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# Insmmed Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

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

*—Company to Share Robust Updates Across Early-Stage Programs at Research Day 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 \$59.3 Million for the Fourth Quarter and \$245.4 Million for the Full Year 2022, Reflecting 30% Annual Growth—*

BRIDGEWATER, N.J., Feb. 23, 2023 /PRNewswire/ -- Insmmed Incorporated (Nasdaq: INSM), a global biopharmaceutical company on a mission to transform the lives of patients with serious and rare diseases, today reported financial results for the fourth quarter and full year ended December 31, 2022 and provided a business update.

"Insmmed had a strong finish to 2022 as we rounded out a year of commercial and clinical execution that set the stage for what I believe will be the most meaningful period in our company's history," commented Will Lewis, Chair and Chief Executive Officer of Insmmed. "As we begin 2023, we are excited to share outputs from across our research and development programs that we hope will demonstrate clear benefit for patients with serious unmet medical needs. We expect that achieving this outcome will bolster the value of our pipeline and potentially enable us to grow from addressing tens of thousands of patients to more than a million. For example, with today's announcement that screening is complete in adult patients in the Phase 3 ASPEN study of brensocatib in bronchiectasis, we are well on our way toward reporting topline results in the second quarter of 2024 and potentially bringing this first-in-disease therapy to patients. Importantly, we are fully capitalized to achieve these milestones and more."

## Recent Pillar Highlights

### Pillar 1: ARIKAYCE

- ARIKAYCE global revenue grew 30% in 2022 compared with 2021, reflecting strong U.S. performance, the ongoing launch in Japan, and contributions from European markets.
- Insmmed continues to advance the development of ARIKAYCE in a frontline setting of patients with *Mycobacterium avium* complex (MAC) lung disease, consisting of the post-marketing confirmatory ARISE and ENCORE trials. Insmmed anticipates 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

- Patient screening has been completed in adult patients in the Phase 3 ASPEN study, a global, randomized, double-blind, placebo-controlled trial to assess the efficacy, safety, and tolerability of brensocatib in bronchiectasis. Insmmed continues to anticipate completing enrollment in this study in the first quarter of 2023 and sharing topline data in the second quarter of 2024.
- As previously shared, Insmmed plans to initiate a Phase 2 study of brensocatib in patients with chronic rhinosinusitis without nasal polyps (CRSsNP) in mid-2023. Subject to U.S. Food and Drug Administration input, the Company anticipates that the trial will enroll approximately 270 patients randomized to either 10 mg brensocatib, 40 mg brensocatib, or placebo over a 24-week treatment period, with a primary endpoint of change in daily sinus total symptom score.

### Pillar 3: TPIP

- Insmmed is currently enrolling two Phase 2 studies of treprostinil palmitil inhalation powder (TPIP), one in patients with pulmonary hypertension associated with interstitial lung disease (PH-ILD) and the other in patients with pulmonary arterial hypertension (PAH).
- The Company anticipates 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

- Insmmed plans to provide an update on its early-stage research portfolio, which encompasses gene therapy, artificial intelligence-driven protein engineering, and protein manufacturing, during an event on May 8, 2023. The event will take place in person in New York and will be webcast live. The Company will offer a deep dive into the various platforms comprising its research engine and an introduction to the experts leading these teams.
- As previously shared, Insmmed anticipates having at least six investigational new drug (IND) applications filed or Phase 1 studies underway from this portfolio by the end of 2025. The first IND is expected to be filed prior to the May 8 event.
- Insmmed anticipates sharing clinical data from a few of the earliest patients in a Phase 1/2 gene therapy study in a musculoskeletal disease in the first half of 2024.

## Fourth Quarter and Full-Year 2022 Financial Results

- Total revenue for the fourth quarter ended December 31, 2022, was \$59.3 million, compared to total revenue of \$56.1 million for the fourth quarter of 2021. Total revenue for the full year 2022 was \$245.4 million, compared to total revenue of \$188.5 million for the full year 2021.
- Total revenue for the full year 2022 comprised ARIKAYCE net sales of \$186.0 million in the U.S., \$56.5 million in Japan, and \$2.9 million in Europe and rest of world. In the fourth quarter of 2022, Insmmed reached an agreement with the French authorities on a final reimbursement price for the temporary authorization for use (Autorisation Temporaire d'Utilisation) program, which resulted in a change in estimate that reduced revenue by approximately \$7.5 million in the fourth quarter of 2022, of which \$5.8 million related to periods prior to 2022.
- Cost of product revenues (excluding amortization of intangibles) was \$13.1 million for the fourth quarter of 2022, compared to \$13.3 million for the fourth quarter of 2021. For the full year 2022, cost of product revenues (excluding amortization of intangibles) was \$55.1 million compared to \$44.2 million in 2021.
- Research and development (R&D) expenses were \$124.8 million for the fourth quarter of 2022, compared to \$76.4 million for the fourth quarter of 2021. For the full year 2022, R&D expenses were \$397.5 million compared to \$272.7 million in 2021.
- Selling, general and administrative (SG&A) expenses for the fourth quarter of 2022 were \$73.5 million, compared to \$65.3 million for the fourth quarter of 2021. For the full year 2022, SG&A expenses were \$265.8 million, compared to \$234.3 million in 2021.

- For the fourth quarter of 2022, Insmmed reported a net loss of \$160.1 million, or \$1.21 per share, compared to a net loss of \$113.0 million, or \$0.95 per share, for the fourth quarter of 2021. For the full year 2022, Insmmed reported a net loss of \$481.5 million, or \$3.91 per share, compared to a net loss of \$434.7 million, or \$3.88 per share, in 2021.

## Balance Sheet, Financial Guidance, and Planned Investments

- As of December 31, 2022, Insmmed had cash, cash equivalents, and marketable securities of \$1.15 billion.
- The Company's total operating expenses for the fourth quarter of 2022 were \$210.8 million and for the full year 2022 were \$702.7 million.
- Insmmed continues to expect full-year 2023 global revenues for ARIKAYCE to be between \$285 million and \$300 million.
- In 2023, Insmmed anticipates 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 confirmatory, frontline clinical trial program for ARIKAYCE (ARISE and ENCORE); and
  - advancement of its earlier-stage pipeline, including the 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 (844) 200-6205 (U.S.) or (929) 526-1599 (international) and referencing access code 397951. 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 March 25, 2023, by dialing (866) 813-9403 (U.S.) or (+44) 204-525-0658 (international) and referencing access code 828224. 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).

## 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. Insmmed'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 Insmmed 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 Insmmed'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® 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 Insmed

Insmed Incorporated is a global biopharmaceutical company on a mission to transform the lives of patients with serious and rare diseases. Insmed's first commercial product is a first-in-disease therapy approved in the United States, Europe, and Japan to treat a chronic, debilitating lung disease. The Company is also progressing a robust pipeline of investigational therapies targeting areas of serious unmet need, including neutrophil-mediated inflammatory diseases and rare pulmonary disorders. Insmed 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.

#### Financial Statements Follow

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
Product revenues, net	\$ 59,300	\$ 56,124	\$ 245,358	\$ 188,461
Operating expenses:				
Cost of product revenues (excluding amortization of intangible assets)	13,069	13,288	55,126	44,152
Research and development	124,763	76,352	397,518	272,744
Selling, general and administrative	73,479	65,266	265,784	234,273
Amortization of intangible assets	1,264	1,262	5,053	5,052
Change in fair value of deferred and contingent consideration liabilities	(1,800)	(966)	(20,802)	7,334
Total operating expenses	210,775	155,202	702,679	563,555
Operating loss	(151,475)	(99,078)	(457,321)	(375,094)
Investment income	8,318	61	11,081	174

Interest expense	(16,448)	(11,350)	(26,446)	(40,473)
Change in fair value of interest rate swap	(1,328)	-	(1,328)	-
Loss on extinguishment of debt	-	-	-	(17,689)
Other income (expense), net	1,130	(2,652)	(5,939)	(3,330)
Loss before income taxes	(159,998)	(113,019)	(480,151)	(436,412)
Provision (benefit) for income taxes	125	(41)	1,383	(1,758)
Net loss	<u>\$ (160,123)</u>	<u>\$ (112,978)</u>	<u>\$ (481,534)</u>	<u>\$ (434,654)</u>
Basic and diluted net loss per share	<u>\$ (1.21)</u>	<u>\$ (0.95)</u>	<u>\$ (3.91)</u>	<u>\$ (3.88)</u>
Weighted average basic and diluted common shares outstanding	<u>132,694</u>	<u>118,502</u>	<u>123,035</u>	<u>112,111</u>

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

	<u>As of</u> <u>December 31, 2022</u>	<u>As of</u> <u>December 31, 2021</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 1,074,036	\$ 716,782
Marketable securities	74,244	-
Accounts receivable	29,713	24,351
Inventory	69,922	67,009
Prepaid expenses and other current assets	25,468	28,898
Total current assets	<u>1,273,383</u>	<u>837,040</u>
Marketable securities, non-current	-	50,043
Fixed assets, net	56,491	52,955
Finance lease right-of-use assets	23,697	9,256
Operating lease right-of-use assets	21,894	33,305
Intangibles, net	68,756	73,809
Goodwill	136,110	136,110
Other assets	76,104	50,990
Total assets	<u>\$ 1,656,435</u>	<u>\$ 1,243,508</u>
<b>Liabilities and shareholders' equity</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 182,117	\$ 125,030
Finance lease liabilities	1,217	609
Operating lease liabilities	6,909	9,527
Total current liabilities	<u>190,243</u>	<u>135,166</u>
Debt, long-term	1,125,250	566,588
Royalty financing agreement	148,015	-
Contingent consideration	51,100	75,668
Finance lease liabilities, long-term	29,636	14,103
Operating lease liabilities, long-term	14,853	21,441
Other long-term liabilities	9,387	20,074
Total liabilities	<u>1,568,484</u>	<u>833,040</u>
Shareholders' equity:		
Common stock, \$0.01 par value; 500,000,000 authorized shares, 135,653,731 and 118,738,266 issued and outstanding shares at December 31, 2022 and December 31, 2021, respectively	1,357	1,187
Additional paid-in capital	2,782,416	2,673,556
Accumulated deficit	(2,696,578)	(2,265,243)
Accumulated other comprehensive income	756	968
Total shareholders' equity	<u>87,951</u>	<u>410,468</u>
Total liabilities and shareholders' equity	<u>\$ 1,656,435</u>	<u>\$ 1,243,508</u>

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