

NEKTAR THERAPEUTICS

FORM 8-K (Current report filing)

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Address	455 MISSION BAY BOULEVARD SOUTH SAN FRANCISCO, CA, 94158
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): November 7, 2017

NEKTAR THERAPEUTICS

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

0-24006
(Commission
File Number)

94-3134940
(IRS Employer
Identification No.)

455 Mission Bay Boulevard South
San Francisco, California 94158
(Address of Principal Executive Offices and Zip Code)

Registrant's telephone number, including area code: (415) 482-5300

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

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

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

Emerging growth company

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

Item 2.02 Results of Operations and Financial Condition.

On November 7, 2017, Nektar Therapeutics, a Delaware corporation (“Nektar”), issued a press release (the “Press Release”) announcing its financial results for the quarter ended September 30, 2017. A copy of the Press Release is furnished herewith as Exhibit 99.1.

On October 31, 2017, Nektar announced that it would hold a Webcast conference call on November 7, 2017 to review its financial results for the quarter ended September 30, 2017. This conference call is accessible through a link that is posted on the home page and Investors section of the Nektar website: <http://www.nektar.com>.

The information in this report, including the exhibit hereto, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the Securities and Exchange Commission made by Nektar Therapeutics, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press release titled “Nektar Therapeutics Reports Financial Results for the Third Quarter of 2017” issued by Nektar Therapeutics on November 7, 2017.

SIGNATURES

Pursuant to the requirement 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.

By: /s/ Mark A. Wilson
 Mark A. Wilson
 General Counsel and Secretary

Date: November 7, 2017



Nektar Therapeutics Reports Financial Results for the Third Quarter of 2017

SAN FRANCISCO, Nov. 7, 2017 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today reported its financial results for the third quarter ended September 30, 2017.

Cash and investments in marketable securities at September 30, 2017 were \$412.2 million as compared to \$389.1 million at December 31, 2016. The cash balance includes the \$150.0 million upfront payment from Nektar's collaboration with Eli Lilly & Company for the development and commercialization of NKTR-358.

"Nektar's immuno-oncology portfolio continues to expand as we add novel drug candidates to our growing pipeline," said Howard W. Robin, President and CEO of Nektar. "NKTR-214 is the first I-O agent to both increase tumor-infiltrating lymphocytes (TILs) and increase PD-1 expression on human immune cells, which uniquely complements checkpoint inhibition and other anti-cancer mechanisms. As the majority of cancer patients have tumors that do not express PD-L1 and these patients receive limited benefit from treatment with checkpoint inhibitors, the potential of NKTR-214 to help patients is significant. Finally, based on recent positive conversations with the agency regarding our regulatory plans for NKTR-181, we are now planning to submit an NDA for NKTR-181 by April 2018 with our data package of over 2,100 patients and healthy volunteers."

Revenue in the third quarter of 2017 was \$152.9 million as compared to \$36.3 million in the third quarter of 2016. Year-to-date revenue for 2017 was \$212.2 million as compared to \$128.0 million in the first nine months of 2016. Revenue in 2017 included recognition of \$127.6 million of the \$150.0 million upfront payment from Nektar's collaboration with Eli Lilly & Company for the development and commercialization of NKTR-358.

Total operating costs and expenses in the third quarter of 2017 were \$83.4 million as compared to \$69.2 million in the third quarter of 2016. Year-to-date total operating costs and expenses in 2017 were \$247.9 million as compared to \$208.7 million for the same period in 2016. Total operating costs and expenses increased primarily as a result of increased research and development (R&D) expense.

Research and development expense in the third quarter of 2017 was \$65.7 million as compared to \$52.0 million in the third quarter of 2016. Year-to-date R&D expense for 2017 was \$187.0 million as compared to \$153.6 million for the same period in 2016. R&D expense was higher in the third quarter and first nine months of 2017 as compared to the same periods in 2016 primarily because of expenses for our pipeline programs, including Phase 3 clinical studies for NKTR-181, Phase 1/2 clinical studies of NKTR-214 and NKTR-358 and IND-enabling activities for NKTR-262 and NKTR-255.

General and administrative expense was \$12.1 million in the third quarter of 2017 as compared to \$10.3 million in the third quarter of 2016. G&A expense in the first nine months of 2017 was \$40.0 million as compared to \$31.5 million for the same period in 2016. G&A expense in the first nine months of 2017 includes a \$3.3 million charge for a litigation settlement related to a cross-license agreement.

Net income in the third quarter of 2017 was \$60.9 million or \$0.39 basic income per share as compared to net loss of \$43.2 million or \$0.32 basic loss per share in the third quarter of 2016. Net loss in the first nine months of 2017 was \$62.9 million or \$0.41 basic loss per share as compared to \$111.3 million or \$0.82 basic loss per share in the first nine months of 2016.

The company also announced upcoming presentations at the following scientific congresses during the fourth quarter of 2017:

Society for Immunotherapy in Cancer (SITC) 32nd Annual Meeting, National Harbor, MD:

Oral Presentation: " *PIVOT-02: Preliminary safety, efficacy and biomarker results from the Phase 1/2 study of CD-122-biased agonist NKTR-214 plus nivolumab in patients with locally advanced/metastatic solid tumors* "

Presenter: Dr. Adi Diab, Assistant Professor, Department of Melanoma Medical Oncology, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, Houston, Texas

Session: Clinical Trials: Novel Combinations

Date: Saturday, November 11, 2017, 5:00 p.m. Eastern Time

Poster #P77: " *The Novel IL-2 Cytokine Immune Agonist NKTR-214 Harnesses the Adaptive and Innate Immune System for the Treatment of Solid Cancers* "

Presenter: Salah Eddine Bentebibel, University of Texas MD Anderson Cancer Center

Session: Biomarkers and Immune Monitoring

Date: Friday, November 10, 2017, 12:30-2:00 p.m. Eastern Time

Poster #P140: " *NKTR-214 enhances anti-tumor T-cell immune responses induced by checkpoint blockade or vaccination* "

Presenter: Meenu Sharma, University of Texas MD Anderson Cancer Center

Session: Cancer Vaccines

Date: Saturday, November 11, 2017, 12:30-2:00 p.m. Eastern Time

Poster #P274: " *Combination of NKTR-214 and radiotherapy (RT) to reverse anergy and expand tumor-specific CD8 T-Cells* "

Presenter: Joshua Walker, Oregon Health & Science University

Session: Combination Therapy

Date: Saturday, November 11, 2017, 12:30-2:00 p.m. Eastern Time

Poster #P275: " *Harnessing the innate and adaptive immune system to eradicate treated and distant untreated solid tumors* "

Presenter: Saul Kivimae, Nektar Therapeutics

Session: Combination Therapy

Date: Friday, November 10, 2017, 12:30-2:00 p.m. Eastern Time

Poster #P332: " *Pre-clinical efficacy and tolerability of NKTR-255, a polymer-conjugated IL-15 for immuno-oncology* "

Presenter: Peiwen Kuo, Nektar Therapeutics

Session: Combination Therapy

Date: Saturday, November 11, 2017, 12:30-2:00 p.m. Eastern Time

Poster #434: " *Great Apes Adenoviral vaccine encoding neoantigens synergizes with immunomodulators to cure established tumors in mice* "

Presenter: Anna Morena D'Alise, Nouscom srl

Session: Personalized Vaccines and Technologies/Personalized Medicines

Date: Saturday, November 11, 2017, 12:30-2:00 p.m. Eastern Time

American College of Neuropsychopharmacology 56th Annual Meeting, Palm Springs, CA:

Poster #T166: " Abuse potential of NKTR-181 in recreational opioid users: results from a randomized, double-blind crossover oral study"

Presenter: Snow Ge, Nektar Therapeutics

Session: Poster Session II

Date: Tuesday, December 5, 2017, 5:30-7:30 p.m. Pacific Time

Conference Call to Discuss Third Quarter 2017 Financial Results

Nektar management will host a conference call to review the results beginning at 5:00 p.m. Eastern Time/2:00 p.m. Pacific Time, Tuesday, November 7, 2017.

This press release and a live audio-only Webcast of the conference call can be accessed through a link that is posted on the home page and Investors section of the Nektar website: <http://ir.nektar.com/index.cfm>. The web broadcast of the conference call will be available for replay through Monday, December 11, 2017.

To access the conference call, follow these instructions:

Dial: (877) 881.2183 (U.S.); (970) 315.0453 (international)

Passcode : 4677348 (Nektar Therapeutics is the host)

In the event that any non-GAAP financial measure is discussed on the conference call that is not described in the press release, or explained on the conference call, related information will be made available on the Investor Relations page at the Nektar website as soon as practical after the conclusion of the conference call.

About Nektar

Nektar Therapeutics is a research-based development stage biopharmaceutical company whose mission is to discover and develop innovative medicines to address the unmet medical needs of patients. Our R&D pipeline of new investigational medicines includes treatments for cancer, auto-immune disease and chronic pain. We leverage Nektar's proprietary and proven chemistry platform in the discovery and design of our new therapeutic candidates. Nektar is headquartered in San Francisco, California, with additional operations in Huntsville, Alabama and Hyderabad, India. Further information about the company and its drug development programs and capabilities may be found online at <http://www.nektar.com>.

Cautionary Note Regarding Forward-Looking Statements

This press release contains uncertain or forward-looking statements which can be identified by words such as: "could," "plan," "expect," "should," "may," "will" and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding the potential therapeutic benefits of and future development plans for our products (including NKTR-181, NKTR-358, NKTR-214, NKTR-262 and NKTR-255), the potential impact of NKTR-181 with respect to the opioid abuse epidemic, the timing and strategy for regulatory filings (including the timing and strategy for filing a new drug application, "NDA") and meetings with representatives of the Food and Drug Administration (FDA) and other governmental officials, and the results of clinical trials. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions and are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results may differ materially from those indicated in the forward-looking statements and you should not rely on such statements. Important factors that could cause our actual results to differ materially from those indicated in the forward-looking statements include: (i) clinical study outcomes remain very unpredictable and it is possible that a clinical study could fail even after positive interim data is observed; (ii) the regulatory pathway to review and approve pharmaceutical products is subject to substantial uncertainty; (iii) the data package required for filing and approval of an NDA to the FDA is very uncertain and difficult to predict due to broad FDA regulatory discretion, established guidance and precedent (e.g., the practice of typically requiring two placebo-controlled pivotal studies to support NDA approvals for drugs like NKTR-181), and changing FDA regulatory guidelines; (iv) the final outcomes and conclusions from sponsor meetings with FDA are subject to substantial FDA discretion associated with issuing final meeting minutes and outcomes; (v) regulations concerning and controlling access to opioid-based pharmaceuticals are strict and is difficult to predict which scheduling category will apply to NKTR-181 if regulatory approval is achieved; (vi) patents may not issue from our patent applications for our drug candidates, patents that have issued may not be enforceable, or additional intellectual property licenses from third parties may be required; and (vii) certain other important risks and uncertainties set forth in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 9, 2017. Any forward-looking statement made by us in this press release is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to update any forward-looking statement.

Contact:

For Investors:

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NEKTAR THERAPEUTICS
CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)
(Unaudited)

	September 30, 2017	December 31, 2016 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 37,967	\$ 59,640
Short-term investments	314,600	329,462
Accounts receivable, net	3,314	15,678
Inventory	13,654	11,109
Other current assets	13,260	10,063
Total current assets	<u>382,795</u>	<u>425,952</u>
Long-term investments	59,596	—
Property, plant and equipment, net	62,396	65,601
Goodwill	76,501	76,501
Other assets	767	817
Total assets	<u>\$ 582,055</u>	<u>\$ 568,871</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 8,563	\$ 2,816
Accrued compensation	19,088	18,280
Accrued clinical trial expenses	7,000	7,958
Other accrued expenses	9,302	4,711
Interest payable	4,198	4,198
Capital lease obligations, current portion	2,482	2,908
Liability related to refundable upfront payment	12,500	12,500
Deferred revenue, current portion	25,491	14,352
Other current liabilities	3,920	4,499
Total current liabilities	<u>92,544</u>	<u>72,222</u>
Senior secured notes, net	244,771	243,464
Liability related to the sale of future royalties, net	98,394	105,950
Deferred revenue, less current portion	56,225	51,887
Other long-term liabilities	5,959	7,223
Total liabilities	<u>497,893</u>	<u>480,746</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	15	15
Capital in excess of par value	2,170,169	2,111,483
Accumulated other comprehensive loss	(1,907)	(2,363)
Accumulated deficit	(2,084,115)	(2,021,010)
Total stockholders' equity	<u>84,162</u>	<u>88,125</u>
Total liabilities and stockholders' equity	<u>\$ 582,055</u>	<u>\$ 568,871</u>

(1) The consolidated balance sheet at December 31, 2016 has been derived from the audited financial statements at that date but does not include all of the information and notes required by generally accepted accounting principles in the United States for complete financial statements.

NEKTAR THERAPEUTICS
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share information)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenue:				
Product sales	\$ 4,448	\$ 14,698	\$ 24,897	\$ 41,664
Royalty revenue	9,302	5,573	23,953	13,150
Non-cash royalty revenue related to sale of future royalties	8,066	7,692	21,367	22,341
License, collaboration and other revenue	131,112	8,373	142,028	50,829
Total revenue	152,928	36,336	212,245	127,984
Operating costs and expenses:				
Cost of goods sold	5,674	7,033	20,794	23,611
Research and development	65,714	51,951	187,032	153,569
General and administrative	12,055	10,253	40,027	31,515
Total operating costs and expenses	83,443	69,237	247,853	208,695
Income (loss) from operations	69,485	(32,901)	(35,608)	(80,711)
Non-operating income (expense):				
Interest expense	(5,540)	(5,614)	(16,452)	(16,918)
Non-cash interest expense on liability related to sale of future royalties	(4,471)	(4,902)	(13,535)	(14,929)
Interest income and other income (expense), net	1,599	332	3,163	1,666
Total non-operating expense, net	(8,412)	(10,184)	(26,824)	(30,181)
Income (loss) before provision for income taxes	61,073	(43,085)	(62,432)	(110,892)
Provision for income taxes	202	139	434	433
Net income (loss)	\$ 60,871	\$ (43,224)	\$ (62,866)	\$ (111,325)
Net income (loss) per share:				
Basic	\$ 0.39	\$ (0.32)	\$ (0.41)	\$ (0.82)
Diluted	\$ 0.37	\$ (0.32)	\$ (0.41)	\$ (0.82)
Weighted average shares outstanding used in computing net income (loss) per share:				
Basic	156,411	137,094	155,153	136,415
Diluted	162,641	137,094	155,153	136,415

NEKTAR THERAPEUTICS
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2017	2016
Cash flows from operating activities:		
Net loss	\$ (62,866)	\$ (111,325)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash royalty revenue related to sale of future royalties	(21,367)	(22,341)
Non-cash interest expense on liability related to sale of future royalties	13,535	14,929
Stock-based compensation	25,118	18,793
Depreciation and amortization	12,081	11,502
Other non-cash transactions	(1,370)	(2,190)
Changes in operating assets and liabilities:		
Accounts receivable, net	12,364	5,698
Inventory	(2,545)	592
Other assets	(2,036)	6,041
Accounts payable	5,729	4,799
Accrued compensation	808	9,735
Accrued clinical trial expenses	(958)	2,726
Other accrued expenses	4,971	2,386
Liability related to refundable upfront payment	—	12,500
Deferred revenue	15,477	(12,665)
Other liabilities	1,046	(5,793)
Net cash used in operating activities	(13)	(64,613)
Cash flows from investing activities:		
Purchases of investments	(314,439)	(142,972)
Maturities of investments	261,112	201,449
Sales of investments	8,823	4,969
Purchases of property, plant and equipment	(7,283)	(3,741)
Net cash (used in) provided by investing activities	(51,787)	59,705
Cash flows from financing activities:		
Payment of capital lease obligations	(2,159)	(5,376)
Proceeds from shares issued under equity compensation plans	32,275	18,041
Net cash provided by financing activities	30,116	12,665
Effect of exchange rates on cash and cash equivalents	11	(32)
Net (decrease) increase in cash and cash equivalents	(21,673)	7,725
Cash and cash equivalents at beginning of period	59,640	55,570
Cash and cash equivalents at end of period	<u>\$ 37,967</u>	<u>\$ 63,295</u>
Supplemental disclosure of cash flow information:		
Cash paid for interest	<u>\$ 14,989</u>	<u>\$ 15,513</u>