

NEKTAR THERAPEUTICS

FORM 8-K (Current report filing)

Filed 03/01/17 for the Period Ending 03/01/17

Address	455 MISSION BAY BOULEVARD SOUTH SAN FRANCISCO, CA 94158
Telephone	4154825300
CIK	0000906709
Symbol	NKTR
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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): March 1, 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))
-

Item 2.02 Results of Operations and Financial Condition.

On March 1, 2017, Nektar Therapeutics, a Delaware corporation (“Nektar”), issued a press release (the “Press Release”) announcing its financial results for the quarter and year ended December 31, 2016. A copy of the Press Release is furnished herewith as Exhibit 99.1.

On February 22, 2017, Nektar announced that it would hold a Webcast conference call on March 1, 2017 to review its financial results for the quarter and year ended December 31, 2016 and give an update on its business. This conference call is accessible through a link that is posted on the home page and Investor 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 Fourth Quarter and Year-End 2016 Financial Results” issued by Nektar Therapeutics on March 1, 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: March 1, 2017

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release titled "Nektar Therapeutics Reports Fourth Quarter and Year-End 2016 Financial Results" issued by Nektar Therapeutics on March 1, 2017.

Nektar Therapeutics Reports Fourth Quarter and Year-End 2016 Financial Results

SAN FRANCISCO, March 1, 2017 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today reported its financial results for the fourth quarter and year ended December 31, 2016.

Cash and investments in marketable securities at December 31, 2016 were \$389.1 million as compared to \$308.9 million at December 31, 2015.

“Nektar begins 2017 in a strong position with highly promising wholly-owned immuno-oncology and immunology clinical programs and several important data readouts expected throughout this year,” said Howard W. Robin, President and Chief Executive Officer of Nektar. “Our Phase 1/2 study evaluating NKTR-214 as a potential combination treatment regimen with Opdivo® in collaboration with Bristol-Myers Squibb is proceeding nicely. We plan to report initial data from the dose-escalation part of the study in the middle of this year. Later this month, we will have data from our Phase 3 efficacy study of NKTR-181 in patients with chronic low back pain. Finally, we are pleased that we will initiate a first-in-human trial shortly for NKTR-358, our proprietary T regulatory cell stimulator, which has the potential to become a first-in-class resolution therapeutic for a wide range of immune disorders.”

Summary of Financial Results

Revenue for the fourth quarter of 2016 was \$37.5 million as compared to \$39.4 million in the fourth quarter of 2015.

Revenue for the year ended December 31, 2016 was \$165.4 million as compared to \$230.8 million in 2015. Revenue in 2016 included recognition of \$31.0 million from AstraZeneca as a result of its sublicense of MOVENTIG® (naloxegol) to Kyowa Kirin in Europe. In addition, product sales, royalty revenue, and non-cash royalty revenue increased in 2016 compared to 2015. Revenue in 2015 included recognition of a total of \$130.0 million of milestone payments from AstraZeneca following the first commercial sale of MOVANTI® in the U.S. in Q1 2015 and the first commercial sale of MOVENTIG in the EU in Q3 2015.

Total operating costs and expenses in the fourth quarter of 2016 were \$69.6 million as compared to \$68.7 million in the fourth quarter of 2015. Total operating costs and expenses increased primarily as a result of higher research and development (R&D) expense. Total operating costs and expenses for the year ended December 31, 2016 were \$278.3 million as compared to \$260.2 million in 2015.

R&D expense in the fourth quarter of 2016 was \$50.2 million as compared to \$47.1 million for the fourth quarter of 2015. R&D expense for the year ended December 31, 2016 was \$203.8 million as compared to \$182.8 million in 2015. R&D expense increased primarily due to expenses for our NKTR-214 and NKTR-358 programs.

General and administrative (G&A) expense was \$12.8 million in the fourth quarter of 2016 as compared to \$13.2 million in the fourth quarter of 2015. G&A expense for the year ended December 31, 2016 was \$44.3 million as compared to \$43.3 million in 2015.

Net loss for the fourth quarter of 2016 was \$42.2 million or \$0.28 loss per share as compared to a net loss of \$54.1 million or \$0.40 loss per share in the fourth quarter of 2015. Net loss for the year ended December 31, 2016 was \$153.5 million or \$1.10 loss per share as compared to a net loss of \$81.2 million or \$0.61 loss per share in 2015.

2016 and Year-to-Date Business Highlights

Nektar Wholly-Owned Programs

- In February 2017, Nektar submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for NKTR-358, a new biologic designed to treat autoimmune disease. Clinical trials are planned for NKTR-358 in patients with systemic lupus erythematosus (SLE) and other indications.
 - In February 2017, Nektar announced positive data from the Phase 1 dose-escalation study of single-agent NKTR-214 in patients with renal cell carcinoma at the ASCO 2017 Genitourinary Cancers Symposium. Clinical benefit and safety data presented included 40% of RCC patients experiencing tumor reductions including one patient with a partial response and a favorable safety and tolerability profile.
 - In January 2017, Nektar announced a new immuno-oncology candidate, NKTR-262, a small molecule agonist that targets toll-like receptors (TLRs) found on innate immune cells in the body. NKTR-262 is being developed as a single intra-tumoral injection to be administered at the start of therapy with NKTR-214. The company plans to file an IND for NKTR-262 by the end of 2017.
 - In December 2016, Nektar initiated a pivotal human abuse liability (HAL) trial for its novel opioid molecule NKTR-181, which is expected to complete in the middle of 2017.
-

- In November 2016, Nektar announced positive data from the Phase 1 dose-escalation study of single-agent NKTR-214 at the Society of Immunotherapy of Cancer Annual Meeting. Results showed encouraging anti-tumor activity including one patient with a partial response and a favorable safety and tolerability profile.
- In September 2016, Nektar and Bristol-Myers Squibb entered into a clinical collaboration to develop NKTR-214 as a potential combination treatment regimen with Bristol-Myers Squibb's *Opdivo*® (nivolumab) in five tumor types and eight potential indications. The dose-escalation part of the trial is underway with initial data expected in the middle of 2017.

Additional Pipeline and Partner Developments

- In December 2016, Shire announced that the U.S. Food and Drug Administration (FDA) approved ADYNOVATE® ([Antihemophilic Factor (Recombinant), PEGylated], an extended circulating half-life recombinant Factor VIII (rFVIII) treatment for hemophilia A, in pediatric patients under 12 years of age. The FDA also approved ADYNOVATE for use in surgical settings for both adult and pediatric patients. ADYNOVATE is under regulatory review in Europe, Switzerland and Canada.
- In September 2016, Bayer presented positive Phase 3 data for Ciprofloxacin DPI at the 26th International Congress of European Respiratory Society. The RESPIRE 1 study assessed the safety and efficacy of Cipro DPI in NCFB patients and met both primary endpoints for the every 14-day dosing arm. The second Phase 3 trial (RESPIRE 2) completed recruitment in September 2016 and data are expected to be released by our partner Bayer in 2017.
- In June 2016, Nektar entered into a partnership with Daiichi Sankyo Europe for Nektar's investigational drug therapy, ONZEALD™ (etirinotecan pegol, NKTR-102), which has completed a Phase 3 clinical trial (the BEACON study) in patients with advanced breast cancer. The agreement grants Daiichi Sankyo Europe exclusive rights to market ONZEALD in Europe (EEA), Switzerland and Turkey. Nektar Therapeutics retained rights to ONZEALD in the United States and the rest of the world. Under the terms of the agreement, Nektar is entitled to milestones and significant double-digit royalties on net sales in Europe.
- In June 2016, Nektar submitted a filing for a Marketing Authorization Agreement (MAA) with the European Medicines Agency for conditional approval for ONZEALD in patients with advanced breast cancer and brain metastases. An opinion from the European CHMP on conditional approval of ONZEALD is expected in the first half of 2017.
- Amikacin Inhale, our second anti-infective Phase 3 program partnered with Bayer, which is being developed for gram-negative pneumonia, is expected to complete in Q2 of 2017. Nektar and Bayer expect to report topline results from this program in the middle of 2017.

Conference Call to Discuss Fourth Quarter and Year-End 2016 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 today, Wednesday, March 1, 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://www.nektar.com>. The web broadcast of the conference call will be available for replay through Monday, April 3, 2017.

To access the conference call, follow these instructions:

Dial: (877) 881.2183 (U.S.); (970) 315.0453 (international)
 Passcode : 75461730 (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 Investors page at the Nektar website as soon as practical after the conclusion of the conference call.

About Nektar Therapeutics

Nektar Therapeutics is a research-based 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>.

MOVANTIK™ is a trademark and MOVENTIG® is a registered trademark of the AstraZeneca group of companies. ADYNOVATE® is a registered trademark of Baxalta Incorporated, a wholly owned, indirect subsidiary of Shire plc. ONZEALD™ is a trademark of Nektar Therapeutics. Opdivo® is a registered trademark of Bristol-Myers Squibb.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements which can be identified by words such as: “anticipate,” “intend,” “plan,” “expect,” “believe,” “should,” “may,” “will” and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding the timing of the availability of Phase 3 data for our NKTR-181 efficacy study and for our partnered programs with Bayer, the timing of the European CHMP decision for conditional approval of ONZEALD, the timing of the availability of data for the dose-escalation study for NKTR-214 in combination with Opdivo, the future clinical development plans for our products (including NKTR-358 and NKTR-262), the timing of availability of future clinical results, the timing of planned regulatory filings, the potential of NKTR-214 in combination with other immunotherapy agents including Bristol-Myers Squibb’s Opdivo (nivolumab), the timing of the completion of the NKTR-181 HAL study, and the potential of our technology and drug candidates in our research and development pipeline. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they 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. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results to differ materially from those indicated in the forward-looking statements include, among others: (i) clinical study outcomes, including the Phase 3 clinical study outcome of NKTR-181, remain very unpredictable and it is possible that a clinical study could fail due to efficacy, safety or other important clinical findings; (ii) the CHMP and FDA have substantial discretion as to whether to grant marketing approval for pharmaceutical products (including ONZEALD and those of our partners) and the decisions from these regulatory authorities are difficult to predict and these decisions have significant financial consequences; (iii) NKTR-214 is in early-stage clinical development and there are substantial risks that can unexpectedly occur for numerous reasons including negative safety and efficacy findings in the ongoing Phase I clinical study notwithstanding positive findings in preclinical studies; (iv) our drug candidates and those of our collaboration partners are in various stages of clinical development and the risk of failure is high and can unexpectedly occur at any stage prior to regulatory approval for numerous reasons including negative safety and efficacy findings even after positive findings in previous preclinical and clinical studies; (v) the timing of the commencement or end of clinical trials and the availability of clinical data may be delayed or unsuccessful due to regulatory delays, slower than anticipated patient enrollment, manufacturing challenges, changing standards of care, evolving regulatory requirements, clinical trial design, clinical outcomes, competitive factors, or delay or failure in ultimately obtaining regulatory approval in one or more important markets; (vi) scientific discovery of new medical breakthroughs is an inherently uncertain process and the future success of applying our technology platform to potential new drug candidates (such as NKTR-181, NKTR-214 and NKTR-358) is therefore highly uncertain and unpredictable and one or more research and development programs could fail; (vii) patents may not issue from our patent applications for our drug candidates including NKTR-181 and NKTR-214, patents that have issued may not be enforceable, or additional intellectual property licenses from third parties may be required; and (viii) certain other important risks and uncertainties set forth in our Annual Report on Form 10-K for the year ended December 31, 2016 filed with the Securities and Exchange Commission on March 1, 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, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

For Investors:

Jennifer Ruddock of Nektar Therapeutics
415-482-5585

Jodi Sievers of Nektar Therapeutics
415-482-5593

For Media:

Dan Budwick of Pure Communications
973-271-6085

dan@purecommunicationsinc.com

NEKTAR THERAPEUTICS
CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)
(Unaudited)

	December 31, 2016 ⁽¹⁾	December 31, 2015 ⁽¹⁾
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 59,640	\$ 55,570
Short-term investments	329,462	253,374
Accounts receivable, net	15,678	19,947
Inventory	11,109	11,346
Other current assets	10,363	9,814
Total current assets	<u>426,252</u>	<u>350,051</u>
Property, plant and equipment, net	65,601	71,336
Goodwill	76,501	76,501
Other assets	517	754
Total assets	<u>\$ 568,871</u>	<u>\$ 498,642</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,816	\$ 2,363
Accrued compensation	18,280	5,998
Accrued clinical trial expenses	7,958	8,220
Other accrued expenses	4,711	4,156
Interest payable	4,198	4,198
Capital lease obligations, current portion	2,908	4,756
Liability related to refundable upfront payment	12,500	-
Deferred revenue, current portion	14,352	21,428
Other current liabilities	4,499	10,127
Total current liabilities	<u>72,222</u>	<u>61,246</u>
Senior secured notes, net	243,464	241,699
Capital lease obligations, less current portion	2,223	1,073
Liability related to the sale of future royalties, net	105,950	116,029
Deferred revenue, less current portion	51,887	62,426
Other long-term liabilities	5,000	9,740
Total liabilities	<u>480,746</u>	<u>492,213</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	-	-
Common stock	15	13
Capital in excess of par value	2,111,483	1,876,072
Accumulated other comprehensive loss	(2,363)	(2,170)
Accumulated deficit	(2,021,010)	(1,867,486)
Total stockholders' equity	<u>88,125</u>	<u>6,429</u>
Total liabilities and stockholders' equity	<u>\$ 568,871</u>	<u>\$ 498,642</u>

(1) The consolidated balance sheets at December 31, 2016 and 2015 have been derived from the audited financial statements at those dates but do 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 December 31,		Year Ended December 31,	
	2016	2015	2016 ⁽¹⁾	2015 ⁽¹⁾
Revenue:				
Product sales	\$ 13,690	\$ 13,973	\$ 55,354	\$ 40,155
Royalty revenue	6,392	1,910	19,542	2,967
Non-cash royalty revenue related to sale of future royalties	7,817	7,306	30,158	22,058
License, collaboration and other revenue	9,553	16,181	60,382	165,604
Total revenue	37,452	39,370	165,436	230,784
Operating costs and expenses:				
Cost of goods sold	6,604	8,364	30,215	34,102
Research and development	50,232	47,135	203,801	182,787
General and administrative	12,760	13,235	44,275	43,266
Total operating costs and expenses	69,596	68,734	278,291	260,155
Loss from operations	(32,144)	(29,364)	(112,855)	(29,371)
Non-operating income (expense):				
Interest expense	(5,550)	(5,791)	(22,468)	(18,282)
Non-cash interest expense on liability related to sale of future royalties	(4,783)	(5,191)	(19,712)	(20,619)
Loss on extinguishment of debt	-	(14,079)	-	(14,079)
Interest income and other income (expense), net	721	325	2,387	1,680
Total non-operating expense, net	(9,612)	(24,736)	(39,793)	(51,300)
Loss before provision for income taxes	(41,756)	(54,100)	(152,648)	(80,671)
Provision for income taxes	443	37	876	506
Net loss	\$ (42,199)	\$ (54,137)	\$ (153,524)	\$ (81,177)
Basic and diluted net loss per share	\$ (0.28)	\$ (0.40)	\$ (1.10)	\$ (0.61)
Weighted average shares outstanding used in computing basic and diluted net loss per share	149,071	134,166	139,596	132,458

(1) The consolidated statements of operations for the years ended December 31, 2016 and 2015 have been derived from the audited financial statements as of those dates but do 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 CASH FLOWS
(In thousands)
(Unaudited)

	Year Ended December 31,	
	2016 ⁽¹⁾	2015 ⁽¹⁾
Cash flows from operating activities:		
Net loss	\$ (153,524)	\$ (81,177)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash royalty revenue related to sale of future royalties	(30,158)	(22,058)
Non-cash interest expense on liability related to sale of future royalties	19,712	20,619
Stock-based compensation	25,850	19,669
Depreciation and amortization	15,351	12,855
Loss from redemption premium and incremental interest on 12% senior secured notes	-	12,500
Write-off of deferred financing costs on 12% senior secured notes	-	1,579
Other non-cash transactions	(2,185)	(2,365)
Changes in operating assets and liabilities:		
Accounts receivable, net	4,269	(16,340)
Inventory	237	1,606
Other assets	(312)	(825)
Accounts payable	518	(412)
Accrued compensation	12,282	249
Accrued clinical trial expenses	(262)	512
Other accrued expenses	191	(2,278)
Interest payable	-	(2,719)
Liability related to refundable upfront payment	12,500	-
Deferred revenue	(17,615)	(17,530)
Other liabilities	(3,878)	3,032
Net cash used in operating activities	<u>(117,024)</u>	<u>(73,083)</u>
Cash flows from investing activities:		
Purchases of investments	(334,659)	(297,608)
Maturities of investments	253,682	226,923
Sales of investments	4,969	42,544
Release of restricted cash	-	25,000
Purchases of property, plant and equipment	(6,392)	(11,195)
Net cash used in investing activities	<u>(82,400)</u>	<u>(14,336)</u>
Cash flows from financing activities:		
Payment of capital lease obligations	(5,945)	(5,187)
Issuance of common stock, net of issuance costs	189,276	-
Proceeds from shares issued under equity compensation plans	20,287	32,208
Proceeds from issuance of 7.75% senior secured notes, net of issuance costs	-	241,262
Repayment of 12% senior secured notes	-	(125,000)
Payment of redemption premium and incremental interest on 12% senior secured notes	-	(12,500)
Net cash provided by financing activities	<u>203,618</u>	<u>130,783</u>
Effect of exchange rates on cash and cash equivalents	(124)	(159)
Net increase in cash and cash equivalents	4,070	43,205
Cash and cash equivalents at beginning of period	55,570	12,365
Cash and cash equivalents at end of period	<u>\$ 59,640</u>	<u>\$ 55,570</u>
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 20,589	\$ 20,225
Cash paid for income taxes	<u>\$ 757</u>	<u>\$ 860</u>

(1) The consolidated statements of cash flows for the years ended December 31, 2016 and 2015 have been derived from the audited financial statements as of those dates but do not include all of the information and notes required by generally accepted accounting principles in the United States for complete financial statements.