

Nektar Therapeutics Reports Fourth Quarter and Year-End 2017 Financial Results

March 1, 2018

SAN FRANCISCO, March 1, 2018 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today reported its financial results for the fourth quarter and year ended December 31, 2017.

Cash and investments in marketable securities at December 31, 2017 were \$353.2 million as compared to \$389.1 million at December 31, 2016. This does not include \$1.85 billion in upfront payments from the new Bristol-Myers Squibb collaboration, which was announced on February 14, 2018.

"This past year was truly transformational for Nektar as we achieved a number of successes with Nektar medicines across our three key therapeutic areas of immuno-oncology, immunology and pain," said Howard W. Robin, President and Chief Executive Officer of Nektar. "In the area of pain, we completed a successful Phase 3 program for NKTR-181 in over 2,100 patients and healthy volunteers that will comprise our NDA submission in the second quarter of this year. In immunology, we entered into a major partnership with Eli Lilly for NKTR-358, a potential first-in-class T regulatory resolution therapeutic, which will be developed to treat a broad range of auto-immune disorders. Finally, in immuno-oncology, the clinical success we achieved with NKTR-214 led to a groundbreaking collaboration with Bristol-Myers Squibb that now enables us to broadly and rapidly advance NKTR-214 into over 20 registrational trials in up to 15,000 patients."

Summary of Financial Results

Revenue for the fourth quarter of 2017 was \$95.5 million as compared to \$37.5 million in the fourth quarter of 2016. Revenue in the fourth quarter of 2017 included a total of \$60.0 million of non-recurring revenue related to a new sublicense agreement, a contract settlement agreement and the recognition of deferred revenue from several collaboration agreements.

Revenue for the year ended December 31, 2017 was \$307.7 million as compared to \$165.4 million in 2016. Revenue in 2017 included recognition of \$130.1 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 fourth quarter of 2017 were \$119.5 million as compared to \$69.6 million in the fourth quarter of 2016. 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, 2017 were \$367.4 million as compared to \$278.3 million in 2016.

R&D expense in the fourth quarter of 2017 was \$81.4 million as compared to \$50.2 million for the fourth quarter of 2016. R&D expense for the year ended December 31, 2017 was \$268.5 million as compared to \$203.8 million in 2016. R&D expense was higher in 2017 as compared to 2016 primarily because of expenses for our pipeline programs, including the completion of 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 (G&A) expense was \$12.3 million in the fourth quarter of 2017 as compared to \$12.8 million in the fourth quarter of 2016. G&A expense for the year ended December 31, 2017 was \$52.4 million as compared to \$44.3 million in 2016.

Net loss for the fourth quarter of 2017 was \$33.8 million or \$0.21 loss per share as compared to a net loss of \$42.2 million or \$0.28 loss per share in the fourth quarter of 2016. Net loss for the year ended December 31, 2017 was \$96.7 million or \$0.62 loss per share as compared to a net loss of \$153.5 million or \$1.10 loss per share in 2016.

2017 and Year-to-Date Business Highlights

- In February 2018, Nektar and Bristol-Myers Squibb entered into a global development and commercialization agreement to evaluate the full potential of NKTR-214 plus Opdivo[®] (nivolumab) in more than 20 indications in 9 tumor types including melanoma, renal cell carcinoma, non-small cell lung cancer, bladder and triple negative breast cancer. The first pivotal studies in melanoma and renal cell carcinoma are expected to be initiated in mid-2018.
- In December 2017, Nektar submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for NKTR-262, a small molecule agonist that targets toll-like receptors (TLRs) found on innate immune cells in the body. The REVEAL Phase 1/2 study will evaluate the safety, tolerability and anti-tumor effect of NKTR-262, administered in combination with NKTR-214 (doublet) and in combination with NKTR-214 and nivolumab (triplet), in patients with locally advanced or metastatic cancers. The company plans to enroll the first patients in the REVEAL study in March of 2018.
- In November 2017, Nektar announced positive data from the dose-escalation stage of the PIVOT-02 study of NKTR-214 in combination with Opdivo at the 2017 SITC conference. Results showed compelling response rates and favorable safety data in both PD-L1 negative and PD-L1 positive patients with melanoma, renal cell carcinoma and non-small cell lung cancer.
- In September 2017, Nektar initiated the PROPEL clinical study to evaluate the efficacy and safety of NKTR-214 in combination with approved checkpoint inhibitors, TECENTRIQ[®](atezolizumab) and KEYTRUDA[®] (pembrolizumab) in patients with bladder and non-small cell lung cancer. Data from the PROPEL study is expected in the second half of 2018.

- In July 2017, Nektar and Eli Lilly announced a strategic collaboration to develop and commercialize NKTR-358, a potential first-in-class resolution therapeutic, that addresses an underlying immune system imbalance in patients with auto-immune conditions. A Phase 1 singe-ascending dose study is underway and a Phase 1/2 multiple-ascending dose study of NKTR-358 in patients with lupus is planned to begin in the second quarter of 2018.
- In July 2017, Nektar announced positive results from a Human Abuse Potential (HAP) study of NKTR-181, a first-in-class opioid analgesic.
- In May 2017, Nektar announced a new research collaboration with Takeda to explore the combination of NKTR-214 with five oncology compounds from Takeda's cancer portfolio including a SYK-inhibitor and a proteasome inhibitor.
- In March 2017, Nektar announced positive results from the SUMMIT-07 Phase 3 efficacy study of NKTR-181 in over 600 patients with chronic low back pain. The primary efficacy endpoint of the study demonstrated significantly improved chronic back pain relief with NKTR-181 compared to placebo (p=0.0019). Key secondary endpoints of the study also achieved high statistical significance. The study demonstrated that NKTR-181 had a favorable safety profile and was well tolerated.

The company also announced upcoming presentations at the following scientific congresses during the first half of 2018:

American Association for Cancer Research (AACR) Annual Meeting 2018, Chicago, IL:

- Abstract 3755/Poster 5: "Comprehensive antitumor immune activation by a novel TLR7/8 targeting agent NKTR-262 combined with CD122-biased immunostimulatory cytokine NKTR-214", Kivimae, S., et al.
 - Session: Immunology: Immunomodulatory Agents and Interventions 1
 - o Session Date and Time: Tuesday, April 17, 2018, 8:00 a.m. 12:00 p.m. Central Time
 - Location: McCormick Place South, Exhibit Hall A, Poster Section 32
- Abstract 2755/Poster 17: "NKTR-262: Prodrug pharmacokinetics in mice, rats, and dogs", Lee, M., et al.
 - Session: Immunology: Immune Mechanisms Invoked by Therapies 1
 - Session Date and Time: Monday, April 16, 2018, 1:00 p.m. 5:00 p.m. Central Time
 - Location: McCormick Place South, Exhibit Hall A, Poster Section 33
- Abstract 123/Poster 13: "Enhanced anti-tumor activity of the combination of entinostat and NKTR-214 in renal and colon cancer tumor models", Wang, L., et al.
 - Session: Tumor Biology: Role of the Innate Immune System in Tumorigenesis
 - Session Date and Time: Sunday, April 15, 2018, 1:00 p.m. 5:00 p.m. Central Time
 - o Location:McCormick Place South, Exhibit Hall A, Poster Section 5
- Abstract 3566/Poster 4: "Enhanced expansion and tumor targeting of adoptively transferred T cells with NKTR-214", Parisi, G., et al.
 - Session: Clinical Research: Adoptive Cell Therapy 3
 - Session Date and Time: Tuesday, April 17, 2018, 8:00 a.m. 12:00 p.m. Central Time
 - o Location:McCormick Place South, Exhibit Hall A, Poster Section 24

Antigen-Specific Immune Tolerance Drug Development Summit 2018, Boston, MA:

- Preclinical Data Presentation: "NKTR-358: A Selective Regulatory T Cell Inducing Agent for the Treatment of Autoimmune and Inflammatory Diseases"
 - Presenter: Jonathan Zalevsky, Ph.D., Nektar Therapeutics
 - o Date and Time: Wednesday, April 25, 2018, 4:20 p.m. Eastern Time

American Academy of Pain Medicine 34th Annual Meeting, Vancouver, BC:

- **Poster:** "Efficacy, safety, and tolerability of NKTR-181 in patients with moderate to severe chronic low-back pain: A Phase 3 study"
 - Presenter: John Markman, M.D., University of Rochester Medical Center
 - Session: Poster Session 2
 - o Date and Time: Friday, April 27, 2018, 6:00 p.m. Pacific Time
- **Poster:** "Measuring withdrawal in a phase 3 study of a new analgesic, NKTR-181, in subjects with moderate-to-severe chronic low-back pain"
 - o Presenter: Jack Henningfield, Ph.D., Pinney Associates
 - Session: Poster Session 2
 - o Date: Friday, April 27, 2018, 6:00 p.m. Pacific Time

Treg Directed Therapy for Autoimmune Disorders Meeting, Boston, MA:

- Preclinical Data Presentation: "NKTR-358: An IL-2 Pathway Agonist that Selectively Expands and Activates Regulatory T cells for the Treatment of Allergy and Autoimmune Disease"
 - o Presenter: Jonathan Zalevsky, Ph.D., Nektar Therapeutics
 - Session: Enhanced Treg-based therapy with the use of IL-2

o Date and Time: Wednesday, May 23, 2018, 3:40 p.m. Eastern Time

3rd Annual Advances in Immuno-Oncology Congress, London, U.K.:

- Presentation: "Accessing The Potential Of An Immunotherapeutic Agent"
 - Presenter: Jonathan Zalevsky, Ph.D., Nektar Therapeutics
 - Session: Translational Immuno-Oncology
 - o Date and Time: Thursday, May 24, 2018, 5:40 p.m. London Time

College on Problems of Drug Dependence 80th Annual Scientific Meeting, San Diego, CA:

- Oral Presentation: "Neuropharmacodynamic Profile of NKTR-181: Correlation to Low Abuse Potential"
 - **Presenter:**Laurie VanderVeen, Ph.D., Nektar Therapeutics
 - Session: Preclinical Opioid
 - o Date and Time: Tuesday, June 12, 2018, 10:15 a.m. 10:30 a.m. Pacific Time
- Oral Presentation: "Assessment of Drug Abuse-Related Events with MADDERS in SUMMIT-07: A Phase-3 Study of
 - NKTR-181 in Patients With Moderate to Severe Chronic Low-Back Pain"
 - o Presenter: Ryan K. Lanier, Ph.D., Analgesic Solutions
 - Session: Pain
 - o Date and Time: Wednesday, June 13, 2018, 1:30 p.m. 1:45 p.m. Pacific Time

Conference Call to Discuss Fourth Quarter and Year-End 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 today, Thursday, March 1, 2018.

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: <u>http://ir.nektar.com/</u>. The web broadcast of the conference call will be available for replay through Monday, April 2, 2018.

To access the conference call, follow these instructions:

Dial: (877) 881.2183 (U.S.); (970) 315.0453 (international) Passcode: 6299239 (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.

Opdivo® is a registered trademark of Bristol-Myers Squibb, TECENTRIQ[®] is a registered trademark of Roche and KEYTRUDA[®] is a registered trademark of Merck.

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," "prepare," "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-214, NKTR-181, NKTR-358, 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 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, 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 it is difficult to predict which scheduling category will apply to NKTR-181 if regulatory approval is achieved; (vi) the timing of regulatory approval for the recently announced strategic collaboration agreement with Bristol-Myers Squibb is uncertain; (vii) 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 (viii) certain other important risks and uncertainties set forth in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 1, 2018. 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.

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NEKTAR THERAPEUTICS CONDENSED CONSOLIDATED BALANCE SHEETS (In thousands)

(Unaudited)

ASSETS	Decer	mber 31, 2017 ⁽¹	Dec	cember 31, 2016	(1)
Current assets:	\$	4 700	\$	50.040	
Cash and cash equivalents Short-term investments	Φ	4,762 291,370	Ф	59,640 329,462	
Accounts receivable, net		5,014		15,678	
Inventory		10,726		11,109	
Other current assets		14,948		10,063	
Total current assets		326,820		425,952	
		520,020		420,902	
Long-term investments		57,088		-	
Property, plant and equipment, net		47,463		65,601	
Goodwill		76,501		76,501	
Other assets		994		817	
Total assets	\$	508,866	\$	568,871	:
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current liabilities:					
Accounts payable	\$	4,782	\$	2,816	
Accrued compensation	Ψ	8,263	Ψ	18,280	
Accrued clinical trial expenses		9,461		7,958	
Other accrued expenses		10,064		4,711	
Interest payable		4,198		4,198	
Liability related to refundable upfront payment		-		12,500	
Deferred revenue, current portion		18,949		14,352	
Other current liabilities		446		7,407	
Total current liabilities		56,163		72,222	
Senior secured notes, net		245,207		243,464	
Liability related to the sale of future royalties, net		94,655		105,950	
Deferred revenue, less current portion		19,021		51,887	
Other long-term liabilities		5,992		7,223	
Total liabilities		421,038		480,746	•
Commitments and contingencies					
Stockholders' equity:					
Preferred stock		-		-	
Common stock		15		15	
Capital in excess of par value		2,207,865		2,111,483	
Accumulated other comprehensive loss		(2,111)		(2,363)	
Accumulated deficit		(2,117,941)		(2,021,010)	
Total stockholders' equity		87,828		88,125	
Total liabilities and stockholders' equity	\$	508,866	\$	568,871	
1. 2					

(1) The consolidated balance sheets at December 31, 2017 and 2016 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 Ende	ed December 31,	Year Ended December 31,		
	2017	2016	2017 (1) 2016 (1)	
Revenue:					
Product sales	\$ 7,791	\$ 13,690	\$ 32,688	\$ 55,354	
Royalty revenue	9,574	6,392	33,527	19,542	
Non-cash royalty revenue related to sale of future royalties	9,164	7,817	30,531	30,158	
License, collaboration and other revenue	68,937	9,553	210,965	60,382	
Total revenue	95,466	37,452	307,711	165,436	
Operating costs and expenses:					
Cost of goods sold	9,753	6,604	30,547	30,215	
Research and development	81,429	50,232	268,461	203,801	
General and administrative	12,337	12,760	52,364	44,275	
Impairment of equipment and other costs for terminated program	15,981		15,981	-	
Total operating costs and expenses	119,500	69,596	367,353	278,291	
Loss from operations	(24,034)	(32,144)	(59,642)	(112,855)	
Non-operating income (expense):					
Interest expense	(5,633)	(5,550)	(22,085)	(22,468)	
Non-cash interest expense on liability related to sale of future royalties	(5,334)	(4,783)	(18,869)	(19,712)	
Interest income and other income (expense), net	1,357	721	4,520	2,387	
Total non-operating expense, net	(9,610)	(9,612)	(36,434)	(39,793)	
Loss before provision for income taxes	(33,644)	(41,756)	(96,076)	(152,648)	
Provision for income taxes	182	443	616	876	
Net loss	\$ (33,826)	\$ (42,199)	\$ (96,692)	\$ (153,524)	
Basic and diluted net loss per share	\$ (0.21)	\$ (0.28)	\$ (0.62)	\$ (1.10)	
Weighted average shares outstanding used in computing basic and diluted net loss per share	158,324	149,071	155,953	139,596	

(1) The consolidated statements of operations for the years ended December 31, 2017 and 2016 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)

(Unaudited)				
	Year Ended December 31,			_
	2017	(1)	2016	(1)
Cash flows from operating activities:		•		
Net loss	\$ (96,692)		\$ (153,524)	
Adjustments to reconcile net loss to net cash used in operating activities:				
Non-cash royalty revenue related to sale of future royalties	(30,531)		(30,158)	
Non-cash interest expense on liability related to sale of future royalties	18,869		19,712	
Stock-based compensation	36,615		25,850	
Depreciation and amortization	14,741		15,351	
Impairment of equipment from terminated program	15,081		-	
Other non-cash transactions	(881)		(2,185)	
Changes in operating assets and liabilities:				
Accounts receivable, net	10,664		4,269	
Inventory	383		237	
Other assets	(4,800)		(312)	
Accounts payable	2,074		518	
Accrued compensation	(10,017)		12,282	
Accrued clinical trial expenses	1,503		(262)	
Other accrued expenses	5,774		191	
Liability related to refundable upfront payment	(12,500)		12,500	
Deferred revenue	(28,269)		(17,615)	
Other liabilities	(2,428)	_	(3,878)	
Net cash used in operating activities	(80,414)		(117,024)	

Cash flows from investing activities:

Purchases of investments Maturities of investments Sales of investments Purchases of property, plant and equipment Net cash used in investing activities	(404,425) 347,743 37,549 (9,676) (28,809)	(334,659) 253,682 4,969 (6,392) (82,400)
Cash flows from financing activities:		
Payment of capital lease obligations	(5,131)	(5,945)
Proceeds from shares issued under equity compensation plans	59,522	20,287
Issuance of common stock, net of issuance costs	-	189,276
Net cash provided by financing activities	54,391	203,618
Effect of exchange rates on cash and cash equivalents	(46)	(124)
Net increase (decrease) in cash and cash equivalents	(54,878)	4,070
Cash and cash equivalents at beginning of year	59,640	55,570
Cash and cash equivalents at end of year	\$ 4,762	\$ 59,640
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 20,116	\$ 20,589
Cash paid for income taxes	\$ 556	\$ 757

(1) The consolidated statements of cash flows for the years ended December 31, 2017 and 2016 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.

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