Insmed Reports Third-Quarter 2024 Financial Results and Provides Business Update

—ARIKAYCE® (amikacin liposome inhalation suspension) Total Revenue of $93.4 Million for the Third Quarter of 2024, Reflecting 18% Growth Over the Third Quarter of 2023—

—NDA Submission for Brensocatib in Bronchiectasis Remains on Track for the Fourth Quarter of 2024 with Potential U.S. Launch Still Expected in Mid-2025—

—Expanded U.S. Sales Force is Now Fully Deployed; Focusing on Bronchiectasis Disease-State Awareness and Supporting the Growth of ARIKAYCE Prior to the Anticipated Launch of Brensocatib—

—Ends the Third Quarter with ~$1.5 Billion in Cash, Cash Equivalents, and Marketable Securities—

—Renegotiates Term Loan with Pharmakon Resulting in a Lower Cost of Capital and an Additional $150 Million in Proceeds to be Received in the Fourth Quarter—

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

BRIDGEWATER, N.J., Oct. 31, 2024 /PRNewswire/ -- Insmed Incorporated (Nasdaq: INSM), a people-first global biopharmaceutical company striving to deliver first- and best-in-class therapies to transform the lives of patients facing serious diseases, today reported financial results for the third quarter ended September 30, 2024, and provided a business update.

"I am pleased with the progress the Company is making across multiple ongoing initiatives this quarter." said Will Lewis, Chair and Chief Executive Officer of Insmed. "We remain on track to file our NDA for brensocatib in the fourth quarter of 2024 and continue to expect a potential U.S. launch in the middle of 2025. We have also made great progress on the clinical side, with the ENCORE and PAH studies nearing full enrollment. All of this has been accomplished while delivering yet another quarter of double-digit growth for ARIKAYCE in each of our three commercial regions. With our demonstrated ability to execute both clinically and commercially, and a strengthened balance sheet due to actions we have taken to lower our cost of capital while adding to our cash balance, we believe we are well-positioned to deliver on the tremendous opportunities ahead."

Recent Pillar Highlights

Pillar 1: ARIKAYCE

- ARIKAYCE global revenue grew 18% in the third quarter of 2024 compared to the third quarter of 2023, reflecting an all-time revenue high and double-digit year-over-year growth in the U.S., Japan, and Europe and rest of world.
- Insmed has closed screening of new patients for the ENCORE study and is now expected to exceed its target enrollment of 400 patients with newly diagnosed or recurrent *Mycobacterium avium* complex (MAC) lung infection who have not started antibiotics.
- The Company is scheduled to meet with the U.S. Food and Drug Administration (FDA) during the fourth quarter to discuss the possibility of an accelerated approval to expand the label for ARIKAYCE to include all patients with MAC lung infection, based on the positive Phase 3 ARISE trial data. Insmed continues to expect that the full data from the ongoing ENCORE trial will be required for approval.

Pillar 2: Brensocatib

- Insmed remains on track to file a New Drug Application (NDA) with the FDA for brensocatib in patients with bronchiectasis in the fourth quarter of 2024. If priority review is granted and brensocatib is approved, Insmed anticipates a U.S. launch in mid-2025. Launches in Europe and Japan are expected in the first half of 2026, pending approvals.
- New subpopulation data from 19 pre-specified categories of patients in the ASPEN study were presented in October 2024 at the American College of Chest Physicians Annual Meeting in Boston. The annualized rate of pulmonary exacerbations favored brensocatib at both the 10 mg and 25 mg doses over placebo for almost all subgroups. In a separate analysis,

least squares mean difference for brensocatib 25 mg demonstrated a reduced decline in post-bronchodilator forced expiratory volume in 1 second (FEV1) at Week 52 versus placebo for all prespecified subgroups.
- Insmed is advancing launch readiness activities in the U.S. and has hired, trained, and deployed 120 additional therapeutic sales specialists in advance of launch, focused on bronchiectasis disease-state awareness with an expanded group of pulmonologists while also supporting the growth of ARIKAYCE.
- The Company continues to enroll patients in the Phase 2b BiRCh trial of brensocatib in patients with chronic rhinosinusitis without nasal polyps (CRSsNP) and anticipates providing top-line data from the study in the second half of 2025.
- The Company is preparing to activate the first U.S. clinical site for its Phase 2 study of brensocatib in patients with hidradenitis suppurativa (HS) by the end of 2024.

Pillar 3: TPIP

- Enrollment remains ongoing in the Phase 2 study of treprostinil palmitil inhalation powder (TPIP) in patients with pulmonary arterial hypertension (PAH), with more than 90% of the target enrollment currently complete.
- Insmed remains on track to report topline results from the PAH study in the second half of 2025.
- The Company continues to anticipate initiating a Phase 3 study of TPIP in patients with pulmonary hypertension associated with interstitial lung disease (PH-ILD) in the second half of 2025.

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 spend.

Corporate Updates

- Insmed has taken the following actions intended to further strengthen its balance sheet and financial position:

  (i) During the third quarter of 2024, the Company completed the redemption of its $225 million convertible notes due in January 2025. Insmed issued approximately 5.7 million shares of common stock in connection with the redemption and earlier conversions of notes.
  (ii) The Company raised an additional $371 million in net proceeds under its at-the-market equity offering program during the third quarter, at an average sales price of $75.64 per share.
  (iii) In October 2024, Insmed entered into an agreement to amend its $350 million term loan with investment funds managed by Pharmakon Advisors, LP. Under the terms of the amended agreement, investment funds managed by Pharmakon Advisors, LP will provide an additional $150 million in proceeds, to be received in the fourth quarter of 2024. The maturity date for the full principal amount was extended to 2029, and will carry a reduced fixed-interest rate in the high-single digits.

- In October 2024, Insmed announced that it has earned the No. 1 ranking in *Science*'s 2024 Top Employers Survey, marking the fourth consecutive year in which Insmed achieved the top ranking. The annual survey polls employees in biotechnology, pharmaceutical, and related industries to determine the 20 best employers, as well as their driving characteristics.

Third-Quarter 2024 Financial Results

- Total revenue for the quarter ended September 30, 2024, was $93.4 million, reflecting 18% year-over-year growth compared to total revenue of $79.1 million for the third quarter of 2023.
- Total revenue for third-quarter 2024 included ARIKAYCE net sales of $66.9 million in the U.S., $21.0 million in Japan, and $5.6 million in Europe and rest of world. Third-quarter 2024 sales demonstrated year-over-year growth of 13% in the U.S., 31% in Japan, and 45% in Europe and rest of world, reflecting continued growth trends for ARIKAYCE in these regions.
- Cost of product revenues (excluding amortization of intangibles) was $21.2 million for the third quarter of 2024, compared to $16.7 million for the third quarter of 2023, primarily reflecting increased sales volumes of ARIKAYCE.
- Research and development (R&D) expenses were $150.8 million for the third quarter of 2024, compared to $109.1 million for the third quarter of 2023. The year-over-year increase in R&D expenses was primarily driven by increases in manufacturing and compensation and benefit-related expenses.
- Selling, general and administrative (SG&A) expenses for the third quarter of 2024 were $118.9 million, compared to $90.6 million for the third quarter of 2023. The year-over-year increase in SG&A expenses resulted primarily from increases in compensation and benefit-related expenses and stock-based compensation costs due to an increase in headcount associated with launch readiness activities for brensocatib.
- For the third quarter of 2024, Insmed reported a net loss of $220.5 million, or $1.27 per share, compared to a net loss of $158.9 million, or $1.11 per share, for the third quarter of 2023.

Balance Sheet, Financial Guidance, and Planned Investments

- As of September 30, 2024, Insmed had cash, cash equivalents, and marketable securities totaling $1,467.9 million.
- Insmed is reiterating its 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 expenditures will be on its clinical and commercial programs, 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 continued growth of ARIKAYCE in its current indication globally, as well as advancement of the clinical trial program intended to potentially support label expansion to include all patients with a MAC lung infection and to satisfy the post-marketing requirement for full approval of its current indication;
  (ii) advancement of brensocatib, including:

    a. activities related to regulatory filing and commercial launch readiness for bronchiectasis and
    b. the ongoing Phase 2 BiRCh trial in patients with CRSsNP and the anticipated Phase 2 program in HS;

  (iii) advancement of its clinical development programs for TPIP; and
  (iv) development of its early-stage research programs.

Conference Call

Insmed will host a conference call beginning today at 8:00 AM Eastern Time. Shareholders and other interested parties may participate in the conference call by dialing (888) 210-2654 (U.S.) and (646) 960-0278 (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 November 7, 2024, by dialing (800) 770-2030 (U.S.) and (609) 800-9909 (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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	$	$	$	$
Product revenues, net	93,425	79,072	259,265	221,515
Operating expenses:				
Cost of product revenues (excluding amortization of intangible assets)	21,170	16,706	59,591	47,130
Research and development	150,809	109,148	418,640	433,982
Selling, general and administrative	118,930	90,626	318,601	254,971
Amortization of intangible assets	1,263	1,263	3,789	3,789
Change in fair value of deferred and contingent consideration liabilities	14,682	8,997	106,482	12,997
Total operating expenses	306,854	226,740	907,103	752,869
Operating loss	(213,429)	(147,668)	(647,838)	(531,354)
Investment income	16,982	10,583	36,050	32,279
Interest expense	(21,054)	(20,288)	(63,363)	(60,910)
Change in fair value of interest rate swap	(3,852)	(1,301)	(1,106)	(1,650)
Other income (expense), net	1,843	285	474	(314)
Loss before income taxes	(219,510)	(158,389)	(675,783)	(561,949)
Provision for income taxes	1,014	544	2,441	1,557

Net loss	$ (220,524)	$ (158,933)	$ (678,224)	$ (563,506)
Basic and diluted net loss per share	$ (1.27)	$ (1.11)	$ (4.27)	$ (4.06)
Weighted average basic and diluted common shares outstanding	173,721	142,899	159,013	138,960

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

	As of September 30, 2024 (unaudited)	As of December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 461,451	$ 482,374
Marketable securities	1,006,457	298,073
Accounts receivable	42,317	41,189
Inventory	98,470	83,248
Prepaid expenses and other current assets	41,150	24,179
Total current assets	1,649,845	929,063
Fixed assets, net	75,265	65,384
Finance lease right-of-use assets	18,951	20,985
Operating lease right-of-use assets	16,030	18,017
Intangibles, net	59,915	63,704
Goodwill	136,110	136,110
Other assets	96,856	96,574
Total assets	$ 2,052,972	$ 1,329,837
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 248,684	$ 214,987
Finance lease liabilities	2,871	2,610
Operating lease liabilities	7,633	8,032
Total current liabilities	259,188	225,629
Debt, long-term	954,831	1,155,313
Royalty financing agreement	160,049	155,034
Contingent consideration	157,600	84,600
Finance lease liabilities, long-term	24,841	27,026
Operating lease liabilities, long-term	9,692	11,013
Other long-term liabilities	3,356	3,145
Total liabilities	1,569,557	1,661,760
Shareholders' equity:		
Common stock, $0.01 par value; 500,000,000 authorized shares, 178,846,991 and 147,977,960 issued and outstanding shares at September 30, 2024 and December 31, 2023, respectively	1,788	1,480
Additional paid-in capital	4,605,449	3,113,487
Accumulated deficit	(4,124,369)	(3,446,145)

Accumulated other comprehensive income (loss)	547	(745)
Total shareholders' equity (deficit)	483,415	(331,923)
Total liabilities and shareholders' equity (deficit)	$ 2,052,972	$ 1,329,837

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 people-first global biopharmaceutical company striving to deliver first- and best-in-class therapies to transform the lives of patients facing serious diseases. The Company is advancing a diverse portfolio of approved and mid- to late-stage investigational medicines as well as cutting-edge drug discovery focused on serving patient communities where the need is greatest. Insmed's most advanced programs are in pulmonary and inflammatory conditions, including a therapy approved in the United States, Europe, and Japan to treat a chronic, debilitating lung disease. The Company's early-stage research programs encompass a wide range of technologies and modalities, including gene therapy, AI-driven protein engineering, protein manufacturing, RNA end-joining, and synthetic rescue.

Headquartered in Bridgewater, New Jersey, Insmed has offices and research locations throughoutthe United States, Europe, and Japan. Insmed is proud to be recognized as one of the best employers in the biopharmaceutical industry, including spending four consecutive years as the No. 1 *Science* Top Employer. 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 U.S., 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; our inability to obtain full approval of ARIKAYCE from the FDA, including the risk that we will not successfully or in a timely manner complete the confirmatory post-marketing clinical trial required for full approval of ARIKAYCE, or our failure to obtain regulatory approval to expand ARIKAYCE's indication to a broader patient population; failure to obtain, or delays in obtaining, regulatory approvals for brensocatib, TPIP or our other product candidates in the US, Europe or Japan or for ARIKAYCE outside the US, Europe or Japan, including separate regulatory approval for Lamira® in each market and for each usage; failure to successfully commercialize brensocatib, TPIP or our other product candidates, if approved by applicable regulatory authorities, or to maintain applicable regulatory approvals for brensocatib, TPIP or our other product candidates, if approved; uncertainties or changes in the degree of market acceptance of ARIKAYCE or, if approved, brensocatib or TPIP by physicians, patients, third-party payors and others in the healthcare community; our inability to obtain and maintain adequate reimbursement from government or third-party payors for ARIKAYCE or, if approved, brensocatib or TPIP, or acceptable prices for ARIKAYCE or, if approved, brensocatib or TPIP; 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; failure of third parties on which the Company is dependent to manufacture sufficient quantities of ARIKAYCE, brensocatib, or TPIP 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; the risks and uncertainties associated with, and the perceived benefits of, our secured senior loan with certain funds managed by Pharmakon Advisors L.P. 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 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; development of unexpected safety or efficacy concerns related to ARIKAYCE, brensocatib, TPIP or our other product candidates; 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; the risk that interim, topline or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available or may be interpreted differently if additional data are disclosed, or that blinded data will not be predictive of unblinded data; 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; 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 AI 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; the risk that we could become involved in costly intellectual property disputes, be unable to adequately protect our intellectual property rights or prevent disclosure of our trade secrets and other proprietary information, and incur costs associated with litigation or other proceedings related to such matters; restrictions or other obligations imposed on us by agreements related to ARIKAYCE, brensocatib or our other 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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