

ACADIA PHARMACEUTICALS INC

Form 10-Q

August 08, 2017

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 June 30, 2017

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number: 000-50768

ACADIA PHARMACEUTICALS INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware 06-1376651
(State of Incorporation) (I.R.S. Employer Identification No.)

3611 Valley Centre Drive, Suite 300

San Diego, California 92130
(Address of Principal Executive Offices) (Zip Code)

(858) 558-2871

(Registrant's Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

(Do not check if a smaller reporting company) Smaller reporting company

Emerging growth company

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

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

Total shares of common stock outstanding as of the close of business on July 31, 2017:

Class	Number of Shares Outstanding
Common Stock, \$0.0001 par value	122,400,306

ACADIA PHARMACEUTICALS INC.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS
ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)

	June 30, 2017 (unaudited)	December 31, 2016
Assets		
Cash and cash equivalents	\$ 143,789	\$ 163,620
Investment securities, available-for-sale	273,531	365,416
Accounts receivable, net	11,594	5,903
Interest and other receivables	784	1,237
Inventory	6,003	4,175
Prepaid expenses	8,044	7,546
Total current assets	443,745	547,897
Property and equipment, net	3,296	3,081
Intangible assets, net	6,277	7,015
Restricted cash	2,475	2,375
Other assets	522	785
Total assets	\$456,315	\$ 561,153
Liabilities and stockholders' equity		
Accounts payable	\$3,588	\$ 3,912
Accrued liabilities	37,325	36,029
Deferred revenue	—	2,644
Total current liabilities	40,913	42,585
Long-term liabilities	262	157
Total liabilities	41,175	42,742
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized at June 30, 2017 and December 31, 2016; no shares issued and outstanding at June 30, 2017 and December 31, 2016	—	—
Common stock, \$0.0001 par value; 225,000,000 shares authorized at June 30, 2017 and December 31, 2016; 122,336,580 shares and 121,367,169 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	12	12
Additional paid-in capital	1,504,778	1,452,272
Accumulated deficit	(1,089,553)	(933,979)

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Accumulated other comprehensive (loss) income	(97)	106
Total stockholders' equity	415,140		518,411
Total liabilities and stockholders' equity	\$456,315		\$ 561,153

The accompanying notes are an integral part of these condensed consolidated financial statements.

ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenues				
Product sales, net	\$30,475	\$97	\$45,761	\$97
Collaborative revenue	—	—	—	4
Total revenues	30,475	97	45,761	101
Operating expenses				
Cost of product sales	2,224	526	4,487	526
License fees and royalties	982	248	1,657	248
Research and development	34,180	20,478	69,589	43,253
Selling, general and administrative	61,523	50,768	127,268	78,259
Total operating expenses	98,909	72,020	203,001	122,286
Loss from operations	(68,434)	(71,923)	(157,240)	(122,185)
Interest income, net	993	601	1,956	1,101
Net loss	\$(67,441)	\$(71,322)	\$(155,284)	\$(121,084)
Net loss per common share, basic and diluted	\$(0.55)	\$(0.63)	\$(1.27)	\$(1.08)
Weighted average common shares outstanding, basic and diluted	122,122	113,308	121,888	112,327

The accompanying notes are an integral part of these condensed consolidated financial statements.

ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Net loss	\$(67,441)	\$(71,322)	\$(155,284)	\$(121,084)
Other comprehensive gain (loss):				
Unrealized gain (loss) on investment securities	(188)	(111)	(199)	196
Foreign currency translation adjustments	(3)	1	(4)	(1)
Comprehensive loss	\$(67,632)	\$(71,432)	\$(155,487)	\$(120,889)

The accompanying notes are an integral part of these condensed consolidated financial statements.

ACADIA PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

(Unaudited)

	Six Months Ended June 30,	
	2017	2016
Cash flows from operating activities		
Net loss	\$(155,284)	\$(121,084)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	33,815	25,838
Amortization of premiums and accretion of discounts on investment securities, available for sale	(297)	(223)
Amortization of intangible assets	738	246
Depreciation	577	342
Loss on disposal of assets	—	5
Changes in operating assets and liabilities:		
Accounts receivable, net	(5,691)	(293)
Interest and other receivables	453	298
Inventory	(1,927)	(2,512)
Prepaid expenses and other current assets	(498)	(4,623)
Restricted cash	(100)	(2,000)
Other assets	263	(782)
Accounts payable	(324)	(648)
Accrued liabilities	1,253	7,001
Deferred revenue	(2,644)	513
Long-term liabilities	105	(35)
Net cash used in operating activities	(129,561)	(97,957)
Cash flows from investing activities		
Purchases of investment securities	(250,007)	(326,629)
Maturities of investment securities	341,990	159,260
Intangible assets	—	(8,000)
Purchases of property and equipment	(749)	(787)
Net cash provided by (used in) investing activities	91,234	(176,156)
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	18,500	289,429
Proceeds from settlement agreement	—	14,320
Net cash provided by financing activities	18,500	303,749
Effect of exchange rate changes on cash	(4)	—
Net (decrease) increase in cash and cash equivalents	(19,831)	29,636
Cash and cash equivalents		
Beginning of period	163,620	102,138

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End of period	\$143,789	\$131,774
Supplemental disclosure of noncash information:		
Property and equipment purchases in accounts payable and accrued liabilities	\$43	\$254
Stock-based compensation capitalized in inventory	\$99	\$355

The accompanying notes are an integral part of these condensed consolidated financial statements.

ACADIA PHARMACEUTICALS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Organization and Business

ACADIA Pharmaceuticals Inc. (the “Company”), based in San Diego, California, is a biopharmaceutical company focused on the development and commercialization of innovative medicines to address unmet medical needs in central nervous system disorders. The Company was originally incorporated in Vermont in 1993 as Receptor Technologies, Inc. and reincorporated in Delaware in 1997.

On April 29, 2016, the U.S. Food and Drug Administration (“FDA”) approved the Company’s first drug, NUPLAZID[®] (pimavanserin), for the treatment of hallucinations and delusions associated with Parkinson’s disease psychosis (“PD Psychosis”). NUPLAZID became available for prescription in the United States on May 31, 2016.

2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company should be read in conjunction with the audited financial statements and notes thereto as of and for the year ended December 31, 2016 included in the Company’s Annual Report on Form 10-K (“Annual Report”) filed with the Securities and Exchange Commission (the “SEC”). The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”) for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, since they are interim statements, the accompanying financial statements do not include all of the information and notes required by GAAP for complete financial statements. In the opinion of management, the accompanying financial statements reflect all adjustments (consisting of normal recurring adjustments) that are necessary for a fair statement of the financial position, results of operations and cash flows for the interim periods presented. Interim results are not necessarily indicative of results for a full year. The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the accompanying notes. Actual results could differ from those estimates.

Accounts Receivable

Accounts receivable are recorded net of customer allowances for distribution fees, prompt payment discounts, chargebacks, and doubtful accounts. Allowances for distribution fees, prompt payment discounts and chargebacks are based on contractual terms. The Company estimates the allowance for doubtful accounts based on existing contractual payment terms, actual payment patterns of its customers and individual customer circumstances. At June 30, 2017, the Company determined that an allowance for doubtful accounts was not required. No accounts were written off during the periods presented.

License Fees and Royalties

The Company expenses amounts paid to acquire licenses associated with products under development when the ultimate recoverability of the amounts paid is uncertain and the technology has no alternative future use when acquired. Acquisitions of technology licenses are charged to expense or capitalized based upon management's assessment regarding the ultimate recoverability of the amounts paid and the potential for alternative future use. The Company has determined that technological feasibility for its product candidates is reached when the requisite regulatory approvals are obtained to make the product available for sale.

In connection with the FDA approval of NUPLAZID in April 2016, the Company made a one-time milestone payment of \$8.0 million pursuant to its 2006 license agreement with the Ipsen Group in which the Company licensed certain intellectual property rights that complement its patent portfolio for its serotonin platform, including NUPLAZID. The Company capitalized the \$8.0 million payment as an intangible asset and is amortizing the asset on a straight-line basis over the estimated useful life of the licensed patents through the second half of 2021. The Company recorded amortization expense related to its intangible asset of \$0.4 million and \$0.7 million for the three and six months ended June 30, 2017, respectively. As of June 30, 2017, estimated future amortization expense related to the Company's intangible asset was \$0.7 million for the remainder of 2017, \$1.5 million for each of 2018, 2019, and 2020, and \$1.0 million for 2021.

Royalties incurred in connection with the Company's license agreement with the Ipsen Group, as disclosed in Note 9, are expensed to license fees and royalties as revenue from product sales is recognized.

Revenue Recognition

Product Sales, Net

The Company's net product sales consist of U.S. sales of NUPLAZID and are recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title to the product and associated risk of loss has passed to the customer, (iii) the price is fixed or determinable, and (iv) collectability is reasonably assured.

NUPLAZID was approved by the FDA on April 29, 2016 and the Company commenced shipments of NUPLAZID to specialty pharmacies ("SPs") and specialty distributors ("SDs") in late May 2016. Prior to April 1, 2017, the Company deferred sales of NUPLAZID and recognized revenue when an SP dispensed product to a patient based on the fulfillment of a prescription and when an SD sold product to a government facility, long-term care pharmacy, or in-patient hospital pharmacy. In the second quarter of 2017 the Company determined that it has sufficient volume of activity to reasonably estimate its allowances for rebates and chargebacks and began recognizing NUPLAZID revenue, net of estimated allowances for rebates, price adjustments, returns, chargebacks, and prompt payment discounts, at the point of sale to the SPs and SDs which is commonly referred to as the "sell-in" revenue recognition model. As a result, the Company recorded a one-time adjustment during the three months ended June 30, 2017, to recognize deferred revenue on previously shipped product. The impact of this adjustment resulted in additional net revenue of \$3.6 million for the three months ended June 30, 2017.

The effect on income from operations and on net income is that the Company is able to recognize revenue earlier on this sell-in method, net of a provision for estimated allowances, since the Company can record revenue once sold to the SP or SD rather than waiting until the product is sold to the end user on a sell-through basis, which it had done for periods prior to April 1, 2017.

Product shipping and handling costs are included in cost of product sales.

The Company recognizes revenue from product sales net of the following allowances and reflects each of these as either a reduction to the related accounts receivable or as an accrued liability, depending on how the amount is settled:

Distribution Fees: Distribution fees include distribution service fees paid to the SPs and SDs based on a contractually fixed percentage of the wholesale acquisition cost ("WAC"), fees for data, and prompt payment discounts. Distribution fees are recorded as an offset to revenue based on contractual terms at the time revenue from the sale is recognized.

Rebates: Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program and the Medicare Part D prescription drug benefit. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements with, or statutory requirements pertaining to, Medicaid and Medicare benefit providers. The allowance for rebates is based on statutory discount rates and expected utilization. The Company's estimates for expected utilization of rebates is based on historical data received from the SPs and SDs since product launch. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for prior quarters' unpaid rebates. If actual future rebates vary from estimates, the Company may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

Chargebacks: Chargebacks are discounts and fees that relate to contracts with government and other entities purchasing from the SDs at a discounted price. The SDs charge back to the Company the difference between the price initially paid by the SDs and the discounted price paid to the SDs by these entities. The Company also incurs group purchasing organization fees for transactions through certain purchasing organizations. The Company estimates sales with these entities and accrues for anticipated chargebacks and organization fees, based on the applicable contractual

terms. If actual future chargebacks vary from these estimates, the Company may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

Co-Payment Assistance: The Company offers co-payment assistance to commercially insured patients meeting certain eligibility requirements. Co-payment assistance is accrued for based on actual program participation and estimates of program redemption using data provided by third-party administrators.

Product Returns: Consistent with industry practice, the Company offers the SPs and SDs limited product return rights for damages, shipment errors, and expiring product; provided that the return is within a specified period around the product expiration date as set forth in the applicable individual distribution agreement. The Company does not allow product returns for product that has been dispensed to a patient. As the Company receives inventory reports from the SPs and SDs and has the ability to control the amount of product that is sold to the SPs and SDs, it is able to make a reasonable estimate of future potential product returns based on this on-hand channel inventory data and sell-through data obtained from the SPs and SDs. In arriving at its estimate, the Company also considers historical product returns, the underlying product demand, and industry data specific to the specialty pharmaceutical distribution industry.

3. Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and common stock equivalents outstanding for the period determined using the treasury stock method. For purposes of this calculation, stock options, employee stock purchase plan rights, and warrants are considered to be common stock equivalents but are not included in the calculations of diluted net loss per share for the periods presented as their effect would be anti-dilutive. The Company incurred net losses for all periods presented and there were no reconciling items for potentially dilutive securities. More specifically, at June 30, 2017 and 2016, stock options, employee stock purchase plan rights, and warrants totaling approximately 16,563,000 shares and 14,404,000 shares, respectively, were excluded from the calculation of diluted net loss per share as their effect would have been anti-dilutive.

4. Stock-Based Compensation

The following table summarizes the total stock-based compensation expense included in the Company's statements of operations for the periods presented (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Cost of product sales	\$881	\$189	\$1,761	\$189
Research and development	6,420	4,780	11,721	9,176
Selling, general and administrative	10,943	8,914	20,333	16,473
	\$18,244	\$13,883	\$33,815	\$25,838

5. Balance Sheet Details

Inventory consisted of the following (in thousands):

June 30, December 31,

	2017	2016
Raw material	\$ 4,088	\$ 1,820
Finished goods	1,915	2,355
	\$ 6,003	\$ 4,175

Accrued liabilities consisted of the following (in thousands):

	June 30,	December 31,
	2017	2016
Accrued compensation and benefits	\$11,072	\$ 14,382
Accrued consulting and professional fees	9,767	9,488
Accrued research and development services	6,077	8,551
Accrued sales allowances	5,792	1,999
Other	4,617	1,609
	\$37,325	\$ 36,029

6. Investment Securities

Investment securities, all classified as available-for-sale, consisted of the following (in thousands):

	June 30, 2017			Estimated
	Amortized	Unrealized	Unrealized	Fair
	Cost	Gains	Losses	Value
U.S. Treasury notes	\$31,794	\$ —	\$ (11)) \$31,783
Government sponsored enterprise securities	62,079	—	(29)) 62,050
Corporate debt securities	53,012	—	(22)) 52,990
Commercial paper	126,753	2	(47)) 126,708
	\$273,638	\$ 2	\$ (109)) \$273,531

	December 31, 2016			Estimated
	Amortized	Unrealized	Unrealized	Fair
	Cost	Gains	Losses	Value
U.S. Treasury notes	\$82,484	\$ 6	\$ (3)) \$82,487
Government sponsored enterprise securities	73,789	1	(5)) 73,785
Corporate debt securities	79,190	—	(72)) 79,118
Commercial paper	129,861	165	—) 130,026
	\$365,324	\$ 172	\$ (80)) \$365,416

At each reporting date, the Company performs an evaluation of impairment to determine if any unrealized losses are other-than-temporary. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition of the issuer, and the Company's intent and ability to hold the investment until recovery of its amortized cost basis. The Company intends, and has the ability, to hold its investments in unrealized loss positions until their amortized cost basis has been recovered. Based on its evaluation, the Company determined that its unrealized losses were not other-than-temporary at June 30, 2017 and December 31, 2016. As of June 30, 2017 and December 31, 2016, all of the Company's available-for-sale investment securities had contractual maturity dates of less than one year.

7. Fair Value Measurements