Insmed Reports First-Quarter 2025 Financial Results and Provides Business Update

—ARIKAYCE® (amikacin liposome inhalation suspension) Total Revenue of $92.8 Million for the First Quarter of 2025, Reflecting 23% Growth Over the First Quarter of 2024—

—NDA for Brensocatib in Patients with Bronchiectasis Remains on Track, with a PDUFA Target Action Date of August 12, 2025—

—Phase 2b Study of TPIP in Patients with PAH Completed; Topline Data Expected in June 2025—

—Enrollment Completed for Phase 2b BiRCh Study of Brensocatib in Patients with CRSsNP; Topline Data Anticipated By the End of 2025—

—MAA Filings for Brensocatib in Patients with Bronchiectasis Accepted by EMA and MHRA—

—Company Reiterates 2025 Global ARIKAYCE Revenue Guidance Range of $405 Million to $425 Million, Reflecting Double-Digit Growth Compared to 2024—

BRIDGEWATER, N.J., May 8, 2025 /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 first quarter ended March 31, 2025 and provided a business update.

"In the first quarter of 2025, Insmed demonstrated executional excellence across our commercial and clinical programs, while simultaneously preparing for critical near-term milestones, including our Phase 2 data readout of TPIP in PAH, and our anticipated FDA approval of brensocatib for bronchiectasis," said Will Lewis, Chair and Chief Executive Officer of Insmed. "Against the backdrop of an evolving regulatory environment, brensocatib's FDA review process remains on track, and we are relentlessly focused on preparing for a frictionless launch for the patients counting on us to succeed. This momentum is anticipated to continue as we expect to unveil data from our Phase 2 BiRCh study of brensocatib in chronic rhinosinusitis without nasal polyps by year-end 2025 and our Phase 3 ENCORE study of ARIKAYCE in all MAC lung disease patients in the first half of 2026. As I reflect on these upcoming catalysts, I couldn't be prouder of the Insmed team working tirelessly to achieve our ambitious vision."

Recent Progress and Anticipated Milestones by Program:

ARIKAYCE

- ARIKAYCE global revenue grew 23% in the first quarter of 2025 compared to the first quarter of 2024, reflecting double-digit year-over-year growth in the U.S., Japan, and Europe.
- The Company anticipates the topline readout of the Phase 3 ENCORE trial in the first half of 2026 in patients with newly diagnosed or recurrent *Mycobacterium avium* complex (MAC) lung disease who have not started antibiotics, which will include the change from baseline in respiratory symptom score at Month 13 and the percentage of patients achieving durable culture conversion at Month 15.
- The Company plans to submit a supplementary new drug application (sNDA) to the U.S. Food and Drug Administration (FDA) for ARIKAYCE in all patients with MAC lung disease in the U.S. in the second half of 2026.

Brensocatib

- In February 2025, the FDA accepted the Company's New Drug Application (NDA) for brensocatib for patients with bronchiectasis, granting the application Priority Review designation with a Prescription Drug User Fee Act (PDUFA) target action date of August 12, 2025. If approved, Insmed expects to immediately launch brensocatib in the U.S.
- Regulatory submissions for brensocatib in the EU and UK have been accepted, with submission in Japan planned for 2025. Insmed anticipates commercial launches for each territory in 2026, pending approval.
- Insmed completed enrollment in the Phase 2b BiRCh study of brensocatib in patients with chronic rhinosinusitis without

nasal polyps (CRSsNP) with 288 patients. The Company remains on track to report topline results by the end of 2025.
- The Company continues to enroll patients in the Phase 2b CEDAR study of brensocatib in patients with hidradenitis suppurativa (HS). Based on current enrollment rates, the Company anticipates the interim futility analysis from the first 100 patients to complete Week 16 of the trial in the first half of 2026.

TPIP

- Insmed completed the Phase 2b study of treprostinil palmitil inhalation powder (TPIP) in pulmonary arterial hypertension (PAH), with topline data anticipated in June of 2025.
- The Company plans to initiate a Phase 3 study of TPIP in patients with pulmonary hypertension associated with interstitial lung disease (PH-ILD) in the second half of 2025.

Gene Therapy

- Insmed initiated the Phase 1 ASCEND clinical study of INS1201, an intrathecally-delivered gene therapy for patients with Duchenne muscular dystrophy (DMD), in the first quarter of 2025, and expects to dose the first patient in the second quarter of 2025.
- The Company's next two gene therapy candidates, which target amyotrophic lateral sclerosis (ALS) and Stargardt disease, are currently advancing toward the clinic.

Pre-Clinical Programs

- Insmed's 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 for the indications being pursued.
- The Company anticipates submitting an average of one to two INDs per year from its pre-clinical research programs.
- Insmed continues to anticipate that the totality of its pre-clinical research programs will comprise less than 20% of overall expenditures.

Corporate Updates

- In April 2025, data from the Phase 3 ASPEN study of brensocatib in patients with bronchiectasis were published in the *New England Journal of Medicine*.
- In April 2025, the Company issued a notice of redemption for all $569.5 million aggregate principal amount of its remaining outstanding 0.75% Convertible Senior Notes Due 2028, with a redemption date of June 6, 2025.
- Insmed plans to present eleven abstracts from across its respiratory portfolio (ARIKAYCE, brensocatib, and TPIP) at the American Thoracic Society (ATS) 2025 International Conference, taking place May 18-21, 2025.
- Insmed intends to expand its U.S. manufacturing footprint and has a project underway to establish a secondary source of brensocatib manufacturing in the U.S.

First-Quarter 2025 Financial Results

- The following table summarizes first-quarter 2025 and 2024 revenues and revenue growth for ARIKAYCE across all commercial regions:

	Three Months Ended March 31,		
(in millions)	**2025**	**2024**	**Growth**
U.S.	$64.3	$56.3	14.1 %
Japan	22.1	14.9	48.3 %
Europe & Rest of World	6.5	4.3	51.8 %
Total Revenues	**$92.8**	**$75.5**	**22.9 %**

- Cost of product revenues (excluding amortization of intangibles) was $21.3 million for the first quarter of 2025, compared to $17.5 million for the first quarter of 2024. The increase in cost of product revenues primarily reflects growth in ARIKAYCE sales.
- Research and development (R&D) expenses were $152.6 million for the first quarter of 2025, compared to $121.1 million for the first quarter of 2024. The increase in R&D expenses was primarily related to increases in compensation and benefit-related expenses and stock-based compensation costs, due to an increase in headcount, as well as an increase in manufacturing expenses.
- Selling, general and administrative (SG&A) expenses for the first quarter of 2025 were $147.5 million, compared to $93.1 million for the first quarter of 2024. The increase in SG&A expenses was primarily related to increases in compensation and benefit-related expenses, as well as stock-based compensation costs, predominantly due to an increase in headcount

in preparation for the anticipated launch of brensocatib in the U.S., pending regulatory approval.
- For the first quarter of 2025, Insmed reported a net loss of $256.6 million, or $1.42 per share, compared to a net loss of $157.1 million, or $1.06 per share, for the first quarter of 2024.

Balance Sheet, Financial Guidance, and Planned Investments

- As of March 31, 2025, Insmed had cash, cash equivalents, and marketable securities totaling approximately $1.2 billion.
- Insmed continues to anticipate full-year 2025 global ARIKAYCE revenues in the range of $405 million to $425 million, representing between 11% and 17% year-over-year growth compared to 2024.
- The Company plans to continue to invest in the following key activities in 2025:

  (i) commercialization and expansion of ARIKAYCE globally;

  (ii) commercial launch of brensocatib in the U.S., if approved, with advancement of regulatory submissions and interactions in the EU, UK, and Japan;

  (iii) advancement of clinical trial programs for brensocatib, including the ongoing Phase 2b BiRCh study in patients with CRSsNP and the Phase 2b CEDAR study in patients with HS;

  (iv) advancement of the Phase 3 ENCORE study 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 disease;

  (v) advancement of the clinical development programs for TPIP, including the Phase 2b study in patients with PAH and the initiation of a Phase 3 study in patients with PH-ILD;

  (vi) advancement of the Phase 1 ASCEND study for INS1201 in DMD; and

  (vii) continued development of its pre-clinical research programs.

Conference Call

Insmed will host a conference call beginning today, May 8, 2025, 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 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 May 15, 2025, 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 March 31,	
	2025	**2024**
Product revenues, net	$ 92,823	$ 75,500
Operating expenses:		
Cost of product revenues (excluding amortization of intangible assets)	21,278	17,457
Research and development	152,577	121,083
Selling, general and administrative	147,545	93,102
Amortization of intangible assets	1,263	1,263
Change in fair value of deferred and contingent consideration liabilities	18,300	(11,900)
Total operating expenses	340,963	221,005
Operating loss	(248,140)	(145,505)
Investment income	13,906	8,783
Interest expense	(21,569)	(21,042)
Change in fair value of interest rate swap	-	2,362
Other income (expense), net	132	(1,100)

Loss before income taxes	(255,671)	(156,502)
Provision for income taxes	912	589
Net loss	$ (256,583)	$ (157,091)
Basic and diluted net loss per share	$ (1.42)	$ (1.06)
Weighted average basic and diluted common shares outstanding	180,860	148,456

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

	As of March 31, 2025 (unaudited)	As of December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 403,247	$ 555,030
Marketable securities	796,204	878,796
Accounts receivable	47,746	52,012
Inventory	100,713	98,578
Prepaid expenses and other current assets	54,782	37,245
Total current assets	1,402,692	1,621,661
Fixed assets, net	88,358	80,052
Finance lease right-of-use assets	17,595	18,273
Operating lease right-of-use assets	10,832	17,257
Intangibles, net	57,389	58,652
Goodwill	136,110	136,110
Other assets	89,759	93,226
Total assets	$ 1,802,735	$ 2,025,231
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 232,674	$ 285,209
Finance lease liabilities	3,054	2,961
Operating lease liabilities	3,505	9,358
Total current liabilities	239,233	297,528
Debt, long-term	1,105,068	1,103,382
Royalty financing agreement	162,508	161,067
Contingent consideration	159,900	144,200
Finance lease liabilities, long-term	23,266	24,064
Operating lease liabilities, long-term	8,480	9,112
Other long-term liabilities	5,121	499
Total liabilities	1,703,576	1,739,852
Shareholders' equity:		
Common stock, $0.01 par value; 500,000,000 authorized shares, 181,900,074 and 179,382,635 issued and outstanding shares at March 31, 2025 and December 31, 2024, respectively	1,819	1,794
Additional paid-in capital	4,714,742	4,645,791
Accumulated deficit	(4,616,500)	(4,359,917)

Accumulated other comprehensive loss	(902)	(2,289)
Total shareholders' equity	99,159	285,379
Total liabilities and shareholders' equity	$ 1,802,735	$ 2,025,231

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, chronic rhinosinusitis without nasal polyps, hidradenitis suppurativa, 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 pulmonary arterial hypertension (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.

About INS1201

INS1201 is an investigational micro-dystrophin adeno-associated virus gene replacement therapy that Insmed is developing as a potential treatment for patients with Duchenne muscular dystrophy. Administered intrathecally, this approach has the potential to target both skeletal and cardiac muscles at lower doses. INS1201 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 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 U.S., 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 U.S., 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, TPIP or our other product candidates 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, TPIP or our other product candidates, or acceptable prices for ARIKAYCE or, if approved, 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; 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 LP 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 or 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; failure to successfully predict the time and cost of development, regulatory approval and commercialization for novel gene therapy products; 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 will not be 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 U.S., 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, 2024 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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