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# Insmmed Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Business and Pipeline Update

--ARIKAYCE® (amikacin liposome inhalation suspension) Total Revenue of \$56.1 Million for the Fourth Quarter and \$188.5 Million for the Full Year 2021; Anticipate at Least 30% Year Over Year Annual Growth for 2022--

--Enrollment Timelines Provided for Brensocatib Phase 3 ASPEN Study and ARIKAYCE Post-Marketing Studies (ARISE and ENCORE)--

--Planning to Advance Brensocatib in Two Additional Potential Indications: Chronic Rhinosinusitis without Nasal Polyps (CRS) and Hidradenitis Suppurativa (HS)--

--Cash Runway into 2024 to Support Company's Ongoing Programs--

BRIDGEWATER, N.J., Feb. 17, 2022 /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, 2021 and provided an update on the Company's business and pipeline.

"Insmmed made tremendous progress across our four pillars throughout 2021, and we begin 2022 from a position of strength, with seven ongoing clinical trials, commercial operations in three major territories, a pathway to ARIKAYCE growth, and a highly innovative research engine to identify what we believe to be the most promising next set of candidates," commented Will Lewis, Chair and Chief Executive Officer of Insmmed. "Importantly, our strong cash position will support advancement across our programs as we continue to lay the groundwork for what we believe will be a meaningful inflection point for the Company. I am enormously proud of our world-class team and what we have been able to achieve on behalf of patients with serious and rare diseases."

## Recent Corporate Developments & Program Highlights

### ARIKAYCE

- Insmmed launched ARIKAYCE in Japan in July of 2021, and early launch progress has been strong, with several positive trends.
- In Europe, ARIKAYCE has now been launched in Germany, the Netherlands, Wales, and Scotland. The Company is pursuing country-by-country reimbursement and launches throughout Europe, with a near-term focus on Italy, France, and England.
- Insmmed continues to advance the post-marketing confirmatory frontline clinical trial program of ARIKAYCE in patients with nontuberculous mycobacterial (NTM) lung disease caused by *Mycobacterium avium* complex (MAC). The ARISE trial, an interventional study designed to validate a patient-reported outcome (PRO) tool in MAC lung disease, is now 50% enrolled. The Company anticipates completing enrollment in the ARISE study in 2022 and having topline data in the first half of 2023. Insmmed anticipates completing enrollment in ENCORE, a pivotal study evaluating the clinical benefits and safety of ARIKAYCE in patients with newly diagnosed MAC lung disease using the PRO tool, by the end of 2023.

### Brensocatib

- The Phase 3 ASPEN study, a global, randomized, double-blind, placebo-controlled trial to assess the efficacy, safety, and tolerability of brensocatib in patients with bronchiectasis, is now 50% enrolled. Insmmed anticipates completing enrollment in this study in early 2023.
- A Phase 2 pharmacokinetic/pharmacodynamic study of brensocatib in patients with cystic fibrosis is underway and Insmmed anticipates sharing data from this study by early 2023.
- Insmmed plans to develop brensocatib in two additional neutrophil-mediated diseases – chronic rhinosinusitis without nasal polyps (CRS) and hidradenitis suppurativa (HS) – and to advance one indication into the clinic in 2022. Both CRS and HS are serious diseases in which patients today face significant unmet needs.

### TIPI

- Insmmed is advancing two Phase 2 studies of treprostinil palmitil inhalation powder (TIPI) in patients with pulmonary arterial hypertension (PAH). The Phase 2a study will measure the impact of TIPI on pulmonary vascular resistance (PVR) over a 24-hour period. The Company anticipates having preliminary data from a small number of patients in this study this year. The Phase 2b study will evaluate the effect of TIPI on PVR and 6-minute walk distance over a 16-week treatment period. As planned, site initiation for this study began in late 2021.
- Site initiation is underway for a Phase 2 study of TIPI in patients with pulmonary hypertension associated with interstitial lung disease (PH-ILD). This study will assess the safety and tolerability of TIPI over a 16-week treatment period.

### Translational Medicine

- Insmmed is advancing a translational medicine portfolio consisting of several technology programs running in parallel. The Company

anticipates filing an Investigational New Drug Application in a non-pulmonary indication for our first candidate from this portfolio by the end of 2022.

#### **Fourth Quarter and Full-Year 2021 Financial Results**

- Total revenue for the fourth quarter ended December 31, 2021 was \$56.1 million, compared to total revenue of \$41.4 million for the fourth quarter of 2020. Total revenue for the full year 2021 was \$188.5 million, compared to total revenue of \$164.4 million for the full year 2020.
- Total revenue for the full year 2021 comprised ARIKAYCE net sales of \$159.5 million in the U.S., \$16.0 million in Japan, and \$12.9 million in Europe and rest of world. This compares to net sales of \$157.5 million in the U.S. and \$6.9 million in Europe for the full year 2020.
- Cost of product revenues (excluding amortization of intangible assets) was \$13.3 million for the fourth quarter of 2021, compared to \$10.9 million for the fourth quarter of 2020. For the full year 2021, cost of product revenues (excluding amortization of intangible assets) was \$44.2 million compared to \$39.9 million in 2020.
- Research and development (R&D) expenses were \$76.4 million for the fourth quarter of 2021, compared to \$67.8 million for the fourth quarter of 2020. For the full year 2021, R&D expenses were \$272.7 million compared to \$181.2 million in 2020.
- Selling, general and administrative (SG&A) expenses for the fourth quarter of 2021 were \$65.3 million, compared to \$56.0 million for the fourth quarter of 2020. For the full year 2021, SG&A expenses were \$234.3 million, compared to \$203.6 million in 2020.
- For the fourth quarter of 2021, Insmmed reported a net loss of \$113.0 million, or \$0.95 per share, compared to a net loss of \$102.2 million, or \$1.00 per share, for the fourth quarter of 2020. For the full year 2021, Insmmed reported a net loss of \$434.7 million, or \$3.88 per share, compared to a net loss of \$294.1 million, or \$3.01 per share, in 2020.

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

As of December 31, 2021, Insmmed had cash and cash equivalents and marketable securities of \$766.8 million. The Company's total operating expenses for the fourth quarter of 2021 were \$155.2 million and for the full year 2021 were \$563.6 million.

Insmmed expects full-year 2022 revenues for ARIKAYCE to increase at least 30% year over year from 2021. The Company anticipates that its cash on hand will support its ongoing programs into 2024.

The Company plans to invest in the following key activities in 2022:

- (i) commercialization and expansion of ARIKAYCE globally;
- (ii) launch activities for ARIKAYCE in initial European countries and in Japan; and clinical trial activities, including (a) advancement of the frontline clinical trial program for ARIKAYCE (ARISE and ENCORE), (b) advancement of brensocaticib, including the Phase 3 ASPEN study in patients with bronchiectasis, (c) advancement of the Phase 2 clinical development programs of TPIP, and (d) advancement of our translational medicine efforts.

#### **Conference Call**

Insmmed will host a conference call beginning today at 8:00 AM Eastern Time. Shareholders and other interested parties may participate in the conference call by dialing (844) 200-6205 (U.S. toll free), (646) 904-5544 (U.S. local), or +1-929-526-1599 (international) and referencing access code 359415. 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 1 hour after its completion through March 17, 2022, by dialing (866) 813-9403 (U.S. toll free), (929) 458-6194 (U.S. local), or +44-204-525-0658 (international) and referencing access code 838814. 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<sup>®</sup> (amikacin liposome inhalation suspension), in Europe as ARIKAYCE<sup>®</sup> Liposomal 590 mg Nebuliser Dispersion, and in Japan as ARIKAYCE<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> Nebulizer System manufactured by PARI Pharma GmbH (PARI).

#### **About PARI Pharma and the Lamira<sup>®</sup> Nebulizer System**

ARIKAYCE is delivered by a novel inhalation device, the Lamira<sup>®</sup> Nebulizer System, developed by PARI. Lamira<sup>®</sup> 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 Brensocaticib**

Brensocaticib 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 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 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 growing 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 timing 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 regulatory approval for the Lamira<sup>®</sup> Nebulizer System and the drug delivery device for TPIP 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 does not prove effective or safe for patients in ongoing and future clinical studies, including the ASPEN study; risk that TPIP does not prove to be effective or safe for patients in ongoing and future clinical studies; 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 PRO 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 or the Company's 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 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; failure to comply with the Company's obligations in the Company's third party agreements; 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; 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 (ERP) 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, 2021 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,	
	2021	2020	2021	2020
Product revenues, net	\$ 56,124	\$ 41,415	\$ 188,461	\$ 164,413
Operating expenses:				

Cost of product revenues (excluding amortization of intangible assets)	13,288	10,862	44,152	39,872
Research and development	76,352	67,814	272,744	181,157
Selling, general and administrative	65,266	56,019	234,273	203,613
Amortization of intangible assets	1,262	1,258	5,052	5,003
Change in fair value of deferred and contingent consideration liabilities	(966)	-	7,334	-
Total operating expenses	<u>155,202</u>	<u>135,953</u>	<u>563,555</u>	<u>429,645</u>
Operating loss	(99,078)	(94,538)	(375,094)	(265,232)
Investment income	61	26	174	1,703
Interest expense	(11,350)	(7,499)	(40,473)	(29,564)
Loss on extinguishment of debt	-	-	(17,689)	-
Other (expense) income, net	(2,652)	419	(3,330)	405
Loss before income taxes	<u>(113,019)</u>	<u>(101,592)</u>	<u>(436,412)</u>	<u>(292,688)</u>
(Benefit) provision for income taxes	(41)	621	(1,758)	1,402
Net loss	<u>\$ (112,978)</u>	<u>\$ (102,213)</u>	<u>\$ (434,654)</u>	<u>\$ (294,090)</u>
Basic and diluted net loss per share	<u>\$ (0.95)</u>	<u>\$ (1.00)</u>	<u>\$ (3.88)</u>	<u>\$ (3.01)</u>
Weighted average basic and diluted common shares outstanding	<u>118,502</u>	<u>102,297</u>	<u>112,111</u>	<u>97,605</u>

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

	<u>As of</u> <u>December 31, 2021</u>	<u>As of</u> <u>December 31, 2020</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 716,782	\$ 532,756
Accounts receivable	24,351	16,562
Inventory	67,009	49,592
Prepaid expenses and other current assets	28,898	23,982
Total current assets	<u>837,040</u>	<u>622,892</u>
Marketable securities	50,043	-
Fixed assets, net	52,955	53,953
Finance lease right-of-use assets	9,256	10,334
Operating lease right-of-use assets	33,305	32,946
Intangibles, net	73,809	49,261
Goodwill	136,110	-
Other assets	50,990	26,769
Total assets	<u>\$ 1,243,508</u>	<u>\$ 796,155</u>
<b>Liabilities and shareholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 35,784	\$ 42,853
Accrued liabilities	60,665	37,807
Accrued compensation	28,581	25,591
Finance lease liabilities	609	1,081
Operating lease liabilities	9,527	11,475
Total current liabilities	<u>135,166</u>	<u>118,807</u>
Debt, long-term	566,588	356,318
Contingent consideration	75,668	-
Finance lease liabilities, long-term	14,103	14,713
Operating lease liabilities, long-term	21,441	21,255
Other long-term liabilities	20,074	9,178
Total liabilities	<u>833,040</u>	<u>520,271</u>

Shareholders' equity:		
Common stock, \$0.01 par value; 500,000,000 authorized shares, 118,738,266 and 102,763,060 issued and outstanding shares at December 31, 2021 and December 31, 2020, respectively	1,187	1,028
Additional paid-in capital	2,673,556	2,105,252
Accumulated deficit	(2,265,243)	(1,830,589)
Accumulated other comprehensive income	968	193
Total shareholders' equity	410,468	275,884
Total liabilities and shareholders' equity	\$ 1,243,508	\$ 796,155

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SOURCE Insmmed Incorporated

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