998	125	2,555	1,383
Net loss	$ (186,061)	$ (160,123)	$ (749,567)	$ (481,534)
Basic and diluted net loss per share	$ (1.28)	$ (1.21)	$ (5.34)	$ (3.91)
Weighted average basic and diluted common shares outstanding	144,806	132,694	140,433	123,035

INSMED INCORPORATED
Consolidated Balance Sheets
(in thousands, except par value and share data)

	As of December 31, 2023	As of December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 482,374	$ 1,074,036
Marketable securities	298,073	74,244
Accounts receivable	41,189	29,713
Inventory	83,248	69,922
Prepaid expenses and other current assets	24,179	25,468
Total current assets	929,063	1,273,383
Fixed assets, net	65,384	56,491
Finance lease right-of-use assets	20,985	23,697
Operating lease right-of-use assets	18,017	21,894
Intangibles, net	63,704	68,756
Goodwill	136,110	136,110
Other assets	96,574	76,104
Total assets	$ 1,329,837	$ 1,656,435

Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 214,987	$ 182,117
Finance lease liabilities	2,610	1,217
Operating lease liabilities	8,032	6,909
Total current liabilities	225,629	190,243
Debt, long-term	1,155,313	1,125,250
Royalty financing agreement	155,034	148,015
Contingent consideration	84,600	51,100
Finance lease liabilities, long-term	27,026	29,636
Operating lease liabilities, long-term	11,013	14,853
Other long-term liabilities	3,145	9,387
Total liabilities	1,661,760	1,568,484
Shareholders' equity:		
Common stock, $0.01 par value; 500,000,000 authorized shares, 147,977,960 and 135,653,731 issued and outstanding shares at December 31, 2023 and December 31, 2022, respectively	1,480	1,357
Additional paid-in capital	3,113,487	2,782,416
Accumulated deficit	(3,446,145)	(2,696,578)
Accumulated other comprehensive (loss) income	(745)	756
Total shareholders' (deficit) equity	(331,923)	87,951
Total liabilities and shareholders' equity	$ 1,329,837	$ 1,656,435

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.

About TPIP

Treprostinil palmitil inhalation powder (TPIP) is a dry powder formulation of treprostinil palmitil, a treprostinil prodrug consisting of treprostinil linked by an ester bond to a 16-carbon chain. Developed entirely in Insmed's laboratories, TPIP is a potentially highly differentiated prostanoid being evaluated for the treatment of patients with PAH, PH-ILD, and other rare and serious pulmonary disorders. TPIP is administered in a capsule-based inhalation device. TPIP 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 throughout the 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 obtain, or delays in obtaining, regulatory approvals for ARIKAYCE outside the U.S., Europe or Japan, or for the Company's product candidates in the U.S., Europe, Japan or other markets, including separate regulatory approval for the Lamira® Nebulizer System in each market and for each usage; failure to continue to successfully commercialize ARIKAYCE, the Company's only approved product, in the U.S., Europe or Japan (amikacin liposome inhalation suspension, Liposomal 590 mg Nebuliser Dispersion, and amikacin sulfate inhalation drug product, respectively), or to maintain U.S., European or Japanese approval for ARIKAYCE; business or economic disruptions due to catastrophes or other events, including natural disasters or public health crises; 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; uncertainties or changes in the degree of market acceptance of ARIKAYCE by physicians, patients, third-party payors and others in the healthcare community; the Company's inability to obtain full approval of ARIKAYCE from the FDA, including the risk that the Company will not successfully or in a timely manner validate a PRO tool and complete the confirmatory post-marketing clinical trial required for full approval of ARIKAYCE; inability of the Company, PARI or the Company's other third-party manufacturers to comply with regulatory requirements related to ARIKAYCE or the Lamira® Nebulizer System; the Company's inability to obtain 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 the Company's other product candidates; inaccuracies in the Company's estimates of the size of the potential markets for ARIKAYCE, brensocatib, TPIP or the Company's other product candidates or in data the Company has 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, the Company's secured senior loan with certain funds managed by Pharmakon Advisors, LP and the Company's royalty financing with OrbiMed Royalty & Credit Opportunities IV, LP, including the Company's ability to maintain compliance with the covenants in the agreements for the senior secured loan and royalty financing and the perceived impact of the restrictions on the Company's operations under these agreements; the Company's 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 the Company's 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 the Company's competitors may obtain orphan drug exclusivity for a product that is essentially the same as a product the Company is 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 the Company's other product candidates due to the Company's limited experience in conducting preclinical development activities and clinical trials necessary for regulatory approval and its 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 the Company's 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 topline, interim or partial data sets are not representative of a complete or larger data set and are subject to change as more patient data becomes available or that blinded data will not be predictive of unblinded data; failure of third parties on which the Company is dependent to manufacture sufficient quantities of ARIKAYCE or the Company's product candidates for commercial or clinical needs, to conduct the Company's clinical trials, or to comply with the Company's agreements or laws and regulations that impact the Company's business or agreements with the Company; the Company's inability to attract and retain key personnel or to effectively manage the Company's growth; the Company's inability to

successfully integrate its recent acquisitions and appropriately manage the amount of management's time and attention devoted to integration activities; risks that the Company's acquired technologies, products and product candidates are not commercially successful; the Company's inability to adapt to its highly competitive and changing environment; the Company's inability to access, upgrade or expand its technology systems or difficulties in updating our existing technology or developing or implementing new technology; risk that the Company is unable to maintain its significant customers; risk that government healthcare reform materially increases the Company's costs and damages its financial condition; 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 U.S., Europe, Japan and globally, including the effect of prolonged periods of inflation, affecting the Company, its suppliers, third-party service providers and potential partners; the Company's inability to adequately protect its intellectual property rights or prevent disclosure of its trade secrets and other proprietary information and costs associated with litigation or other proceedings related to such matters; restrictions or other obligations imposed on the Company by agreements related to ARIKAYCE or the Company's product candidates, including its license agreements with PARI and AstraZeneca AB, and failure of the Company to comply with its obligations under such agreements; the cost and potential reputational damage resulting from litigation to which the Company is or may become a party, including product liability claims; risk that the Company's operations are subject to a material disruption in the event of a cybersecurity attack or issue; the Company's limited experience operating internationally; changes in laws and regulations applicable to the Company's business, including any pricing reform, and failure to comply with such laws and regulations; the Company's history of operating losses, and the possibility that the Company may never achieve or maintain profitability; goodwill impairment charges affecting the Company's results of operations and financial condition; inability to repay the Company's existing indebtedness and uncertainties with respect to the Company's 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.

With respect to the blended and blinded data observed from the ongoing TPIP studies noted above, the dose titration, efficacy, and safety analyses were based on data available as of August 28, September 12, and October 23, 2023, respectively. These findings may not be representative of results after the studies are completed and all data is collected and analyzed. As a result, later interim data readouts and final data from these studies may be materially different than the observations described above, including with respect to efficacy, safety and tolerability of TPIP.

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