Insmed Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Business Update

--ARIKAYCE EU Launch Progresses, with Product Now Available and Reimbursed in Germany and the Netherlands--
--Frontline Clinical Trial Program of ARIKAYCE® (amikacin liposome inhalation suspension) in Nontuberculous Mycobacterial (NTM) Lung Disease Caused by Mycobacterium avium complex (MAC) Initiated in Q4 2020--
--Phase 3 ASPEN Study of Brensocatib in Bronchiectasis Initiated in Q4 2020--
--Topline Results from Phase 1 Study of Treprostinil Palmitil Inhalation Powder (TPIP) Support Continued Development with Once-Daily Dosing--
--ARIKAYCE Total Revenue of $164.4 Million for the Full Year 2020--

BRIDGEWATER, N.J., Feb. 25, 2021 /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 fourth quarter and full year ended December 31, 2020 and provided a business update.

"2020 was the most productive and significant year in Insmed's history, as we evolved from a single-product company with a successful U.S. launch to a truly global organization advancing three distinct, value-creating programs. I am incredibly proud of our team's performance, which is all the more exemplary against the backdrop of COVID-19," commented Will Lewis, Chair and Chief Executive Officer of Insmed. "In the fourth quarter, we initiated both the Phase 3 ASPEN study of brensocatib in patients with bronchiectasis and the ARIKAYCE frontline clinical trial program in patients with NTM lung disease caused by MAC; advanced our ARIKAYCE launch in Europe and prepared for a potential approval and launch in Japan while maintaining steady performance in the U.S.; and advanced the development of TPIP, for which we announced positive Phase 1 data just last week. We begin 2021 with incredible momentum and believe we have the capabilities and talent to achieve our ambitious vision."

Recent Corporate Developments & Program Highlights

ARIKAYCE

- ARIKAYCE has now been launched in both Germany and the Netherlands following approval by the European Commission in October 2020 for the treatment of NTM lung infections caused by MAC in adults with limited treatment options who do not have cystic fibrosis (CF). Consideration should be given to official guidance on the appropriate use of antibacterial agents. Insmed will continue to work to secure reimbursement and launch in other European markets throughout 2021 and into 2022.
- In Japan, Insmed continues to anticipate launching ARIKAYCE in mid-2021, pending approval by the Ministry of Health, Labour, and Welfare of our application for the treatment of patients with NTM lung disease caused by MAC who did not sufficiently respond to prior treatment.
- In December 2020, the first patient was dosed in the post-approval confirmatory frontline clinical trial program of ARIKAYCE in patients with NTM lung disease caused by MAC. The program consists of ARISE, an interventional study designed to validate a patient-reported outcome (PRO) tool in MAC lung disease, and ENCORE, a pivotal trial designed to establish, using the PRO tool validated in the ARISE trial, the clinical benefits and evaluate the safety of ARIKAYCE in patients with newly diagnosed MAC lung disease. More information on these studies is available at clinicaltrials.gov (ARISE: NCT04677543; ENCORE: NCT04677569).

Brensocatib

- In November 2020, the European Medicines Agency (EMA) granted Priority Medicines (PRIME) designation to brensocatib for the treatment of non-cystic fibrosis bronchiectasis (NCFBE), recognizing the potential for brensocatib to offer a new treatment approach for patients with bronchiectasis.
- In December 2020, the first patient was dosed in the Phase 3 ASPEN study of brensocatib in patients with bronchiectasis. ASPEN is a global, randomized, double-blind, placebo-controlled Phase 3 study to assess the efficacy, safety, and tolerability of brensocatib in patients with bronchiectasis. Patients with bronchiectasis due to CF may not be enrolled in the study. More information on this study is available at clinicaltrials.gov (NCT04594369).
- Insmed plans to initiate a Phase 2 pharmacokinetic multiple-dose study of brensocatib in patients with CF by mid-2021.
- Insmed anticipates that topline data from STOP-COVID19, the investigator-initiated trial of brensocatib in hospitalized patients with COVID-19, will be shared by early Q2 2021.

TPIP

- Insmed has completed the Phase 1 healthy volunteer trial designed to assess the pharmacokinetics and tolerability profile of TPIP. As reported on February 19, 2021, data from the study demonstrated that TPIP was generally well tolerated, with a pharmacokinetic profile that supports continued development with once-daily dosing. Insmed plans to present full data from this study at an upcoming medical meeting.
- Insmed plans to advance the development of TPIP with two parallel studies in patients with pulmonary arterial hypertension (PAH). One is an open-label, proof-of-mechanism study to understand the impact of TPIP on pulmonary vascular resistance (PVR) over a 24-hour period. The Company anticipates sharing topline data from this study in the second half of 2021. The other study will aim to investigate the effect of TPIP on PVR and 6-minute walk distance over a 16-week treatment period using an up-titration, once-daily dosing schedule. The Company plans to initiate this trial in the fourth quarter of 2021.
- The Company also plans to initiate a study of TPIP in patients with pulmonary hypertension associated with interstitial lung disease (PH-ILD).

Fourth Quarter and Full-Year 2020 Financial Results

- Total revenue for the fourth quarter ended December 31, 2020 was $41.4 million, compared to total revenue of $45.7 million for the fourth quarter of 2019. Total revenue for the full year 2020 was $164.4 million, compared to total revenue of $136.5 million for the full year 2019.
- Cost of product revenues (excluding amortization of intangible assets) was $10.9 million for the fourth quarter of 2020, compared to $8.7 million for the fourth quarter of 2019. For the full year 2020, cost of product revenues was $39.9 million compared to $24.2 million in 2019.
- Research and development (R&D) expenses were $67.8 million for the fourth quarter of 2020, compared to $32.6 million for the fourth quarter of 2019. For the full year 2020, R&D expenses were $181.2 million compared to $131.7 million in 2019.
- Selling, general and administrative (SG&A) expenses for the fourth quarter of 2020 were $56.0 million, compared to $50.2 million for the fourth quarter of 2019. For the full year 2020, SG&A expenses were $203.6 million, compared to $210.8 million in 2019.
- For the fourth quarter of 2020, Insmed reported a GAAP net loss of $102.2 million, or $1.00 per share, compared to a GAAP net loss of $53.0 million, or $0.59 per share, for the fourth quarter of 2019. For the full year 2020, Insmed reported a GAAP net loss of $294.1 million, or $3.01 per share, compared to a GAAP net loss of $254.3 million, or $3.01 per share, in 2019.

Balance Sheet and Planned Investments

As of December 31, 2020, Insmed had cash and cash equivalents of $532.8 million. The Company's total operating expenses for the fourth quarter of 2020 were $136.0 million and for the full year 2020 were $429.6 million. Adjusted R&D expenses for the fourth quarter of 2020 were $63.6 million and for the full year 2020 were $164.6 million. Adjusted SG&A expenses for the fourth quarter were $49.1 million and for the full year 2020 were $174.8 million. Adjusted R&D expenses and adjusted SG&A expenses are non-GAAP measures, which we describe further below.

The Company plans to invest in the following key activities in 2021:

(i) U.S. commercialization of ARIKAYCE;
(ii) clinical trial activities, including (a) advancement of the frontline clinical trial program for ARIKAYCE (ARISE and ENCORE), (b) advancement of the Phase 3 ASPEN study of brensocatib in patients with bronchiectasis, (c) advancement of clinical development of TPIP, and (d) the advancement of our earlier-stage research pipeline; and
(iii) launch activities for ARIKAYCE in initial European countries and potential launch activities for ARIKAYCE in Japan.

Conference Call

Insmed 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) 340-0284 (domestic) or (236) 712-2425 (international) and referencing conference ID number 4261618. The call will also be webcast live on the company's website at www.insmed.com.

A replay of the conference call will be accessible approximately two hours after its completion through March 27, 2021 by dialing (800) 585-8367 (domestic) or (416) 621-4642 (international) and referencing conference ID number 4261618. 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.

Non-GAAP Financial Measures

In addition to the U.S. generally accepted accounting principles (GAAP) results, this earnings release includes non-GAAP financial measures: adjusted R&D expenses, which Insmed defines as R&D expenses less stock-based compensation expense and depreciation; and adjusted SG&A expenses, which Insmed defines as SG&A expenses less stock-based compensation, depreciation, and certain milestones related to ARIKAYCE, which are payable under our amended agreements with Cystic Fibrosis Foundation Therapeutics, Inc. (CFFT). A reconciliation of these non-GAAP financial measures to their most directly comparable GAAP financial measure is presented in the table attached to this press release.

Management believes that these non-GAAP financial measures are useful to both management and investors in analyzing our ongoing business and operating performance. Management believes that providing this non-GAAP information to investors, in addition to the GAAP results, allows investors to view our financial results in the way that management views financial results. Management does not intend the presentation of these non-GAAP financial measures to be considered in isolation or as a substitute for results prepared in accordance with GAAP. In addition, these non-GAAP financial measures may differ from similarly named measures used by other companies.

About ARIKAYCE

ARIKAYCE is approved in the United States as ARIKAYCE® (amikacin liposome inhalation suspension) and in the EU as ARIKAYCE® Liposomal 590 mg Nebuliser Dispersion. 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 non-cystic fibrosis bronchiectasis (NCFBE) 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 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 ≥5% for patients using ARIKAYCE plus background regimen compared to patients treated with background regimen alone were dysphonia (47% vs 1%), cough (39% vs 17%), bronchospasm (29% vs 11%), hemoptysis (18% vs 13%), ototoxicity (17% vs 10%), upper airway irritation (17% vs 2%), musculoskeletal pain (17% vs 8%), fatigue and asthenia (16% vs 10%), exacerbation of underlying pulmonary disease (15% vs 10%), diarrhea (13% vs 5%), nausea (12% vs 4%), pneumonia (10% vs 8%), headache (10% vs 5%), pyrexia (7% vs 5%), vomiting (7% vs 4%), rash (6% vs 2%), decreased weight (6% vs 1%), change in sputum (5% vs 1%), and chest discomfort (5% vs 3%).

Drug Interactions: Avoid concomitant use of ARIKAYCE with medications associated with neurotoxicity, nephrotoxicity, and ototoxicity. Some diuretics can enhance aminoglycoside toxicity by altering aminoglycoside concentrations in serum and tissue. Avoid concomitant use of ARIKAYCE with ethacrynic acid, furosemide, urea, or intravenous mannitol.

Overdosage: Adverse reactions specifically associated with overdose of ARIKAYCE have not been identified. Acute toxicity should be treated with immediate withdrawal of ARIKAYCE, and baseline tests of renal function should be undertaken. Hemodialysis may be helpful in

removing amikacin from the body. In all cases of suspected overdosage, physicians should contact the Regional Poison Control Center for information about effective treatment.

U.S. INDICATION

LIMITED POPULATION: ARIKAYCE® is indicated in adults, who have limited or no alternative treatment options, for the treatment of *Mycobacterium avium* complex (MAC) lung disease as part of a combination antibacterial drug regimen in patients who do not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy. As only limited clinical safety and effectiveness data for ARIKAYCE are currently available, reserve ARIKAYCE for use in adults who have limited or no alternative treatment options. This drug is indicated for use in a limited and specific population of patients.

This indication is approved under accelerated approval based on achieving sputum culture conversion (defined as 3 consecutive negative monthly sputum cultures) by Month 6. Clinical benefit has not yet been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Limitation of Use: ARIKAYCE has only been studied in patients with refractory MAC lung disease defined as patients who did not achieve negative sputum cultures after a minimum of 6 consecutive months of a multidrug background regimen therapy. The use of ARIKAYCE is not recommended for patients with non-refractory MAC lung disease.

Patients are encouraged to report negative side effects of prescription drugs to the FDA. Visit **www.fda.gov/medwatch**, or call 1–800–FDA–1088. You can also call the Company at 1-844-4-INSMED.

Please see Full Prescribing Information.

About Insmed

Insmed Incorporated is a 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 and the European Union 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.

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. or Europe, or for the Company's product candidates in the U.S., Europe, Japan or other markets; failure to successfully commercialize ARIKAYCE, the Company's only approved product, in the U.S. or Europe (amikacin liposome inhalation suspension and Liposomal 590 mg Nebuliser Dispersion, respectively), or to maintain U.S. or European approval for ARIKAYCE; business or economic disruptions due to catastrophes or other events, including natural disasters or public health crises; impact of the novel coronavirus (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 timely and successfully complete the study to validate a PRO tool and the confirmatory post-marketing study required for full approval of ARIKAYCE; inability of the Company, PARI Pharma GmbH (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 or its 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; 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 our 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 adapt to its highly competitive and changing environment; 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 its 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; 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; 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, 2020 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 and Reconciliation 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,	
	2020	**2019**	**2020**	**2019**
Product revenues, net	$ 41,415	$ 45,708	$ 164,413	$ 136,467
Operating expenses:				
Cost of product revenues (excluding amortization of intangible assets)	10,862	8,706	39,872	24,212
Research and development	67,814	32,630	181,157	131,711
Selling, general and administrative	56,019	50,206	203,613	210,796
Amortization of intangible assets	1,258	1,248	5,003	4,993
Total operating expenses	135,953	92,790	429,645	371,712
Operating loss	(94,538)	(47,082)	(265,232)	(235,245)
Investment income	26	2,042	1,703	9,921
Interest expense	(7,499)	(7,348)	(29,564)	(27,705)
Other income (expense), net	419	(276)	405	(531)
Loss before income taxes	(101,592)	(52,664)	(292,688)	(253,560)
Provision for income taxes	621	324	1,402	777
Net loss	$ (102,213)	$ (52,988)	$ (294,090)	$ (254,337)
Basic and diluted net loss per share	$ (1.00)	$ (0.59)	$ (3.01)	$ (3.01)
Weighted average basic and diluted common shares outstanding	102,297	89,466	97,605	84,560

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

	As of December 31, 2020	As of December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 532,756	$ 487,429
Accounts receivable	16,562	19,232
Inventory	49,592	28,313
Prepaid expenses and other current assets	23,982	20,220
Total current assets	622,892	555,194
Intangibles, net	49,261	53,682
Fixed assets, net	53,953	60,180
Finance lease right-of-use assets	10,334	15,256
Operating lease right-of-use assets	32,946	37,673
Other assets	26,769	20,314
Total assets	$ 796,155	$ 742,299
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 42,853	$ 13,184
Accrued expenses	37,807	40,375

Accrued compensation	25,591	19,140
Finance lease liabilities	1,081	1,221
Operating lease liabilities	11,475	11,040
Other current liabilities	-	280
Total current liabilities	118,807	85,240
Debt, long-term	356,318	335,940
Finance lease liabilities, long-term	14,713	19,529
Operating lease liabilities, long-term	21,255	29,308
Other long-term liabilities	9,178	10,608
Total liabilities	520,271	480,625
Shareholders' equity:		
Common stock, $0.01 par value; 500,000,000 authorized shares, 102,763,060 and 89,682,387 issued and outstanding shares at December 31, 2020 and December 31, 2019, respectively	1,028	897
Additional paid-in capital	2,105,252	1,797,286
Accumulated deficit	(1,830,589)	(1,536,499)
Accumulated other comprehensive income (loss)	193	(10)
Total shareholders' equity	275,884	261,674
Total liabilities and shareholders' equity	$ 796,155	$ 742,299

INSMED INCORPORATED
Reconciliation of GAAP to Non-GAAP Results
(in thousands)
(unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	**2019**	**2020**	**2019**
GAAP research and development	$ 67,814	$ 32,630	$ 181,157	$ 131,711
Stock-based compensation expense	(3,010)	(1,630)	(11,789)	(8,210)
Depreciation	(1,205)	(883)	(4,751)	(2,695)
Adjusted R&D expenses (non-GAAP)	$ 63,599	$ 30,117	$ 164,617	$ 120,806
GAAP selling, general and administrative	$ 56,019	$ 50,206	$ 203,613	$ 210,796
Stock-based compensation expense	(5,769)	(4,258)	(24,369)	(18,761)
Depreciation	(1,113)	(1,056)	(4,396)	(2,493)
CFFT milestone payments	-	-	-	(10,249)
Adjusted SG&A expenses (non-GAAP)	$ 49,137	$ 44,892	$ 174,848	$ 179,293

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