ANTARES PHARMA, INC.
Form 10-Q
November 06, 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 September 30, 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 every Interactive Data File required to be submitted 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 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	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 November 1, 2018 was 157,541,269.

ANTARES PHARMA, INC.

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PART I – FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS
ANTARES PHARMA, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share amounts)

	September 30, 2018 (Unaudited)	December 31, 2017
Assets		
Current Assets:		
Cash and cash equivalents	$ 28,160	$ 26,562
Short-term investments	—	4,993
Accounts receivable	15,483	11,878
Inventories	11,275	9,275
Deferred costs	275	505
Prepaid expenses and other current assets	1,806	2,323
Total current assets	56,999	55,536
Equipment, molds, furniture and fixtures, net	15,325	16,158
Patent rights, net	998	1,401
Goodwill	1,095	1,095
Other assets	148	148
Total Assets	$ 74,565	$ 74,338
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 7,497	$ 5,957
Accrued expenses and other liabilities	9,124	6,982
Deferred gain	7,500	—
Deferred revenue	811	2,794
Total current liabilities	24,932	15,733
Long-term debt	25,059	24,858
Deferred revenue – long term	200	200
Total liabilities	50,191	40,791
Stockholders' Equity:		
Preferred Stock: $0.01 par, authorized 3,000 shares, none outstanding	—	—
Common Stock: $0.01 par; 300,000 shares authorized; 157,521 and 156,675 issued and outstanding at September 30, 2018 and December 31, 2017, respectively	1,575	1,567
Additional paid-in capital	306,435	302,965
Accumulated deficit	(282,934)	(270,285)

Accumulated other comprehensive loss	(702)	(700)
	24,374	33,547
Total Liabilities and Stockholders' Equity	$ 74,565	$ 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 September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue:				
Product sales	$11,597	$13,328	$33,641	$30,709
Licensing and development revenue	2,554	1,504	5,624	8,952
Royalties	3,717	220	5,468	815
Total revenue	17,868	15,052	44,733	40,476
Cost of revenue:				
Cost of product sales	6,982	7,600	20,195	16,682
Cost of development revenue	307	923	1,240	3,677
Total cost of revenue	7,289	8,523	21,435	20,359
Gross profit	10,579	6,529	23,298	20,117
Operating expenses:				
Research and development	3,611	3,289	10,581	9,535
Selling, general and administrative	8,327	8,186	23,606	23,013
Total operating expenses	11,938	11,475	34,187	32,548
Operating loss	(1,359)	(4,946)	(10,889)	(12,431)
Interest expense	(674)	(626)	(1,959)	(794)
Other income	97	119	199	197
Net loss	$(1,936)	$(5,453)	$(12,649)	$(13,028)
Basic and diluted net loss per common share	$(0.01)	$(0.03)	$(0.08)	$(0.08)
Basic and diluted weighted average common shares outstanding	157,471	156,401	157,076	155,852

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

(UNAUDITED)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Net loss	$(1,936)	$(5,453)	$(12,649)	$(13,028)
Foreign currency translation adjustment	(2)	(4)	(2)	13
Comprehensive loss	$(1,938)	$(5,457)	$(12,651)	$(13,015)

See accompanying notes to consolidated financial statements.

ANTARES PHARMA, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(UNAUDITED)

	Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	$(12,649)	$(13,028)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3,655	2,371
Depreciation and amortization	1,808	1,520
Accretion of interest expense	157	66
Amortization of debt issuance costs	43	18
Other	(7)	52
Changes in operating assets and liabilities:		
Accounts receivable	(3,606)	(1,069)
Inventories	(2,000)	(2,615)
Prepaid expenses and other assets	517	(300)
Deferred costs	230	560
Accounts payable	1,518	702
Accrued expenses and other current liabilities	2,157	550
Deferred revenue	(1,983)	(4,309)
Net cash used in operating activities	(10,160)	(15,482)
Cash flows from investing activities:		
Proceeds from sale of assets	7,500	—
Proceeds from maturities of investment securities	5,000	—
Purchases of investment securities	—	(9,964)
Purchases of equipment, molds, furniture and fixtures	(526)	(879)
Additions to patent rights	(40)	(83)
Net cash provided by (used in) investing activities	11,934	(10,926)
Cash flows from financing activities:		
Proceeds from issuance of long-term debt	—	25,000
Payment of debt issuance costs	—	(293)
Proceeds from exercise of stock options	366	1,670
Taxes paid related to net share settlement of equity awards	(543)	(249)
Net cash (used in) provided by financing activities	(177)	26,128
Effect of exchange rate changes on cash	1	(1)
Net increase (decrease) in cash and cash equivalents	1,598	(281)
Cash and cash equivalents:		
Beginning of period	26,562	27,715
End of period	$28,160	$27,434
Supplemental disclosure of non-cash investing activities:		

Purchases of equipment, molds, furniture and fixtures recorded in accounts payable and accrued expenses	$56	$93
Additions to patent rights recorded in accounts payable and accrued expenses	$—	$6

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 commercializes, for itself or with partners, novel therapeutic products using its advanced drug delivery technology to enhance existing drug compounds and delivery methods. The Company's intramuscular and 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 commercial products and ongoing product development programs in various stages of development. The Company has formed significant strategic alliances with Teva Pharmaceutical Industries, Ltd. ("Teva"), AMAG Pharmaceuticals, Inc. ("AMAG") and Pfizer Inc. ("Pfizer".)

The Company developed XYOSTED™ (testosterone enanthate) injection, which is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone, and was approved by the U.S. Food and Drug Administration ("FDA") on September 28, 2018. XYOSTED™ is the only FDA approved subcutaneous testosterone enanthate product for once-weekly, at-home self-administration. The Company is preparing for the commercial launch of XYOSTED™ by the end of 2018. The Company also markets and sells its proprietary product OTREXUP® (methotrexate) injection in the U.S., which 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. Sumatriptan Injection USP 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.

Through a license, development and supply agreement with Teva, Antares developed and is the exclusive supplier of the device for an epinephrine auto injector product to be sold in the U.S. Teva's epinephrine auto injector drug-device combination product, indicated for emergency treatment of severe allergic reactions in adults and certain pediatric patients, was approved by the FDA in August 2018.

The Company is also developing two multi-dose pen injector products in collaboration with Teva, a combination drug device rescue pen in collaboration with Pfizer, and has other ongoing internal research and development programs.

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 and nine months ended September 30, 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 services is transferred to customers at an amount that reflects the consideration to which the entity expects to be entitled to in

ANTARES PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(in thousands, except per share amounts)

(UNAUDITED)

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 and nine months ended September 30, 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. The Company is currently evaluating the impact of ASU 2016-02 on its consolidated financial statements and currently expects that 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

From time to time, the Company has invested in U.S. Treasury bills and government agency notes that are classified as held-to-maturity because of the Company's intent and ability to hold the securities to maturity. Investments with maturities of one year or less are classified as short-term. These securities are carried at their amortized cost and fair value is determined by quoted market prices. At September 30, 2018, the Company had no short-term investments, and at December 31, 2017, the Company's investments had a carrying value of $4,993, 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 $352 and $510 at September 30, 2018 and December 31, 2017, respectively. Inventories consist of the following:

	September 30, 2018	December 31, 2017
Inventories:		
Raw material	$ 117	$ 118
Work in process	8,140	6,223
Finished goods	3,018	2,934
	$ 11,275	$ 9,275

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(UNAUDITED)

Equipment, Molds, Furniture, and Fixtures

Equipment, molds, furniture, and fixtures are stated at cost, net of accumulated depreciation, and are depreciated using the straight-line method over their estimated useful lives ranging from three to ten years. As of September 30, 2018 and December 31, 2017, the Company's equipment, molds, furniture and fixtures totaled $15,325 and $16,158, respectively, which is presented net of accumulated depreciation of $6,820 and $5,445 as of September 30, 2018 and December 31, 2017, respectively. Depreciation expense was $1,376 and $1,068 for the nine months ended September 30, 2018 and 2017, respectively.

Long-term debt

The carrying value of the Company's term loan was $25,059 and $24,858 as of September 30, 2018 and December 31, 2017, respectively, which is presented net of unamortized debt issuance costs. As of September 30, 2018, the prime-based variable interest rate was 9.50%. 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 at the transaction price, which is the 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 product 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 based on historical trends, inventory levels remaining in the distribution channel, the terms of contracts in place and other known factors or market expectations.

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.

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(in thousands, except per share amounts)

(UNAUDITED)

The Company's typical payment terms for development contracts may 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 September 30, 2018, the aggregate value of remaining performance obligations, excluding contracts with an original expected length of one year or less, was $5.6 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 International Center S.A (together with Ferring Pharmaceuticals Inc. and Ferring B.V. individually and collectively referred to as "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 was agreed 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 received in May 2018 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 to be paid 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 nine months ended September 30, 2018, the Company satisfied certain conditions and received the second and third installments of $2.75 million and $4.75 million, respectively. These 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 September 30, 2018, the Plan had approximately 2,800 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 nine months ended September 30, 2018:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2017	12,149	$ 2.04		
Granted	2,633	2.72		
Exercised	(415)	1.05		
Cancelled/Forfeited	(143)	2.21		
Outstanding at September 30, 2018	14,224	2.19	7.1	$ 16,971
Exercisable at September 30, 2018	9,932	$ 2.06	6.2	$ 13,240

The per share weighted average fair value of all options granted during the nine months ended September 30, 2018 and 2017 was $1.44 and $1.37, respectively, estimated on the date of grant using the Black-Scholes option pricing model based on the assumptions noted in the table below. Expected volatilities are based on the historical volatility of the Company's stock price. The weighted average expected life is based on both historical and anticipated employee behavior.

	For the Nine Months Ended September 30,	
	2018	2017
Risk-free interest rate	2.8%	1.8%
Annualized volatility	53.7%	53.3%
Weighted average expected life, in years	6.0	6.0
Expected dividend yield	0.0%	0.0%

During the nine months ended September 30, 2018, stock option exercises resulted in cash proceeds to the Company of $366 and the issuance of 385 shares of common stock. A portion of the stock options were net exercised, whereby the Company withheld 30 shares, the fair value of which was equivalent to the aggregate exercise price and tax withholding on the date of exercise. For the nine months ended September 30, 2017, stock option exercises resulted in proceeds of $1,670 and the issuance of 1,063 shares of common stock.

The Company recognized $2,158 and $1,680 of compensation expense related to stock options for the nine months ended September 30, 2018 and 2017, respectively, and $811 and $693 for the three months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, there was $5,331 of total unrecognized compensation cost related to non-vested outstanding stock options that is expected to be recognized over a weighted average period of approximately 2.0 years.

Long Term Incentive Program

The Company’s Board of Directors has approved a long-term incentive program (“LTIP”) for the benefit of the Company’s senior executives. Pursuant to the LTIP, the Company’s senior executives have been awarded stock options, restricted stock

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(in thousands, except per share amounts)

(UNAUDITED)

units (“RSU”) and performance stock units (“PSU”) with targeted values based on values granted to similarly situated senior executives in the Company’s peer group.

The stock options have a ten-year term, have an exercise price equal to the closing price of the Company’s common stock on the date of grant, vest in quarterly installments over three years, were otherwise granted on the same standard terms and conditions as other stock options granted pursuant to the Plan and are included in the stock options table above. The RSUs vest in three equal annual installments. The PSU awards made to the senior executives vest and convert into shares of the Company’s common stock based on the Company’s attainment of certain performance goals as established by the Company’s Board of Directors over a performance period, which is typically three years.

The PSU awards and RSU awards granted under the long-term incentive program are summarized in the following table:

	Performance Stock Units		Restricted Stock Units	
	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2017	1,456	$ 2.20	1,157	$ 2.12
Granted	611	2.89	611	2.70
Vested/settled	(173)	2.18	(500)	1.99
Forfeited/expired	—	—	—	—
Outstanding at September 30, 2018	1,894	$ 2.48	1,268	$ 2.46

The LTIP awards granted in 2018 include PSUs that may be earned based on the Company’s achievement of certain corporate development goals, 2020 net revenue and total shareholder return (“TSR”) relative to the Nasdaq Biotechnology Index at the end of the performance period. The performance period is January 1, 2018 to December 31, 2020, and depending on the outcome of the individual performance goals, a recipient may ultimately earn a number of shares greater or less than their target number of shares granted, ranging from 0% to 150% of the PSUs granted. The fair value of the TSR PSUs is expensed over the performance period and was determined using a Monte Carlo simulation utilizing the following inputs and assumptions:

	2018 Award

Closing stock price on grant date	$ 2.70	
Performance period starting price	$ 1.92	
Term of award (in years)	2.57	
Volatility	64.9	%
Risk-free interest rate	2.6	%
Expected dividend yield	0.0	%
Fair value per TSR PSU	$ 3.27	

In connection with PSU awards, the Company recognized compensation expense of $456 and $152 for the three months ended September 30, 2018 and 2017, respectively and $636 and $240 for the nine months ended September 30, 2018 and 2017, respectively. Compensation expense recognized in connection with RSU awards was $338 and $243 for the three months ended September 30, 2018 and 2017, respectively, and $861 and $451 for the nine months ended September 30, 2018 and 2017, respectively.

The LTIP awards that vested during the nine months ended September 30, 2018 and 2017 were net-share settled such that the Company withheld shares with a value equivalent to the employees' minimum statutory obligation for the applicable income and other employment taxes, and remitted the cash to the appropriate taxing authorities. The total shares withheld to satisfy tax obligations were 211 and 98 in the nine months ended September 30, 2018 and 2017, respectively, based on the fair value of the shares on the respective vesting date as determined by the Company's closing stock price on such date. Total withholding for employees' tax obligations to be paid to the taxing authorities were $543 and $249 for the nine months ended September 30, 2018 and 2017, respectively, which is reflected as a financing activity within the consolidated statements of cash flows. Net-share settlements have the effect of share repurchases by the Company as they reduce the number of shares that would have otherwise been issued as a result of the vesting and do not represent an expense to the Company.

ANTARES PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(in thousands, except per share amounts)

(UNAUDITED)

5. Revenues, Significant Customers and Concentrations of Risk

The following table presents the Company's revenue on a disaggregated basis by types of products and services and major product lines:

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
OTREXUP®	$4,094	$4,624	$11,820	$13,111
Sumatriptan Injection USP	3,983	6,375	9,438	12,264
Auto injector and pen injector devices	1,829	1,571	7,925	2,225
Needle-free injector devices and components	1,691	758	4,458	3,109
Total product sales	11,597	13,328	33,641	30,709
Licensing and development revenue	2,554	1,504	5,624	8,952
Royalties	3,717	220	5,468	815
Total revenue	$17,868	$15,052	$44,733	$40,476

Revenues disaggregated by customer location are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
United States of America	$16,027	$14,174	$39,448	$37,009
Europe	1,830	750	5,044	3,018
Other	11	128	241	449
	$17,868	$15,052	$44,733	$40,476

Significant customers from which the Company derived 10% or more of its total revenue in any of the periods presented are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Teva	$6,099	$7,664	$14,582	$17,044
AMAG	5,321	1,768	12,046	6,338
McKesson	1,481	2,339	5,051	6,333
AmerisourceBergen	1,887	1,470	4,703	4,323

Ferring	2,202	724	5,662	3,018

6. Net Loss Per Share

Basic loss per common share is computed by dividing net loss applicable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted loss per common share reflects the potential dilution from the exercise or conversion of securities into common stock. Potentially dilutive stock options and other share-based awards excluded from dilutive loss per share because their effect was anti-dilutive totaled 17,386 and 15,085 at September 30, 2018 and 2017, respectively.

7. Commitments and Contingencies

Pending Litigation

On October 23, 2017, Randy Smith filed a complaint in the District of New Jersey, captioned Randy Smith, Individually and on Behalf of All Others Similarly Situated v. Antares Pharma, Inc., Robert F. Apple and Fred M. Powell ("Smith"), Case No. 3:17-cv-08945-MAS-DEA, on behalf of a putative class of persons who purchased or otherwise acquired Antares securities between December 21, 2016 and October 12, 2017, inclusive, asserting claims for purported violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, against Antares, Robert F. Apple and Fred M. Powell. The Smith complaint

ANTARES PHARMA, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(in thousands, except per share amounts)

(UNAUDITED)

contends that defendants made false and/or misleading statements and/or failed to disclose that: (i) Antares had provided insufficient data to the FDA in connection with the NDA for XYOSTED™; and (ii) accordingly, Antares had overstated the approval prospects for XYOSTED™. On July 27, 2018, the court entered an order appointing Serghei Lungu as lead plaintiff, Pomerantz LLP as lead counsel, and Lite DePalma Greenberg, LLC as liaison counsel for plaintiff. On August 3, 2018, the parties submitted a stipulation and proposed order, setting forth an agreed-upon schedule for responding to the complaint, which the court granted. Pursuant to that order, plaintiff filed a Consolidated Amended Class Action Complaint on October 9, 2018 and defendants intend to file a motion to dismiss on or before November 26, 2018. The Company believes that the claims in the Smith action lack merit and intends to defend them vigorously.

On January 12, 2018, a stockholder of the Company filed a derivative civil action, captioned Chiru Mackert, derivatively on behalf of Antares Pharma, Inc., v. Robert F. Apple, et al. (“Mackert”), in the Superior Court of New Jersey Chancery Division, Mercer County (Case No. C-000011-18). On January 17, 2018, another stockholder filed a derivative action in the same court, captioned Vikram Rao, Derivatively on Behalf of Antares Pharma, Inc. v. Robert F. Apple, et al. (“Rao”) (Case No. C-000004-18). Both complaints name Robert F. Apple, Fred M. Powell, Thomas J. Garrity, Jacques Gonella, Anton Gueth, Leonard S. Jacob, Marvin Samson and Robert P. Roche, Jr. as defendants, and the Company as nominal defendant, and they assert claims for breach of fiduciary duties, unjust enrichment, abuse of control, gross mismanagement, and waste of corporate assets arising from the same facts underlying the Smith securities class action. The plaintiffs seek damages, corporate governance and internal procedure reforms and improvements, restitution, reasonable attorneys’ fees, experts’ fees, costs, and expenses. The parties have filed a stipulation consolidating the two actions and staying the proceedings pending the court’s decision on defendants’ anticipated motion to dismiss the Smith action.

On January 17, 2018, a stockholder of the Company filed a derivative civil action, captioned Robert Clark, Derivatively on Behalf of Antares Pharma, Inc. v. Robert F. Apple, et al. (“Clark”) (Case No. 3:18-cv-00703-MAS-DEA), against Robert F. Apple, Thomas J. Garrity, Jacques Gonella, Leonard S. Jacob, Marvin Samson, Anton G. Gueth and Robert P. Roche, Jr. as defendants, and Company as a nominal defendant. The action was filed in the U.S. District Court for the District of New Jersey and asserts claims for breach of fiduciary duties, unjust enrichment, abuse of control, waste of corporate assets, and a violation of Section 14(a) of the Securities Exchange Act of 1934. This complaint relates to the same facts underlying the Smith securities class action and the other derivative actions. The plaintiff in Clark seeks damages, corporate governance and internal procedure reforms and improvements, reasonable attorneys’ fees, accountants’ and experts’ fees, costs, and expenses. The parties have filed a stipulation staying the action pending the court’s decision on defendants’ anticipated motion to dismiss the Smith action.

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Item 2.MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward-Looking Statements

Certain statements in this report, including statements in the management's discussion and analysis section set forth below, may be considered "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended that involve risks and uncertainties. Forward-looking statements can be identified by the words "expect," "estimate," "plan", "project," "anticipate," "should," "intend," "may," "will," "believe," "continue" or other words and terms of similar meaning in connection with any discussion of, among other things, future operating or financial performance, strategic initiatives and business strategies, regulatory or competitive environments, our intellectual property and product development. In particular, these forward-looking statements include, among others, statements about:

- our expectations regarding sales of OTREXUP® (methotrexate) injection;
- our expectations regarding sales of Sumatriptan Injection USP to our partner, Teva Pharmaceutical Industries, Ltd. ("Teva"), and Teva's ability to successfully distribute and sell Sumatriptan Injection USP;
- our expectations regarding commercialization of XYOSTED™ (testosterone enanthate) injection for testosterone replacement therapy, and future revenue related thereto;
- our plans and ongoing process of hiring and onboarding approximately 60 additional sales representatives;
- our expectations of pricing, reimbursement, marketing and distribution strategies related to XYOSTED™;
- our plans to make XYOSTED™ available to patients before the end of 2018;
- our expectations regarding the ability of our partner, AMAG Pharmaceuticals, Inc. ("AMAG"), to continue to successfully commercialize the Makena® auto injector product, and any future revenue related thereto;
- our expectations regarding the ability of our partner, Teva, to successfully commercialize the VIBEX® Epinephrine Pen ("epinephrine auto injector"), and any future revenue related thereto;
- our expectations regarding continued product development with Teva of the teriparatide multi-dose disposable pen injector and exenatide multi-dose disposable pen injector, and Teva's ability to obtain FDA approval and AB-rating for each of those products;
- our plans to develop a rescue pen for an undisclosed drug and our intention to enter into a separate supply agreement with Pfizer, Inc. ("Pfizer") for the same;
- our expectations about the timing and successful completion of the sale of our worldwide rights, including certain assets, for the needle-free auto injector device product line to Ferring International Center S.A. (together with Ferring Pharmaceuticals Inc. and Ferring B.V. individually and collectively referred to as "Ferring");
- our expectations about the timing and outcome of pending or potential claims and litigation, including without limitation, the pending securities class action and derivative actions;
- our expectations regarding trends in pharmaceutical drug delivery and drug pricing;
- our anticipated continued reliance on contract manufacturers to manufacture our and our partners' products;
- our anticipated continued reliance on third parties to provide certain services for our products including logistics, warehousing, distribution, invoicing, contract administration and chargeback processing;
- our sales and marketing plans;
- our product development and commercialization plans regarding our other products and product candidates;
- timing and results of our research and development projects, including clinical trials, and our anticipated continued reliance on third parties in conducting studies, trials and other research and development activities;
- our future cash flows and our ability to support our operations;
- our estimates and expectations regarding the sufficiency of our cash resources, anticipated capital requirements and our need for and ability to obtain additional financing;

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- our expectations and estimates with regard to current accounting practices and the potential impact of new accounting pronouncements and tax legislation;
- our expectations regarding our financial and operating results for the year ending December 31, 2018; and
- other statements regarding matters that are not historical facts or statements of current condition.

Forward-looking statements are based on assumptions that we have made in light of our industry experience as well as our perceptions of historical trends, current conditions, expected future developments and other factors we believe are appropriate under the circumstances. As you read and consider this report, you should understand that these statements are not guarantees of performance results. Forward-looking statements involve known and unknown risks, uncertainties and assumptions, and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. While we believe that we have a reasonable basis for each forward-looking statement contained in this report, we caution you that these statements are based on a combination of facts and factors currently known by us and projections of the future about which we cannot be certain. Many factors may affect our ability to achieve our objectives, including:

- delays in product introduction or unsuccessful marketing and commercialization efforts by us or our partners;
- interruptions in supply or an inability to adequately manage third party contract manufacturers to meet customer supply requirements;
- our inability to obtain or maintain adequate third-party payer coverage of marketed products;
- the timing and results of our or our partners' research projects or clinical trials of product candidates in development including projects with Teva and Pfizer;
- actions by the FDA or other regulatory agencies with respect to our products or product candidates of our partners;
- our inability to generate continued growth in product, product development, licensing and royalties;
- the lack of market acceptance of our and our partners' products and future revenues from these products;
- a decrease in business from our major customers and partners;
- our inability to compete successfully against new and existing competitors or to leverage our research and development capabilities or our marketing capabilities;
- our inability to establish and maintain sales and marketing capability, effectively market our products and services or obtain and maintain arrangements with our customers, partners and manufacturers;
- changes or delays in the regulatory review and approval process;
- our inability to effectively protect our intellectual property;
- costs associated with future litigation and the outcome of such litigation;
- our inability to attract and retain key personnel;
- our inability to obtain additional financing, reduce expenses or generate funds when necessary; and
- adverse economic and political conditions.

In addition, you should refer to the "Risk Factors" sections of this report and of our Annual Report on Form 10-K for the year ended December 31, 2017 for a discussion of other factors that may cause our actual results to differ materially from those described by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements contained in this report will prove to be accurate and, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material.

We encourage readers of this report to understand forward-looking statements to be strategic objectives rather than absolute targets of future performance. Forward-looking statements speak only as of the date they are made. We do not intend to update publicly any forward-looking statements to reflect circumstances or events that occur after the date the forward-looking statements are made or to reflect the occurrence of unanticipated events except as required by law. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, if at all.

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The following discussion and analysis, the purpose of which is to provide investors and others with information that we believe to be necessary for an understanding of our financial condition, changes in financial condition and results of operations, should be read in conjunction with the financial statements, notes thereto and other information contained in this report.

Overview

Company Overview and Recent Developments

Antares Pharma, Inc. ("Antares," "we," "our," "us" or the "Company") is a specialty pharmaceutical company focused primarily on the development and commercialization of self-administered parenteral pharmaceutical products and technologies. Our strategy is to identify new or existing approved drug formulations and apply our drug delivery technology to enhance the drug compounds and delivery methods. We develop, manufacture and commercialize, for ourselves or with partners, novel therapeutic products using our advanced drug delivery systems that are designed to improve safety and efficacy, reduce side effects, and enhance patient comfort and adherence. Our intramuscular and 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 as well as disposable multi-dose pen injectors. We have a portfolio of proprietary and partnered commercial products and ongoing product development programs in various stages of development. We have formed significant strategic alliances and partnership arrangements with industry leading pharmaceutical companies including Teva, AMAG and Pfizer.

We developed XYOSTED™ (testosterone enanthate) injection, which is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone and was approved by the U.S. Food and Drug Administration ("FDA") on September 28, 2018. XYOSTED™ is the only FDA approved subcutaneous testosterone enanthate product for once-weekly, at-home self-administration and is approved in three dosage strengths, 50 mg, 75 mg and 100 mg. We are currently in the process of onboarding approximately 60 sales representatives and are working on our pricing, reimbursement, marketing and distribution strategies. We expect to make XYOSTED™ available to patients before the end of 2018.

We market and sell our proprietary product OTREXUP® (methotrexate) injection, a subcutaneous methotrexate for once weekly self-administration with an easy-to-use, single dose, disposable auto injector, indicated for adults with severe active rheumatoid arthritis, children with active polyarticular juvenile idiopathic arthritis and adults with severe recalcitrant psoriasis. To date, we have received FDA approval for dosage strengths of 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 22.5 mg and 25 mg of OTREXUP®.

Through our commercialization partner Teva, we sell Sumatriptan Injection USP indicated in the U.S. for the acute treatment of migraine and cluster headache in adults. We received FDA approval of our 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 is the Company's first ANDA approval of a complex generic and second product approved using the VIBEX® auto injector platform.

We developed and supply a variation of our VIBEX® QuickShot® subcutaneous auto injector for use with AMAG's progestin hormone drug Makena® (hydroxyprogesterone caproate injection) under an exclusive license and development agreement. The Makena® subcutaneous auto injector drug-device combination product 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, which was approved by the FDA in February 2018. We are the exclusive supplier of the devices and the final assembled and packaged commercial product, which was launched in the U.S. for commercial sale by AMAG in March 2018, and we receive royalties on net sales of the product.

In collaboration with Teva, we developed and supply the device for an epinephrine auto injector product pursuant to an exclusive license, development and supply agreement. Teva's epinephrine auto injector drug-device combination product, indicated for emergency treatment of severe allergic reactions including those that are life threatening (anaphylaxis) in adults and certain pediatric patients, was approved by the FDA in August 2018 as a generic drug product with an AB rating, meaning that it is therapeutically equivalent to Mylan, Inc.'s branded products EpiPen® and EpiPen Jr® and therefore, subject to state law, substitutable at the pharmacy. Under the license development and supply agreement, Antares is responsible for supply of the device, which is sold to Teva, and Teva is responsible for commercialization and distribution of the final product for which we receive royalties on net sales. Teva has indicated it is preparing to launch the generic epinephrine auto injector product in the fourth quarter of 2018.

In August 2018, we entered into a collaboration agreement with Pfizer to develop a combination drug device rescue pen. This rescue pen will utilize the Antares QuickShot® auto injector and an undisclosed Pfizer drug. We will develop the product and Pfizer will be responsible for obtaining FDA approval of the combination product. We intend to enter into a separate supply agreement with Pfizer pursuant to which we will provide fully packaged commercial ready finished product to Pfizer and Pfizer will then be responsible for commercializing the product in the United States, pending FDA approval, for which the Company will receive royalties on net sales.

We are collaborating with Teva on a multi-dose pen for a generic form of BYETTA® (exenatide injection) for the treatment of diabetes, and another multi-dose pen for a generic form of Forteo® (teriparatide [rDNA origin] injection) for the treatment of osteoporosis. Teva continues to work through the regulatory process with the FDA for exenatide and teriparatide using the ANDA pathway. Teva and Eli Lilly and Company ("Lilly") settled their Paragraph IV patent litigation related to Teva's ANDA for teriparatide, the terms of which have not been disclosed. Teva also successfully completed a decentralized procedure registration process in 17 countries in Europe for teriparatide, and is awaiting patent clearance in the EU prior to launch.

We also make reusable, needle-free injection devices that administer injectable drugs, which are currently marketed primarily through Ferring and JCR Pharmaceuticals Co., Ltd., for use with human growth hormone. In October 2017, we entered into an asset purchase agreement (the "Asset Purchase Agreement") with Ferring (the "Ferring Transaction") 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 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 the needle-free product manufacturing; a third installment of $4.75 million received in May 2018 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 needle-free product in certain territories and the final transfer of certain product-related inventory, equipment and agreements to Ferring (the "Completion Date"), which we anticipate may occur by the end of 2018. The completion of the transaction is subject to significant conditions and uncertainties, and the second and third installments are refundable to Ferring under certain circumstances if completion of the transaction does not occur within a specified timeframe. There can be no assurances that the Completion Date will occur within this estimated timeframe or at all.

We will continue to manufacture and supply needle-free devices until the Completion Date and will receive payment for devices and a royalty on net product sales in accordance with the existing license and supply agreements.

Critical Accounting Policies

Our management's discussion and analysis of our results of operations and financial condition is based upon our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of our financial statements in accordance with GAAP requires us to make judgments and estimates that affect the reported amounts of assets, liabilities, revenues and expenses. We have identified certain of our significant accounting policies that we believe to be the most critical to understanding our results of operations and financial condition because they require the most subjective and complex judgments. The following supplements our critical accounting policies, which are fully described under "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2017.

Revenue Recognition

Effective January 1, 2018, we adopted Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers (Topic 606), as amended ("Topic 606") using the modified retrospective transition method. This new standard supersedes the former revenue recognition requirements in Topic 605 Revenue Recognition ("Topic 605"). Our results of operations for reporting periods beginning on or after January 1, 2018 are presented under Topic 606, while prior period amounts, as reported, are not adjusted. The effects of the adoption of the new standard were not material

to our consolidated financial statements, and the difference between the amount of revenue recognized for the three months ended September 30, 2018 under Topic 606 as compared to the amount of revenue that would have been recognized under Topic 605 was not material. The following is a summary, and the critical aspects, of our revenue recognition policy under Topic 606.

We generate revenue from proprietary and partnered product sales, license and development activities and royalty arrangements. Revenue is recognized when or as we transfer control of the promised goods or services to our customers in an amount that reflects the consideration to which we expect to be entitled to in exchange for those goods or services.

We enter into contracts with customers and partners that often contain multiple elements such as licensing, development, manufacturing and commercialization components. These arrangements are often complex and we may receive various types of consideration over the life of the arrangement, including: up-front fees, reimbursements for research and development services, milestone payments, payments on product shipments, margin sharing arrangements, license fees and royalties.

In assessing our revenue arrangements, we must identify the contract and consider whether one or more contracts or elements should be combined to form a contract, determine the transaction price including an estimation of any variable consideration we expect to receive under the contract, identify each of our performance obligations or promises of goods or services to the customer, allocate the transaction price to each of the performance obligations, and recognize revenue when or as the performance obligations are satisfied. Each of these steps in the revenue recognition process requires management to make judgements and/or estimates. The most significant judgements and estimates include: the estimation of product returns and sales allowances and other variable consideration such as expected contract margin and royalties. We base these estimates on historical experience and a review of the facts and circumstances that exist as of each reporting date.

Results of Operations

We reported a net loss of $1.9 million and $5.5 million for the three months ended September 30, 2018 and 2017, respectively, and $12.6 million and $13.0 million for the nine months ended September 30, 2018 and 2017, respectively. Net loss per share was $0.01 for the three months ended September 30, 2018 as compared to $0.03 for the three months ended September 30, 2017, and was $0.08 for both the nine months ended September 30, 2018 and 2017. Operating results for the three and nine months ended September 30, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018. The following is an analysis and discussion of our operations for the three and nine months ended September 30, 2018 as compared to the same periods in 2017.

Revenues

Total revenue for the three months ended September 30, 2018 and 2017 was $17.9 million and $15.1 million, respectively, and was $44.7 million and $40.5 million for the nine months ended September 30, 2018 and 2017, respectively, representing period over period growth in total revenue of 19% and 11% for the three and nine months ended September 30, 2018, respectively. The increases in total revenue for the three and nine months ended September 30, 2018 as compared to 2017 were primarily attributable to product revenue and royalties related to sales of the Makena® auto injector product to AMAG and a $2.0 million milestone payment received from Teva in connection with the FDA approval of Teva's epinephrine auto injector. The table below and following discussion provides additional details about the components of and changes in our revenue mix (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
OTREXUP®	$4,094	$4,624	$11,820	$13,111
Sumatriptan Injection USP	3,983	6,375	9,438	12,264
Auto injector and pen injector devices	1,829	1,571	7,925	2,225
Needle-free injector devices and components	1,691	758	4,458	3,109
Total product sales	11,597	13,328	33,641	30,709
Licensing and development revenue	2,554	1,504	5,624	8,952
Royalties	3,717	220	5,468	815
Total revenue	$17,868	$15,052	$44,733	$40,476

OTREXUP®

For the three months ended September 30, 2018 and 2017, we recognized revenue of $4.1 million and $4.6 million, respectively, from sales of OTREXUP®, which is presented net of estimated product returns and sales allowances. The

net decrease in OTREXUP® sales revenue for the three months ended September 30, 2018 as compared to the three months ended September 30, 2017 was primarily a result of an increase in plan rebates and other sales allowances.

For the nine months ended September 30, 2018, we recognized $11.8 million in OTREXUP® sales as compared to $13.1 million for the nine months ended September 30, 2017. Revenue recognized for OTREXUP® sales in the nine months ended September 30, 2018 was driven by an increase in unit sales in comparison to prior year; however, the overall decrease in OTREXUP® revenue in comparison to the nine months ended September 30, 2017 was attributable to an increase in plan rebates and other sales allowances in 2018, and the recognition of an additional $1.3 million of revenue in the first quarter of 2017 as a result of a change in estimation and recognition method for revenues that were previously deferred. Prior to the first quarter of 2017, due to lack of sufficient sales and returns history, revenue was initially deferred upon shipment to distributors and recognized based on estimated prescriptions dispensed or expiration of customer right of return. We began recognizing revenue upon delivery to distributors, net of estimated returns, in the first quarter of 2017.

Sumatriptan Injection USP

We sell, through our commercialization partner Teva, Sumatriptan Injection USP indicated in the U.S. for the acute treatment of migraine and cluster headache in adults. We recognized $4.0 million and $6.4 million for the three months ended September 30, 2018 and 2017, respectively and $9.4 million and $12.3 million for the nine months ended September 30, 2018 and 2017, respectively. The decrease in revenue for the three and nine months ended September 30, 2018 compared to 2017, respectively, is attributable to fluctuations in quantities and timing of product shipments to Teva, lower unit sales and lower contract margin recognized and received thereon.

Auto injector and pen injector devices

Product sales of auto injector devices were $1.8 million and $1.6 million for the three months ended September 30, 2018 and 2017, respectively, and $7.9 million and $2.2 million for the nine months ended September 30, 2018 and 2017, respectively. We manufacture and sell devices and device components to Teva, and fully assembled and packaged Makena® product to AMAG. The increase in sales of auto injector devices for the three and nine months ended September 30, 2018 as compared to the same periods in 2017 was primarily attributable to sales of Makena® auto injectors to AMAG, which was approved by the FDA and launched in the U.S. for commercial sale by AMAG in the first quarter of 2018, and sales of pre-commercial devices and components to Teva related to the pen injector programs. Teva's generic epinephrine auto injector product was approved by the FDA in August 2018 and Teva has indicated it is preparing to launch the generic epinephrine auto injector product in the fourth quarter of 2018.

Needle-free injector devices and components

Revenue from reusable needle-free injector devices and disposable components was $1.7 million and $0.8 million for the three months ended September 30, 2018 and 2017, respectively, and $4.5 million and $3.1 million for the nine months ended September 30, 2018 and 2017, respectively. These revenues were generated primarily from sales to Ferring, which sells our needle-free injector for use with its hGH products in Europe, Asia and the U.S. In October 2017, we announced the sale of the worldwide rights related to the needle-free auto injector product to Ferring and anticipate that the transaction may be completed by the end of 2018. During the transfer and completion period, we will continue to manufacture and supply devices until the completion date and will receive payment for devices and a royalty on net product sales in accordance with the existing license and supply agreements. Revenue from sales of needle free injector devices and components increased for the three and nine months ended September 30, 2018 as compared to 2017 due to additional sales made to Ferring as we work toward the transfer and completion of the transaction.

Licensing and development revenue

Licensing and development revenue includes license fees received from partners for the right to use our intellectual property and amounts earned in joint development arrangements with partners under which we perform development activities or develop new products on their behalf. Licensing and development revenue was $2.6 million and $1.5 million for the three months ended September 30, 2018 and 2017, respectively, and $5.6 million and $9.0 million for the nine months ended September 30, 2018 and 2017, respectively. The increase in licensing and development revenue for the three-month period ended September 30, 2018 as compared to the same period in 2017 was principally a result of the $2.0 million milestone received from Teva in connection with the FDA approval of Teva's epinephrine auto injector product in August 2018. The decrease in licensing and development revenue for the nine-month period ended September 30, 2018 as compared to 2017 was principally a result of a reduction in development activities with AMAG for the Makena® auto injector product, which was approved by the FDA in February 2018 and is now in the commercialization stage.

Royalties

Royalty revenue was $3.7 million and $0.2 million for the three months ended September 30, 2018 and 2017, respectively, and $5.5 million and $0.8 million for the nine months ended September 30, 2018 and 2017, respectively. The increase in royalty revenue was principally attributable to the launch of the Makena® auto injector product by AMAG in the first quarter of 2018, upon which we earn royalties based on a percentage of AMAG's net sales of the product. We also receive royalties on sales of gel-based products commercialized through partners, and from Ferring related to needle-free injector device sales and on its sales of ZOMACTON™. However, as discussed above, in October 2017 we announced the sale of the worldwide rights related to the needle-free device product line to Ferring and anticipate that the transaction may be completed by the end of 2018. During the transfer and completion period, we will continue to manufacture and supply needle-free devices until the Completion Date and will receive payment for devices and a royalty on net product sales in accordance with the existing license and supply agreements.

Cost of Revenue and Gross Profit

The following table summarizes our total revenue, cost of revenue and gross profit (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Total revenue	$17,868	$15,052	$44,733	$40,476
Total cost of revenue	7,289	8,523	21,435	20,359
Gross profit	$10,579	$6,529	$23,298	$20,117
Gross profit percentage	59 %	43 %	52 %	50 %

Our gross profit was $10.6 million and $6.5 million for the three months ended September 30, 2018 and 2017, respectively, and $23.3 million and $20.1 million for the nine months ended September 30, 2018 and 2017, respectively. The increase in our gross profit was primarily attributable to an increase in royalties received from sales of Makena® auto injectors and a $2.0 million license and development milestone received from Teva in connection with the FDA approval of the epinephrine auto injector product, both of which have no associated costs, offset by a decrease in our product gross profit. Product revenue, cost of sales and gross profit are summarized in the following table (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Product sales	$11,597	$13,328	$33,641	$30,709
Cost of product sales	6,982	7,600	20,195	16,682
Product gross profit	$4,615	$5,728	$13,446	$14,027
Product gross margin percentage	40 %	43 %	40 %	46 %

Product gross profit decreased for the three and nine months ended September 30, 2018 as compared to the same periods in 2017, primarily due to lower net revenue from OTREXUP® sales, lower contract margin received from Teva on sales of Sumatriptan Injection USP, and an increase in sales of Makena® auto injectors to AMAG, which have a lower product sales margin than our proprietary products and provide for back-end royalties on net sales made by AMAG. The cost of product sales includes product acquisition costs from third-party manufacturers and internal manufacturing and overhead expenses.

Other variations in revenue, cost of revenue and gross profit are attributable to our development activities, which fluctuate depending on the mix of development projects in progress and stages of completion in each period. The cost of development revenue consists primarily of direct external costs, some of which may have been previously incurred and deferred. The cost of development revenue in each period was primarily related to revenue recognized under the Teva auto injector and pen injector programs and development activities for the Makena® auto injector with AMAG.

Research and Development

Research and development expenses consist of external costs for clinical studies and analysis activities, design work and prototype development, FDA fees, personnel costs and other general operating expenses associated with our research and development activities. Research and development expenses were $3.6 million and $3.3 million for the three months ended September 30, 2018 and 2017, respectively, and $10.6 million and $9.5 million for the nine months ended September 30, 2018 and 2017, respectively. The increase in research and development costs on a comparative basis is primarily due to additional spending associated with undisclosed potential new products and post-CRL activities for XYOSTED™, which was approved by the FDA on September 28, 2018.

Selling, General and Administrative

Selling, general and administrative expenses were $8.3 million and $8.2 million for three months ended September 30, 2018 and 2017, respectively, and $23.6 million and $23.0 million for the nine months ended September 30, 2018 and 2017, respectively. The increase in selling, general and administrative expenses was attributable to an increase in compensation and benefits expense, primarily related to annual salary increases and non-cash stock-based compensation, including performance-based awards for executives.

Liquidity and Capital Resources

At September 30, 2018, we had cash and cash equivalents of $28.2 million. Our principal liquidity needs are to fund the commercial launch of XYOSTED™ and our ongoing research and development activities, and for the payment of other operating expenses. We have not historically generated, and do not currently expect to generate, enough revenue or operating cash flow to sustain or grow our operations and we expect to continue to support our operations by raising capital. Our primary sources of liquidity are cash receipts from sales, proceeds from equity offerings and debt issuance. We believe that the combination of our current cash and cash equivalents, projected product sales, development revenue milestones and royalties will provide us with sufficient funds to meet our obligations and support operations through at least the next twelve months from the date of this report.

Long-Term Debt Financing

In June 2017, we entered into a loan and security agreement for a term loan of up to $35.0 million (the "Term Loan"), the proceeds of which are to be used for working capital and general corporate purposes. The first advance of $25.0 million was funded upon execution of the Loan Agreement in June 2017. Payments under the Loan Agreement are interest only until the first principal payment is due on August 1, 2019, provided that the interest only period may be extended to February 1, 2020 if the certain corporate milestones are achieved. The Loan Agreement also requires us to pay a fee equal to 4.25% of the total original principal amount of all term loan advances, which is due upon repayment of the Term Loan at either maturity or earlier repayment.

At the Market Common Stock Offering Program

In August 2017, we entered into a sales agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen") under which we may offer and sell, from time to time at our sole discretion, shares of common stock having an aggregate offering price of up to $30.0 million through Cowen as our sales agent and/or principal. Cowen may sell the common stock by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415 of the Securities Act of 1933, as amended. We will pay Cowen a commission of 3.0% of the gross sales proceeds of any common stock sold through Cowen under the Sales Agreement. We are not obligated to make any sales of our common stock under the Sales Agreement and as of the date of this report we have not sold any common stock pursuant to the Sales Agreement.

Net Cash Flows from Operating Activities

Operating cash inflows are generated primarily from product sales, license and development fees and royalties. Operating cash outflows consist principally of expenditures for manufacturing costs, personnel costs, general and administrative expenses, research and development projects, and sales and marketing activities. Fluctuations in cash used in operating activities are primarily a result of the timing of cash receipts and disbursements. Net cash used in operating activities was $10.2 million for the nine months ended September 30, 2018 and $15.5 million for the nine months ended September 30, 2017. The net cash used in operating activities was primarily driven by our net loss, inventory build, changes in accounts receivable and deferred revenue, and other changes in operating assets and liabilities due to timing of cash receipts and cash payments.

Net Cash Flows from Investing Activities

Net cash provided by investing activities was $11.9 million for the nine months ended September 30, 2018 as compared to net cash used in investing activities of $10.9 million for the nine months ended September 30, 2017. The net cash inflow for the nine months ended September 30, 2018 was attributable to the receipt of $7.5 million in connection with the Ferring Transaction and proceeds from maturities of investments of $5.0 million offset by

payments for capital expenditures and patent acquisition costs. The cash outflow for the nine months ended September 30, 2017 was attributable to purchases of investment securities of $10.0 million and payments for capital expenditures and patent acquisition costs.

Net Cash Flows from Financing Activities

The net cash flows used in financing activities was $0.2 million for the nine months ended September 30, 2018, and consisted of cash proceeds received from the exercise of stock options offset by amounts remitted to taxing authorities in connection with net-share settled awards for which we withheld shares equivalent to the value of the employees' minimum statutory obligation for the applicable income and other employment taxes. Cash provided by financing activities for the nine months ended September 30, 2017 was $26.1 million, which included $25.0 million in proceeds from the issuance of long-term debt and $1.6 million received in connection with the exercise of stock options, net of payments for debt issuance costs of $0.3 million and $0.2 million remitted to taxing authorities in connection with net-share settled equity awards.

Contractual Obligations

There have been no changes or material modifications to our contractual obligations as presented in our Annual Report on Form 10-K as of and for the year ended December 31, 2017.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, including any arrangements with any structured finance, special purpose or variable interest entities.

Research and Development Programs

Our research and development programs consist primarily of clinical, regulatory, formulation development, engineering, device development and commercial development activities for our current products, next generation versions of current products, and new proprietary and partnered products and technologies in development. Our internal research and development team works with external consultants, industry experts, physicians and other medical personnel in an effort to drive a robust product development pipeline. We also have a business development team that actively seeks and evaluates product opportunities and business alliances. In addition, our clinical, quality and regulatory teams are committed to verifying and maintaining the safety and efficacy of our products according to regulatory standards enforced by the FDA and other international regulatory bodies. The following is a discussion of our significant research and development programs.

XYOSTED™ (testosterone) injection. We developed XYOSTED™ (testosterone enanthate) injection for self-administered weekly injections of testosterone enanthate in a preservative-free formulation indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. XYOSTED™ was approved by the FDA on September 28, 2018 and is the only FDA approved subcutaneous testosterone enanthate product for once-weekly, at-home self-administration. XYOSTED™ is approved in three dosage strengths, 50 mg, 75 mg and 100 mg.

As a post-marketing requirement, the FDA has asked us to conduct a label comprehension study that assesses patients' understanding of key risk messages in the Medication Guide for XYOSTED™ and a study of testosterone replacement therapy in pediatric males ages 14 years and older for conditions associated with a deficiency or absence of endogenous testosterone. The label comprehension study must be completed by 2020 and the pediatric study must be completed by the end of 2026. The conduct of these studies will require a dedication of funds and resources.

Partnered Development Projects. We have entered into license and development agreements and collaboration arrangements with our pharmaceutical partners Teva and Pfizer to conduct research and development activities related to our VIBEX® disposable pressure assisted auto injectors and our disposable pen injectors to be used in drug/device combination products. The development programs consist of various activities including determination of the device design, development of prototype tooling, production of prototype devices for testing and clinical studies, and development of commercial tooling and assembly equipment. The following is a summary of the development stages for each of the partnered products in development.

VIBEX® auto injector with epinephrine

We, in collaboration with Teva, developed a VIBEX® auto injector device for a product containing epinephrine. Teva was responsible for development work on the drug epinephrine, and we were responsible for development of the device. Teva filed an ANDA for the VIBEX® epinephrine pen as a generic substitute of Mylan's branded product, EpiPen®, which was as approved by the FDA in August 2018 as a generic drug product with an AB rating, meaning

that it is therapeutically equivalent to Mylan, Inc.'s branded products EpiPen® and EpiPen Jr® and therefore, subject to state law, substitutable at the pharmacy. Teva has indicated it is preparing to launch the generic epinephrine auto injector product in the fourth quarter of 2018.

Exenatide multi-dose disposable pen injector

We designed and produced, under a license, development and supply agreement with Teva, a multi-dose disposable pen injector for use with a generic form of BYETTA® (exenatide injection) for the treatment of diabetes. Teva is working through the U.S. regulatory approval process for its exenatide pen using the ANDA pathway.

Teriparatide multi-dose disposable pen injector

We also designed and produced for Teva another multi-dose disposable pen for a generic form of Forteo® (teriparatide [rDNA origin] injection) for the treatment of osteoporosis. Teva is working through the U.S. regulatory approval process for a generic version of Forteo® (teriparatide [rDNA origin] injection) using the ANDA pathway. Teva and Lilly settled their Paragraph IV patent litigation, the terms of which have not been disclosed. Teva also successfully completed a decentralized procedure registration process in 17 countries in Europe for teriparatide, and is awaiting patent clearance in the EU prior to launch.

Rescue pen (undisclosed drug)

In August 2018, we entered into a collaboration agreement with Pfizer to develop a combination drug device rescue pen. This rescue pen will utilize the Antares QuickShot® auto injector and an undisclosed Pfizer drug. We will develop the product and Pfizer will be responsible for obtaining FDA approval of the combination product. We intend to enter into a separate supply agreement with Pfizer pursuant to which we will provide fully packaged commercial ready finished product to Pfizer and Pfizer will then be responsible for commercializing the product in the United States, pending FDA approval, for which the Company will receive royalties on net sales.

Other Research and Development Costs. In addition to our development of XYOSTED™ and our device development projects with Teva and Pfizer, we incur direct costs associated with other internal research and development projects and indirect costs that include personnel costs, administrative and other operating costs related to managing our research and development activities.

Recently Issued Accounting Pronouncements Not Yet Adopted

In February 2016, the Financial Accounting Standards Board issued Accounting Standard Update (“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. We are in the process of evaluating the impact that the adoption of ASU 2016-02 will have on our consolidated financial statements and currently expect that most of our operating lease commitments will be subject to the new standard and recognized as operating lease liabilities and right-of-use assets upon our adoption of ASU 2016-02 effective January 1, 2019.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary market risk exposure is foreign exchange rate fluctuations of the Swiss Franc to the U.S. dollar as the financial position and operating results of our subsidiaries in Switzerland are translated into U.S. dollars for consolidation. Our exposure to foreign exchange rate fluctuations also arises from transferring funds to our Swiss subsidiaries in Swiss Francs. In addition, we have exposure to exchange rate fluctuations between the Euro and the U.S. dollar. We do not currently use derivative financial instruments to hedge against exchange rate risk. The effect of foreign exchange rate fluctuations on our financial results for the period ended September 30, 2018 was not material.

We may be exposed to interest rate risk and interest rate fluctuations as a result of our long-term debt financing we obtained in June 2017. Our Term Loan, with a current outstanding principal of $25.0 million accrues interest at a calculated prime-based variable rate with a maximum interest rate of 9.50%, which was the rate in effect as of September 30, 2018.

Item 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

The Company's management, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this report. The evaluation was performed to determine whether the Company's disclosure controls and procedures have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by the Company in reports filed under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and is accumulated and communicated to management, including the Company's principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based on such evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures as of the end of the period covered by this report were effective.

Internal Control over Financial Reporting

There have not been any changes in the Company's internal control over financial reporting during the fiscal quarter to which this report relates that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II - OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

On October 23, 2017, Randy Smith filed a complaint in the District of New Jersey, captioned Randy Smith, Individually and on Behalf of All Others Similarly Situated v. Antares Pharma, Inc., Robert F. Apple and Fred M. Powell ("Smith"), Case No. 3:17-cv-08945-MAS-DEA, on behalf of a putative class of persons who purchased or otherwise acquired Antares securities between December 21, 2016 and October 12, 2017, inclusive, asserting claims for purported violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 against Antares, Robert F. Apple and Fred M. Powell. The Smith complaint contends that defendants made false and/or misleading statements and/or failed to disclose that: (i) Antares had provided insufficient data to the FDA in connection with the NDA for XYOSTED™; and (ii) accordingly, Antares had overstated the approval prospects for XYOSTED™. On July 27, 2018, the court entered an order appointing Serghei Lungu as lead plaintiff, Pomerantz LLP as lead counsel, and Lite DePalma Greenberg, LLC as liaison counsel for plaintiff. On August 3, 2018, the parties submitted a stipulation and proposed order, setting forth an agreed-upon schedule for responding to the complaint, which the court granted. Pursuant to that order, plaintiff filed a Consolidated Amended Class Action Complaint on October 9, 2018 and defendants intend to file a motion to dismiss on or before November 26, 2018. The Company believes that the claims in the Smith action lack merit and intends to defend them vigorously.

On January 12, 2018, a stockholder of our Company filed a derivative civil action, captioned Chiru Mackert, derivatively on behalf of Antares Pharma, Inc., v. Robert F. Apple, et al. ("Mackert"), in the Superior Court of New Jersey Chancery Division, Mercer County (Case No. C-000011-18). On January 17, 2018, another stockholder filed a derivative action in the same court, captioned Vikram Rao, Derivatively on Behalf of Antares Pharma, Inc. v. Robert F. Apple, et al. ("Rao") (Case No. C-000004-18). Both complaints name Robert F. Apple, Fred M. Powell, Thomas J. Garrity, Jacques Gonella, Anton Gueth, Leonard S. Jacob, Marvin Samson and Robert P. Roche, Jr. as defendants, and the Company as nominal defendant, and they assert claims for breach of fiduciary duties, unjust enrichment, abuse of control, gross mismanagement, and waste of corporate assets arising from the same facts underlying the Smith securities class action. The plaintiffs seek damages, corporate governance and internal procedure reforms and improvements, restitution, reasonable attorneys' fees, experts' fees, costs, and expenses. The parties have filed a stipulation consolidating the two actions and staying the proceedings pending the court's decision on defendants' anticipated motion to dismiss the Smith action.

On January 17, 2018, a stockholder of our Company filed a derivative civil action, captioned Robert Clark, Derivatively on Behalf of Antares Pharma, Inc. v. Robert F. Apple, et al. ("Clark") (Case No. 3:18-cv-00703-MAS-DEA), against Robert F. Apple, Thomas J. Garrity, Jacques Gonella, Leonard S. Jacob, Marvin Samson, Anton G. Gueth and Robert P. Roche, Jr. as defendants, and Company as a nominal defendant. The action was filed in the U.S. District Court for the District of New Jersey and asserts claims for breach of fiduciary duties, unjust enrichment, abuse of control, waste of corporate assets, and a violation of Section 14(a) of the Securities Exchange Act of 1934. This complaint relates to the same facts underlying the Smith securities class action and the other derivative actions. The plaintiff in Clark seeks damages, corporate governance and internal procedure reforms and improvements, reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses. The parties have filed a stipulation staying the action pending the court's decision on defendants' anticipated motion to dismiss the Smith action.

Item 1A. RISK FACTORS

In addition to the information contained in this report, you should carefully consider the risk factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2017, which could materially affect our business, financial condition or future results. There have been no material changes to these risk factors other than the supplemental information and risk factors discussed below. The risks described in our Annual Report on Form 10-K and discussed below are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

Risks Related to Our Operations

We have limited sales and marketing experience and limited experience working with payers on coverage issues, and we can provide no assurance on the successful launch and commercialization of our products.

We have limited sales and marketing experience, and limited experience working with payers on coverage issues. The launch and successful commercialization of a new product requires substantial dedication of financial and other resources and include steps related to manufacturing, logistics, sales and marketing, and establishing insurance coverage and reimbursement. We launched OTREXUP® in February 2014, and are in the process of launching XYOSTED™. Although we have hired and expect to continue to hire highly qualified personnel with specialized expertise, as a company, we have limited experience commercializing pharmaceutical products on our own. In order to commercialize our products, we have built and expect to continue to build our sales, marketing, distribution, managerial and other non-technical capabilities and have made and expect to continue to make arrangements with third parties to perform these services when needed. In January 2015, we hired sales representatives and district managers to fill our sales territories for OTREXUP®. In connection with the launch of XYOSTED™, we will begin the process of onboarding approximately 60 sales representatives and are working on our pricing, reimbursement, marketing and distribution strategies.

If we are unable to successfully implement our sales and marketing plans and drive adoption by patients and physicians of our products through our sales, marketing and commercialization efforts, then we may not be able to generate sustainable revenues growth from product sales which will have a material adverse effect on our business and future product opportunities.

Similarly, we may not be successful in maintaining the necessary commercial infrastructure, including sales representatives, managed care, medical affairs and pharmacovigilance teams. The development of commercialization capabilities to market of our products has been and will continue to be expensive and time-consuming. As we continue to develop, maintain and grow these capabilities, we will have to compete with other pharmaceutical companies to recruit, hire, train and retain sales and marketing personnel. If we have underestimated the necessary sales and marketing capabilities or have not established the necessary infrastructure to support successful commercialization, or if our efforts to do so take more time and expense than anticipated, our ability to market and sell any drug products may be adversely affected.

There is no guarantee that patients and healthcare providers will adopt our or our partners' products, and that we and our partners will be able to receive adequate payer coverage and reimbursement. New information concerning our or our partners' products learned through required post-approval studies and product use may also result in changes to our or our partners' products. Should any of these events occur, they could have a material and adverse effect on our operations and business.

There is no guarantee that patients and healthcare providers will adopt any newly approved products, or that insurers will provide adequate coverage and reimbursement. Any labeled limitations on the use of a product or warnings could discourage adoption of the product by patients, healthcare providers, and insurers. By example, the XYOSTED™ label includes a boxed warning concerning blood pressure increases that can increase the risk for major adverse cardiovascular events. Teva's epinephrine auto injector drug-device combination product is also subject to certain labeled warnings. These could ultimately discourage patients from using and healthcare providers from prescribing our and our partners' products.

Moreover, we and our partners may experience a delay in receiving coverage and reimbursement for any new products or may not receive adequate levels of coverage or reimbursement at all. Product labeling restrictions and warnings may also discourage payers from providing adequate levels of coverage and reimbursement. We and our partners,

accordingly, may need to take steps to assist patients to afford our products, such as offering bridge programs, free-trial, discounts, rebates and co-pay coupon programs. These programs, however, may not ultimately be successful.

If patients and healthcare providers do not adopt any new product, or if insurers restrict patient access or disadvantage our or our partners' products in their formularies or otherwise do not provide adequate coverage and reimbursement, we and our partners may not be able to generate sustainable revenues growth from product sales and royalties which will have a material adverse effect on our business and future product opportunities.

Any post-approval requirements, including phase IV studies and Risk Evaluation and Mitigation Strategies, or REMS, may also require the dedication of substantial time and resources. By example, as a post-marketing requirement for XYOSTED™, the FDA has asked us to conduct a label comprehension study that assesses patients' understanding of key risk messages in the Medication Guide for XYOSTED™ and a study of testosterone replacement therapy in pediatric males ages 14 years and older for conditions associated with a deficiency or absence of endogenous testosterone. The label comprehension study findings may result in revisions to the Medication Guide to optimize patients' understanding of important risks of XYOSTED™ and potentially other label restrictions. Additionally, the outcome of any post-approval studies, including the pediatric study, is uncertain and may not result in

an expanded label indication or could result in additional labeling requirements or other post-approval restrictions or regulatory actions. The label comprehension study must be completed by 2020 and the pediatric study by the end of 2026. The conduct of these studies will require dedication of funds and resources.

Additionally, use of our or our partners' products by patients and in phase IV and post-marketing studies may result in the discovery of new information concerning the products. By example, the products may be found to be less effective than initially demonstrated, or new, more severe, or more frequent adverse events or side effects may be reported. This may result in regulatory or other actions, including, product liability actions, enforcement actions, distribution and manufacturing restrictions, changes to product labeling and promotional materials, the imposition of post-market requirements, such as REMS or additional phase IV studies, withdrawal of marketing application approvals, withdrawal of the product from the market, refusal to approve new marketing applications or supplements, product recalls, clinical holds and suspension of clinical studies, safety alerts, dear healthcare provider letters, adverse publicity, and reimbursement and insurance coverage consequences, among others. Should any of these events occur, they could have a material and adverse effect on our operations and business.

If we or our partners are unable to achieve and maintain adequate levels of coverage and reimbursement for our or our partners' products or any of our or our partners' future products for which we or our partners receive regulatory approval, their commercial success may be severely hindered.

Successful sales of our products depend on the availability of adequate coverage and reimbursement from third-party payers. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payers to reimburse all or part of the costs associated with their prescription drugs. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payers is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Assuming coverage is approved, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for our products will depend significantly on access to third-party payers' drug formularies, or lists of medications for which third-party payers provide coverage and reimbursement. Health plans often used tiered formularies that prefer one branded product in a therapeutic class over another through different patient co-payment amounts, and disadvantaging some products through techniques such as step therapy and prior authorization. Many states use formularies and preferred drug lists to obtain supplemental Medicaid rebates in excess of those required for Medicaid coverage. The industry competition to be included in such formularies and not disadvantaged often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payers may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. Additionally, certain third-party payers restrict or block access to patients for new products until a clinical review has occurred or clinical evidence is provided to support the benefits for covered patients. These restrictions may be imposed for months or longer and some third-party payers may refuse to add new products to their formularies or otherwise restrict patient access. To ensure sales, manufacturers often must provide multiple discounts on the same drug in the chain of distribution to the health care provider and the payer. Further, manufacturers are required to assume responsibility for Medicare Part D prescription costs for innovator drugs and biologics and authorized generics while the beneficiary is in the coverage gap. Increasingly, payers are looking for metrics and performance-based pricing to justify increased cost of therapeutic advancements. Even if coverage is obtained, the net realization from price concessions may negatively impact our profitability. Government health programs also impose inflation penalties which may have adverse consequences if

we increase prices in the future.

Our partnered products encounter similar issues in obtaining reimbursement from third-party payers. While we are unable to control the reimbursement rate or discounts contracted with third-party payers by our partners, these rates ultimately affect our profit sharing on Sumatriptan Injection USP and royalties on products such as the Makena® Subcutaneous Auto-Injector, the Teva epinephrine auto injector drug-device combination product, Elestrin® and Gelnique®.

Third-party payers, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the U.S., no uniform policy of coverage and reimbursement for drug products exists among third-party payers. Therefore, coverage and reimbursement for drug products can differ significantly from payer to payer.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the U.S. and in international markets. Third-party coverage and reimbursement for OTREXUP®, XYOSTED™ or any of our other products and product candidates for which we may receive regulatory approval may not be available or adequate in either the U.S. or international markets, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

We depend on Teva to manufacture the drug and finished packaged product and to distribute and commercialize the epinephrine auto-injector in the U.S.

We have entered into a license, development and supply agreement with Teva, pursuant to which Antares developed and is the exclusive supplier of the device for an epinephrine auto injector product to be marketed by Teva in the U.S. Teva's ANDA for a generic epinephrine auto injector drug-device combination product was approved by the FDA in August 2018 and Teva is preparing for a launch of the product.

There is no guarantee that our partnership with Teva will be successful. Teva controls the manufacture and supply of the drug, epinephrine, and the final assembly of the devices and packaging of the finished product, and has complete control over the launch and continuous commercialization and sale of the epinephrine auto injector product. If, at any time, Teva ceases to manufacture and supply the epinephrine drug or fails to produce sufficient supplies of the drug, Teva will be unable to produce a finished product and we may be unable to sell our auto injectors for this product to Teva resulting in less revenue for us.

In addition, if Teva is unable to complete the final assembly and packaging of the finished epinephrine auto injector product, we may receive less revenue than desired or expected. If Teva is unable to produce sufficient supplies of the drug or finished epinephrine auto injector product in accordance with cGMPs, Teva may be subject to regulatory enforcement action. We will also rely on Teva to commercialize and distribute the product, including determining the price and payer coverage. If Teva is unsuccessful in commercializing the product, the resulting revenue may be lower than expected. Additionally, Teva controls the business strategy, manufacturing and distribution decisions concerning the epinephrine auto injector product. Such decisions by Teva may be beyond our control and may impact the success of the epinephrine auto injector product. As a result, we may receive less revenue than desired or expected.

Further, Teva is subject to potential competition regarding another generic version of the epinephrine auto injector product, such additional competition could result in receiving less revenue than expected.

We rely on third parties to manufacture our and our partners' products. If we do not develop and maintain relationships with manufacturers and/or assemblers of our and our partners' drug/device products or product candidates, or if such third parties are unable to manufacture or supply product, or assemble and package the final products, we may be unable to successfully manufacture, assembly, package and sell our and our partners' products, which could have a material adverse effect on our business.

We do not possess the facilities to manufacture commercial quantities of our or our partners' drug/device combination products or components, including OTREXUP®, XYOSTED™, VIBEX® Sumatriptan Injection USP, epinephrine auto-injector devices, Makena® auto injectors or any other of our or our partners' products or product candidates. We also do not possess the facilities to manufacture clinical supplies of any product candidates or components. We must contract with third parties to produce products, components, and product candidates and to assemble and package products and components according to specifications and government regulations. The future development and delivery of our and our partners' products and product candidates depends on the capability, timely, profitable and competitive performance of these third parties. There is also no assurance that such third parties will be willing to manufacture, assemble or sell the drug/device products or components. A limited number of manufacturers exist that are capable of manufacturing our and our partners' products, components, and product candidates. We and our partners may fail to contract with the necessary third parties or we and our partners may contract with third parties on terms that may not be favorable to us.

Our and our partners' contract manufacturers must comply with all applicable manufacturing requirements, including cGMPs for drug products and QSRs for medical devices. Before approving any marketing application, FDA will inspect the product manufacturing facilities. We and/or our partners must obtain FDA approval for a product's or

product candidate’s manufacturing process and facilities to receive product marketing approval, which we and/or our partners may never obtain or may not be able to maintain. Moreover, following product approval, FDA regularly also inspects drug and device manufacturers to ensure continued compliance with FDA’s requirements. If we or our partners are not able to obtain or maintain this approval and regulatory compliance, we and/or they would not be able to receive product approval, and commercialize and/or sell the applicable products. Moreover, should any manufacturer fail to comply with the applicable regulatory requirements, we, our partners, and/or the manufacturer may face regulatory consequences, including enforcement actions and/or product recalls. Additionally, use of contract manufacturers exposes us to risks in the manufacturer's business such as their potential inability to perform from a technical, operational or financial standpoint. Failure by a contract manufacturer to supply product, could have a material adverse effect on our ability to generate revenue and profit.

In addition, contract manufacturers may utilize their own technology, technology developed by us, technology developed by our partners, or technology acquired or licensed from third parties. When contract manufacturers develop proprietary process technology, our reliance on such contract manufacturers is increased. Technology transfer from the original contract manufacturer may be required. Any such technology transfer may also require transfer of requisite data for regulatory purposes, including information contained in a proprietary drug or device master file held by a contract manufacturer. We and/or our partners would be dependent on

the contract manufacturer for the maintenance and right of reference to the drug or device master file. If the contract manufacturer fails to maintain a drug or device master file or withdraws our or our partners' right of reference, we and/or our partners may no longer be able to manufacture, develop, market, and sell our or our partners' products or product candidates. FDA approval of the new manufacturer and manufacturing site, as well as certain changes to the manufacturing process, would also be required.

We rely on multiple commercial supply arrangements with third-party manufacturers for, including, without limitation:

- the production and supply of the methotrexate, sumatriptan and testosterone drug substance in pre-filled syringes;
- the manufacture of prefillable syringes;
- the manufacture of device components;
- the manufacture and partial assembly of VIBEX® and Quickshot auto injectors; and
- the final assembly and packaging of our products and product candidates and our certain of partners' products and product candidates.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured products ourselves, including:

- reliance on the third party for regulatory compliance, quality assurance and adequate training in management of manufacturing staff;
- the possible breach of the manufacturing agreement or purchase orders by the third party because of factors beyond our control;
- failure to supply adequate quantities of product or product candidates or failure to supply product or product candidates meeting the required product specification or other manufacturing requirements; and
- the possibility of termination or non-renewal of the agreement or purchase orders by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

We and our partners depend on these third-party manufacturers to comply with cGMPs/QSRs enforced by the FDA and other regulatory requirements and to deliver materials on a timely basis. To the extent that a contract manufacturer cannot deliver adequate quantities of clinical supplies, our or our partners' product development efforts may be delayed. To the extent that a contract manufacturer cannot deliver adequate quantities of commercial products, our commercialization efforts would be inhibited and as a result our revenue and profit may be adversely impacted. In addition, because regulatory approval to manufacture a drug is site-specific, the FDA and other regulatory authorities will repeatedly inspect our and our partners' current and future third-party manufacturers' facilities for compliance with cGMPs/QSRs. If we, our partners, or third-party manufacturers fail to comply with applicable regulatory requirements, a regulatory agency may issue warning letters or suspend or withdraw our regulatory approval for approved or in-market products, refuse to approve any marketing applications, or refuse to allow future or current development of product candidates, among other things. Our third-party manufacturers may also fail to pass the audits by our or our partners' internal quality and regulatory group. Any of these actions could delay or prevent our development of products, delay or prevent the submission of these products for regulatory approval, delay or prevent marketing approval, or result in insufficient product or product candidate quantity to support commercial demand or development. We may also be required to replace manufacturers, which would be time consuming and expensive, and we may not be able to reach favorable agreements with or FDA approval for alternative manufacturers. As a result, our business, financial condition and results of operations could be seriously harmed. See additional risk factors associated with manufacturing in the section "Risks Related to Regulatory Matters."

In addition, we may consider entering into additional manufacturing arrangements with third party manufacturers. In each case, we will incur significant costs in obtaining the regulatory approvals and taking the other steps necessary to

begin commercial production by these manufacturers.

Item 2.UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

Item 3. DEFAULT UPON SENIOR SECURITIES
None.

Item 4. MINE SAFETY DISCLOSURES
Not applicable.

Item 5. OTHER INFORMATION
None.

Item 6. EXHIBITS
(a) Exhibit Index

Exhibit No.	Description
10.1#	Employment Agreement dates as of August 6, 2018 between Antares Pharma, Inc. and James P. Tursi, M.D.
31.1#	Certificate of the Chief Executive Officer of Antares Pharma, Inc. required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2#	Certificate of the Chief Financial Officer of Antares Pharma, Inc. required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1##	Certificate of the Chief Executive Officer of Antares Pharma, Inc. required by Rule 13a-14(b) under the Securities Exchange Act of 1934, as amended, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2##	Certificate of the Chief Financial Officer of Antares Pharma, Inc. required by Rule 13a-14(b) under the Securities Exchange Act of 1934, as amended, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS#	XBRL Instance Document
101.SCH#	XBRL Taxonomy Extension Schema Document
101.CAL#	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB#	XBRL Taxonomy Extension Label Linkbase Document
101.PRE#	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF#	XBRL Taxonomy Extension Definition Document

Filed herewith.
Furnished herewith.

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SIGNATURES

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

ANTARES PHARMA, INC.

November 6, 2018	/s/ Robert F. Apple Robert F. Apple President and Chief Executive Officer (Principal Executive Officer)
November 6, 2018	/s/ Fred M. Powell Fred M. Powell Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)