Nektar Therapeutics Reports Fourth Quarter and Year-End 2021 Financial Results

February 28, 2022

SAN FRANCISCO, Feb. 28, 2022 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today reported financial results for the fourth quarter and full year ended December 31, 2021.

Cash and investments in marketable securities at December 31, 2021 were approximately $0.8 billion as compared to $1.2 billion at December 31, 2020.

"We are pleased with the significant progress that Nektar has made advancing our clinical pipeline in 2021 in the areas of solid tumors, liquid tumors and auto-immune disorders," said Howard W. Robin, President and CEO of Nektar. "In the first half of 2022, we expect topline results from three of our six registrational trials evaluating bempegaldesleukin in combination with a checkpoint inhibitor in melanoma, renal cell carcinoma and bladder cancer. We look forward to collaborating with our partner Bristol Myers to support timely potential regulatory filings for the first three studies and to complete preparations to support a potential commercial launch."

Mr. Robin continued, "Our second oncology cytokine program, NKTR-255, a full IL-15 agonist, is being combined with multiple mechanisms in both solid tumors and hematological malignancies and we are excited that Merck KGaA and Pfizer will evaluate the combination of NKTR-255 with avelumab in the JAVELIN Bladder Medley, which is expected to start in the first half of 2022. Eli Lilly and Nektar also made significant progress in 2021 and we now have NKTR-358 in a broad set of clinical trials, including Phase 2 studies in lupus and ulcerative colitis with another planned in atopic dermatitis and a fourth planned in another auto-immune indication. In December of 2021, Lilly presented the first proof-of-concept data for NKTR-358 in atopic dermatitis which showed sustained disease control for at least 6 months after last treatment dose and highlighted the potential for this T regulatory cell stimulating agent to differentiate from standard of care."

Summary of Financial Results

Revenue in the fourth quarter of 2021 was $25.0 million as compared to $23.5 million in the fourth quarter of 2020. Revenue for the year ended December 31, 2021 was $101.9 million as compared to $152.9 million in 2020 and was lower due to the recognition of $50.0 million in total milestones from Bristol-Myers Squibb for the initiation of registrational trials of bempegaldesleukin plus Opdivo® in adjuvant melanoma and muscle invasive bladder cancer in 2020.

Total operating costs and expenses in the fourth quarter of 2021 were $137.9 million as compared to $134.2 million in the fourth quarter of 2020. The increase was due to an increase in G&A expense. Total operating costs and expenses for the full year 2021 were $548.0 million as compared to $578.0 million in 2020. Operating costs and expenses for the full year 2021 decreased as compared to 2020 primarily due to the recording of $45.2 million impairment charge in 2020 resulting from the discontinuation of the NKTR-181 program.

R&D expense in the fourth quarter of 2021 was $99.6 million as compared to $102.7 million for the fourth quarter of 2020. R&D expense for the year ended December 31, 2021 was $400.3 million as compared to $408.7 million in 2020.

G&A expense was $32.1 million in the fourth quarter of 2021 and $27.1 million in the fourth quarter of 2020. G&A expense for the full year 2021 was $122.8 million compared to $104.7 million in 2020. G&A expense increased primarily due to an increase in pre-commercial costs for bempegaldesleukin.

Net loss for the fourth quarter of 2021 was $145.6 million or $0.79 basic and diluted loss per share as compared to a net loss of $117.2 million or $0.65 basic and diluted loss per share in the fourth quarter of 2020. Net loss for the year ended December 31, 2021 was $523.8 million or $2.86 basic and diluted loss per share as compared to a net loss of $444.4 million or $2.49 basic and diluted loss per share in 2020.

2021 Business Highlights:

- In December 2021, Nektar announced Phase 1b proof-of-concept data for NKTR-358, a novel T regulatory cell stimulator, in patients with moderate-to-severe atopic dermatitis. The data demonstrate the potential for NKTR-358 to differentiate from standard of care and supports Eli Lilly's planned Phase 2 study in this indication.
- In December 2021, Nektar presented data from the dose-escalation portion of its ongoing Phase 1 study of NKTR-255 in patients with relapsed/refractory hematologic malignancies at the 63rd American Society of Hematology (ASH) Annual Meeting. The data supports the development of NKTR-255 in combination with anticancer agents that induce antibody dependent cellular toxicity as well as CAR-T therapies.
- In November 2021, Nektar presented clinical data from the ongoing PROPEL study evaluating bempegaldesleukin plus KEYTRUDA® (pembrolizumab) in patients with non-small cell lung cancer at the 2021 European Society for Medical

Oncology Immuno-Oncology (ESMO-IO) Congress.

- In November 2021, Nektar presented initial clinical results from the Phase 1/2 study of NKTR-255 in combination with cetuximab in solid tumors in a late-breaking abstract at the 2021 Society for Immunotherapy of Cancer (SITC) Annual Meeting. The data showed early evidence of clinical benefit in the first patients treated in the dose-escalation portion of the study.
- In October 2021, Bristol-Myers Squibb and Nektar completed enrollment in the Phase 3 first-line metastatic melanoma study evaluating bempegaldesleukin combined with Opdivo® versus Opdivo® in 760 patients with previously untreated, unresectable or metastatic melanoma.
- In September 2021, Nektar entered into a new oncology clinical collaboration with Merck KGaA, Darmstadt, Germany and Pfizer Inc. to evaluate the maintenance regimen of NKTR-255 in combination with avelumab, a PD-L1 inhibitor, in patients with locally advanced or metastatic urothelial carcinoma (UC) in the Phase II JAVELIN Bladder Medley study. The study is expected to begin enrolling patients in the second quarter of 2022.
- In July 2021, data from the Phase 2 study of bempegaldesleukin combined with Opdivo® was published in the *Journal of Clinical Oncology*, highlighting the encouraging safety and efficacy data in patients with first-line metastatic melanoma.
- In May 2021, Nektar announced the publication of preclinical data in the *Journal of Translational Autoimmunity* describing NKTR-358 as a first-in-class, composition of stable PEG conjugates of native IL-2 designed to selectively stimulate T regulatory cell function.
- In May 2021, Nektar announced its first publication of preclinical data highlighting anti-tumor properties of IL-15 agonist, NKTR-255, in the *Journal for ImmunoTherapy of Cancer.*
- In February 2021, Nektar announced a clinical trial collaboration and supply agreement with Merck for a Phase 2/3 study of bempegaldesleukin in combination with KEYTRUDA® (pembrolizumab) for first-line treatment of patients with metastatic or unresectable recurrent squamous cell carcinoma of the head and neck (SCCHN) whose tumors express PD-L1.
- In February 2021, Nektar announced a financing and co-development collaboration with SFJ Pharmaceuticals® for the development of bempegaldesleukin plus KEYTRUDA® (pembrolizumab) in SCCHN. SFJ agreed to fund up to $150 million to support the planned Phase 2/3 study and to manage clinical trial operations for the study. In return, Nektar agreed to pay SFJ success-based annual milestone payments over a period of seven to eight years, which are contingent upon receipt of certain U.S. regulatory approvals for specified indications for bempegaldesleukin, and will begin following completion of the SCCHN study.

Conference Call to Discuss Fourth Quarter and Year-End 2021 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, Monday, February 28, 2022.

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/. The web broadcast of the conference call will be available for replay through March 28, 2022.

To access the conference call, follow these instructions:

Dial: (877) 881-2183 (U.S.); (970) 315-0453 (International)
Conference ID: 8890486 (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 this press release, or explained on the conference call, related information will be made available on the Investors section of the Nektar website as soon as practical after the conclusion of the conference call.

About Nektar

Nektar Therapeutics is a biopharmaceutical company with a robust, wholly owned R&D pipeline of investigational medicines in oncology, immunology, and virology as well as a portfolio of approved partnered medicines. 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 forward-looking statements which can be identified by words such as: "will," "may," "design," "potential," "initiate," "plan," "advance" and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding the therapeutic potential of, and future development plans for, bempegaldesleukin, NKTR-358 and NKTR-255, the prospects and plans for our collaborations with other companies, and the timing of the initiation of clinical studies and the data readouts for our drug candidates. 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) our statements regarding the therapeutic potential of bempegaldesleukin, NKTR-358 and NKTR-255 are based on preclinical and clinical findings and observations and are subject to change as research and development continue; (ii) bempegaldesleukin, NKTR-358 and NKTR-255 are investigational agents and continued research and development for these drug candidates is subject to substantial risks, including negative safety and efficacy findings in ongoing clinical studies (notwithstanding positive findings in earlier preclinical and clinical studies); (iii) bempegaldesleukin, NKTR-358 and NKTR-255 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; (iv) 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; (v) 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 (vi) certain other important risks and uncertainties set forth in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 5, 2021. 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.

Contact:

For Investors:
Vivian Wu of Nektar Therapeutics
628-895-0661

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

NEKTAR THERAPEUTICS
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)
(Unaudited)

ASSETS	December 31, 2021	December 31, 2020 (1)
Current assets:		
Cash and cash equivalents	$ 25,218	$ 198,955
Short-term investments	708,737	862,941
Accounts receivable	22,492	38,889
Inventory	15,801	15,292
Other current assets	23,333	21,928
Total current assets	795,581	1,138,005
Long-term investments	64,828	136,662
Property, plant and equipment, net	60,510	59,662
Operating lease right-of-use assets	117,025	126,476
Goodwill	76,501	76,501
Other assets	2,744	1,461
Total assets	$ 1,117,189	$ 1,538,767
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	9,747	22,139
Accrued compensation	15,735	14,532
Accrued clinical trial expenses	26,809	44,207
Other accrued expenses	15,468	20,986
Operating lease liabilities, current portion	17,441	13,915
Total current liabilities	85,200	115,779
Operating lease liabilities, less current portion	125,736	136,373
Development derivative liability	27,726	-
Liabilities related to the sales of future royalties, net	195,427	200,340
Other long-term liabilities	3,592	8,980
Total liabilities	437,681	461,472
Commitments and contingencies		

Stockholders' equity:		
Preferred stock	-	-
Common stock	19	18
Capital in excess of par value	3,516,641	3,388,730
Accumulated other comprehensive loss	(4,157)	(2,295)
Accumulated deficit	(2,832,995)	(2,309,158)
Total stockholders' equity	679,508	1,077,295
Total liabilities and stockholders' equity	$ 1,117,189	$ 1,538,767

(1) The consolidated balance sheet at December 31, 2021 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,	
	2021	2020	2021	2020
Revenue:				
	$	$	$	$
Product sales	5,890	2,884	23,725	17,504
Royalty revenue	-	(412)	-	30,999
Non-cash royalty revenue related to the sales of future royalties	19,079	20,562	77,746	48,563
License, collaboration and other revenue	40	428	436	55,849
Total revenue	25,009	23,462	101,907	152,915
Operating costs and expenses:				
Cost of goods sold	6,163	4,323	24,897	19,477
Research and development	99,614	102,724	400,269	408,678
General and administrative	32,142	27,136	122,844	104,682
Impairment of assets and other costs for terminated program	-	-	-	45,189
Total operating costs and expenses	137,919	134,183	548,010	578,026
Loss from operations	(112,910)	(110,721)	(446,103)	(425,111)
Non-operating income (expense):				
Change in fair value of development derivative liability	(383)	-	(8,023)	-
Non-cash interest expense on liabilities related to the sales of future royalties	(8,127)	(8,183)	(47,313)	(30,267)
Loss on revaluation of liability related to the sale of future royalties	(24,410)	-	(24,410)	-
Interest income and other income (expense), net	181	1,829	2,569	18,282
Interest expense	-	-	-	(6,851)
Total non-operating expense, net	(32,739)	(6,354)	(77,177)	(18,836)
Loss before provision for income taxes	(145,649)	(117,075)	(523,280)	(443,947)
Provision for income taxes	(4)	128	557	493
	$	$	$	$
Net loss	(145,645)	(117,203)	(523,837)	(444,440)
	$	$	$	$
Basic and diluted net loss per share	(0.79)	(0.65)	(2.86)	(2.49)
Weighted average shares outstanding used in computing basic and diluted net loss per share	184,964	179,684	183,298	178,581

NEKTAR THERAPEUTICS
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)
(Unaudited)

	Year ended December 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (523,837)	$ (444,440)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash royalty revenue related to the sales of future royalties	(77,746)	(48,563)
Non-cash interest expense on liabilities related to the sales of future royalties	47,313	30,267
Loss on revaluation of liability related to the sale of future royalties	24,410	-
Change in fair value of development derivative liability	8,023	-
Non-cash research and development expense	16,703	-
Stock-based compensation	94,674	94,261
Depreciation and amortization	14,146	14,182
Impairment of advance payments to contract manufacturers and equipment for terminated program	-	20,351
Amortization of premiums (discounts), net and other non-cash transactions	6,730	3,943
Changes in operating assets and liabilities:		
Accounts receivable	12,397	1,913
Inventory	(509)	(2,627)
Operating leases, net	2,340	2,743
Other assets	(2,688)	4,476
Accounts payable	(11,690)	2,382
Accrued compensation	1,203	4,697
Other accrued expenses	(23,524)	8,644
Deferred revenue	(605)	(5,516)
Net cash used in operating activities	(412,660)	(313,287)
Cash flows from investing activities:		
Purchases of investments	(960,689)	(987,533)
Maturities of investments	1,166,951	1,449,304
Sales of investments	11,504	41,700
Purchases of property, plant and equipment	(14,989)	(7,258)
Net cash provided by investing activities	202,777	496,213
Cash flows from financing activities:		
Proceeds from sale of future royalties, net of $3.8 million of transaction costs	-	146,250
Repayment of senior notes	-	(250,000)
Cash receipts from development derivative liability	3,000	-
Proceeds from shares issued under equity compensation plans	33,238	23,396
Net cash provided by (used in) financing activities	36,238	(80,354)
Effect of foreign exchange rates on cash and cash equivalents	(92)	20
Net increase (decrease) in cash and cash equivalents	(173,737)	102,592
Cash and cash equivalents at beginning of year	198,955	96,363
Cash and cash equivalents at end of year	$ 25,218	$ 198,955
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ -	$ 9,742
Cash paid for income taxes	$ 325	$ 539
Operating lease right-of-use assets recognized in exchange for lease liabilities	$ 1,057	$ 2,133
Accounts receivable recognized in exchange for long-term liabilities	$ -	$ 4,000

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