



Nektar Therapeutics Reports Fourth Quarter and Year-End 2018 Financial Results

February 28, 2019

SAN FRANCISCO, Feb. 28, 2019 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today reported financial results for the fourth quarter and full year ended December 31, 2018.

Cash and investments in marketable securities at December 31, 2018 were \$1.9 billion as compared to \$353.2 million at December 31, 2017.

"2018 was a remarkable year for Nektar accentuated by new collaborations with leading pharmaceutical companies that validate the depth and innovation of our pipeline," said Howard W. Robin, President and Chief Executive Officer of Nektar. "We entered 2019 in an exceptionally strong financial position. We are working closely with the FDA during the ongoing review of our NDA for NKTR-181 while simultaneously preparing for a potential commercial launch later this year. We continue to design and execute on our broad registrational program for NKTR-214 (bempegaldesleukin¹) with our partner Bristol-Myers Squibb. NKTR-358 is advancing in the ongoing clinical study in lupus patients and two new studies in additional auto-immune conditions are planned to start in 2019. NKTR-262, our TLR agonist is being evaluated in a Phase 1/2 study and finally, NKTR-255, our next I-O candidate is slated to move into the clinic first in patients with multiple myeloma and then in combination with CAR-T therapy."

Summary of Financial Results

Revenue for the fourth quarter of 2018 was \$39.8 million as compared to \$95.5 million in the fourth quarter of 2017. 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, 2018 was \$1.2 billion as compared to \$307.7 million in 2017 and included the recognition of \$1.06 billion of license revenue from the Bristol-Myers Squibb collaboration agreement.

Total operating costs and expenses in the fourth quarter of 2018 were \$140.1 million as compared to \$119.5 million in the fourth quarter of 2017. Total operating costs and expenses for 2018 were \$505.4 million as compared to \$367.4 million in 2017. Total operating costs and expenses increased primarily as a result of increased research and development (R&D) expense.

R&D expense in the fourth quarter of 2018 was \$108.9 million as compared to \$81.4 million for the fourth quarter of 2017. R&D expense for the year ended December 31, 2018 was \$399.5 million as compared to \$268.5 million in 2017. R&D expense was higher in the fourth quarter and full year 2018 as compared to the same periods in 2017 primarily because of expenses for our pipeline programs, including the continued development of bempegaldesleukin in Phase 2 and registrational studies and related manufacturing costs, costs related to the NKTR-181 New Drug Application and NKTR-181 pre-commercial manufacturing, Phase 1 clinical studies of NKTR-358, the Phase 1 study of NKTR-262 in combination with bempegaldesleukin and IND-enabling activities for NKTR-255.

General and administrative (G&A) expense was \$23.8 million in the fourth quarter of 2018 as compared to \$12.3 million in the fourth quarter of 2017. G&A expense for 2018 was \$81.4 million as compared to \$52.4 million in 2017. G&A expense was higher in the fourth quarter and full year 2018 as compared to the same periods in 2017 primarily due to an increase in non-cash stock-based compensation expense.

Net loss for the fourth quarter of 2018 was \$98.2 million or \$0.57 basic and diluted loss per share as compared to a net loss of \$33.8 million or \$0.21 basic and diluted loss per share in the fourth quarter of 2017. Net income for the year ended December 31, 2018 was \$681.3 million or \$3.78 diluted earnings per share as compared to a net loss of \$96.7 million or \$0.62 basic and diluted loss per share in 2017.

2018 and Year-to-Date Business Highlights

- In February 2019, Nektar presented clinical data from first-line Stage IV urothelial carcinoma patients enrolled in the PIVOT-02 study of bempegaldesleukin with nivolumab at the 2019 ASCO Genitourinary Cancers Symposium.
- In December 2018, Nektar and Gilead entered into a research collaboration to explore the potential of NKTR-255, an IL-15 agonist, in virology. The collaboration will evaluate NKTR-255 in combination with antiretroviral therapies in Gilead's portfolio.
- In December 2018, Nektar and Bristol-Myers Squibb initiated PIVOT-10, a potential registrational study evaluating bempegaldesleukin with nivolumab in cisplatin-ineligible urothelial carcinoma patients whose tumors express PD-L1 (Combined Positive Score \leq 10).
- In December 2018, Nektar and Bristol-Myers Squibb initiated PIVOT-09, a Phase 3 study of bempegaldesleukin with nivolumab versus tyrosine kinase inhibitor (TKI) monotherapy in patients with advanced metastatic renal cell carcinoma.
- In November 2018, Nektar presented data for first-line Stage IV melanoma patients from the ongoing PIVOT-02 study at the 2018 Society for Immunotherapy of Cancer Annual Meeting.
- In November 2018, Nektar entered into a new clinical collaboration with Pfizer Inc. to evaluate several combination regimens in multiple cancer settings including metastatic castration-resistant prostate cancer (mCRPC) and squamous cell carcinoma of the head and neck (SCCHN). Under the collaboration, Pfizer will initiate a Phase 1b/2 clinical trial to evaluate the anti-cancer activity of the combined agents, avelumab, talazoparib and bempegaldesleukin and separately avelumab, enzalutamide and bempegaldesleukin.

- In September 2018, Nektar and Bristol-Myers Squibb initiated the Phase 3 study of bempegaldesleukin with nivolumab as compared to nivolumab monotherapy in participants with previously untreated unresectable or metastatic melanoma.
- In July 2018, the U.S. Food and Drug Administration filed and accepted a New Drug Application (NDA) for NKTR-181, a first-in-class opioid analgesic, to treat chronic low back pain in adult patients new to opioid therapy. In February 2019, Nektar received notification from the FDA that the review period for NKTR-181 has been extended by three months. The new Prescription Drug User Fee Act (PDUFA) date is now August 29, 2019. The FDA extended the action date to allow time to review data from two additional preclinical studies that Nektar conducted which were requested by the FDA early on in our review process. The new preclinical data are supportive of the company's abuse liability package included in the NDA filing for NKTR-181.
- In June 2018, Nektar presented data from the ongoing PIVOT study for bempegaldesleukin with nivolumab at the 2018 ASCO Meeting. Pre-specified efficacy criteria were achieved in three tumor types: first-line melanoma, first-line renal cell carcinoma and first-line urothelial cancer.
- In May 2018, Nektar began dosing patients with systemic lupus erythematosus in a new Phase 1b multiple ascending dose study of NKTR-358, an IL-2 regulatory T cell stimulator, designed to correct the underlying immune system dysfunction found in patients with immune disorders.
- In April 2018, Nektar announced a new clinical collaboration agreement with Takeda to evaluate bempegaldesleukin with TAK-659, a dual SYK and FLT-3 inhibitor in liquid and solid tumors. The first of these studies, a Phase 1b study in patients with Non-Hodgkin Lymphoma, was initiated in January of 2019.
- In April 2018, Nektar presented preclinical data for its immuno-oncology pipeline at the 2018 AACR Annual Meeting. Preclinical data presented by Nektar researchers and collaborators demonstrated that bempegaldesleukin combines with multiple modalities including TLR agonism and adoptive cell therapy.
- In April 2018, Nektar began dosing patients in the REVEAL Phase 1/2 study, which will evaluate NKTR-262, Nektar's wholly-owned novel toll-like receptor 7/8 agonist, in combination with bempegaldesleukin. The dose-escalation phase of the study is continuing.
- In February 2018, Nektar and Bristol-Myers Squibb entered into a global development and commercialization agreement to evaluate the full potential of bempegaldesleukin with nivolumab in more than 20 indications in 9 tumor types.

The company also announced upcoming presentations and speaking engagements at the following scientific congresses during the first half of 2019:

ASCO-SITC Clinical Immuno-Oncology Symposium, San Francisco, CA

- Oral presentation (Abstract #28): *"Phase 1b: Preliminary clinical activity and immune activation for NKTR-262 (TLR 7/8 agonist) plus NKTR-214 (CD122-biased agonist) in patients (pts) with locally advanced or metastatic solid tumors (REVEAL Phase 1b/II Trial)"*
 - Presenter: Dr. Adi Diab, MD Anderson Cancer Center
 - Session: Oral Abstract Session B
 - Session Date & Time: March 1, 2019, 1:00 p.m.-2:15 p.m. Pacific Time

26th International Molecular Medicine Tri-Conference, San Francisco, CA

- Presentation Title: *"Advanced Cytokine Engineering for Immunotherapy"*
 - Presenter: Steven Doberstein, Ph.D., Nektar Therapeutics
 - Session: Emerging Immuno-Oncology Targets Session
 - Session Date & Time: March 12, 2019, at 11:25 a.m. Pacific Time

Keystone Symposia Cancer Immunotherapy: Mechanistic Insights to Improve Clinical Benefit, Whistler, BC, Canada

- Presentation Title: *"Intratumoral expansion of CD8+ T cells and depletion of Tregs after treatment with NKTR-214, a first-in-class, CD122-preferential IL-2 pathway agonist"*
 - Presenter: Willem Overwijk, Ph.D., Nektar Therapeutics
 - Session: Immune Checkpoints: Basic Mechanisms and Novel Targets
 - Session Date & Time: March 13, 2019, 8:00 a.m.-11:00 a.m. Pacific Time

CHI's Fourth Annual Immuno-Oncology Summit Europe, London, UK

- Presentation Title: *"Exploratory Studies up to IND with NKTR-255, a Memory T-Cell Stimulating Cytokine"*
 - Presenter: Saul Kivimae, Ph.D., Nektar Therapeutics
 - Session: Importance of Cytokines/Innovative Approaches with Clinical Benefit
 - Session Date and Time: March 19, 2019, at 16:45 Greenwich Mean Time

ICI-IO Combinations Summit, Boston, MA

- Presentation Title: *"Supercharging the Tumor Microenvironment: Lessons from NKTR-214 and OPDIVO"*

- Presenter: Willem Overwijk, Ph.D., Nektar Therapeutics
- Session Date and Time: March 20, 2019, at 11:30 a.m. Eastern Time

American Association for Cancer Research (AACR) Annual Meeting 2019, Atlanta, GA

- Abstract 2256/Poster Board 15: *"Combination of neoantigen DNA plasmid vaccine VB10.NEO and NKTR-214, a CD122-biased immunostimulatory cytokine, induces strong neoantigen-specific T cell responses and sustained tumor regression in pre-clinical models,"* Granum, S., et al.
 - Session: Clinical Research - Combination Immunotherapies 1
 - Session Date and Time: April 1, 2019, 1:00 p.m.-5:00 p.m. Eastern Time
 - Location: Georgia World Congress Center, Exhibit Hall B, Poster Section 19
- Abstract 3210/Poster Board 20: *"A potential immunotherapeutic approach for the treatment of osteosarcoma,"* Wahba, A., et al.
 - Session: Immunology – Combination Immunotherapies 2
 - Session Date & Time: Tuesday, April 2, 2019, 8:00 a.m.-12:00 p.m. Eastern Time
 - Location: Georgia World Congress Center, Exhibit Hall B, Poster Section 2
- Abstract 3265/Poster Board 15: *"NKTR-255, a polymer-conjugated IL-15 enhances anti-tumor NK cell responses and synergizes with monoclonal antibodies to provide long-term survival in human lymphoma model,"* Miyazaki, T., et al.
 - Session: Immunology - Novel Immunomodulatory Agents
 - Session Date and Time: April 2, 2019, 8:00 a.m.-12:00 p.m. Eastern Time
 - Location: Georgia World Congress Center, Exhibit Hall B, Poster Section 25

15th Annual PEGS Boston Summit, Boston, MA

- Keynote: *"Harnessing Potent Cytokine Agonist Pathways by Polymer Engineering to Develop Novel Immune Therapeutic Agents"*
 - Presenter: Loui Madakamutil, Ph.D., Nektar Therapeutics
 - Session: Latest Developments in Agonist Immunotherapy – Cytokines and OX40 Targets
 - Presentation Date and Time: Thursday, April 11, 2019 1:50 p.m. Eastern Time

6th Immunotherapy of Cancer Conference (ITOC6), Vienna, Austria

- Poster P2.12: *"Mechanism of Action of NKTR-214, a first-in-class, CD122-preferential IL-2 pathway agonist"*
 - Presenter: Willem Overwijk, Ph.D., Nektar Therapeutics
 - Session: Emerging Concepts/Novel Agents
 - Session Dates and Times: April 11, 2019, at 18.20 Central European Time and April 12, 2019, from 14.00-14.30 Central European Time

Conference Call to Discuss Fourth Quarter and Year-End 2018 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, February 28, 2019. 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: <https://ir.nektar.com/events-and-presentations/events>. The web broadcast of the conference call will be available for replay through Thursday, March 28, 2019.

To access the conference call, follow these instructions:

Dial: (877) 881-2183 (U.S.); (970) 315-0453 (international)
 Passcode: 4988768 (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

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, autoimmune disease and chronic pain. We leverage our 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 Nektar and its drug development programs and capabilities may be found online at 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: "advance," "continue," "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 investigational products (including bempegaldesleukin, NKTR-181, NKTR-358, NKTR-262 and NKTR-255), the timing of receiving a response in connection with our pending new drug application, "NDA" for NKTR-181, 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) the timing of the commencement or end of clinical studies 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, and enrollment competition; (ii) the timing and probability of regulatory approval, if any, for NKTR-181 is uncertain and difficult to predict; (iii) scientific discovery of new medical breakthroughs is an inherently uncertain process and the future success of applying our technology platform to drug candidates (such as bempegaldesleukin, NKTR-262, NKTR-358, and NKTR-255) is therefore highly uncertain and unpredictable and one or more of these programs may fail; (iv) 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 (v) certain other important risks and uncertainties set forth in Nektar's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 8, 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.

1. rINN (recommended International Nonproprietary Name)

Contact:

For Investors:
Jennifer Ruddock of Nektar Therapeutics
415-482-5585

Ashleigh Barreto of Nektar Therapeutics
628-895-0694

For Media:
Jodi Sievers of Nektar Therapeutics
415-482-5593

Dan Budwick of 1AB
973-271-6085
dan@1abmedia.com

NEKTAR THERAPEUTICS
CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)
(Unaudited)

ASSETS	<u>December 31, 2018</u>	<u>December 31, 2017</u> ⁽¹⁾
Current assets:		
Cash and cash equivalents	\$ 194,905	\$ 4,762
Short-term investments	1,140,445	291,370
Accounts receivable	43,213	5,014
Inventory	11,381	10,726
Advance payments to contract manufacturers	26,450	7,155
Other current assets	<u>21,293</u>	<u>7,793</u>
Total current assets	1,437,687	326,820
Long-term investments	582,889	57,088
Property, plant and equipment, net	48,851	47,463
Goodwill	76,501	76,501
Other assets	<u>4,244</u>	<u>994</u>
Total assets	<u>\$ 2,150,172</u>	<u>\$ 508,866</u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	\$ 5,854	\$ 4,782
Accrued compensation	9,937	8,263
Accrued contract manufacturing expenses	23,841	3,845
Accrued clinical trial expenses	14,700	9,461
Other accrued expenses	9,087	6,219
Interest payable	4,198	4,198
Deferred revenue, current portion	13,892	18,949
Other current liabilities	<u>493</u>	<u>446</u>
Total current liabilities	82,002	56,163
Senior secured notes, net	246,950	245,207
Liability related to the sale of future royalties, net	82,911	94,655
Deferred revenue, less current portion	10,744	19,021
Other long-term liabilities	9,990	5,992

Total liabilities	432,597	421,038
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	-	-
Common stock	17	15
Capital in excess of par value	3,147,925	2,207,865
Accumulated other comprehensive loss	(6,316)	(2,111)
Accumulated deficit	(1,424,051)	(2,117,941)
Total stockholders' equity	<u>1,717,575</u>	<u>87,828</u>
Total liabilities and stockholders' equity	<u>\$ 2,150,172</u>	<u>\$ 508,866</u>

(1) The consolidated balance sheet at December 31, 2017 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 December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Revenue:				
Product sales	\$ 4,360	\$ 7,791	\$ 20,774	\$ 32,688
Royalty revenue	12,078	9,574	41,976	33,527
Non-cash royalty revenue related to sale of future royalties	8,971	9,164	33,308	30,531
License, collaboration and other revenue	14,417	68,937	1,097,265	210,965
Total revenue	<u>39,826</u>	<u>95,466</u>	<u>1,193,323</u>	<u>307,711</u>
Operating costs and expenses:				
Cost of goods sold	7,461	9,753	24,412	30,547
Research and development	108,883	81,429	399,536	268,461
General and administrative	23,777	12,337	81,443	52,364
Impairment of equipment and other costs for terminated program	-	15,981	-	15,981
Total operating costs and expenses	<u>140,121</u>	<u>119,500</u>	<u>505,391</u>	<u>367,353</u>
Income (loss) from operations	(100,295)	(24,034)	687,932	(59,642)
Non-operating income (expense):				
Interest expense	(5,415)	(5,633)	(21,582)	(22,085)
Non-cash interest expense on liability related to sale of future royalties	(6,388)	(5,334)	(21,196)	(18,869)
Interest income and other income (expense), net	12,048	1,357	37,571	4,520
Total non-operating income (expense), net	245	(9,610)	(5,207)	(36,434)
Income (loss) before provision for income taxes	(100,050)	(33,644)	682,725	(96,076)
Provision (benefit) for income taxes	(1,838)	182	1,412	616
Net income (loss)	<u>\$ (98,212)</u>	<u>\$ (33,826)</u>	<u>\$ 681,313</u>	<u>\$ (96,692)</u>
Net income (loss) per share:				
Basic	<u>\$ (0.57)</u>	<u>\$ (0.21)</u>	<u>\$ 4.02</u>	<u>\$ (0.62)</u>
Diluted	<u>\$ (0.57)</u>	<u>\$ (0.21)</u>	<u>\$ 3.78</u>	<u>\$ (0.62)</u>
Weighted average shares outstanding used in computing net income (loss) per share:				
Basic	<u>173,271</u>	<u>158,324</u>	<u>169,600</u>	<u>155,953</u>
Diluted	<u>173,271</u>	<u>158,324</u>	<u>180,119</u>	<u>155,953</u>

NEKTAR THERAPEUTICS
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Year Ended December 31,	
	2018	2017
Cash flows from operating activities:		
Net income (loss)	\$ 681,313	\$ (96,692)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Non-cash royalty revenue related to sale of future royalties	(33,308)	(30,531)
Non-cash interest expense on liability related to sale of future royalties	21,196	18,869
Stock-based compensation	88,101	36,615
Depreciation and amortization	10,870	14,741
Impairment of equipment from terminated program	-	15,081
Accretion of discounts, net and other non-cash transactions	(10,952)	(881)
Changes in operating assets and liabilities:		
Accounts receivable	(25,505)	10,664
Inventory	(655)	383
Other assets	(31,652)	(4,800)
Accounts payable	971	2,074
Accrued compensation	1,674	(10,017)
Other accrued expenses	27,947	7,277
Deferred revenue	(15,331)	(28,269)
Other liabilities	3,545	(14,928)
Net cash provided by (used in) operating activities	718,214	(80,414)
Cash flows from investing activities:		
Purchases of investments	(2,271,250)	(404,425)
Maturities of investments	890,957	347,743
Sales of investments	11,963	37,549
Purchases of property, plant and equipment	(14,239)	(9,676)
Sales of property and plant	2,633	-
Net cash used in investing activities	(1,379,936)	(28,809)
Cash flows from financing activities:		
Payment of capital lease obligations	-	(5,131)
Issuance of common stock	790,231	-
Proceeds from shares issued under equity compensation plans	61,735	59,522
Net cash provided by financing activities	851,966	54,391
Effect of exchange rates on cash and cash equivalents	(101)	(46)
Net increase (decrease) in cash and cash equivalents	190,143	(54,878)
Cash and cash equivalents at beginning of year	4,762	59,640
Cash and cash equivalents at end of year	\$ 194,905	\$ 4,762
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 19,471	\$ 20,116
Cash paid for income taxes	\$ 618	\$ 556

 View original content: <http://www.prnewswire.com/news-releases/nektar-therapeutics-reports-fourth-quarter-and-year-end-2018-financial-results-300804496.html>

SOURCE Nektar Therapeutics