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Insmmed Reports Fourth Quarter and Full Year 2018 Financial Results and Provides Business Update

--ARIKAYCE® (amikacin liposome inhalation suspension) U.S. Net Product Sales of \$9.2 Million for the Fourth Quarter and Full Year 2018--

--Company Provides Full-Year 2019 ARIKAYCE Revenue Guidance of \$80 Million to \$90 Million--

--Six-Month Phase 2 WILLOW Study of INS1007 in Non-Cystic Fibrosis Bronchiectasis Remains on Track to Complete Enrollment in Mid-2019--

BRIDGEWATER, N.J., Feb. 22, 2019 /PRNewswire/ -- Insmmed Incorporated (Nasdaq: INSM), a global biopharmaceutical company on a mission to transform the lives of patients with serious and rare diseases, today reported financial results for the fourth quarter and full year ended December 31, 2018 and provided a business update.

"2018 was a pivotal year for Insmmed, with the U.S. approval and launch of ARIKAYCE® (amikacin liposome inhalation suspension), the first and only FDA-approved treatment for patients with refractory *Mycobacterium avium* complex (MAC) lung disease. We are very pleased with the strong momentum we've seen since launch, including a wide breadth of prescribers, steady additions of new patients, and positive reimbursement trends," commented Will Lewis, Chairman and Chief Executive Officer of Insmmed. "In 2019, we are focused on continuing our efforts to execute a successful U.S. launch while pursuing our strategic priorities, including completing the design and protocol of the confirmatory study required for the full U.S. approval of ARIKAYCE, which is intended to support use of ARIKAYCE in a front-line setting; accelerating our global expansion to support potential regulatory filings for ARIKAYCE in Europe and Japan; and advancing our pipeline to bring other potential therapies to market for patients with serious and rare diseases."

Fourth Quarter and Full-Year 2018 Financial Results

- Total revenue for the fourth quarter and full year ended December 31, 2018 was \$9.8 million, comprising U.S. net sales of \$9.2 million and ex-U.S. net sales of \$0.6 million. The ex-U.S. net sales reflect utilization from the Temporary Authorization for Use (Autorisation Temporaire d'Utilisation or ATU) program in France.
- Cost of product revenues (excluding amortization of intangible assets) was \$2.4 million for the fourth quarter of 2018. Prior to the approval of ARIKAYCE, the company expensed manufacturing and material costs as research and development expenses.
- Research and development expenses were \$39.9 million for the fourth quarter of 2018, compared with \$33.9 million for the fourth quarter of 2017. For the full year of 2018, research and development expenses were \$145.3 million compared with \$109.7 million for the full year of 2017. The increase was primarily due to an increase in external manufacturing expenses and higher compensation and related expenses due to an increase in headcount.
- Selling, general and administrative expenses for the fourth quarter of 2018 were \$54.0 million, compared with \$31.4 million for the fourth quarter of 2017. For the full year of 2018, selling, general and administrative expenses were \$168.2 million compared with \$79.2 million for the full year of 2017. The increase was primarily due to higher compensation and related expenses due to an increase in headcount and an increase in expenses relating to pre-commercial planning activities in preparation for the launch of ARIKAYCE.
- For the fourth quarter of 2018, Insmmed reported a net loss of \$91.6 million, or \$1.19 per share, compared with a net loss of \$65.4 million, or \$0.85 per share, for the fourth quarter of 2017. For the full year of 2018, Insmmed reported a net loss of \$324.3 million, or \$4.22 per share, compared with a net loss of \$192.6 million, or \$2.89 per share, for the full year of 2017.

Recent Corporate Developments & Program Highlights

Strong Start to U.S. ARIKAYCE Launch

ARIKAYCE was granted accelerated approval by the U.S. Food and Drug Administration (FDA) on September 28, 2018, for the treatment of refractory MAC lung disease as part of a combination antibacterial drug regimen for adult patients who have limited or no alternative treatment options. As previously reported, as of December 31, 2018, more than 500 patients in the U.S. had initiated treatment with ARIKAYCE and approximately 600 physicians in the U.S. had written at least one prescription for the therapy.

The Company expects to complete the design and protocol of the confirmatory clinical study during the first half of 2019 required for the full U.S. approval of ARIKAYCE by the FDA, which is intended to support the use of ARIKAYCE in a front-line setting for patients with MAC lung disease.

Global Expansion Under Way

The Company is continuing its global expansion efforts to support potential regulatory filings for ARIKAYCE in Europe in mid-2019 and in Japan in the first half of 2020. In January 2019, Insmmed opened a new office in Tokyo to support the growth of the workforce in Japan.

The Company is also progressing with the buildout of its new, state-of-the-art corporate headquarters in Bridgewater, NJ, with an anticipated move during the second half of 2019. Insmmed also continues to invest in the buildout of an additional contract manufacturing facility with Patheon UK Limited to increase the long-term production capacity for ARIKAYCE commercial inventory.

Enrollment Remains on Track for WILLOW Study

Insmmed continues to advance the development of INS1007 for patients with non-CF bronchiectasis and expects to complete enrollment in the six-month Phase 2 WILLOW study in mid-2019.

Financial Guidance and Balance Sheet

As of December 31, 2018, Insmmed had cash and cash equivalents of \$495.1 million. The Company's total costs and expenses for the fourth quarter of 2018 were \$97.6 million and for the full year of 2018 were \$317.2 million. The cash-based operating expenses for the fourth quarter of

2018 were \$86.9 million and for the full year of 2018 were \$283.7 million.

The Company expects full-year 2019 revenues for ARIKAYCE to be in the range of \$80 million to \$90 million.

The Company is investing in the following key activities in 2019:

- (i) continued support of the U.S. launch and commercialization of ARIKAYCE;
- (ii) clinical trials including (a) the ARIKAYCE post-marketing confirmatory study, which will be conducted in a front-line setting, (b) the six-month Phase 2 WILLOW study of INS1007 in patients with non-CF bronchiectasis, and (c) the advancement of other pipeline programs including INS1009 and our earlier-stage research pipeline;
- (iii) global expansion in Europe and Japan to support regulatory and pre-commercial activities in those regions; and
- (iv) build-out of an additional third-party manufacturing facility to increase long-term production capacity for ARIKAYCE and a new corporate headquarters facility.

As a result of these activities, Insmed expects cash-based operating expenses to be in the range of \$150 million to \$170 million for the first half of 2019. In addition, the Company expects capital expenditures to be in the range of \$25 million to \$35 million for the first half of 2019.

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 1-888-317-6003 (domestic) or 1-412-317-6061 (international) and referencing conference ID number 5106939. 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 1, 2019 by dialing 1-877-344-7529 (domestic) or 1-412-317-0088 (international) and referencing conference ID number 10128650. 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 cash-based operating expenses, a non-GAAP financial measure, which Insmed defines as total costs and expenses excluding cost of product revenues, stock-based compensation expense, depreciation and amortization of intangibles. 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 presentation, 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 MAC Lung Disease

Mycobacterium avium complex (MAC) lung disease is a rare and serious disorder that can significantly increase morbidity and mortality. Patients with MAC lung disease can experience a range of symptoms that often worsen over time, including chronic cough, dyspnea, fatigue, fever, weight loss, and chest pain. In some cases, MAC lung disease can cause severe, even permanent damage to the lungs, and can be fatal.

MAC lung disease is an emerging public health concern worldwide with significant unmet needs. Current guideline-based treatment involves the use of multi-drug regimens that are not specifically approved for MAC lung disease. The course of treatment is often two years or more and is inadequate in treating the disease in many patients.

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.

IMPORTANT SAFETY INFORMATION

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 $\geq 5\%$ 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.

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 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 ARIKAYCE® (amikacin liposome inhalation suspension), which is approved in the United States 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. MAC lung disease is a rare and often chronic infection that can cause irreversible lung damage and can be fatal. Insmmed'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 payers 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 successfully 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 payers 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; the expected rates of patient uptake or the duration of expected treatment; 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; 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 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 regulatory approvals for ARIKAYCE outside the U.S. or for the Company's product candidates in the U.S., Europe, Japan or other markets; 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 imposed on the Company by its material license agreements, 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; limited experience operating internationally; changes in laws and regulations applicable to the Company's business 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 and move into the leased space at the Company's new headquarters 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, 2018 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

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
	(unaudited)			
Revenues	\$ 9,835	\$ -	\$ 9,835	\$ -
Costs and expenses:				
Cost of product revenues (excluding amortization of intangible assets)	2,423	-	2,423	-
Research and development	39,925	33,949	145,283	109,749
Selling, general and administrative	53,960	31,404	168,218	79,171
Amortization of intangible assets	1,249	-	1,249	-
Total costs and expenses	97,557	65,353	317,173	188,920
Operating loss	(87,722)	(65,353)	(307,338)	(188,920)
Investment income	2,831	975	10,341	1,624
Interest expense	(6,667)	(1,466)	(25,472)	(5,925)
Loss on extinguishment of debt	-	-	(2,209)	-
Other income, net	52	94	602	300
Loss before income taxes	(91,506)	(65,750)	(324,076)	(192,921)
Provision (benefit) for income taxes	67	(366)	201	(272)
Net loss	\$ (91,573)	\$ (65,384)	\$ (324,277)	\$ (192,649)
Basic and diluted net loss per share	\$ (1.19)	\$ (0.85)	\$ (4.22)	\$ (2.89)

Weighted average basic and diluted common shares outstanding

77,096

76,596

76,889

66,576

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

	As of December 31, 2018	As of December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 495,072	\$ 381,165
Accounts receivable	5,515	-
Inventory, net	7,032	-
Prepaid expenses and other current assets	11,327	8,279
Total current assets	<u>518,946</u>	<u>389,444</u>
Intangible assets, net	58,675	58,200
Fixed assets, net	22,636	12,432
Other assets	4,299	1,971
Total assets	<u>\$ 604,556</u>	<u>\$ 462,047</u>
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 17,741	\$ 14,671
Accrued expenses	38,254	17,142
Accrued compensation	22,208	12,197
Other current liabilities	1,529	646
Total current liabilities	<u>79,732</u>	<u>44,656</u>
Long-term debt, net	316,558	55,567
Other long-term liabilities	-	765
Total liabilities	<u>396,290</u>	<u>100,988</u>
Shareholders' equity:		
Common stock, \$0.01 par value; 500,000,000 authorized shares, 77,307,521 and 76,610,508 issued and outstanding shares at December 31, 2018 and December 31, 2017, respectively	773	766
Additional paid-in capital	1,489,664	1,318,181
Accumulated deficit	(1,282,162)	(957,885)
Accumulated other comprehensive loss	(9)	(3)
Total shareholders' equity	<u>208,266</u>	<u>361,059</u>
Total liabilities and shareholders' equity	<u>\$ 604,556</u>	<u>\$ 462,047</u>

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
Total costs and expenses - GAAP	\$ 97,557	\$ 65,353	\$ 317,173	\$ 188,920
Cost of product revenues (excluding amortization of intangible assets)	(2,423)	-	(2,423)	-
Stock-based compensation expense	(6,035)	(4,741)	(26,240)	(18,073)
Depreciation	(925)	(733)	(3,577)	(2,901)
Amortization of intangibles	(1,249)	-	(1,249)	-
Cash-based operating expenses - Non-GAAP	<u>\$ 86,925</u>	<u>\$ 59,879</u>	<u>\$ 283,684</u>	<u>\$ 167,946</u>

Contact:

Blaine Davis
Insmmed Incorporated
(908) 947-2841
blaine.davis@insmed.com

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