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): May 11, 2020

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

Delaware	**001-37519**	**45-2748244**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 May 11, 2020, Aimmune Therapeutics, Inc. ("Aimmune" or the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2020, and its financial position as of March 31, 2020. The Company will conduct a conference call to review its financial results on May 11, 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 May 11, 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: May 11, 2020

By: /s/ Eric H. Bjerkholt
Eric H. Bjerkholt
Chief Financial Officer

Exhibit 99.1

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

- *Continues to be launch ready for PALFORZIA™*
- *EU and Swiss regulatory reviews for PALFORZIA remain on schedule*
- *Uninterrupted drug supply for all ongoing clinical trials*
- *$371.6 million cash, cash equivalents and investments on-hand and implementing numerous cash-preservation measures*
- *Webcast and conference call today at 4:30 p.m. ET*

BRISBANE, California, May 11, 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 ended March 31, 2020.

"We have remained in close contact with allergists during the shelter-in-place, and their enthusiasm for initiating PALFORZIA therapy, as they begin to reopen their practices, remains as high as when it was approved in January," said Jayson Dallas, M.D., President and Chief Executive Officer of Aimmune Therapeutics. "In addition, market research conducted among patient-caregivers suggests the demand for PALFORZIA has not changed. Our overall fundamentals and long-term prospects remain strong."

Corporate Highlights:

- **COVID-19.** The COVID-19 pandemic has paused the commercial launch of PALFORZIA. Under the Risk Evaluation and Mitigation Strategy, or REMS, for PALFORZIA, the first dose of each up-dosing level must be administered in a certified healthcare setting and, due to the strains placed on the providers of healthcare services by COVID-19, including shelter-in-place restrictions, many patients are not able to access physicians in a manner sufficient to commence treatment with PALFORZIA. Similarly, patients who have commenced treatment, but who have not yet advanced through the up-dosing phase, have been restricted from accessing the necessary healthcare settings and, as a result, are being maintained at their existing dose levels. To date, our commercial and clinical supply chain for PALFORZIA has not been significantly impacted to date by the COVID-19 pandemic. There have been no disruptions in our supply chain of drug manufacturers necessary to conduct our clinical trials, and we believe that we will be able to supply the clinical material needs of our ongoing clinical studies. We are ready to support allergists and their practices to continue initiating new patients on PALFORZIA therapy as soon as they are ready to reopen their practices.

- **Strong balance sheet.** The Company remains well-capitalized, supported by the $200 million investment from Nestlé Health Science and the draw of the $85 million second loan tranche from KKR announced in February 2020. We had cash, cash equivalents and investments of $371.6 million as of March 31, 2020. In light of the launch pause caused by COVID-19, the Company is taking numerous active steps to conserve financial resources. We anticipate that based on our current business plan, these financial resources fully fund the Company.

PALFORZIA Commercialization Update:

- **U.S. commercial launch.** Aimmune has equipped its Practice Account Managers (PAMs) in the United States with technology so they can provide support to allergists' practices remotely as they adhere to social distancing requirements. PAMs will continue to virtually engage with allergists to provide information on the REMS process and training on how to safely incorporate PALFORZIA into allergy practices until they are able to resume in-person interactions.

- **Formulary coverage.** Formulary adoption conversations with payers are proceeding virtually. As of the end of April, there were 15 plans in the U.S. which have either interim or permanent policies written regarding PALFORZIA. These plans represent approximately 43 million lives. Until the product is formally covered on formularies, allergists can initiate patients on treatment via the use of the medical exception processes provided by payers.

- **Product supply**. The Company does not currently anticipate any material supply chain issues. The facilities manufacturing the Company's products and product candidates remain fully operational, and the Company has sufficient product on hand to meet demand for PALFORZIA for the foreseeable future and expects to remain in a position to continue to manufacture new product as necessary.

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 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:

- Aimmune is evaluating and implementing risk mitigation-based approaches for remote clinical trial monitoring and activities, including remote patient assessment, to ensure completion of trials in line with the FDA-issued guidance on the *Conduct of Clinical Trials of Medical Products during the COVID-19 Pandemic*.
- Study medication continues to be delivered uninterrupted to all patients in North America and throughout Europe.
- All clinical trials are currently ongoing, however new subject screenings and enrollment are being impacted by physical distancing requirements:
    - 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 although enrollment has paused. If the Company is able to recommence enrollment of patients in the near term, it expects to complete enrollment in the second half of 2020 and data in the first half of 2021.
    - In part as a cost saving measure, the Company has closed enrollment in the AR201 Phase 2 clinical trial in patients with egg allergy. The trial continues for the patients who are

currently enrolled, and the Company intends to review the data from these patients when available and then determine the best path forward.
    - Regeneron's Phase 2 trial of PALFORZIA with adjunctive dupilumab in peanut-allergic patients is continuing.
- Aimmune recently completed a positive pre-IND meeting with the U.S Food and Drug Administration (FDA) regarding the Company's multi-tree nut program, and the Company is preparing the development plan for this new program.
- Following Aimmune's February 2020 in-licensing of AIMab7195, the Company continues its plans to develop AIMab7195 as an adjunctive treatment with the Company's existing CODIT pipeline assets, including PALFORZIA, to explore treatment outcomes, including the potential path to remission, in patients with food allergies.

Upcoming Milestones:

4Q 2020	Expected EMA action date for PALFORZIA in the European Union
1H 2021	Expected data from POSEIDON Phase 3 clinical trial
1H 2021	Expect data from Phase 2 clinical trial of AR201 in patients with egg allergy
Mid-2021	Expected Swissmedic action date for PALFORZIA in Switzerland

First Quarter 2020 Financial Results

For the quarter ended March 31, 2020, net loss was $86.4 million, compared to net loss of $54.3 million for the comparable period in 2019. On a per share basis, net loss for the quarter ended March 31, 2020, was $1.34, compared to net loss per share of $0.87 for the comparable period in 2019. The weighted average shares outstanding for the quarter ended March 31, 2020 was 64.5 million compared to 62.0 million for the comparable period in 2019.

Non-GAAP net loss for the quarter ended March 31, 2020 was $66.1 million, or $1.03 per share, compared to non-GAAP net loss of $46.5 million, or $0.75 per share, for the comparable period in 2019. Non-GAAP net loss excludes stock-based compensation as well as upfront cash and equity payments associated with the execution of a development license agreement in the first quarter of 2020.

Net product revenue for the quarter ended March 31, 2020 was $0.6 million and consisted of sales of PALFORZIA, which was approved by FDA in January 2020. We commenced shipments of PALFORZIA in March 2020.

Cost of revenue for the quarter ended March 31, 2020 was $0.3 million, which included the cost for the write-off of one manufacturing lot which did not meet our stringent manufacturing specifications. Prior to regulatory approval of PALFORZIA, we incurred expenses to manufacture PALFORZIA, which were recorded as research and development expense. We expect to sell inventory previously expensed to research and development over approximately the current year, and accordingly we expect our costs of

product sales of PALFORZIA to increase as a percentage of net sales in future periods as we produce and sell inventory that reflects the full cost of manufacturing the product.

Research and development expenses for the quarter ended March 31, 2020 were $36.5 million, compared to $31.3 million for the comparable period in 2019. The increase was primarily due to the $10.0 million equity and cash upfront payments in February 2020 made to Xencor, Inc. for the license of AIMab7195. The increase was partially offset by decreased clinical trial costs primarily due to the close-out of certain PALFORZIA clinical trials and decreased manufacturing costs as we began capitalizing costs for inventory upon FDA approval of PALFORZIA. Adjusting for the AIMab7195 license fee, the first quarter continued a trend of reduced quarterly research and development expense.

Selling, general and administrative expenses for the quarter ended March 31, 2020 were $49.1 million, compared to $23.7 million for the comparable period in 2019. The increase was primarily due to
additional headcount to support the commercialization of PALFORZIA, including a specialty field team of approximately 80 Practice Account Managers targeting practicing allergists, and other costs related to medical affairs and the preparations for commercial launch.

Cash, cash equivalents, and investments totaled $371.6 million on March 31, 2020, compared to $158.2 million on December 31, 2019. The increase primarily reflects cash provided in February 2020 from Nestlé Health Sciences' additional equity investment of $200.0 million and additional borrowings under our debt agreement with KKR of $85.0 million. The increase was partially offset by cash used in operations, which included approximately $15.0 million in cash expenses unique to the first quarter.

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), which excludes from GAAP net loss (and the related per share measures) stock-based compensation expense as well as upfront cash and equity payments associated with the execution of a development license agreement in the first quarter of 2020.

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 3077398. 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 AIMab7195

AIMab7195 is an anti-IgE monoclonal antibody with enhanced binding to the Fc gamma receptor IIb (FcγRIIb). IgE recognizes and interacts with allergens and, as a result, can activate immune cells, such as mast cells and basophils, that drive an allergic response in patients. AIMab7195 is designed to clear IgE rapidly from circulation, to prevent the production of IgE by preventing the activation of IgE-positive B cells, and to block IgE from interacting with its receptor on immune cells. AIMab7195 has been evaluated in two Phase 1 studies that enrolled more than 100 healthy volunteers and patients with allergy and atopic disease.

In February 2020, Aimmune licensed exclusive worldwide rights to Xencor's XmAb®7195 for any human therapeutic use; the company intends to focus its efforts on its development as a component of next-generation food allergy treatments.

About AR201

AR201 is an investigational biological drug in Phase 2 clinical development for use in oral immunotherapy for egg allergy. Academic studies of the oral immunotherapy approach for egg allergy treatment have shown efficacy, and Aimmune is studying this more broadly with AR201 in order to enable widespread availability of a potential treatment.

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 ≥ 5% and ≥ 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

With a mission to improve the lives of people with food allergies, Aimmune Therapeutics is a biopharmaceutical company developing and commercializing 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 potential benefits of PALFORZIA, AR201 and AIMab7195; Aimmune's expectations regarding the commercial launch of PALFORZIA; Aimmune's expectations regarding, including the timing of a potential acceptance and applicable review period of the MAA for AR101 by the EMA and by Swissmedic; Aimmune's expectations on the timing of completing a phase 2 clinical trial for AR201; Aimmune's expectations on the planned timing for the completion of enrollment and announcement of data from the POSEIDON clinical trial for PALFORZIA; Aimmune's expectations on the mechanisms of action of AIMab7195; 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 sufficiency of its cash resources; 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; 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 Annual Report on Form 10-K for the year ended December 31, 2019. 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)

	March 31, 2020 (Unaudited)	December 31, 2019 (1)
Assets		
Cash and cash equivalents	$ 298,418	$ 79,880
Short-term investments	59,933	63,633
Trade receivables, net	772	—
Inventories	4,076	—
Prepaid expenses and other current assets	4,621	5,564
Total current assets	367,820	149,077
Long-term investments	13,256	14,661
Property and equipment, net	27,506	28,604
Operating lease right-of-use assets	10,913	11,512
Prepaid expenses and other assets	557	515
Total assets	$ 420,052	$ 204,369
Liabilities and Stockholders' Equity		
Current liabilities	$ 45,419	$ 47,448
Long term debt, net of discount	128,250	41,028
Operating lease liabilities, non-current	9,824	10,524
Other liabilities	1,512	1,345
Stockholders' equity	235,047	104,024
Total liabilities and stockholders' equity	$ 420,052	$ 204,369

(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)

	Quarter Ended March 31,	
	2020	**2019**
Product revenue, net	$ 575	$ —
Costs and operating expenses		
Cost of revenue	257	—
Research and development	36,463	31,316
Selling, general and administrative	49,138	23,712
Total costs and operating expenses	85,858	55,028
Loss from operations	(85,283)	(55,028)
Interest income	978	1,901
Interest expense	(2,229)	(1,144)
Other income, net	221	34
Loss before provision for income taxes	(86,313)	(54,237)
Provision for income taxes	119	29
Net loss	$ (86,432)	$ (54,266)
Net loss per common share, basic and diluted	$ (1.34)	$ (0.87)
Shares used in computing net loss per common share, basic and diluted	64,514	62,022

	Quarter Ended March 31,	
	2020	**2019**
GAAP net loss	$ (86,432)	$ (54,266)
Non-GAAP adjustments:		
Stock-based compensation:		
Cost of revenue	4	—
Research and development expenses	4,061	2,743
Selling, general and administrative expenses	6,238	5,022
Upfront cash and equity payments associated with a development agreement	10,000	—
Non-GAAP net loss	$ (66,129)	$ (46,501)
GAAP net loss per share, basic and diluted	$ (1.34)	$ (0.87)
Non-GAAP net loss per share, basic and diluted	$ (1.03)	$ (0.75)
Shares used in computing net loss per share, basic and diluted	64,514	62,022