

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): July 30, 2020

AIMMUNE THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-37519
(Commission File Number)

45-2748244
(IRS Employer Identification Number)

8000 Marina Blvd, Suite 300
Brisbane, CA 94005
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (650) 614-5220

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	AIMT	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Conditions.

On July 30, 2020, Aimmune Therapeutics, Inc. (“Aimmune” or the “Company”) issued a press release announcing its financial results for the quarter and six months ended June 30, 2020, and its financial position as of June 30, 2020. The Company will conduct a conference call to review its financial results on July 30, 2020, at 4:30 p.m., Eastern Time. The full text of the press release is furnished as Exhibit 99.1 hereto.

The information in this Item 2.02 of this Form 8-K and the Exhibit 99.1 attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section, or incorporated by reference into any filings of the Company made under the Securities Act of 1933, as amended, regardless of any general incorporation language in the filing unless specifically stated so therein.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press release dated July 30, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AIMMUNE THERAPEUTICS, INC.

Date: July 30, 2020

By: /s/ Eric H. Bjerkholt

Eric H. Bjerkholt

Chief Financial Officer



Aimmune Therapeutics Announces Second Quarter 2020 Financial Results and Provides Recent Operational Highlights

- *PALFORZIA® launch gaining momentum as allergist offices begin to re-open*
- *EU and Swiss regulatory reviews for PALFORZIA remain on schedule*
- *Enrollment in phase 3 POSEIDON trial has resumed*
- *\$318 million cash, cash equivalents and investments*
- *Cost control measures limited second quarter EPS loss*
- *Webcast and conference call today at 4:30 p.m. ET*

BRISBANE, California, July 30, 2020 – Aimmune Therapeutics, Inc. (Nasdaq: AIMT), a biopharmaceutical company developing and commercializing treatments for potentially life-threatening food allergies, today announced financial results for the quarter and six months ended June 30, 2020.

“We are encouraged that an increasing number of allergy practices around the country have re-opened since June. As a result, we have also seen a corresponding inflection in our leading indicator launch metrics. Given this momentum, we have initiated a targeted digital and print marketing campaign to create greater awareness of PALFORZIA among patients and their caregivers in the U.S.,” said Jayson Dallas, M.D., President and Chief Executive Officer of Aimmune Therapeutics. “Our overall business fundamentals and long-term prospects remain strong, and we are confident in the thoughtful manner in which we are navigating this ongoing pandemic.”

PALFORZIA Commercialization Update:

- **U.S. commercial launch.** As regions in the United States re-open, allergists are working through a backlog of their existing allergy patients and are also beginning to offer PALFORZIA to their peanut-allergic patients, which is ahead of our expectations. As of the end of July, nearly 1,000 allergists and 600 allergy practices are REMS certified. Approximately 100 allergists have enrolled patients in the REMS, and half of these allergists have enrolled more than one patient. The Company is seeing some clinics beginning to fully operationalize PALFORZIA at scale with double-digit numbers of new patient starts. These REMS enrollment figures represent a sharp increase since May.
- **Payor progress.** As of the end of July, there were 39 plans in the U.S. which have either interim or permanent policies written regarding PALFORZIA, representing approximately 102 million lives. The Company anticipates that it will continue engaging in conversations with payors and that these discussions will lead to additional policy decisions by payors throughout the remainder of this year. Until PALFORZIA is formally covered on formularies, allergists can initiate patients on treatment via the use of the medical exception processes provided by payors.



- **Supply chain.** The facilities manufacturing PALFORZIA remain fully operational. The Company has not had, nor does it anticipate, any material supply chain issues as a result of the COVID-19 pandemic. The Company has sufficient product on hand to meet demand for PALFORZIA for the foreseeable future in the United States and Europe and expects to remain in a position to continue to manufacture new product as necessary.

PALFORZIA Scientific Presentations:

- **Long-term safety and efficacy data.** At the European Academy of Allergy and Clinical Immunology (EAACI) Digital Congress in June, Aimmune presented long-term safety, efficacy and immunological data from ARC004, an open-label, rollover study of the landmark pivotal PALISADE trial of PALFORZIA. After two years of daily treatment, more than 80% of patients were successfully desensitized to tolerate 2,000 mg of peanut protein, or 4,043 mg cumulatively, which is the equivalent of about 14 peanut kernels. Additionally, the safety profile of PALFORZIA, as measured by treatment-related exposure adjusted adverse events, improved over time.
- **Patient-reported satisfaction data.** The Company also presented patient-reported treatment satisfaction data from the European phase 3 ARTEMIS trial of PALFORZIA, evaluated after nine months of daily treatment. The research showed that patients were highly satisfied with, and confident in, the efficacy of daily treatment with PALFORZIA.

PALFORZIA European Regulatory Update:

- The European Medicines Agency (EMA) review of the marketing authorization application (MAA) for PALFORZIA is ongoing and remains on track. The Company has received the Day 180 questions and expects a standard overall review period for its MAA for PALFORZIA, with a target action date in the fourth quarter of 2020.
- The Swissmedic review of PALFORZIA is ongoing and remains on track. The target action date is mid-2021.

Pipeline Update:

- All clinical trials are currently ongoing, and study medication continues to be delivered uninterrupted to all patients in North America and throughout Europe.
 - The POSEIDON (ARC005) phase 3 clinical trial to explore the efficacy and safety of PALFORZIA in young peanut-allergic children ages 1 to <4 years is ongoing. Enrollment has resumed, and, subject to the Company's ability to continue to enroll patients in light of the pandemic, the Company expects data in 2021.
 - The AR201 phase 2 clinical trial in patients with egg allergy continues for patients currently enrolled, and the Company intends to review the data from these patients in the first half of 2021 to determine the best development path forward.
 - Regeneron's phase 2 trial of PALFORZIA with adjunctive dupilumab in peanut-allergic patients is continuing.



- o Aimmune recently completed a productive pre-IND meeting with the U.S Food and Drug Administration (FDA) regarding the Company’s multi-tree nut program that helped identify a clear path forward to the submission of an IND.
- o The Company continues its development of AIMab7195 as an adjunctive treatment with the Company’s existing CODIT pipeline assets, including PALFORZIA, to explore the potential path to remission in patients with food allergies. The Company expects to file an IND in the first quarter of 2021.

Upcoming Milestones:

4Q 2020	Expected EMA action date for PALFORZIA in the European Union
1Q 2021	Expected filing of IND for AIMab7195
1H 2021	Expected data from phase 2 clinical trial of currently enrolled AR201 in patients with egg allergy
Mid-2021	Expected Swissmedic action date for PALFORZIA in Switzerland
2H 2021	Expected data from POSEIDON phase 3 clinical trial (subject to the Company’s ability to continue to enroll patients in light of the pandemic)

Second Quarter 2020 Financial Results

Revenue to date comprises initial stocking by specialty pharmacy and distribution partners and is not an indication of prescription pull-through to patients in the second quarter. Given stocking of inventory in the first quarter, and the closure of most allergists' offices through the end of May due to COVID-19, limited new orders in the second quarter were off-set by fixed management and data access fees, resulting in no net product revenue for the quarter ended June 30, 2020. For the six months ended June 30, 2020, net revenue was \$575,000.

Cost of revenue was also impacted by the pandemic leading to a delay in the PALFORZIA launch. Cost of revenue for the quarter and six months ended June 30, 2020 was \$4.9 million and \$5.1 million, respectively, and is primarily comprised of a \$4.5 million write-off of inventory during the quarter ended June 30, 2020. Due to the unusual circumstances caused by the pandemic in the second quarter, the Company does not expect this inventory write-off to be a recurring event.

Research and development expenses for the quarter and six months ended June 30, 2020 were \$23.0 million, and \$59.5 million, respectively, compared to \$32.0 million and \$63.3 million for the comparable periods in 2019. The decreases reflect cost containment measures and the close-out of certain PALFORZIA clinical trials. The research and development expense for the six months ended June 30, 2020 includes the \$10.0 million license fee for AIMab7195.

Selling, general and administrative expenses for the quarter and six months ended June 30, 2020 were \$38.1 million and \$87.2 million, respectively, compared to \$31.2 million and \$54.9 million for the comparable periods in 2019. The increases from the prior year were primarily due to additional headcount to support the commercialization of PALFORZIA, including the hiring of a specialty field force of



approximately 80 Practice Account Managers and other costs related to medical affairs and the commercial launch.

For the quarter and six months ended June 30, 2020, GAAP net loss was \$69.2 million and \$155.7 million, respectively, compared to GAAP net loss of \$62.9 million and \$117.1 million for the comparable periods in 2019. On a per share basis, GAAP net loss for the quarter and six months ended June 30, 2020, was \$1.06 and \$2.40, respectively, compared to net loss per share of \$1.01 and \$1.88 for the comparable periods in 2019. The weighted average shares outstanding for the quarter and six months ended June 30, 2020 were 65.2 million and 64.8 million, respectively, compared to 62.3 million and 62.2 million for the comparable periods in 2019.

Non-GAAP net loss for the quarter and six months ended June 30, 2020 was \$52.9 million and \$119.1 million, respectively, compared to \$54.1 million and \$100.6 million for the comparable periods in 2019. On a per share basis, non-GAAP net loss for the quarter and six months ended June 30, 2020, was \$0.81 and \$1.84, respectively, compared to \$0.87 and \$1.62 for the comparable periods of 2019. Non-GAAP net loss excludes stock-based compensation, upfront cash and equity payments associated with the execution of the AIMab7195 license agreement in the first quarter of 2020 and inventory charges recorded in the second quarter of 2020.

Cash, cash equivalents, and investments totaled \$318.1 million on June 30, 2020, compared to \$371.6 million on March 31, 2020.

Non-GAAP Financial Measures

To supplement our financial results presented in accordance with GAAP, we present non-GAAP net loss (and the related per share measures).

We believe that the presentation of these non-GAAP financial measures provides useful supplementary information to, and facilitates additional analysis by, investors. In particular, we believe that these non-GAAP financial measures, when considered together with our financial information prepared in accordance with GAAP, can enhance investors' and analysts' ability to meaningfully compare our results from period to period, and to identify operating trends in our business. We have excluded stock-based compensation expense because such amounts are non-cash expenses that may vary significantly from period to period as a result of changes not directly or immediately related to the operational performance for the periods presented. We have excluded upfront cash and stock payments associated with the execution of a development license agreement because such amounts are not considered normal operating expenses due to their nature, variability of amounts, and lack of predictability as to occurrence and/or timing. We also regularly use these non-GAAP financial measures internally to understand, manage and evaluate our business and to make operating decisions.

These non-GAAP financial measures are provided in addition to, not a substitute for, measures of financial performance prepared in accordance with GAAP. We encourage investors to carefully consider our results under GAAP, as well as our supplemental non-GAAP financial information and the reconciliation between these presentations, to more fully understand our business. The reconciliations between GAAP and non-GAAP results are presented in this earnings release.



Conference Call Details

In connection with this announcement, Aimmune Therapeutics will host a conference call and webcast today at 4:30 p.m. ET. To access the live call by phone, dial (877) 497-1438 (domestic) or (262) 558-6296 (international) and enter the passcode 6195241. To access a live or recorded webcast of the call, please visit the Investor Relations section of the Aimmune Therapeutics website at www.aimmune.com. The recorded webcast will be available for approximately 30 days following the call.

About PALFORZIA™

PALFORZIA [Peanut (*Arachis hypogaea*) Allergen Powder-dnfp] was approved by the U.S. Food and Drug Administration (FDA) in January 2020 as the first approved treatment for patients with peanut allergy. It is an oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. PALFORZIA is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial dose escalation may be administered to patients aged 4 through 17 years. Up-dosing and maintenance may be continued in patients 4 years of age and older. PALFORZIA is to be used in conjunction with a peanut-avoidant diet. PALFORZIA is not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

INDICATION

PALFORZIA is an oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. PALFORZIA is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial Dose Escalation may be administered to patients aged 4 through 17 years. Up-Dosing and Maintenance may be continued in patients 4 years of age and older.

PALFORZIA is to be used in conjunction with a peanut-avoidant diet.

Limitations of Use: Not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

IMPORTANT SAFETY INFORMATION

Boxed WARNING:

PALFORZIA can cause anaphylaxis, which may be life threatening and can occur at any time during PALFORZIA therapy.

Prescribe injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use.

Do not administer PALFORZIA to patients with uncontrolled asthma.

Dose modifications may be necessary following an anaphylactic reaction.



Observe patients during and after administration of the Initial Dose Escalation and the first dose of each Up-Dosing level, for at least 60 minutes.

PALFORZIA is available only through a restricted program called the PALFORZIA REMS.

CONTRAINDICATIONS

PALFORZIA is contraindicated in patients with uncontrolled asthma, or with a history of eosinophilic esophagitis and other eosinophilic gastrointestinal disease.

WARNINGS AND PRECAUTIONS

Anaphylaxis

PALFORZIA can cause anaphylaxis, which may be life threatening. PALFORZIA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the PALFORZIA REMS because of the risk of anaphylaxis. Only prescribers, healthcare settings, pharmacies, and patients certified and enrolled in the REMS Program can prescribe, receive, dispense or administer PALFORZIA.

Anaphylaxis has been reported during all phases of PALFORZIA dosing, including Maintenance and in subjects who have undergone recommended Up-Dosing and dose modification procedures.

Do not initiate PALFORZIA treatment in a patient who has had severe or life-threatening anaphylaxis within the previous 60 days. PALFORZIA may not be suitable for patients with certain medical conditions that may reduce the ability to survive anaphylaxis, including but not limited to markedly compromised lung function, severe mast cell disorder, or cardiovascular disease. In addition, PALFORZIA may not be suitable for patients taking medications that can inhibit or potentiate the effects of epinephrine.

All Initial Dose Escalation doses and the first dose of each Up-Dosing level must be administered in a certified health care setting.

Patients may be more likely to experience allergic reactions following PALFORZIA administration in the presence of cofactors such as exercise, hot water exposure, intercurrent illness (e.g., viral infection), or fasting. Other potential cofactors may include menstruation, sleep deprivation, nonsteroidal anti-inflammatory drug use, or uncontrolled asthma. Patients should be proactively counseled about the potential for the increased risk of anaphylaxis in the presence of these cofactors. If possible, adjust the time of dosing to avoid these cofactors. If it is not possible to avoid these cofactors, consider withholding PALFORZIA temporarily.

Asthma

Uncontrolled asthma is a risk factor for a serious outcome, including death, in anaphylaxis. Ensure patients with asthma have their asthma under control prior to initiation of PALFORZIA.



PALFORZIA should be temporarily withheld if the patient is experiencing an acute asthma exacerbation. Following resolution of the exacerbation, resumption of PALFORZIA should be undertaken cautiously. Re-evaluate patients who have recurrent asthma exacerbations and consider discontinuation of PALFORZIA.

Eosinophilic Gastrointestinal Disease

Discontinue PALFORZIA and consider a diagnosis of eosinophilic esophagitis in patients who experience severe or persistent gastrointestinal symptoms, including dysphagia, vomiting, nausea, gastroesophageal reflux, chest pain, or abdominal pain.

Gastrointestinal Adverse Reactions

Gastrointestinal adverse reactions were commonly reported in PALFORZIA-treated subjects, and dose modification should be considered for patients who report these reactions. For severe or persistent gastrointestinal symptoms consider a diagnosis of eosinophilic esophagitis.

ADVERSE REACTIONS

The most common adverse events reported in subjects treated with PALFORZIA (incidence $\geq 5\%$ and $\geq 5\%$ than placebo) are abdominal pain, vomiting, nausea, oral pruritus, oral paresthesia, throat irritation, cough, rhinorrhea, sneezing, throat tightness, wheezing, dyspnea, pruritus, urticaria, anaphylactic reaction, and ear pruritus.

Please see full Prescribing Information, including Boxed WARNING, and Medication Guide at www.PALFORZIA.com.

For more information about PALFORZIA, please call 1-844-PALFORZ (1-844-725-3679) or visit www.PALFORZIA.com.

About Aimmune Therapeutics

Aimmune Therapeutics, Inc. is a biopharmaceutical company developing and commercializing treatments for potentially life-threatening food allergies. With a mission to improve the lives of people with food allergies, Aimmune is developing and commercializing oral treatments for potentially life-threatening food allergies. The Company's Characterized Oral Desensitization ImmunoTherapy (CODIT™) approach is intended to provide meaningful levels of protection against allergic reactions resulting from accidental exposure to food allergens by desensitizing patients with defined, precise amounts of key allergens. Aimmune has one FDA-approved medicine for peanut allergy and other investigational therapies in development to treat other food allergies. For more information, please visit www.aimmune.com.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those



expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding: Aimmune's expectations regarding the impact of COVID-19 on its business, including on the commercial launch of PALFORZIA, the Company's clinical trials and the Company's supply chain; Aimmune's expectations regarding the potential benefits of PALFORZIA, AR201 and AIMab7195; Aimmune's expectations regarding the commercial launch of PALFORZIA; Aimmune's expectations that it will continue to be able to engage in discussions with payors in the United States for PALFORZIA and that these discussions will lead to additional policy decisions by payors for the remainder of 2020; Aimmune's expectations that it will be in a position to manufacture sufficient commercial supplies of PALFORZIA for the foreseeable future; Aimmune's expectations regarding the timing of a potential regulatory action date for the MAA for AR101 by the EMA and by Swissmedic; Aimmune's expectations on the timing of receiving data from a phase 2 clinical trial for AR201; Aimmune's expectations on the planned timing for the announcement of data from the POSEIDON clinical trial for PALFORZIA; Aimmune's expectations on the timing for the filing of an IND with the FDA for AIMab7195; Aimmune's plan to file an IND with the FDA for Aimmune's multi-tree nut program; and Aimmune's expectations regarding potential applications of the CODIT™ approach to treating life-threatening food allergies. Risks and uncertainties that contribute to the uncertain nature of the forward-looking statements include: the risk that the COVID-19 worldwide pandemic may continue to negatively impact the business, research and clinical operations of Aimmune or its partners; the degree of acceptance of PALFORZIA among physicians, patients, healthcare payors, patient advocacy groups and the general medical community; Aimmune's ability to obtain favorable coverage and reimbursement from third-party payors for PALFORZIA; Aimmune's ability to implement and comply with the REMS for PALFORZIA; Aimmune's or any of its collaborative partners' ability to initiate and/or complete clinical trials; the unpredictability of the regulatory process; the possibility that Aimmune's or any of its collaborative partners' clinical trials will not be successful; Aimmune's dependence on the success of PALFORZIA; Aimmune's reliance on third parties for the manufacture of Aimmune's products and product candidates; possible regulatory developments in the United States and foreign countries; and Aimmune's ability to attract and retain senior management personnel. These and other risks and uncertainties are described more fully in Aimmune's most recent filings with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarter ended June 30, 2020. All forward-looking statements contained in this press release speak only as of the date on which they were made. Aimmune undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

This press release concerns PALFORZIA, which has been approved for marketing in the United States by the FDA; AR101, a product candidate that is under clinical investigation in Europe; AR201, a product candidate under clinical investigation in the United States; and AIMab7195, a product candidate that Aimmune expects will be under clinical investigation. AR201 and AIMab7195 have not been approved for marketing by the FDA, the EMA or Swissmedic. AR101 in Europe, AR201 and AIMab7195 are currently limited to investigational use, and no representation is made as to their safety or effectiveness for the purposes for which they are being investigated.

PALFORZIA®, AIMMUNE™, AIMMUNE THERAPEUTICS® and CODIT™ are trademarks of Aimmune Therapeutics, Inc.



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AIMMUNE THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)

	June 30, 2020 (Unaudited)	December 31, 2019 (1)
Assets		
Cash and cash equivalents	\$ 266,559	\$ 79,880
Short-term investments	47,394	63,633
Trade receivables, net	25	—
Inventories	5,646	—
Prepaid expenses and other current assets	4,017	5,564
Total current assets	<u>323,641</u>	<u>149,077</u>
Long-term investments	4,127	14,661
Property and equipment, net	26,540	28,604
Operating lease right-of-use assets	10,397	11,512
Prepaid expenses and other assets	581	515
Total assets	<u>\$ 365,286</u>	<u>\$ 204,369</u>
Liabilities and Stockholders' Equity		
Current liabilities	\$ 43,001	\$ 47,448
Long term debt, net of discount	131,462	41,028
Operating lease liabilities, non-current	9,323	10,524
Other liabilities	1,642	1,345
Stockholders' equity	<u>179,858</u>	<u>104,024</u>
Total liabilities and stockholders' equity	<u>\$ 365,286</u>	<u>\$ 204,369</u>

(1) Derived from the audited financial statements, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2019.



AIMMUNE THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)

	<u>Quarter Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Product revenue, net	\$ —	\$ —	\$ 575	\$ —
Costs and operating expenses				
Cost of revenue	4,850	—	5,107	—
Research and development	23,047	31,988	59,510	63,304
Selling, general and administrative	38,094	31,200	87,232	54,912
Total costs and operating expenses	<u>65,991</u>	<u>63,188</u>	<u>151,849</u>	<u>118,216</u>
Loss from operations	(65,991)	(63,188)	(151,274)	(118,216)
Interest income	428	1,710	1,406	3,611
Interest expense	(3,212)	(1,262)	(5,441)	(2,406)
Other income, net	(148)	(90)	73	(56)
Loss before provision for income taxes	(68,923)	(62,830)	(155,236)	(117,067)
Provision for income taxes	321	48	440	77
Net loss	<u>\$ (69,244)</u>	<u>\$ (62,878)</u>	<u>\$ (155,676)</u>	<u>\$ (117,144)</u>
Net loss per common share, basic and diluted	<u>\$ (1.06)</u>	<u>\$ (1.01)</u>	<u>\$ (2.40)</u>	<u>\$ (1.88)</u>
Shares used in computing net loss per common share, basic and diluted	65,182	62,332	64,848	62,178

	<u>Quarter Ended June 30,</u>		<u>Six Months Ended</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
GAAP net loss	\$ (69,244)	\$ (62,878)	\$ (155,676)	\$ (117,144)
Non-GAAP adjustments:				
Stock-based compensation:				
Cost of revenue	81	—	85	—
Research and development expenses	3,483	2,957	7,544	5,700
Selling, general and administrative expenses	8,250	5,783	14,488	10,805
Upfront cash and equity payments associated with a development agreement	—	—	10,000	—
Inventory write-offs	4,501	—	4,501	—
Non-GAAP net loss	<u>\$ (52,929)</u>	<u>\$ (54,138)</u>	<u>\$ (119,058)</u>	<u>\$ (100,639)</u>
GAAP net loss per share, basic and diluted	<u>\$ (1.06)</u>	<u>\$ (1.01)</u>	<u>\$ (2.40)</u>	<u>\$ (1.88)</u>
Non-GAAP net loss per share, basic and diluted	<u>\$ (0.81)</u>	<u>\$ (0.87)</u>	<u>\$ (1.84)</u>	<u>\$ (1.62)</u>
Shares used in computing net loss per share, basic and diluted	65,182	62,332	64,848	62,178