



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

Insmmed Reports First Quarter 2020 Financial Results and Provides Business Update

--Company Supports Investigator-Initiated Study of Brensocatic (Formerly INS1007) in Severe COVID-19 and Continues to Advance Development in Bronchiectasis--

--ARIKAYCE® (amikacin liposome inhalation suspension) Total Revenue of \$36.9 Million for the First Quarter 2020; Global Growth and Label Expansion Efforts Advance--

BRIDGEWATER, N.J., April 30, 2020 /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 first quarter ended March 31, 2020, and provided a business update.

"The start of 2020 saw an unprecedented global event with the COVID-19 pandemic. We are proud to be fighting this disease alongside many in the biopharmaceutical industry by supporting an investigator-initiated study of brensocatic, formerly known as INS1007, in patients with severe COVID-19. While we continue to advance this novel treatment candidate in bronchiectasis, we are hopeful that Insmmed can contribute in the fight against COVID-19," commented Will Lewis, Chairman and Chief Executive Officer of Insmmed. "I am also pleased that in an incredibly challenging environment, we have been able to support the NTM lung disease community remotely and provide an uninterrupted supply of ARIKAYCE while working to ensure the safety of all stakeholders, including our employees. With meaningful advances in our pipeline; important growth catalysts for ARIKAYCE; and a strong balance sheet, we believe we are well-positioned to stay the course through these challenging times and continue to serve patients in need."

First Quarter 2020 Financial Results

- Total revenue for the first quarter ended March 31, 2020, was \$36.9 million, comprising U.S. net sales of \$35.2 million and ex-U.S. net sales of \$1.7 million. This compares to total revenue of \$21.9 million for the first quarter of 2019.
- Cost of product revenues (excluding amortization of intangible assets) was \$8.4 million for the first quarter of 2020, compared to \$4.2 million for the first quarter of 2019.
- Research and development (R&D) expenses were \$36.2 million for the first quarter of 2020, compared to \$31.2 million for the first quarter of 2019. The increase in R&D expenses is primarily attributable to an increase in compensation and benefit-related expenses, including stock-based compensation expense, due to an increase in headcount and increases in manufacturing and regulatory, quality assurance, and medical affairs costs.
- Selling, general, and administrative (SG&A) expenses for the first quarter of 2020 were \$51.3 million, compared to \$54.8 million for the first quarter of 2019. The decrease in SG&A expenses is primarily due to a decrease in compensation and benefit-related costs and external costs related to ARIKAYCE® (amikacin liposome inhalation suspension).
- For the first quarter of 2020, Insmmed reported a GAAP net loss of \$66.4 million, or \$0.74 per share, compared to a GAAP net loss of \$74.2 million, or \$0.96 per share, for the first quarter of 2019.

Recent Corporate Developments & Program Highlights

Brensocatic Program Updates:

As previously announced:

- ***Phase 3 Study in Bronchiectasis:*** Insmmed plans to initiate a Phase 3 program with brensocatic in patients with bronchiectasis in the second half of 2020, following alignment with the U.S. Food and Drug Administration (FDA) on trial design.
- ***Investigator-Initiated Study in Severe COVID-19:*** Insmmed is supporting an investigator-initiated study of brensocatic in patients with severe COVID-19. The randomized, double-blind, placebo-controlled trial is expected to enroll up to 300 patients hospitalized with confirmed COVID-19 and will be led by the University of Dundee in the UK.
- ***AstraZeneca Option Exercise:*** In March 2020, AstraZeneca AB exercised an option pursuant to the companies' October 2016 license agreement under which AstraZeneca can advance clinical development of brensocatic in the indication of chronic obstructive pulmonary disease (COPD) or asthma up to and including Phase 2b clinical trials. Insmmed retains full development and commercialization rights for brensocatic in all other indications and geographies.

ARIKAYCE Label Expansion

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 ARIKAYCE 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.

Global Growth

Insmed remains on track in preparing for potential approvals and commercial launches of ARIKAYCE in both Japan and Europe. In Japan, the Company announced in March that it had submitted a new drug application to the Ministry of Health, Labour and Welfare for ARIKAYCE for the treatment of patients with NTM lung disease caused by MAC who did not sufficiently respond to prior treatment. In Europe, pending approval of the marketing authorization application for ARIKAYCE, the Company anticipates a potential launch in Germany by the end of 2020, followed shortly thereafter by the UK.

Treprostinil Palmitil (Formerly INS1009) Advancement

Insmed is advancing treprostinil palmitil, formerly known as 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 treprostinil palmitil in the second half of 2020.

COVID-19 Response

In March 2020, Insmed implemented, and continues to maintain, a number of corporate initiatives in response to the global COVID-19 pandemic. These include a remote working policy for all employees, including field-based therapeutic specialists and employees who support ARIKAYCE prescribers, to aid the global containment effort. The Company is providing remote support and engagement options to both healthcare professionals and patients prescribed ARIKAYCE.

Importantly, Insmed has observed no disruptions to date in its supply chain for the production of ARIKAYCE. The Company believes it has enough active pharmaceutical ingredient used in ARIKAYCE to meet anticipated global requirements, including commercial, clinical and compassionate use, through the end of 2022.

Balance Sheet

As of March 31, 2020, Insmed had cash and cash equivalents of \$428.9 million. The Company's total operating expenses for the first quarter of 2020 were \$88.8 million. Adjusted operating expenses, as defined below, for the first quarter of 2020 were \$76.3 million.

The Company plans to continue investing 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, the initiation of a study to validate the PRO and, in parallel, a confirmatory clinical study of ARIKAYCE, (b) the advancement of brensocaticil into a Phase 3 program in patients with bronchiectasis, and (c) the advancement of treprostinil palmitil and our earlier-stage research pipeline; and
- (iii) expansion in Japan and Europe to support pre-commercial activities for ARIKAYCE in those regions.

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 2121512. 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 May 14, 2020 by dialing (877) 344-7529 (domestic) or (412) 317-0088 (international) and referencing replay access code 10142785. 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 are payable under our amended agreements with Cystic Fibrosis Foundation Therapeutics, Inc. (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 Brensocatib (Formerly INS1007)

Brensocatib 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. Brensocatib may decrease the damaging effects of inflammatory diseases such as bronchiectasis by inhibiting DPP1 and its activation of NSPs.

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 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 brensocaticib, a novel oral reversible inhibitor of dipeptidyl peptidase 1 with therapeutic potential in non-cystic fibrosis bronchiectasis and other inflammatory diseases, and treprostinil palmitil, 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: the risk that brensocaticib does not prove effective or safe for patients in the STOP-COVID19 study; 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 our business, employees, including key personnel, patients, partners and suppliers; the risk that the full data set from the WILLOW study, our six-month Phase 2 trial of brensocaticib in patients with NCBFE or data generated in further clinical trials of brensocaticib will not be consistent with the top-line results of the study; 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 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 brensocaticib; inaccuracies in the Company's estimates of the size of the potential markets for ARIKAYCE or brensocaticib 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, brensocaticib and the Company's other 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

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

	Three Months Ended March 31,	
	2020	2019
Revenues, net	\$ 36,860	\$ 21,902
Cost of product revenues (excluding amortization of intangible assets)	8,438	4,150
Gross profit	<u>28,422</u>	<u>17,752</u>
Operating expenses:		
Research and development	36,184	31,203
Selling, general and administrative	51,346	54,810
Amortization of intangible assets	1,249	1,248
Total operating expenses	<u>88,779</u>	<u>87,261</u>
Operating loss	(60,357)	(69,509)
Investment income	1,404	2,416
Interest expense	(7,411)	(6,726)
Other income (expense), net	36	(119)
Loss before income taxes	<u>(66,328)</u>	<u>(73,938)</u>
Provision for income taxes	<u>36</u>	<u>215</u>
Net loss	<u>\$ (66,364)</u>	<u>\$ (74,153)</u>
Basic and diluted net loss per share	<u>\$ (0.74)</u>	<u>\$ (0.96)</u>
Weighted average basic and diluted common shares outstanding	<u>89,779</u>	<u>77,541</u>

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

	As of March 31, 2020 (unaudited)	As of December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 428,942	\$ 487,429
Accounts receivable	17,154	19,232
Inventory	30,645	28,313
Prepaid expenses and other current assets	15,769	20,220
Total current assets	492,510	555,194
Intangibles, net	52,433	53,682
Fixed assets, net	58,638	60,180
Finance lease right-of-use assets	14,896	15,256
Operating lease right-of-use assets	36,137	37,673
Other assets	21,911	20,314
Total assets	\$ 676,525	\$ 742,299
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 18,188	\$ 13,184
Accrued expenses	32,687	40,375
Accrued compensation	8,949	19,140
Finance lease liabilities	1,263	1,221
Operating lease liabilities	10,367	11,040
Other current liabilities	78	280
Total current liabilities	71,532	85,240
Debt, long-term	340,939	335,940
Finance lease liabilities, long-term	19,196	19,529
Operating lease liabilities, long-term	27,197	29,308
Other long-term liabilities	10,960	10,608
Total liabilities	469,824	480,625
Shareholders' equity:		
Common stock, \$0.01 par value; 500,000,000 authorized shares, 89,859,549 and 89,682,387 issued and outstanding shares at March 31, 2020 and December 31, 2019, respectively	899	897
Additional paid-in capital	1,808,712	1,797,286
Accumulated deficit	(1,602,863)	(1,536,499)
Accumulated other comprehensive loss	(47)	(10)
Total shareholders' equity	206,701	261,674
Total liabilities and shareholders' equity	\$ 676,525	\$ 742,299

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

Three Months Ended March 31,	
2020	2019

Total operating expenses - GAAP	\$ 88,779	\$ 87,261
Stock-based compensation expense	(9,002)	(6,936)
Depreciation	(2,266)	(1,069)
Amortization of intangibles	(1,249)	(1,248)
Adjusted operating expenses - Non-GAAP	\$ 76,262	\$ 78,008

Contact:

Investors:

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

Media:

Mandy Fahey
Senior Director, Corporate Communications
Insmed
(732) 718-3621
amanda.fahey@insmed.com

SOURCE Insmed Incorporated
