ANTARES PHARMA, INC.
Form 10-Q
May 08, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D)

OF THE SECURITIES EXCHANGE ACT OF 1934.

For the quarterly period ended March 31, 2018

Commission File Number 1-32302

ANTARES PHARMA, INC.

A Delaware Corporation IRS Employer Identification No. 41-1350192
100 Princeton South, Suite 300

Ewing, New Jersey 08628

(609) 359-3020

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and

post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer”, “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer		Accelerated filer
Non–accelerated filer	(do not check if a smaller reporting company)	Smaller reporting company
		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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The number of shares outstanding of the registrant’s Common Stock, $.01 par value, as of May 1, 2018 was 156,825,557.

ANTARES PHARMA, INC.

INDEX

PART I – FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS
ANTARES PHARMA, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share amounts)

	March 31, 2018 (Unaudited)	December 31, 2017
Assets		
Current Assets:		
Cash and cash equivalents	$ 23,111	$ 26,562
Short-term investments	4,997	4,993
Accounts receivable	12,494	11,878
Inventories	9,929	9,275
Deferred costs	432	505
Prepaid expenses and other current assets	2,074	2,323
Total current assets	53,037	55,536
Equipment, molds, furniture and fixtures, net	15,892	16,158
Patent rights, net	1,267	1,401
Goodwill	1,095	1,095
Other assets	148	148
Total Assets	$ 71,439	$ 74,338
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 6,652	$ 5,957
Accrued expenses and other liabilities	6,868	6,982
Deferred gain	2,750	—
Deferred revenue	1,797	2,794
Total current liabilities	18,067	15,733
Long-term debt	24,925	24,858
Deferred revenue – long term	200	200
Total liabilities	43,192	40,791
Stockholders' Equity:		
Preferred Stock: $0.01 par, authorized 3,000 shares, none outstanding	—	—
Common Stock: $0.01 par; 300,000 shares authorized; 156,821 and 156,675 issued and outstanding at March 31, 2018 and December 31, 2017, respectively	1,568	1,567
Additional paid-in capital	303,847	302,965
Accumulated deficit	(276,478)	(270,285)
Accumulated other comprehensive loss	(690)	(700)
	28,247	33,547

Total Liabilities and Stockholders' Equity	$ 71,439	$ 74,338

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

(UNAUDITED)

	For the Three Months Ended March 31,	
	2018	2017
Revenue:		
Product sales	$10,949	$10,037
Licensing and development revenue	1,285	1,640
Royalties	469	330
Total revenue	12,703	12,007
Cost of revenue:		
Cost of product sales	6,536	5,448
Cost of development revenue	650	771
Total cost of revenue	7,186	6,219
Gross profit	5,517	5,788
Operating expenses:		
Research and development	3,320	3,087
Selling, general and administrative	7,816	7,467
Total operating expenses	11,136	10,554
Operating loss	(5,619)	(4,766)
Interest expense	(631)	—
Other income	57	30
Net loss	$(6,193)	$(4,736)
Basic and diluted net loss per common share	$(0.04)	$(0.03)
Basic and diluted weighted average common shares outstanding	156,724	155,215

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

(UNAUDITED)

	For the Three Months Ended March 31,	
	2018	2017
Net loss	$(6,193)	$(4,736)
Foreign currency translation adjustment	10	4
Comprehensive loss	$(6,183)	$(4,732)

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(UNAUDITED)

	Three Months Ended March 31,	
	2018	2017
Cash flows from operating activities:		
Net loss	$(6,193)	$(4,736)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	985	536
Depreciation and amortization	604	494
Accretion of interest expense	52	—
Amortization of debt issuance costs	15	—
Amortization of premiums and discounts on investment securities	(4)	—
Changes in operating assets and liabilities:		
Accounts receivable	(608)	1,190
Inventories	(655)	(1,525)
Prepaid expenses and other assets	250	(144)
Deferred costs	73	61
Accounts payable	550	1,139
Accrued expenses and other current liabilities	(99)	1,225
Deferred revenue	(999)	(2,222)
Net cash used in operating activities	(6,029)	(3,982)
Cash flows from investing activities:		
Proceeds from sale of assets	2,750	—
Purchases of equipment, molds, furniture and fixtures	(61)	(427)
Additions to patent rights	(10)	(9)
Net cash provided by (used in) investing activities	2,679	(436)
Cash flows from financing activities:		
Proceeds from exercise of stock options	28	381
Taxes paid related to net share settlement of equity awards	(130)	—
Net cash (used in) provided by financing activities	(102)	381
Effect of exchange rate changes on cash	1	(1)
Net decrease in cash and cash equivalents	(3,451)	(4,038)
Cash and cash equivalents:		
Beginning of period	26,562	27,715
End of period	$23,111	$23,677
Supplemental disclosure of non-cash investing activities:		
Purchases of equipment, molds, furniture and fixtures recorded in accounts payable and accrued expenses	$173	$94

Additions to patent rights recorded in accounts payable and accrued expenses	$6	$48

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(in thousands, except per share amounts)

(UNAUDITED)

1. Description of Business

Antares Pharma, Inc. ("Antares" or the "Company") is a specialty pharmaceutical company focused primarily on the development and commercialization of self-administered parenteral pharmaceutical products and technologies. The Company develops and manufactures, for itself or with partners, novel therapeutic products using its advanced drug delivery technology to enhance the existing drug compounds and delivery methods. The subcutaneous injection technology platforms include the VIBEX® and VIBEX® QuickShot® pressure-assisted auto injector systems suitable for branded and generic injectable drugs in unit dose containers and disposable multi-dose pen injectors. The Company has a portfolio of proprietary and partnered products, including approved commercial products and several partnered product candidates in advanced stages of development. The Company has formed significant strategic alliances with Teva Pharmaceutical Industries, Ltd. ("Teva") and AMAG Pharmaceuticals, Inc. ("AMAG"), and has multiple ongoing internal and partnered product development programs.

The Company markets and sells its proprietary product OTREXUP® (methotrexate) injection in the U.S. OTREXUP® is the first subcutaneous methotrexate for once weekly self-administration with an easy-to-use, single dose, disposable auto injector approved by the FDA. OTREXUP® is indicated for adults with severe active rheumatoid arthritis, children with active polyarticular juvenile idiopathic arthritis and adults with severe recalcitrant psoriasis, and was launched for commercial sale in February 2014.

Through its commercialization partner Teva, the Company sells Sumatriptan Injection USP, indicated in the U.S. for the acute treatment of migraine and cluster headache in adults. In December 2015, the Company received FDA approval for an Abbreviated New Drug Application ("ANDA") for 4 mg/0.5 mL and 6 mg/0.5 mL single-dose prefilled syringe auto-injectors, a generic equivalent to Imitrex® STATdose Pen®. Sumatriptan Injection USP represents the Company's first ANDA approval of a complex generic and second product approved using the VIBEX® auto injector platform, and was launched for commercial sale in June 2016.

In collaboration with AMAG, the Company developed a subcutaneous auto injector for use with AMAG's progestin hormone drug Makena® (hydroxyprogesterone caproate injection) under an exclusive license and development agreement. In February 2018, the FDA approved AMAG's supplemental New Drug Application ("sNDA") for the Makena® subcutaneous auto injector drug-device combination product, which is a ready-to-administer treatment indicated to reduce the risk of preterm birth in women pregnant with one baby and who spontaneously delivered one preterm baby in the past. The Company is the exclusive supplier of the devices and final assembled and packaged commercial product. AMAG launched the product for commercial sale in the first quarter of 2018.

The Company is developing XYOSTED™ (testosterone enanthate) injection for testosterone replacement therapy, and submitted a 505(b)(2) New Drug Application ("NDA") to the FDA in December 2016. In October 2017, the Company received a Complete Response Letter (the "CRL") from the FDA for XYOSTED™, which identified two deficiencies. In February 2018, the Company met with the FDA to discuss a potential path forward for submission of a

response to the CRL for XYOSTED™. In March 2018, the Company provided a resubmission in response to the CRL, which was accepted by the FDA and assigned a target action date of September 29, 2018.

2. Basis of Presentation and Significant Accounting Policies

The accompanying unaudited consolidated financial statements have been prepared in accordance with generally accepted accounting principles ("GAAP") in the U.S. for interim financial information and with the instructions to Form 10-Q and Article 10 of the Securities and Exchange Commission's Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the U.S. for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. The accompanying consolidated financial statements and notes thereto should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2017. Operating results for the three months ended March 31, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018.

Accounting Pronouncements Recently Adopted

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers (Topic 606), supplemented with a number of subsequent amendments issued by the FASB and collectively referred to herein as "Topic 606". This guidance supersedes the revenue recognition requirements in Topic 605 Revenue Recognition ("Topic 605") and requires entities to recognize revenues when control of promised goods or

ANTARES PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(in thousands, except per share amounts)

(UNAUDITED)

services is transferred to customers at an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services. The Company adopted Topic 606 as of January 1, 2018 using the modified retrospective transition method. Results for reporting periods beginning on or after January 1, 2018 are presented under Topic 606, while prior period amounts, as reported, were not adjusted. The cumulative effects of the adoption of the new standard were not material to the Company or its consolidated financial statements. In addition, the difference between the amount of revenue recognized for the three months ended March 31, 2018 under Topic 606 as compared to the amount of revenue that would have been recognized under Topic 605 is not material. See Revenue Recognition below for additional information about the Company's revenue recognition policy in accordance with Topic 606.

In May 2017, the FASB issued ASU No. 2017-05, Other Income – Gains and Losses from the Derecognition of Nonfinancial Assets (Subtopic 610-20): Clarifying the Scope of Asset Derecognition Guidance and Accounting for Partial Sales of Nonfinancial Assets ("ASU 2017-05"). The amendments clarify that an entity should identify each distinct nonfinancial asset or in-substance nonfinancial asset promised to a counterparty and derecognize each asset when a counterparty obtains control of it. The Company adopted ASU 2017-05 effective January 1, 2018, which did not have any impact on the consolidated financial statements or result in any adjustment to opening retained earnings. See additional information about the impact of this standard in connection the accounting for the sale of assets discussed in Note 3.

In May 2017, the FASB issued ASU No. 2017-09, Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting ("ASU 2017-09"), which provides guidance on determining which changes to terms and conditions of share-based awards require an entity to apply modification accounting under Topic 718. This new standard is effective for annual reporting periods beginning after December 15, 2017. The adoption of ASU 2017-09 did not have a significant impact on the Company's consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02"). This new standard requires entities to recognize on its balance sheet assets and liabilities associated with the rights and obligations created by leases with terms greater than twelve months. This new standard is effective for annual reporting periods beginning after December 15, 2018, and interim periods within those annual periods and early adoption is permitted. The Company is currently evaluating the impact of ASU 2016-02 on its consolidated financial statements and currently expects that most of its operating lease commitments will be subject to the new standard and recognized as operating lease liabilities and right-of-use assets in the statement of financial position upon adoption of ASU 2016-02 effective January 1, 2019.

Investments

The Company's investments consist of U.S. government agency notes that are classified as held-to-maturity because the Company has the intent and ability to hold the securities to maturity. Investments with maturities of one year or less are classified as short-term. The securities are carried at their amortized cost and the fair value is determined by

quoted market prices. At March 31, 2018 and December 31, 2017, the Company's investments had a carrying value of $4,997 and $4,993, respectively, which approximated fair value.

Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is determined on a first-in, first-out basis. Certain components of the Company's products are provided by a limited number of vendors, and the Company's production, assembly, warehousing and distribution operations are outsourced to third-parties where substantially all of the Company's inventory is located. Disruption of supply from key vendors or third-party suppliers may have a material adverse impact on the Company's operations. The Company provides a reserve for potentially excess, dated or obsolete inventories based on an analysis of inventory on hand compared to forecasts of future sales, which was $522 and $510 at March 31, 2018 and December 31, 2017, respectively. Inventories consist of the following:

ANTARES PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(in thousands, except per share amounts)

(UNAUDITED)

	March 31, 2018	December 31, 2017
Inventories:		
Raw material	$ 118	$ 118
Work in process	7,248	6,223
Finished goods	2,563	2,934
	$ 9,929	$ 9,275

Long-term debt

The carrying value of the Company's term loan was $24,925 and $24,858 as of March 31, 2018 and December 31, 2017, respectively, which is presented net of unamortized debt issuance costs. As of March 31, 2018, the prime-based variable interest rate was 9.25%. The Company believes that the carrying value of the term loan approximates its fair value based on the borrowing rates currently available for loans with similar terms.

Revenue Recognition

The Company generates revenue from product sales, license and development activities and royalty arrangements. Revenue is recognized when or as the Company transfers control of the promised goods or services to its customers in an amount that reflects the consideration to which it expects to be entitled to in exchange for those goods or services.

The Company sells its proprietary product OTREXUP® to wholesale pharmaceutical distributors. Product revenue from sales of OTREXUP® is recognized upon delivery of the goods to distributors and is presented net of estimated returns and product sales allowances for wholesaler discounts, prompt pay discounts, chargebacks, rebates and other patient discount programs. The Company estimates returns and product sales allowances using the expected value method based on historical trends and other known factors. Rebates are estimated using the most likely method based on historical trends and the terms of contracts in place.

The Company sells Sumatriptan Injection USP to Teva under a license, supply and distribution agreement. The Company is initially compensated at cost for shipments of product to Teva and is entitled to receive 50 percent of the net profits from commercial sales made by Teva. The Company recognizes revenue, including the estimated variable consideration it expects to receive for contract margin on future commercial sales, upon shipment of the goods to Teva. The estimated variable consideration is recognized at an amount the Company believes is not subject to significant reversal based on historical experience and is adjusted at each reporting period if the most likely amount of expected consideration changes or becomes fixed.

The Company is the exclusive supplier of the Makena® subcutaneous auto injector product to AMAG under a manufacturing agreement. Because the product that the Company produces for AMAG is custom product with no alternative use and the Company has a right to payment for performance completed to date, control is continuously transferred to the customer with respect to the product supply and therefore revenue is recognized at the transaction price as product is manufactured pursuant to firm purchase orders. The amount of revenue recognized in excess of the amount billed to the customer, if any, is recorded in accounts receivable due to the short-term nature in which the amount is ultimately expected to be billed and collected from the customer.

The Company generally contracts with its partners/customers for license, development and supply arrangements involving highly-customized customer-specific deliverables and development activities that often span multiple phases of a product lifecycle and include multiple performance obligations. For such arrangements, the Company allocates consideration to each performance obligation at inception of the arrangement based on relative standalone selling price, which is generally determined based on the expected cost plus margin. License fees received in exchange for the grant of a license to the Company's functional intellectual property ("IP") such as patented technology and know-how in connection with a partnered development arrangement are generally recognized at inception of the arrangement or over the development period depending on the facts and circumstances, as the license is not generally distinct from the non-licensed goods or services to be provided under the contract. Sales or usage based royalties for which the license is the predominant item to which the royalties relate are recognized at the later of when sales or usage occurs. Other forms of variable consideration, such as milestone payments that are contingent upon the occurrence of future events, are evaluated and recorded at the most likely amount, and to the extent that it is probable that a significant reversal will not occur when the associated uncertainty is resolved.

ANTARES PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(in thousands, except per share amounts)

(UNAUDITED)

The Company's typical payment terms for development contracts include an upfront payment equal to a percentage of the total contract value with the remaining portion to be billed upon completion and transfer of the individual deliverables or satisfaction of the individual performance obligations. The Company records a liability for the cash received in advance of performance, which is presented within deferred revenue on the balance sheet and recognized as revenue when the associated performance obligations have been satisfied. The advance payment typically is not considered a significant financing component because it is used to meet working capital demands that can be higher in the early stages of a contract.

Revenues from development contracts and partnered product supply arrangements, other than the product supplied under the AMAG manufacturing agreement described above, are recognized at the point in time in which the performance obligation is satisfied and control of the good or service is transferred to the customer. Factors that may indicate that the transfer of control has occurred include the transfer of legal title, transfer of physical possession, the customer has obtained the significant risks and rewards of ownership of the assets and the Company has a present right to payment.

Most often, amendments or modifications to existing development contracts are for goods or services that are distinct from the initial contract and are accounted for as a separate contract.

The Company has elected to recognize the cost for freight and shipping activities as fulfilment cost. Amounts billed to customers for shipping and handling are included as part of the transaction price and recognized as revenue when control of underlying products is transferred to the customer. The related shipping and freight charges incurred by the Company are included in cost of revenue.

Remaining Performance Obligations

Remaining performance obligations represents the transaction price of firm orders and development contract deliverables for which work has not been completed or orders fulfilled, and excludes potential purchase orders under ordering-type supply contracts with indefinite delivery or quantity. As of March 31, 2018, the aggregate value of remaining performance obligations, excluding contracts with an original expected length of one year or less, was $2.3 million. The Company expects to recognize revenue on the remaining performance obligations over the next twelve months.

3. Sale of Assets

In October 2017, the Company entered into an asset purchase agreement (the "Asset Purchase Agreement") with Ferring to sell the worldwide rights, including certain assets, related to the needle-free auto injector device product line for a total purchase price of $14.5 million.

The purchase price is to be paid in four installments consisting of the following: a $2.0 million non-refundable upfront payment, which was received upon entry into the Asset Purchase Agreement and the transfer of certain assets; a

second installment of $2.75 million received in February 2018 upon delivery of certain documentation and satisfaction of certain conditions primarily related to product manufacturing; a third installment of $4.75 million payable upon satisfaction of certain conditions including further document transfer, Ferring's successful completion of a regulatory audit by a notified body, and a pilot manufacturing run under Ferring's supervision; and a final installment of $5.0 million upon Ferring's receipt of the CE Mark needed to continue to commercialize the product in certain territories and the final transfer of certain product-related inventory, equipment and agreements to Ferring, which the Company anticipates may occur by the end of 2018.

In the fourth quarter of 2017, the Company recognized a gain on sale of assets upon receipt of the $2.0 million non-refundable upfront payment and transfer of certain manufacturing equipment and patents to Ferring. The second and third installments are refundable to Ferring under certain circumstances if completion of the transaction does not occur within a specified timeframe. Given the uncertainty about the payment and refundability of each subsequent milestone, under ASU 2017-05, the gain on the remaining milestone payments will be recognized when it becomes probable that a significant reversal of the gain will not occur, to be reviewed and updated at each reporting period. During the three months ended March 31, 2018, the Company satisfied certain conditions and received the second installment of $2.75 million. Cash proceeds received in excess of recognized gain have been recorded as deferred gain in the accompanying consolidated balance sheet.

ANTARES PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(in thousands, except per share amounts)

(UNAUDITED)

4. Share-Based Compensation

The Company's 2008 Equity Compensation Plan (the "Plan") allows for grants in the form of incentive stock options, nonqualified stock options, stock units, stock awards, stock appreciation rights, and other stock-based awards. All of the Company's officers, directors, employees, consultants and advisors are eligible to receive grants under the Plan. The maximum number of shares authorized for issuance under the amended and restated Plan is 32,200 and the maximum number of shares of stock that may be granted to any one employee for qualified performance-based compensation during a calendar year is 4,000 shares. Options to purchase shares of common stock are granted at exercise prices not less than 100% of fair market value on the dates of grant. The term of each option is ten years and the options typically vest in quarterly installments over a three-year period with a minimum vesting period of one year. As of March 31, 2018, the Plan had approximately 6,600 shares available for grant. Stock option exercises are satisfied through the issuance of new shares.

Stock Options

The following is a summary of stock option activity under the Plan as of and for the three months ended March 31, 2018:

	Number of	Weighted Average Exercise	Weighted Average Remaining	Aggregate