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Insmmed Reports Third Quarter 2020 Financial Results and Provides Business Update

--ARIKAYCE® (amikacin liposome inhalation suspension) Total Revenue of \$43.6 Million for Third Quarter 2020--

--Marketing Authorization for ARIKAYCE® Liposomal 590 mg Nebuliser Dispersion Granted in European Union--

--Supplemental New Drug Application (sNDA) Approved by U.S. FDA for ARIKAYCE, Adding Culture Conversion Data Beyond 12 Months to Label--

--Three Key Clinical Trials Expected to Begin by End of 2020: Phase 3 ASPEN Study of Brensocatib in Non-Cystic Fibrosis Bronchiectasis (NCFBE), Pivotal ENCORE Study of ARIKAYCE in Front-Line NTM, and ARISE Study to Validate PRO Tool in NTM--

--Phase 1 Study of Treprostinil Palmitil Inhalation Powder (TPIP) Under Way with Four Dosing Strengths Completed--

BRIDGEWATER, N.J., Oct. 29, 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 third quarter ended September 30, 2020, and provided a business update.

"I am pleased to report on a very productive third quarter for Insmmed as we made significant progress across our programs while maintaining ARIKAYCE performance in the U.S. amidst the ongoing pandemic," commented Will Lewis, Chair and Chief Executive Officer of Insmmed. "Driven by the efforts of a world-class team, we reached several critical milestones for ARIKAYCE, including marketing authorization in the European Union, approval of an sNDA that adds meaningful efficacy data to our U.S. label, and continued advancement of our frontline clinical program. Importantly, we also advanced plans to initiate a global, registrational Phase 3 study of brensocatib in NCFBE and initiated a Phase 1 study of TPIP. As we look ahead to 2021, we believe we are well-positioned to carry this momentum forward and execute on our goals."

Third Quarter 2020 Financial Results

- Total revenue for the third quarter ended September 30, 2020, was \$43.6 million, comprising U.S. net sales of \$42.0 million and ex-U.S. net sales of \$1.6 million. This compares to total revenue of \$38.9 million for the third quarter of 2019.
- Cost of product revenues (excluding amortization of intangible assets) was \$10.6 million for the third quarter of 2020, compared to \$6.4 million for the third quarter of 2019.
- Research and development (R&D) expenses were \$41.4 million for the third quarter of 2020, compared to \$34.3 million for the third quarter of 2019.
- Selling, general, and administrative (SG&A) expenses for the third quarter of 2020 were \$46.6 million, compared to \$53.3 million for the third quarter of 2019.
- For the third quarter of 2020, Insmmed reported a GAAP net loss of \$63.7 million, or \$0.63 per share, compared to a GAAP net loss of \$60.7 million, or \$0.68 per share, for the third quarter of 2019.

Recent Corporate Developments & Program Highlights

ARIKAYCE Global Advancement

On October 28, 2020, Insmmed announced that the European Commission (EC) had granted marketing authorization for ARIKAYCE Liposomal 590 mg Nebuliser Dispersion for the treatment of nontuberculous mycobacterial (NTM) lung infections caused by *Mycobacterium avium* complex (MAC) in adults with limited treatment options who do not have cystic fibrosis (CF). Consideration should be given to official guidance on the appropriate use of antibacterial agents. The Company plans to launch ARIKAYCE first in Germany, with the United Kingdom and other European markets to follow, subject to local reimbursement processes.

In Japan, Insmmed continues to anticipate launching ARIKAYCE in the middle of 2021, pending approval of its new drug application for the treatment of patients with NTM lung disease caused by MAC who did not sufficiently respond to prior treatment.

ARIKAYCE Label Expansion

On October 19, 2020, the U.S. Food and Drug Administration (FDA) approved an sNDA for ARIKAYCE, adding important efficacy data regarding the durability and sustainability of culture conversion to the ARIKAYCE label. The data, which are from the Phase 3 CONVERT study of ARIKAYCE, demonstrate that the addition of ARIKAYCE to guideline-based therapy (GBT) was associated with sustained culture conversion through the end of treatment as well as durable culture conversion three months post-treatment compared with GBT alone.

Insmmed also continues to advance plans to pursue regulatory approval of ARIKAYCE as a front-line therapy for patients with MAC lung disease. The Company plans to initiate two clinical trials in the fourth quarter of 2020 that will be conducted in parallel: ENCORE, a pivotal study intended to fulfill the post-marketing requirement to allow full approval of ARIKAYCE in the U.S., and ARISE, an interventional study designed to validate the patient-reported outcome (PRO) tool that will be used to measure efficacy in ENCORE.

Brensocatib Advancement

In September 2020, data from the Phase 2 WILLOW study of brensocatib in patients with NCFBE were published online in the *New England Journal of Medicine* and presented during a late-breaking session at the European Respiratory Society International Congress 2020.

Insmmed remains on track to initiate its planned registrational Phase 3 ASPEN trial of brensocatib in patients with NCFBE by the end of 2020. The Company has

also announced plans to advance a clinical development program for brensocatib in patients with CF.

TPIP Advancement

In September 2020, Insmmed announced that it had initiated a Phase 1 healthy volunteer trial of TPIP in the United States. The objective of this first-in-human single ascending dose and multiple ascending dose study is to assess the pharmacokinetics and tolerability profile of TPIP. Four dosing strengths have now been completed. Top-line data from the full Phase 1 study are expected in the first quarter of 2021 and the Company has announced plans to initiate a Phase 2a study in patients with pulmonary arterial hypertension (PAH) in early 2021.

Balance Sheet

As of September 30, 2020, Insmmed had cash and cash equivalents of \$588.8 million. The Company's total operating expenses for the third quarter of 2020 were \$89.2 million. Adjusted operating expenses, a non-GAAP measure defined below, for the third quarter of 2020 were \$76.8 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) initiation of ENCORE, the pivotal study intended to allow full approval of ARIKAYCE in the U.S. and, in parallel, ARISE, the interventional study to validate the PRO tool that will be used in ENCORE, (b) initiation of the Phase 3 ASPEN study of brensocatib in patients with NCFBE, and (c) the advancement of TPIP; and
- (iii) expansion in Japan and Europe to support pre-commercial activities for ARIKAYCE in Japan and launch activities for ARIKAYCE in initial European countries.

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 (833) 340-0284 (domestic) or (236) 712-2425 (international) and referencing conference ID number 8292364. 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 November 12, 2020 by dialing (800) 585-8367 (domestic) or (416) 621-4642 (international) and referencing conference ID number 8292364. 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 adjusted operating expenses, a non-GAAP financial measure, which Insmmed 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

ARIKAYCE is approved in the United States as ARIKAYCE[®] (amikacin liposome inhalation suspension) and in the EU as ARIKAYCE[®] Liposomal 590 mg Nebuliser Dispersion. Current international treatment guidelines recommend the use of ARIKAYCE for appropriate patients. ARIKAYCE is a novel, inhaled, once-daily formulation of amikacin, an established antibiotic that was historically administered intravenously and associated with severe toxicity to hearing, balance, and kidney function. 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, while limiting systemic exposure. ARIKAYCE is administered once daily using the Lamira[®] Nebulizer System manufactured by PARI Pharma GmbH (PARI).

About PARI Pharma and the Lamira[®] Nebulizer System

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

About Brensocatib

Brensocatib is a small molecule, oral, reversible inhibitor of dipeptidyl peptidase 1 (DPP1) being developed by Insmmed for the treatment of patients with non-cystic fibrosis bronchiectasis (NCFBE) and other neutrophil-mediated diseases. DPP1 is an enzyme responsible for activating neutrophil serine proteases (NSPs), such as neutrophil elastase, in neutrophils when they are formed in the bone marrow. Neutrophils are the most common type of white blood cell and play an essential role in pathogen destruction and inflammatory mediation. In chronic inflammatory lung diseases, neutrophils accumulate in the airways and result in excessive active NSPs that cause lung destruction and inflammation. Brensocatib may decrease the damaging effects of inflammatory diseases such as bronchiectasis by inhibiting DPP1 and its activation of NSPs.

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 is a first-in-disease therapy approved in the United States and the European Union to treat a chronic, debilitating lung disease. The Company is also progressing a robust pipeline of investigational therapies targeting areas of serious unmet need, including neutrophil-mediated inflammatory diseases and rare pulmonary disorders. Insmed is headquartered in Bridgewater, New Jersey, with a growing footprint across Europe and in Japan. For more information, visit www.insmed.com.

Forward-looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. "Forward-looking statements," as that term is defined in the Private Securities Litigation Reform Act of 1995, are statements that are not historical facts and involve a number of risks and uncertainties. Words herein such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "intends," "potential," "continues," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) may identify forward-looking statements.

The forward-looking statements in this press release are based upon the Company's current expectations and beliefs, and involve known and unknown risks, uncertainties and other factors, which may cause the Company's actual results, performance and achievements and the timing of certain events to differ materially from the results, performance, achievements or timing discussed, projected, anticipated or indicated in any forward-looking statements. Such risks, uncertainties and other factors include, among others, the following: failure to obtain, or delays in obtaining, regulatory approvals for ARIKAYCE outside the U.S. or European Union or for the Company's product candidates in the U.S., Europe, Japan or other markets; failure to successfully commercialize or maintain U.S. or EU approval for ARIKAYCE, the Company's only approved product; business or economic disruptions due to catastrophes or other events, including natural disasters or public health crises; impact of the novel coronavirus (COVID-19) pandemic and efforts to reduce its spread on the Company's business, employees, including key personnel, patients, partners and suppliers; the risk that brensocaticib does not prove effective or safe for patients in future clinical studies, including the ASPEN and STOP-COVID19 studies; uncertainties in the degree of market acceptance of ARIKAYCE by physicians, patients, third-party payors and others in the healthcare community; the Company's inability to obtain full approval of ARIKAYCE from the 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 Pharma GmbH (PARI) or the Company's other third-party manufacturers to comply with regulatory requirements related to ARIKAYCE or the Lamira[®] Nebulizer System; the Company's inability to obtain adequate reimbursement from government or third-party payors for ARIKAYCE or acceptable prices for ARIKAYCE; development of unexpected safety or efficacy concerns related to ARIKAYCE or the Company's product candidates; inaccuracies in the Company's estimates of the size of the potential markets for ARIKAYCE or its product candidates or in data the Company has used to identify physicians, expected rates of patient uptake, duration of expected treatment, or expected patient adherence or discontinuation rates; the Company's inability to create an effective direct sales and marketing infrastructure or to partner with third parties that offer such an infrastructure for distribution of ARIKAYCE or any of the Company's product candidates that are approved in the future; failure to obtain regulatory approval to expand ARIKAYCE's indication to a broader patient population; failure to successfully conduct future clinical trials for ARIKAYCE, brensocaticib, TPIP and the Company's other product candidates due to the Company's limited experience in conducting preclinical development activities and clinical trials necessary for regulatory approval and its potential inability to enroll or retain sufficient patients to conduct and complete the trials or generate data necessary for regulatory approval, among other things; risks that our clinical studies will be delayed or that serious side effects will be identified during drug development; failure of third parties on which the Company is dependent to manufacture sufficient quantities of ARIKAYCE or the Company's product candidates for commercial or clinical needs, to conduct the Company's clinical trials, or to comply with 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 manufacturing facility approved by the appropriate regulatory authorities and unexpected expenses associated with those plans.

The Company may not actually achieve the results, plans, intentions or expectations indicated by the Company's forward-looking statements because, by their nature, forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. For additional information about the risks and uncertainties that may affect the Company's business, please see the factors discussed in Item 1A, "Risk Factors," in the Company's Annual Report on Form 10-K for the year ended December 31, 2019, the Company's Quarterly Reports on Form 10-Q for the quarters ended March 31, 2020 and June 30, 2020 and any subsequent Company filings with the Securities and Exchange Commission (SEC).

The Company cautions readers not to place undue reliance on any such forward-looking statements, which speak only as of the date of this press release. The Company disclaims any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Financial Statements and Reconciliation Follow

(in thousands, except per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues, net	\$ 43,643	\$ 38,885	\$ 122,998	\$ 90,759
Cost of product revenues (excluding amortization of intangible assets)	10,622	6,437	29,010	15,506
Gross profit	<u>33,021</u>	<u>32,448</u>	<u>93,988</u>	<u>75,253</u>
Operating expenses:				
Research and development	41,411	34,340	113,343	99,081
Selling, general and administrative	46,585	53,347	147,594	160,590
Amortization of intangible assets	1,248	1,249	3,745	3,745
Total operating expenses	<u>89,244</u>	<u>88,936</u>	<u>264,682</u>	<u>263,416</u>
Operating loss	(56,223)	(56,488)	(170,694)	(188,163)
Investment income	70	2,885	1,677	7,879
Interest expense	(7,185)	(6,846)	(22,065)	(20,357)
Other expense, net	(4)	(85)	(14)	(255)
Loss before income taxes	<u>(63,342)</u>	<u>(60,534)</u>	<u>(191,096)</u>	<u>(200,896)</u>
Provision for income taxes	317	148	781	453
Net loss	<u>\$ (63,659)</u>	<u>\$ (60,682)</u>	<u>\$ (191,877)</u>	<u>\$ (201,349)</u>
Basic and diluted net loss per share	<u>\$ (0.63)</u>	<u>\$ (0.68)</u>	<u>\$ (2.00)</u>	<u>\$ (2.43)</u>
Weighted average basic and diluted common shares outstanding	<u>101,615</u>	<u>89,245</u>	<u>96,029</u>	<u>82,907</u>

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

	As of September 30, 2020 (unaudited)	As of December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 588,753	\$ 487,429
Accounts receivable	15,196	19,232
Inventory	43,483	28,313
Prepaid expenses and other current assets	19,717	20,220
Total current assets	<u>667,149</u>	<u>555,194</u>
Intangibles, net	49,937	53,682
Fixed assets, net	55,314	60,180
Finance lease right-of-use assets	10,603	15,256
Operating lease right-of-use assets	32,505	37,673
Other assets	25,207	20,314
Total assets	<u>\$ 840,715</u>	<u>\$ 742,299</u>
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 22,147	\$ 13,184
Accrued expenses	35,149	40,375
Accrued compensation	16,283	19,140
Finance lease liabilities	582	1,221
Operating lease liabilities	9,741	11,040
Other current liabilities	-	280
Total current liabilities	<u>83,902</u>	<u>85,240</u>
Debt, long-term	351,127	335,940
Finance lease liabilities, long-term	15,003	19,529
Operating lease liabilities, long-term	23,198	29,308
Other long-term liabilities	10,424	10,608
Total liabilities	<u>483,654</u>	<u>480,625</u>

Shareholders' equity:

Common stock, \$0.01 par value; 500,000,000 authorized shares, 101,803,701 and 89,682,387 issued and outstanding shares at September 30, 2020 and December 31, 2019, respectively	1,018	897
Additional paid-in capital	2,084,305	1,797,286
Accumulated deficit	(1,728,376)	(1,536,499)
Accumulated other comprehensive income (loss)	114	(10)
Total shareholders' equity	<u>357,061</u>	<u>261,674</u>
Total liabilities and shareholders' equity	<u>\$ 840,715</u>	<u>\$ 742,299</u>

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2020	2019	2020	2019
Total operating expenses - GAAP	\$ 89,244	\$ 88,936	\$ 264,682	\$ 263,416
Stock-based compensation expense	(8,909)	(6,794)	(27,379)	(21,083)
Depreciation	(2,295)	(1,004)	(6,829)	(3,249)
Amortization of intangibles	(1,248)	(1,249)	(3,745)	(3,745)
CFFT milestone payments	-	(7,249)	-	(10,249)
Adjusted operating expenses - Non-GAAP	<u>\$ 76,792</u>	<u>\$ 72,640</u>	<u>\$ 226,729</u>	<u>\$ 225,090</u>

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