



[Home](#) / [Investors](#) / [News Releases](#)

Insmmed Reports Second Quarter 2019 Financial Results and Provides Business Update

--ARIKAYCE® (amikacin liposome inhalation suspension) U.S. Net Product Sales \$29.0 Million for the Second Quarter of 2019--
--Marketing Authorization Application for ARIKAYCE Submitted and Validated by European Medicines Agency--
--Company Raises Full-Year 2019 ARIKAYCE Revenue Guidance to Range of \$110 Million to \$120 Million--
--Cash-Based Operating Expenses for First Half of 2019 at Low End of Guidance Range at \$155 Million; Expected to be \$140 Million to \$155 Million for Second Half of 2019--

BRIDGEWATER, N.J., Aug. 1, 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 second quarter ended June 30, 2019 and provided a business update.

"We are very excited about the continued strength of the U.S. launch of ARIKAYCE® (amikacin liposome inhalation suspension), the first and only FDA-approved treatment for patients with refractory MAC lung disease, including the breadth and depth of prescribing, addition of new patients, and positive reception from the payer community throughout the first three quarters of launch," commented Will Lewis, Chairman and Chief Executive Officer of Insmmed. "While the U.S. launch remains our greatest area of focus, we are pleased to have made significant progress on our other strategic priorities this quarter, including filing for regulatory approval of ARIKAYCE in the EU, advancing our planned regulatory filings in Japan, and completing enrollment in the Phase 2 WILLOW study of INS1007. As we move into the second half of the year as a fully operational commercial-stage company, we plan to execute against these priorities with a disciplined approach to investment."

Second Quarter 2019 Financial Results

- Total revenue for the second quarter ended June 30, 2019 was \$30.0 million, comprising U.S. net sales of \$29.0 million and ex-U.S. net sales of \$1.0 million. The ex-U.S. net product sales include \$0.9 million from the Temporary Authorization for Use (Autorisation Temporaire d'Utilisation or ATU) program in France and \$0.1 million from the named patient program in Germany, both compassionate use programs.
- Cost of product revenues (excluding amortization of intangible assets) was \$4.9 million for the second quarter of 2019.
- Research and development expenses were \$33.5 million for the second quarter of 2019, compared with \$35.7 million for the second quarter of 2018.
- Selling, general and administrative expenses for the second quarter of 2019 were \$52.4 million, compared with \$37.2 million for the second quarter of 2018. The increase was primarily due to higher expenses related to commercial activities for ARIKAYCE, including disease awareness, patient support activities, and field operations and, to a lesser extent, an increase in headcount, including non-cash stock-based compensation.
- For the second quarter of 2019, Insmmed reported a GAAP net loss of \$66.5 million, or \$0.81 per share, compared with a GAAP net loss of \$76.4 million, or \$1.00 per share, for the second quarter of 2018.
- During the second quarter of 2019, Insmmed completed a public offering of 10.7 million new shares of common stock that resulted in net cash proceeds of \$261.2 million, after deducting underwriting discounts and commissions and other offering-related expenses.

Recent Corporate Developments & Program Highlights

Global Expansion Efforts Advance with Submission of MAA for ARIKAYCE to EMA

In July, Insmmed submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for ARIKAYCE for the treatment of persistent MAC lung infection as part of a combination antibacterial drug regimen in adults. The MAA was subsequently validated by the EMA. The proposed indication reflects the same population of refractory MAC lung disease patients for which ARIKAYCE is approved in the U.S.

ARIKAYCE previously received Orphan Drug Designation in the European Union (EU) for the treatment of nontuberculous mycobacterial (NTM) lung disease. MAC is the predominant pathogenic species in NTM lung disease in the United States, Europe, and Japan. The Company anticipates a 12-month review cycle with a potential launch of ARIKAYCE in certain European countries as early as the second half of 2020 if the MAA is approved.

In addition, the Company remains on track to submit a new drug application for ARIKAYCE in Japan in the first half of 2020.

Additional EU Patent Granted for ARIKAYCE

In July, the European Patent Office issued an additional patent to Insmmed for ARIKAYCE in MAC lung disease. The claims of the patent relate in part to pharmaceutical compositions of amikacin encapsulated in liposomes, including ARIKAYCE, for treating or providing prophylaxis against MAC lung disease, where the composition is administered via aerosolization to the lungs of a patient once daily in a single dosing session for at least three months. The patent extends exclusivity of ARIKAYCE in Europe to May 15, 2035.

ARIKAYCE Launch and Lifecycle Management

Insmmed continues to advance the U.S. launch of ARIKAYCE, which was granted accelerated approval by the U.S. Food and Drug Administration (FDA) in September 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 a next step toward advancing a post-approval confirmatory clinical trial for ARIKAYCE, the Company has initiated efforts to develop an appropriate patient reported outcome (PRO) tool that will enable the assessment of therapies for the treatment of NTM lung disease. If the PRO tool is verified, Insmmed plans to conduct the confirmatory study of ARIKAYCE in a frontline setting of patients with MAC lung disease as well as a separate study in patients with NTM lung disease caused by *Mycobacterium abscessus*.

Data from Phase 3 CONVERT Study Presented as Late-Breaker at ATS

In May, longer-term data on the sustainability and durability of culture conversion from the Phase 3 CONVERT Study of ARIKAYCE were presented in a late-breaking oral session at the American Thoracic Society International Conference. The data showed that among patients who achieved culture conversion by Month 6, 80.0% (52/65) of those receiving ARIKAYCE plus guideline-based therapy (GBT) sustained culture conversion for up to 12 months of treatment after the first dose that defined culture conversion compared to 30.0% (3/10) of patients receiving GBT alone ($p=0.0014$). Three months after the completion of treatment, 63.1% (41/65) of patients receiving ARIKAYCE plus GBT maintained durable culture conversion, compared to 0.0% (0/10) of patients receiving GBT alone ($p=0.0002$).

Enrollment Completed in WILLOW Study

Insmmed has completed enrollment in the six-month Phase 2 WILLOW study of INS1007 for patients with non-cystic fibrosis (CF) bronchiectasis. Top-line data are expected in early 2020.

Financial Guidance and Balance Sheet

As of June 30, 2019, Insmmed had cash and cash equivalents of \$601.3 million. The Company's total costs and expenses for the second quarter of 2019 were \$92.1 million, compared with total costs and expenses for the second quarter of 2018 of \$72.9 million. Cash-based operating expenses for the second quarter of 2019 were \$77.4 million, compared with cash-based operating expenses for the second quarter of 2018 of \$65.3 million.

The Company now expects full-year 2019 revenues for ARIKAYCE to be in the range of \$110 million to \$120 million.

The Company plans to continue to invest in the following key activities in 2019:

- (i) support of the U.S. launch and commercialization of ARIKAYCE;
- (ii) clinical trials including (a) the development and verification of a PRO for NTM lung disease as a pivotal step toward initiating a confirmatory clinical study of ARIKAYCE, (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 pre-commercial activities in those regions and potential regulatory filings in Japan; and
- (iv) buildout of an additional third-party manufacturing facility to increase long-term production capacity for ARIKAYCE and a new corporate headquarters facility.

Insmmed expects cash-based operating expenses to be in the range of \$140 million to \$155 million for the second half of 2019. In addition, the Company expects capital expenditures, including those related to the buildout of a new corporate headquarters facility as well as payments classified within other assets for the future right-of-use asset related to the buildout of an additional third-party manufacturing facility, to be in the range of \$20 million to \$30 million for the second half of 2019.

Conference Call

Insmmed 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 5579948. 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 August 8, 2019 by dialing 1-877-344-7529 (domestic) or 1-412-317-0088 (international) and referencing replay access code 10133256. 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 Insmmed 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 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 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. Insmmed'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 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.

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 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) 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 develop and validate the 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 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 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; 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 as a result of the United Kingdom's planned exit from the EU; 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 its 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 agreements related to ARIKAYCE or the Company's product candidates, including the Company's license agreements with PARI and AstraZeneca AB, and failure to comply with the Company's 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 and failure to comply with such laws and regulations; inability to repay the Company's existing indebtedness and uncertainties with respect to its 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 to build out an additional 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 risk 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 in the Company's subsequent 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) (unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenues, net	\$ 29,972	\$ -	\$ 51,874	\$ -
Costs and expenses:				
Cost of product revenues (excluding amortization of intangible assets)	4,919	-	9,069	-
Research and development	33,538	35,722	64,741	65,820
Selling, general and administrative	52,433	37,160	107,243	69,813
Amortization of intangible assets	1,248	-	2,496	-
Total costs and expenses	92,138	72,882	183,549	135,633
Operating loss	(62,166)	(72,882)	(131,675)	(135,633)
Investment income	2,578	2,729	4,994	4,769
Interest expense	(6,785)	(6,488)	(13,511)	(12,130)
Loss on extinguishment of debt	-	-	-	(2,209)
Other (expense) income, net	(51)	244	(170)	330
Loss before income taxes	(66,424)	(76,397)	(140,362)	(144,873)
Provision for income taxes	90	40	305	88
Net loss	\$ (66,514)	\$ (76,437)	\$ (140,667)	\$ (144,961)
Basic and diluted net loss per share	\$ (0.81)	\$ (1.00)	\$ (1.77)	\$ (1.89)

Weighted average basic and diluted common shares
outstanding

81,806

76,767

79,685

76,693

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

	As of June 30, 2019 (unaudited)	As of December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 601,260	\$ 495,072
Accounts receivable	11,638	5,515
Inventory	20,160	7,032
Prepaid expenses and other current assets	15,856	11,327
Total current assets	648,914	518,946
Intangibles, net	56,179	58,675
Fixed assets, net	38,913	22,636
Operating lease right-of-use assets	42,316	-
Other assets	16,461	4,299
Total assets	\$ 802,783	\$ 604,556
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 17,031	\$ 17,741
Accrued expenses	49,363	38,254
Accrued compensation	10,218	22,208
Lease liabilities	9,184	-
Other current liabilities	234	1,529
Total current liabilities	86,030	79,732
Debt, long-term	326,128	316,558
Long-term lease liabilities	33,530	-
Other long-term liabilities	522	-
Total liabilities	446,210	396,290
Shareholders' equity:		
Common stock, \$0.01 par value; 500,000,000 authorized authorized shares, 89,207,455 and 77,307,521 issued and outstanding shares at June 30, 2019 and December 31, 2018, respectively	892	773
Additional paid-in capital	1,778,517	1,489,664
Accumulated deficit	(1,422,829)	(1,282,162)
Accumulated other comprehensive loss	(7)	(9)
Total shareholders' equity	356,573	208,266
Total liabilities and shareholders' equity	\$ 802,783	\$ 604,556

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

	Three Months Ended June 30, 2019	2018	Six Months Ended June 30, 2019	2018
Total costs and expenses - GAAP	\$ 92,138	\$ 72,882	\$ 183,549	\$ 135,633
Cost of product revenues (excluding amortization of intangible assets)	(4,919)	-	(9,069)	-
Stock-based compensation expense	(7,353)	(6,629)	(14,289)	(12,303)
Depreciation	(1,176)	(929)	(2,245)	(1,698)
Amortization of intangibles	(1,248)	-	(2,496)	-
Cash-based operating expenses - Non-GAAP	\$ 77,442	\$ 65,324	\$ 155,450	\$ 121,632

Contact:

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