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# Insmed Reports First Quarter 2023 Financial Results and Provides Business Update

*—Enrollment Complete in Phase 3 ASPEN Trial of Brensocatib in Adult Patients with Bronchiectasis; Topline Data Readout on Track for Second Quarter of 2024—*

*—Company to Provide Detailed Update on Early-Stage Research Programs on May 8, 2023—*

*—Company on Track to Share Topline Data from Post-Marketing ARISE Study of ARIKAYCE® (amikacin liposome inhalation suspension) in Third Quarter of 2023—*

*—ARIKAYCE Total Revenue of \$65.2 Million for the First Quarter of 2023, Reflecting 23% Annual Growth Over the First Quarter of 2022—*

*—Company Reaffirms Full-Year 2023 Guidance for Global ARIKAYCE Revenues of Between \$285 Million and \$300 Million—*

BRIDGEWATER, N.J., May 4, 2023 [/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 first quarter ended March 31, 2023 and provided a business update.

"Insmed began 2023 with solid momentum, demonstrated by a strong quarter of global revenues from our commercial business and continued execution of our clinical development pipeline of mid-to-late-stage assets," commented Will Lewis, Chair and Chief Executive Officer of Insmed. "In the first quarter, we achieved our goal of enrollment completion of adult patients in the Phase 3 ASPEN trial. The pace of enrollment and widespread geographic reach of this study speak to the global enthusiasm for this program as well as the tireless efforts of the Insmed teams that facilitated this significant accomplishment. In parallel, we also continue to advance our early-stage research efforts. I am tremendously excited to debut several components of our early-stage platforms at our upcoming research day, including the indications, development candidates, proprietary technologies, and preclinical data to support our efforts. Importantly, the event will also allow us to showcase some of the Insmed team leaders who are driving innovation in the treatment of serious and rare diseases."

## Recent Pillar Highlights

### ***Pillar 1: ARIKAYCE***

- ARIKAYCE global revenue grew 23% in the first quarter of 2023 compared with the first quarter of 2022, reflecting strong performance in the U.S., as well as the ongoing launches in Japan and Europe.
- Insmed continues to advance the post-marketing, confirmatory trial program for ARIKAYCE, consisting of the ARISE and ENCORE trials in patients with newly diagnosed or recurrent *Mycobacterium avium* complex (MAC) lung infection who have not started antibiotics. Insmed continues to anticipate sharing topline efficacy and safety data from the ARISE study in the third quarter of 2023 and completing enrollment in the ENCORE study by the end of 2023.

### ***Pillar 2: Brensocatib***

- Enrollment has been completed in over 1,700 adult patients across nearly 40 countries in the pivotal ASPEN study, a global Phase 3 trial designed to assess the efficacy, safety, and tolerability of brensocatib in bronchiectasis. Insmed continues to expect the topline data readout from the ASPEN study in the second quarter of 2024.
- Baseline characteristics for evaluable adult patients enrolled in the ASPEN study were made available this morning and can be found at [https://investor.insmed.com/download/ASPEN\\_Baseline.pdf](https://investor.insmed.com/download/ASPEN_Baseline.pdf). The preliminary comparison to the respective baseline characteristics from the Phase 2 WILLOW study demonstrates a broadly similar baseline profile for participants in both studies across key metrics.

- Due to the rapid enrollment of ASPEN, Insmed expects the pace of enrollment of its planned Phase 2 study of brensocatib in patients with chronic rhinosinusitis without nasal polyps (CRSsNP) to be stronger than previously expected. For that reason, Insmed has chosen to adjust the initiation timing of the CRSsNP study from mid-2023 to the fourth quarter of 2023, which has the added benefit of reducing near-term cash deployment.

### ***Pillar 3: TPIP***

- Insmed is currently enrolling a Phase 2 study of treprostinil palmitil inhalation powder (TPIP) in patients with pulmonary hypertension associated with interstitial lung disease (PH-ILD) and a Phase 2 study in patients with pulmonary arterial hypertension (PAH).
- The Company continues to anticipate sharing interim, blinded dose titration and safety and tolerability data from both the PH-ILD and PAH studies in the second half of 2023, pending the rate of enrollment. Topline results from the PH-ILD study are on track to be shared in the first half of 2024.

### ***Pillar 4: Early-Stage Research***

- On May 8, 2023, Insmed plans to provide a detailed update on its early-stage research portfolio, encompassing artificial intelligence (AI)-driven protein engineering, gene therapy, and protein manufacturing. The Company will provide an in-depth introduction to several of its early-stage programs as well as the experts leading each of these research engines. The event, titled "The Future of Rare at Insmed: Functional Genes, AI-Enhanced Proteins, Glowing Algae, and More," will be held in New York and will also be webcast live.
- As previously shared, Insmed anticipates having at least six investigational new drug (IND) applications filed from this portfolio by the end of 2025.
- The Company expects to initiate a Phase 1/2 study of its first gene therapy candidate in the second half of 2023 and anticipates sharing early clinical data from that program in the first half of 2024.

### **Corporate Updates**

- In April 2023, Insmed appointed Makoto Nakamura to the role of General Manager in Japan, where he will oversee commercial operations for ARIKAYCE and support the preparation of potential future product launches in the country. Mr. Nakamura has extensive experience leading commercial divisions in Japan for global pharmaceutical companies including Gilead Sciences and Pfizer, Inc.

### **First-Quarter 2023 Financial Results**

- Total revenue for the first quarter ended March 31, 2023, was \$65.2 million, reflecting 23% year-over-year growth compared to total revenue of \$53.1 million for the first quarter of 2022.
- Total revenue for the first quarter of 2023 was comprised of ARIKAYCE net sales of \$49.1 million in the U.S., \$13.2 million in Japan, and \$3.0 million in Europe and rest of world, reflecting 20% and 23% year-over-year growth in the U.S. and Japan, respectively.
- Cost of product revenues (excluding amortization of intangibles) was \$13.8 million for the first quarter of 2023, compared to \$12.2 million for the first quarter of 2022.
- Research and development (R&D) expenses were \$127.9 million for the first quarter of 2023, compared to \$84.4 million for the first quarter of 2022 and \$124.8 million for the fourth quarter of 2022. The increase in R&D expenses compared to fourth-quarter 2022 was driven by a non-cash charge of \$10.3 million related to the acquisition of Vertuis Bio, Inc. in January 2023.
- Selling, general and administrative (SG&A) expenses for the first quarter of 2023 were \$79.9 million, compared to \$56.7 million for the first quarter of 2022 and \$73.5 million for the fourth quarter of 2022. The modest increase in SG&A expenses compared to fourth-quarter 2022 primarily reflects additional investments in launch readiness activities.
- Insmed reported a net loss of \$159.8 million, or \$1.17 per share, for the first quarter of 2023, compared to a net loss of \$94.6 million, or \$0.80 per share, for the first quarter of 2022, and a net loss of \$160.1 million, or \$1.21 per share, for the fourth quarter of 2022.

### **Balance Sheet, Financial Guidance, and Planned Investments**

- As of March 31, 2023, Insmed had cash, cash equivalents, and marketable securities totaling \$999 million, down from \$1.15 billion as of December 31, 2022. Higher cash burn in first-quarter 2023 was primarily driven by items that are not expected to recur in the remaining quarters of 2023, such as the annual employee incentive compensation payout.
- Insmed continues to expect full-year 2023 global revenues for ARIKAYCE to be between \$285 million and \$300 million.
- Insmed continues to anticipate that over 80% of total 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 invest in the following key activities in 2023:
  - commercialization and expansion of ARIKAYCE globally;
  - advancement of brensocatib, including the Phase 3 ASPEN study in patients with bronchiectasis and commercial launch readiness activities, as well as development across additional neutrophil-mediated diseases;
  - advancement of the clinical trial program for ARIKAYCE (ARISE and ENCORE), 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;
  - advancement of its Phase 2 clinical development programs for TPIP; and
  - development of its early-stage research platforms.

## Conference Call

Insmmed 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 (833) 470-1428 (U.S.) or (929) 526-1599 (international) and referencing access code 468531. The call will also be webcast live on the Company's website at [www.insmed.com](http://www.insmed.com).

A replay of the conference call will be accessible approximately 30 minutes after its completion through June 3, 2023, by dialing (866) 813-9403 (U.S.) or (+44) 204-525-0658 (international) and referencing access code 281829. 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](http://www.insmed.com).

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

	<b>Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
Product revenues, net	\$ 65,214	\$ 53,107
Operating expenses:		
Cost of product revenues (excluding amortization of intangible assets)	13,830	12,191
Research and development	127,865	84,356
Selling, general and administrative	79,914	56,748
Amortization of intangible assets	1,263	1,263
Change in fair value of deferred and contingent consideration liabilities	(9,500)	(11,618)
Total operating expenses	213,372	142,940
Operating loss	(148,158)	(89,833)
Investment income	10,524	137
Interest expense	(20,003)	(3,291)
Change in fair value of interest rate swap	(1,533)	-
Other expense, net	(111)	(1,249)
Loss before income taxes	(159,281)	(94,236)
Provision for income taxes	483	385
Net loss	\$ (159,764)	\$ (94,621)
Basic and diluted net loss per share	\$ (1.17)	\$ (0.80)
Weighted average basic and diluted common shares outstanding	136,355	118,929

### INSMED INCORPORATED Consolidated Balance Sheets (in thousands, except per share and share data)

(in thousands, except par value and share data)

	As of March 31, 2023 (unaudited)	As of December 31, 2022
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 968,907	\$ 1,074,036
Marketable securities	29,774	74,244
Accounts receivable	30,523	29,713
Inventory	71,317	69,922
Prepaid expenses and other current assets	28,542	25,468
Total current assets	1,129,063	1,273,383
Fixed assets, net	59,556	56,491
Finance lease right-of-use assets	23,019	23,697
Operating lease right-of-use assets	21,154	21,894
Intangibles, net	67,493	68,756
Goodwill	136,110	136,110
Other assets	81,322	76,104
Total assets	\$ 1,517,717	\$ 1,656,435
<b>Liabilities and shareholders' equity</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 179,005	\$ 182,117
Finance lease liabilities	2,158	1,217
Operating lease liabilities	6,821	6,909
Total current liabilities	187,984	190,243
Debt, long-term	1,132,188	1,125,250
Royalty financing agreement	150,173	148,015
Contingent consideration	38,600	51,100
Finance lease liabilities, long-term	29,015	29,636
Operating lease liabilities, long-term	14,534	14,853
Other long-term liabilities	9,876	9,387
Total liabilities	1,562,370	1,568,484
Shareholders' equity:		
Common stock, \$0.01 par value; 500,000,000 authorized		
shares, 136,429,216 and 136,653,731 issued and outstanding	1,364	1,357
shares at March 31, 2023 and December 31, 2022, respectively	2,809,242	2,782,416
Additional paid-in capital	(2,856,342)	(2,696,578)
Accumulated deficit	1,083	756
Accumulated other comprehensive income	(44,653)	87,951
Total shareholders' (deficit) equity	\$ 1,517,717	\$ 1,656,435
Total liabilities and shareholders' equity		

## 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 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 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  $\geq 5\%$  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<sup>®</sup> 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](http://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 Insmmed**

Insmmed Incorporated is a global biopharmaceutical company on a mission to transform the lives of patients with serious and rare diseases. Insmmed'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 also progressing a robust pipeline of investigational therapies targeting areas of serious unmet need, including neutrophil-mediated inflammatory diseases and rare pulmonary disorders. Insmmed is headquartered in Bridgewater, New Jersey, with a footprint across Europe and in Japan. For more information, visit [www.insmed.com](http://www.insmed.com).

## **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 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; impact of the COVID-19 pandemic and efforts to reduce its spread on the Company's business, employees, including key personnel, patients, partners and suppliers; 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 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 U.S. Food and Drug Administration, including the risk that the Company will not successfully or in a timely manner complete the study to validate a patient reported outcome tool and 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 our 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 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, among other things; risks that the Company's clinical studies will be delayed or that serious side effects will be identified during drug development; 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; 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; 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; business disruptions or expenses related to the upgrade to the Company's enterprise resource planning system; 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, 2022 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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