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Insmed Reports First Quarter 2021 Financial Results and Provides Business Update

--ARIKAYCE® (amikacin liposome inhalation suspension) Approved in Japan for Patients with NTM Lung Disease Caused by MAC Who Did Not Sufficiently Respond to Prior Treatment with a Multidrug Regimen--
--ARIKAYCE European Launch Under Way with Commercial Sales in Germany and the Netherlands--
--Enrollment Progresses in Phase 3 ASPEN Study of Brensocatib in Patients with Bronchiectasis and in Post-Marketing ARISE and ENCORE Studies of ARIKAYCE in Frontline NTM Lung Disease Caused by MAC--
--Treprostinil Palmitil Inhalation Powder (TPIP) Advancing to Phase 2 Development in Pulmonary Arterial Hypertension (PAH)--
--ARIKAYCE Total Revenue of \$40.2 Million for the First Quarter 2021--

BRIDGEWATER, N.J., May 6, 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 first quarter ended March 31, 2021 and provided a business update.

"Insmed is off to a strong start in 2021, with important advancements across each of our three programs and our earlier-stage research activities, as well as meaningful progress in the buildout of our global organization," commented Will Lewis, Chair and Chief Executive Officer of Insmed. "In the first quarter of the year, we were very pleased to secure approval of ARIKAYCE in Japan—the third major territory where our lead product is now approved. Despite the ongoing challenges of COVID-19, we demonstrated steady ARIKAYCE performance in the U.S. and advanced our European launch. We continue to enroll patients in 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, and are working to advance TPIP to Phase 2 clinical development. I am very proud of the Insmed team's steadfast dedication to the ambitious patient-centered vision we have set for this company."

Recent Corporate Developments & Program Highlights

ARIKAYCE

- ARIKAYCE was granted approval by Japan's Ministry of Health, Labour, and Welfare on March 23, 2021, for the treatment of patients with nontuberculous mycobacterial (NTM) lung disease caused by *Mycobacterium avium* complex (MAC) who did not sufficiently respond to prior treatment with a multidrug regimen. The launch of ARIKAYCE in Japan is anticipated in mid-2021.
- Insmed continues to advance the European launch of ARIKAYCE following its approval by the European Commission in October of 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. ARIKAYCE has been launched in both Germany and the Netherlands, at a price in line with the U.S. list price.
- Enrollment continues in the post-approval confirmatory frontline clinical trial program of ARIKAYCE in patients with NTM lung disease caused by MAC, which was initiated in December of 2020. 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

- Enrollment continues in the Phase 3 ASPEN study of brensocatib in patients with bronchiectasis, which was

initiated in December of 2020. ASPEN is a global, randomized, double-blind, placebo-controlled Phase 3 study to assess the efficacy, safety, and tolerability of brensocatic 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/pharmacodynamic multiple-dose study of brensocatic in patients with CF in mid-2021.
- Enrollment is complete in the investigator-initiated STOP-COVID19 trial of brensocatic in hospitalized patients with COVID-19 and Insmed anticipates that topline data will be shared in the second quarter of 2021.

TPIP

- Following positive data from the Phase 1 healthy volunteer trial of TPIP, which we reported earlier this year, Insmed plans to advance two Phase 2 studies of TPIP in patients with PAH: an open-label study to understand the impact of TPIP on pulmonary vascular resistance (PVR) over a 24-hour period, and a study evaluating the effect of TPIP on PVR and 6-minute walk distance over a 16-week treatment period. The Company anticipates sharing preliminary data from a small number of patients in the first study in the second half of 2021.
- Insmed also plans to initiate a Phase 2 study of TPIP in patients with pulmonary hypertension associated with interstitial lung disease and continues to explore potential development pathways for TPIP in idiopathic pulmonary fibrosis.

First Quarter 2021 Financial Results

- Total revenue for the first quarter ended March 31, 2021 was \$40.2 million, compared to total revenue of \$36.9 million for the first quarter of 2020.
- Cost of product revenues (excluding amortization of intangible assets) was \$9.8 million for the first quarter of 2021, compared to \$8.4 million for the first quarter of 2020.
- Research and development (R&D) expenses were \$61.4 million for the first quarter of 2021, compared to \$36.2 million for the first quarter of 2020.
- Selling, general and administrative (SG&A) expenses for the first quarter of 2021 were \$51.6 million, compared to \$51.3 million for the first quarter of 2020.
- For the first quarter of 2021, Insmed reported a GAAP net loss of \$91.6 million, or \$0.89 per share, compared to a GAAP net loss of \$66.4 million, or \$0.74 per share, for the first quarter of 2020.

Balance Sheet and Planned Investments

As of March 31, 2021, Insmed had cash and cash equivalents of \$409.8 million. The Company's total operating expenses for the first quarter of 2021 were \$124.0 million. Adjusted R&D expenses for the first quarter of 2021 were \$56.5 million and adjusted SG&A expenses for the first quarter of 2021 were \$43.6 million. Adjusted R&D expenses and adjusted SG&A expenses are non-GAAP measures, which we describe further below.

The Company plans to continue 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 brensocatic 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 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 2257423. 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 June 5, 2021 by dialing (800) 585-8367 (domestic) or (416) 621-4642 (international) and referencing conference ID number 2257423. 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 and depreciation. 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), in Europe as ARIKAYCE® Liposomal 590 mg Nebuliser Dispersion, and in Japan as ARIKAYCE® inhalation 590 mg (amikacin sulfate inhalation drug product). Current international treatment guidelines recommend the use of ARIKAYCE for appropriate patients. ARIKAYCE is a novel, inhaled, once-daily formulation of amikacin, an established antibiotic that was historically administered intravenously and associated with severe toxicity to hearing, balance, and kidney function. Insmed's proprietary PULMOVANCE® liposomal technology enables the delivery of amikacin directly to the lungs, where liposomal amikacin is taken up by lung macrophages where the infection resides, while limiting systemic exposure. ARIKAYCE is administered once daily using the Lamira® Nebulizer System manufactured by PARI Pharma GmbH (PARI).

About PARI Pharma and the Lamira® Nebulizer System

ARIKAYCE is delivered by a novel inhalation device, the Lamira® Nebulizer System, developed by PARI. Lamira® is a quiet, portable nebulizer that enables efficient aerosolization of ARIKAYCE via a vibrating, perforated membrane. Based on PARI's 100-year history working with aerosols, PARI is dedicated to advancing inhalation therapies by developing innovative delivery platforms to improve patient care.

About Brensocatib

Brensocatib is a small molecule, oral, reversible inhibitor of dipeptidyl peptidase 1 (DPP1) being developed by Insmed for the treatment of patients with bronchiectasis and other neutrophil-mediated diseases. DPP1 is an enzyme responsible for activating neutrophil serine proteases (NSPs), such as neutrophil elastase, in neutrophils when they are formed in the bone marrow. Neutrophils are the most common type of white blood cell and play an essential role in pathogen destruction and inflammatory mediation. In chronic inflammatory lung diseases, neutrophils accumulate in the airways and result in excessive active NSPs that cause lung destruction and inflammation. Brensocatib may decrease the damaging effects of inflammatory diseases such as bronchiectasis by inhibiting DPP1 and its activation of NSPs. Brensocatib is an investigational drug product that has not been approved for any indication in any jurisdiction.

About TPIP

Treprostinil palmitil inhalation powder (TPIP) is a dry powder formulation of treprostinil palmitil, a treprostinil prodrug consisting of treprostinil linked by an ester bond to a 16-carbon chain. Developed entirely in Insmed's laboratories, TPIP is a potentially highly differentiated prostanoid being evaluated for the treatment of patients with PAH 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, or call 1-800-FDA-1088. You can also call the Company at 1-844-4-INSMED.

Please see [Full Prescribing Information](#).

About Insmmed

Insmmed Incorporated is a global biopharmaceutical company on a mission to transform the lives of patients with serious and rare diseases. Insmmed's first commercial product is a first-in-disease therapy approved in the United States, Europe, and Japan to treat a chronic, debilitating lung disease. The Company is also progressing a robust pipeline of investigational therapies targeting areas of serious unmet need, including neutrophil-mediated inflammatory diseases and rare pulmonary disorders. Insmmed is headquartered in Bridgewater, New Jersey, with a 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., Europe or Japan (amikacin liposome inhalation suspension, Liposomal 590 mg Nebuliser Dispersion, and inhalation 590 mg (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

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 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
March 31,**

	2021	2020
Product revenues, net	\$ 40,214	\$ 36,860
Operating expenses:		
Cost of product revenues (excluding amortization of intangible assets)	9,844	8,438
Research and development	61,390	36,184
Selling, general and administrative	51,550	51,346
Amortization of intangible assets	1,263	1,249
Total operating expenses	<u>124,047</u>	<u>97,217</u>
Operating loss	(83,833)	(60,357)
Investment income	33	1,404
Interest expense	(7,559)	(7,411)
Other (expense) income, net	(43)	36
Loss before income taxes	<u>(91,402)</u>	<u>(66,328)</u>
Provision for income taxes	<u>239</u>	<u>36</u>
Net loss	<u>\$(91,641)</u>	<u>\$(66,364)</u>
Basic and diluted net loss per share	<u>\$ (0.89)</u>	<u>\$ (0.74)</u>
Weighted average basic and diluted common shares outstanding	<u>103,040</u>	<u>89,779</u>

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

	As of March 31, 2021 (unaudited)	As of December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 409,751	\$ 532,756
Accounts receivable	17,628	16,562
Inventory	52,060	49,592
Prepaid expenses and other current assets	21,565	23,982
Total current assets	<u>501,004</u>	<u>622,892</u>
Intangibles, net	47,998	49,261
Fixed assets, net	52,684	53,953
Finance lease right-of-use assets	10,064	10,334
Operating lease right-of-use assets	34,279	32,946
Other assets	46,362	26,769
Total assets	<u>\$ 692,391</u>	<u>\$ 796,155</u>
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 22,422	\$ 42,853
Accrued expenses	41,289	37,807
Accrued compensation	10,149	25,591
Finance lease liabilities	1,119	1,081
Operating lease liabilities	6,418	11,475
Total current liabilities	81,397	118,807
Debt, long-term	361,575	356,318
Finance lease liabilities, long-term	14,417	14,713
Operating lease liabilities, long-term	24,068	21,255
Other long-term liabilities	<u>9,298</u>	<u>9,178</u>

Total liabilities	490,755	520,271
Shareholders' equity:		
Common stock, \$0.01 par value; 500,000,000 authorized shares, 103,278,670 and 102,763,060 issued and outstanding shares at March 31, 2021 and December 31, 2020, respectively	1,033	1,028
Additional paid-in capital	2,122,743	2,105,252
Accumulated deficit	(1,922,230)	(1,830,589)
Accumulated other comprehensive income	90	193
Total shareholders' equity	201,636	275,884
Total liabilities and shareholders' equity	\$ 692,391	\$ 796,155

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

	Three Months Ended March 31,	
	2021	2020
GAAP research and development	\$ 61,390	\$ 36,184
Stock-based compensation expense	(3,684)	(2,842)
Depreciation	(1,252)	(1,158)
Adjusted R&D expenses (non-GAAP)	\$ 56,454	\$ 32,184
GAAP selling, general and administrative	\$ 51,550	\$ 51,346
Stock-based compensation expense	(6,851)	(6,160)
Depreciation	(1,136)	(1,108)
Adjusted SG&A expenses (non-GAAP)	\$ 43,563	\$ 44,078

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