Insmed Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Business Update

--ARIKAYCE® (amikacin liposome inhalation suspension) Total Revenue of $45.7 Million for the Fourth Quarter 2019 and $136.5 Million for the Full Year 2019--
--Company Provides Full-Year 2020 ARIKAYCE Revenue Guidance of $180 Million to $220 Million--
--Phase 2 WILLOW Study of INS1007 in Patients with Non-Cystic Fibrosis Bronchiectasis Achieves Primary and Key Secondary Endpoint--

BRIDGEWATER, N.J., Feb. 25, 2020 /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, 2019 and provided a business update.

"2019 was a transformative year for Insmed as we evolved into a commercial-stage organization and advanced our global infrastructure. I am incredibly proud of our team's performance in the first full year of the ARIKAYCE U.S. launch, and we look forward to serving even more patients with the same level of dedication as we prepare for a potential approval and commercial launch in Europe and regulatory filings in Japan," commented Will Lewis, Chairman and Chief Executive Officer of Insmed. "With our recent announcement of positive top-line Phase 2 data for INS1007 in non-cystic fibrosis bronchiectasis, in addition to other meaningful advancements in our pipeline, we are well on our way toward building a robust portfolio of therapies that address the unmet needs of small patient populations experiencing big health problems."

Fourth Quarter and Full-Year 2019 Financial Results

- Total revenue for the fourth quarter ended December 31, 2019 was $45.7 million, comprising U.S. net sales of $44.3 million and ex-U.S. net sales of $1.4 million. Total revenue for the full year 2019 was $136.5 million, comprising U.S. net sales of $132.1 million and ex-U.S. net sales of $4.4 million. This compares to total revenue of $9.8 million for the fourth quarter and full year 2018.
- Cost of product revenues (excluding amortization of intangible assets) was $8.7 million for the fourth quarter of 2019, compared to $2.4 million for the fourth quarter of 2018. For the full year 2019, cost of product revenues was $24.2 million compared to $2.4 million in 2018. The increase in cost of product revenues is attributable to the increase in revenues.
- R&D expenses were $32.6 million for the fourth quarter of 2019, compared to $39.9 million for the fourth quarter of 2018. For the full year 2019, R&D expenses were $131.7 million compared to $145.3 million in 2018. The decrease in R&D is primarily due to the Company capitalizing inventory subsequent to the September 2018 U.S. Food and Drug Administration (FDA) approval of ARIKAYCE and capitalizing certain costs related to the investment in our long-term production capacity at Patheon in 2019.
- Selling, general and administrative (SG&A) expenses for the fourth quarter of 2019 were $50.2 million, compared to $54.0 million for the fourth quarter of 2018. For the full year 2019, SG&A expenses were $210.8 million, compared to $168.2 million in 2018. The decrease in SG&A in the fourth quarter is primarily due to a decrease in external expenses related to ARIKAYCE. The increase in SG&A for the full year is primarily due to an increase in external expenses related to ARIKAYCE and a milestone owed in connection with amended agreements with the Cystic Fibrosis Foundation Therapeutics, Inc. (CFFT).
- For the fourth quarter of 2019, Insmed reported a GAAP net loss of $53.0 million, or $0.59 per share, compared to a GAAP net loss of $91.6 million, or $1.19 per share, for the fourth quarter of 2018. For the full year 2019, Insmed reported a GAAP net loss of $254.3 million, or $3.01 per share, compared to a GAAP net loss of $324.3 million, or $4.22 per share, in 2018.

Recent Corporate Developments & Program Highlights

Positive Top-Line Results from WILLOW Study

On February 3, 2020, Insmed announced positive top-line results from the Phase 2 WILLOW study evaluating the efficacy, safety, and pharmacokinetics of INS1007 in adults with non-cystic fibrosis bronchiectasis. The study met both its primary endpoint of time to first pulmonary exacerbation over the 24-week treatment period as well as a key secondary endpoint of reduction in the frequency of pulmonary exacerbations versus placebo. The Company plans to advance INS1007 to Phase 3 development.

ARIKAYCE Lifecycle Management

Insmed continues to advance the post-approval confirmatory clinical trial for ARIKAYCE in a front-line setting of patients with *Mycobacterium avium* complex (MAC) lung disease as well as the development of an appropriate patient reported outcome (PRO) tool that will enable the assessment of therapies for the treatment of nontuberculous mycobacterial (NTM) lung disease. Insmed plans to initiate both the confirmatory study and a study to validate the PRO in the second half of 2020 and to run these studies in parallel, pending alignment with the FDA. The Company also plans to advance into a separate registrational Phase 3 study in patients with NTM lung disease caused by *Mycobacterium abscessus*.

INS1009 Advancement

Insmed is advancing INS1009, a dry powder, inhaled treprostinil prodrug formulation, for the potential treatment of pulmonary arterial hypertension. The Company plans to file an Investigational New Drug application and initiate a Phase 1 study of INS1009 this year.

Global Expansion

Pending the approval of our marketing authorization application in Europe, Insmed anticipates a potential launch of ARIKAYCE in Germany

by the end of 2020, followed shortly thereafter by the UK. The Company plans to file for approval of ARIKAYCE in Japan in the first quarter of 2020. In addition, Insmed has engaged DKSH Korea Ltd. to provide services to support an expanded access program on a named patient basis in South Korea.

Leadership Updates

Recent senior leadership appointments include Fred Zussa, Senior Vice President, Business Development, and Anjan Chatterjee, MD, MBA, MPH, Senior Vice President, Medical Affairs. Fred joins the Company from Celgene Corporation, where he was a senior member of the Corporate Strategy and Development group. He is responsible for sourcing, evaluating, and transacting business development activities for Insmed. Anjan joins Insmed from Boehringer Ingelheim, where he most recently served as Corporate Vice President. He is responsible for expanding and leading the global Medical Affairs function for ARIKAYCE as well as for our pipeline candidates as they advance toward late-stage development.

Financial Guidance and Balance Sheet

As of December 31, 2019, Insmed had cash and cash equivalents of $487.4 million. The Company's total operating expenses for the fourth quarter of 2019 were $84.1 million and for the full year of 2019 were $347.5 million. Adjusted operating expenses, as defined below, for the fourth quarter of 2019 were $75.0 million and for the full year 2019 were $300.1 million.

The Company expects full-year 2020 revenues for ARIKAYCE to be in the range of $180 million to $220 million.

The Company plans to invest in the following key activities in 2020:

(i) U.S. commercialization of ARIKAYCE;
(ii) clinical trial activities, including (a) the development of a PRO for NTM lung disease as well as the initiation of a study to validate the PRO and, in parallel, a confirmatory clinical study of ARIKAYCE (b) the advancement of INS1007 into a Phase 3 program in patients with bronchiectasis, and (c) the advancement of INS1009 and our earlier-stage research pipeline; and
(iii) expansion in Europe and Japan to support pre-commercial activities for ARIKAYCE in those regions and potential regulatory filings in Japan.

As a result of these activities, Insmed expects adjusted operating expenses to be in the range of $340 million to $360 million for 2020.

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 (888) 317-6003 (domestic) or (412) 317-6061 (international) and referencing conference ID number 3317351. 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 one hour after its completion through March 3, 2020 by dialing (877) 344-7529 (domestic) or (412) 317-0088 (international) and referencing replay access code 10139238. A webcast of the call will also be archived for 90 days under the Investors 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 adjusted operating expenses, a non-GAAP financial measure, which Insmed defines as total operating expenses less stock-based compensation expense, depreciation, amortization of intangibles and certain milestones related to ARIKAYCE, which is payable under our amended agreements with CFFT. A reconciliation of this non-GAAP financial measure to its most directly comparable GAAP financial measure is presented in the table attached to this press release.

Management believes that this non-GAAP financial measure is 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 this non-GAAP financial measure to be considered in isolation or as a substitute for results prepared in accordance with GAAP. In addition, this non-GAAP financial measure may differ from similarly named measures used by other companies.

About ARIKAYCE® (amikacin liposome inhalation suspension)

ARIKAYCE is the first and only FDA-approved therapy indicated for the treatment of *Mycobacterium avium* complex (MAC) lung disease as part of a combination antibacterial drug regimen for adult patients with limited or no alternative treatment options. 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. This approach prolongs the release of amikacin in the lungs 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® (amikacin liposome inhalation suspension) 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 liquid medications, including liposomal formulations such as 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 and new pharmaceutical formulations that work together to improve patient care.

About INS1007

INS1007 is a small molecule, oral, reversible inhibitor of dipeptidyl peptidase I (DPP1) being developed by Insmed for the treatment of patients with bronchiectasis. 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. INS1007 may decrease the damaging effects of

inflammatory diseases such as bronchiectasis by inhibiting DPP1 and its activation of NSPs.

IMPORTANT SAFETY INFORMATION FOR ARIKAYCE

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.

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, ARIKAYCE® (amikacin liposome inhalation suspension), is the first and only therapy approved in the United States for the treatment of refractory *Mycobacterium avium* complex (MAC) lung disease as part of a combination antibacterial drug regimen for adult patients with limited or no alternative treatment options. MAC lung disease is a chronic, debilitating condition that can cause severe and permanent lung damage. Insmed's earlier-stage clinical pipeline includes INS1007, a novel oral reversible inhibitor of dipeptidyl peptidase 1 with therapeutic potential in non-cystic fibrosis bronchiectasis and other inflammatory diseases, and INS1009, an inhaled formulation of a treprostinil prodrug that may offer a differentiated product profile for rare pulmonary disorders, including pulmonary arterial hypertension. 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 successfully commercialize or maintain U.S. approval for ARIKAYCE, the Company's only approved product; 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 FDA, including the risk that the Company will not timely and successfully complete the study to validate a PRO tool and complete the confirmatory post-marketing study required for full approval; 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; inaccuracies in the Company's estimates of the size of the potential markets for ARIKAYCE 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; failure to obtain regulatory approval to expand ARIKAYCE's indication to a broader patient population; risks that the full set of data from the WILLOW study will not be consistent with the top-line results of the study; failure to successfully conduct future clinical trials for ARIKAYCE and the Company's product candidates, including due to the Company's limited experience in conducting preclinical development activities and clinical trials necessary for regulatory approval and the Company's inability to enroll or retain sufficient patients to conduct and complete the trials or generate data necessary for regulatory approval; risks that the Company's clinical studies will be delayed or that serious side effects will be identified during drug development; failure to obtain, or delays in obtaining, regulatory approvals for ARIKAYCE outside the U.S. or for the Company's product candidates in the U.S., Europe, Japan or other markets, including the United Kingdom as a result of its recent exit from the European Union; 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 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 FDA-approved third-party manufacturing facility 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, 2019 and any subsequent Company filings with the Securities and Exchange Commission.

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 Securities and Exchange Commission, 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

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Consolidated Statements of Net Loss
(in thousands, except per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
Revenues, net	$ 45,708	$ 9,835	$ 136,467	$ 9,835
Cost of product revenues (excluding amortization of intangible assets)	8,706	2,423	24,212	2,423
Gross profit	37,002	7,412	112,255	7,412
Operating expenses:				
Research and development	32,630	39,925	131,711	145,283
Selling, general and administrative	50,206	53,960	210,796	168,218
Amortization of intangible assets	1,248	1,249	4,993	1,249
Total operating expenses	84,084	95,134	347,500	314,750
Operating loss	(47,082)	(87,722)	(235,245)	(307,338)
Investment income	2,042	2,831	9,921	10,341
Interest expense	(7,348)	(6,667)	(27,705)	(25,472)
Loss on extinguishment of debt	-	-	-	(2,209)
Other (expense) income, net	(276)	52	(531)	602
Loss before income taxes	(52,664)	(91,506)	(253,560)	(324,076)
Provision for income taxes	324	67	777	201
Net loss	$ (52,988)	$ (91,573)	$ (254,337)	$ (324,277)
Basic and diluted net loss per share	$ (0.59)	$ (1.19)	$ (3.01)	$ (4.22)
Weighted average basic and diluted common shares outstanding	89,466	77,096	84,560	76,889

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

	As of December 31, 2019	As of December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 487,429	$ 495,072
Accounts receivable	19,232	5,515
Inventory	28,313	7,032
Prepaid expenses and other current assets	20,220	11,327
Total current assets	555,194	518,946
Intangibles, net	53,682	58,675
Fixed assets, net	60,180	22,636
Finance lease right-of-use assets	15,256	-
Operating lease right-of-use assets	37,673	-
Other assets	20,314	4,299
Total assets	$ 742,299	$ 604,556
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 13,184	$ 17,741
Accrued expenses	40,375	38,254
Accrued compensation	19,140	22,208
Finance lease liabilities	1,221	-
Operating lease liabilities	11,040	-
Other current liabilities	280	1,529
Total current liabilities	85,240	79,732
Debt, long-term	335,940	316,558
Finance lease liabilities, long-term	19,529	-
Operating lease liabilities, long-term	29,308	-
Other long-term liabilities	10,608	-
Total liabilities	480,625	396,290
Shareholders' equity:		
Common stock, $0.01 par value; 500,000,000 authorized		

shares, 89,682,387 and 77,307,521 issued and outstanding shares at December 31, 2019 and 2018, respectively	897	773
Additional paid-in capital	1,797,286	1,489,664
Accumulated deficit	(1,536,499)	(1,282,162)
Accumulated other comprehensive loss	(10)	(9)
Total shareholders' equity	261,674	208,266
Total liabilities and shareholders' equity	$ 742,299	$ 604,556

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	**2018**	**2019**	**2018**
Total operating expenses - GAAP	$ 84,084	$ 95,134	$ 347,500	$ 314,750
Stock-based compensation expense	(5,888)	(6,035)	(26,971)	(26,240)
Depreciation	(1,939)	(925)	(5,188)	(3,577)
Amortization of intangibles	(1,248)	(1,249)	(4,993)	(1,249)
CFFT milestone payments	-	-	(10,249)	-
Adjusted operating expenses - Non-GAAP	**$ 75,009**	**$ 86,925**	**$ 300,099**	**$ 283,684**

Contact:

Investors:

Argot Partners
Laura Perry or Heather Savelle
(212) 600-1902
insmed@argotpartners.com

Media:

Mandy Fahey
Senior Director, Corporate Communications
Insmed
(732) 487-7468
amanda.fahey@insmed.com

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