Chinook Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Corporate Updates

February 27, 2023

SEATTLE, Feb. 27, 2023 (GLOBE NEWSWIRE) -- Chinook Therapeutics, Inc. (Nasdaq: KDNY), a biopharmaceutical company focused on the discovery, development and commercialization of precision medicines for kidney diseases, today reported financial results for the fourth quarter and year ended December 31, 2022 and provided corporate updates.

“During 2022, we made excellent progress across our pipeline, including driving strong enrollment of our phase 3 ALIGN, phase 2 AFFINITY and phase 1/2 BION-1301 clinical trials, generating compelling clinical data from our atrasentan and BION-1301 programs for IgA nephropathy (IgAN), initiating our phase 1 clinical trial of CHK-336 in healthy volunteers and continuing to advance our preclinical programs for rare, severe chronic kidney diseases,” said Eric Dobmeier, president and chief executive officer of Chinook Therapeutics. “Our mission at Chinook is to change the course of kidney care by developing therapies that make dialysis and transplant unnecessary for patients living with kidney disease. With our strong financial position and growing team, we look forward to an exciting 2023 when we will be presenting data from all three of our clinical programs at medical conferences, commencing a phase 3 study of BION-1301 in patients with IgAN mid-year and reporting topline proteinuria data from the ongoing phase 3 ALIGN study of atrasentan.”

2022 and Recent Accomplishments

Atrasentan

Atrasentan is a potent and selective endothelin A (ET_A) receptor antagonist that has potential therapeutic benefit in multiple chronic kidney diseases by reducing proteinuria and having direct anti-inflammatory and anti-fibrotic effects to preserve kidney function. The phase 3 ALIGN trial is evaluating atrasentan in patients with IgAN and the phase 2 AFFINITY basket trial is evaluating atrasentan in patients with proteinuric glomerular diseases.

- Enrollment in the phase 3 ALIGN trial of atrasentan now exceeds 270 patients. The interim proteinuria endpoint analysis will be performed on the first 270 patients enrolled.

- In response to review of the statistical analysis plan for the ALIGN trial, Chinook received correspondence from the U.S. Food and Drug Administration (FDA) last week recommending that evaluation of the interim proteinuria endpoint analysis for accelerated approval in the ALIGN trial be delayed from week 24 to week 36. The FDA referenced the likelihood that the later timepoint would allow for a greater amount of eGFR data to be evaluated at the time of accelerated approval. Chinook plans to engage with the FDA as soon as possible to discuss their advice. If Chinook shifts the interim proteinuria endpoint analysis of the ALIGN trial to 36 weeks, topline proteinuria data would be expected in the fourth quarter of 2023. Therefore, Chinook is updating its timing to report topline proteinuria data from the ALIGN trial to the second half of 2023.

- Chinook has completed enrollment of the IgAN patient cohort of the AFFINITY trial, and continues to enroll the other cohorts, including patients with focal segmental glomerulosclerosis (FSGS), Alport syndrome and diabetic kidney disease in combination with SGLT2 inhibitors. Chinook plans to report additional data from cohorts of the AFFINITY trial in the second half of 2023.

- In November 2022, the United States Patent and Trademark Office (USPTO) issued U.S. Patent No. 11,491,137, titled, “Methods of Improving Renal Function,” which is directed to methods of treating patients with IgAN with atrasentan, and expires in 2040 absent any patent term extensions.

- Several presentations on atrasentan were delivered at nephrology conferences throughout 2022, including:

    - Updated interim data from the IgAN patient cohort of the phase 2 AFFINITY trial demonstrated consistent and clinically meaningful proteinuria reductions in patients with IgAN already on a maximally tolerated and stable dose of a RAS inhibitor. Specifically, atrasentan demonstrated mean reductions in 24-hour urine protein creatinine ratio (UPCR) of 38.1% at six weeks of treatment, 48.3% at 12 weeks of treatment and 54.7% at 24 weeks of treatment. After 24 weeks of treatment, 15 of the 19 patients (79%) who had completed this visit had greater than a 40% reduction in UPCR. There were no meaningful changes in blood pressure or acute eGFR effects, suggesting proteinuria reductions were not primarily due to hemodynamic effects of atrasentan, and there were no increases in BNP or mean bodyweight, suggesting minimal fluid retention. Atrasentan was well-tolerated, with no treatment-related serious adverse events. (ASN Kidney Week 2022)

    - Preclinical research on single-cell RNA-seq of a mouse model of IgAN, revealing a prominent expansion of failed repair proximal tubular epithelial cells, which was reversed by atrasentan but not by ACE inhibition. (ASN Kidney

Week 2022)

- Preclinical mechanistic data describing atrasentan's effect to block mesangial cell injury and the pathogenic transcriptional networks driving IgAN progression in a model system. (59th ERA Congress)

BION-1301

BION-1301 is a novel anti-APRIL monoclonal antibody currently in phase 2 development for patients with IgAN. BION-1301's potentially disease-modifying approach to treating IgAN by reducing circulating levels of galactose-deficient IgA1 (Gd-IgA1) has been demonstrated clinically in both healthy volunteers and patients with IgAN.

- Chinook has finalized trial design, is conducting site and country feasibility and completing global regulatory interactions to enable initiation of a phase 3 trial of BION-1301 in mid-2023.

- Chinook has completed enrollment of 30 patients in Cohort 2 of Part 3 of the ongoing phase 1/2 trial of BION-1301. Patients in Cohort 2 receive a subcutaneous (SC) dose of 600 mg of BION-1301 every two weeks. Chinook plans to report additional data from Cohorts 1 and 2 in the first and second half of 2023.

- Chinook presented interim data from Cohorts 1 and 2 in a poster presentation at ASN Kidney Week 2022 in November, further demonstrating BION-1301's disease-modifying potential in IgAN by generating rapid and durable reductions in mechanistic biomarkers and corresponding clinically meaningful proteinuria reductions within three months of initiating treatment, which was consistent across both cohorts.

  In Cohort 1, patients transitioned from intravenous (IV) dosing at 450 mg every two weeks to SC dosing at 600 mg every two weeks after at least 24 weeks of treatment. Reductions in IgA and Gd-IgA1 were maintained beyond 52 weeks of treatment. Reductions in IgM, and to a lesser extent IgG, were also observed. BION-1301 demonstrated mean reductions in 24-hour UPCR of 30.4% in seven patients at 12 weeks of treatment, 48.8% in eight patients at 24 weeks of treatment, 66.9% in eight patients at 52 weeks of treatment, 67.4% in four patients at 76 weeks of treatment and 71.0% in two patients at 100 weeks of treatment.

  In Cohort 2, SC BION-1301 treatment resulted in rapid and sustained reductions in IgA and Gd-IgA1, IgM, and to a lesser extent IgG, through 24 weeks of treatment, highly consistent with Cohort 1. BION-1301 demonstrated mean reductions in 24-hour UPCR of 28.7% in 15 patients at 12 weeks of treatment and 53.8% in 9 patients at 24 weeks of treatment, similar to reductions observed at the same timepoints in Cohort 1.

  In both cohorts, BION-1301 was well-tolerated, with no serious adverse events or treatment discontinuations due to adverse events, and no anti-drug antibodies observed.

- BION-1301 was granted orphan drug designation for the treatment of primary IgAN by the European Commission in July 2022.

CHK-336

CHK-336 is an oral small molecule lactate dehydrogenase A (LDHA) inhibitor with liver-targeted tissue distribution that Chinook is developing for the treatment of patients with primary hyperoxaluria (PH) and other kidney stone disorders driven by endogenous overproduction of oxalate.

- The phase 1 single ascending dose (SAD) and multiple ascending dose (MAD) clinical trial evaluating CHK-336 in healthy volunteers is ongoing, and initial data from this trial is expected in the first half of 2023.

- Chinook presented a poster on CHK-336 at ASN Kidney Week 2022, demonstrating preclinical efficacy in PH1 and PH2 mouse models, and the potential for benefit in non-genetic hyperoxalurias caused by oxalate overproduction was also described.

Precision Medicine Research & Discovery

Chinook is focused on the discovery and development of novel precision medicines for rare, severe chronic kidney diseases (CKDs) with defined genetic or molecular drivers of disease initiation and progression, and efficient development paths. Chinook has multiple preclinical programs across the discovery, target validation, lead identification and lead optimization stages to generate future clinical pipeline candidates. Chinook is leveraging its ongoing strategic collaboration with Evotec to identify and validate novel targets and enable patient stratification strategies through access to the NURTuRE CKD Patient Biobank, which provides comprehensive PANOMICS characterization of thousands of CKD patients with prospective clinical follow-up and retained bio-samples of urine and blood for exploratory biomarker analysis.

- Chinook delivered an oral presentation at ASN Kidney Week 2022 in November on a multi-omics approach to the characterization of IgAN in the NURTuRE cohort, integrating clinical, histological, transcriptomic and serum proteomic data to gain deeper insights into patient stratification and IgAN disease pathogenesis. Also at ASN, Chinook presented a poster in collaboration with Evotec on a human data-driven, patient-centric and multi-omics-enabled target identification framework

focused on common cellular and molecular mechanisms of CKD by leveraging the NURTuRE and QUOD patient cohorts.

- Chinook delivered an oral presentation at the 59th ERA Congress in May 2022 on the approach used in collaboration with Evotec to leverage the NURTuRE CKD biobank to generate mechanistic disease understanding for patient-centric, integrated target and biomarker discovery that will enable the development of novel precision treatments for CKD patient subsets.

Corporate

- Chinook recently announced the appointment of Andrew Oxtoby as Chief Commercial Officer. Under Andrew's leadership, Chinook will develop its go-to-market strategy and build a commercial organization in preparation for the potential launch of atrasentan and future pipeline products. Andrew brings to Chinook over 20 years of experience in marketing, sales, finance and commercial leadership roles at Aimmune Therapeutics and Eli Lilly and Company.

- Sairopa B.V. (Sairopa) entered into an exclusive agreement with Exelixis, Inc. in November 2022 for the development of ADU-1805, a monoclonal antibody targeting SIRPα, and received an upfront payment of $40.0 million. The U.S. Food and Drug Administration (FDA) recently cleared Sairopa's Investigational New Drug (IND) Application to evaluate the safety and pharmacokinetics of ADU-1805 in adults with advanced solid tumors, which triggers a $35.0 million milestone payment that will be paid to Sairopa in the first quarter of 2023. Under the terms of the agreement, Sairopa is eligible to receive additional payments if Exelixis exercises its option and upon achievement of specified development, commercial and net sales milestones, as well as tiered royalties on net sales worldwide. As of December 31, 2022, Chinook owned approximately a 36% interest in Sairopa and has one seat on its board of directors. Chinook will hold its shares in Sairopa until there is a liquidation event, at which time, in accordance with the CVR agreement, 50% of any net proceeds will accrue to the benefit of the CVR holders, net of deductions permitted, including taxes and certain other expenses.

- Chinook closed a $120.7 million public offering in May 2022, which included the exercise in full of the underwriters' option to purchase additional shares of common stock.

- Chinook announced an outreach initiative in collaboration with the IgA Nephropathy Foundation and Komodo Health in April 2022, leveraging data and technology to drive awareness of IgAN and engage key medical providers at nephrology practices across the U.S., with the goal of ensuring patients have access to optimal support and treatment options earlier in their disease journey.

Fourth Quarter and Full Year Ended December 31, 2022 Financial Results

- **Cash Position –** Cash, cash equivalents and marketable securities totaled $385.3 million as of December 31, 2022, compared to $355.1 million as of December 31, 2021.

- **Revenue –** Revenue for the quarter and year ended December 31, 2022 was $0.5 million and $6.1 million, respectively, compared to $51.2 million and $51.6 million for the same periods in 2021. The higher revenue amounts in 2021 were primarily due to $41.2 million non-cash revenue recognized under Chinook's license agreement with SanReno Therapeutics and a $10.0 million milestone payment earned under the collaboration agreement with Merck.

- **Expenses –**

    - Research and development expenses for the quarter and year ended December 31, 2022 were $43.0 million and $141.2 million, respectively, compared to $24.9 million and $97.0 million, respectively, for the same periods in 2021. The increase was primarily due to higher employee-related costs, including stock-based compensation expense, an increase in licensing and contract research and manufacturing costs, consulting and outside services fees, as well as facilities and other costs to continue the progression of our research and clinical programs.

    - General and administrative expenses for the quarter and year ended December 31, 2022 were $9.8 million and $36.3 million, respectively, compared to $7.7 million and $31.9 million, respectively, for the same periods in 2021. The increase was primarily due to higher employee-related costs, including stock-based compensation expense, higher consulting and outside services costs to support our operations, and other costs. These increases were partially offset by a decrease in facilities costs.

    - The change in fair value of contingent consideration and contingent value rights liabilities for the quarter and year ended December 31, 2022 resulted in expenses of $7.3 million and $12.0 million, respectively, compared to expenses of $5.8 million and $27.3 million, respectively, for the same periods in 2021. The increase in these

non-cash expenses in the quarter ended December 31, 2022 was primarily due to an increase in the fair value of the contingent value rights liability related to the preferred shares in Sairopa mainly as a result of Sairopa entering into a license agreement with Exelixis in November 2022. The decrease in the year ended December 31, 2022 was primarily due to a higher fair value in 2021 that included the impact of earning a milestone payment under the license agreement with Merck.

- **Net Loss –** Net loss for the quarter ended December 31, 2022 was $62.6 million, or $0.90 per share, compared to net income of $7.5 million, or $0.15 per basic share for the same period in 2021. Net loss for the year ended December 31, 2022 was $187.9 million, or $2.92 per share, compared to $102.9 million, or $2.26 per share for the same period in 2021.

About Chinook Therapeutics, Inc.
Chinook Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing precision medicines for kidney diseases. Chinook's product candidates are being investigated in rare, severe chronic kidney disorders with opportunities for well-defined clinical pathways. Chinook's lead program is atrasentan, a phase 3 endothelin receptor antagonist for the treatment of IgA nephropathy and proteinuric glomerular diseases. BION-1301, an anti-APRIL monoclonal antibody, is being evaluated in a phase 1/2 trial for IgA nephropathy. CHK-336, an oral small molecule LDHA inhibitor for the treatment of hyperoxalurias, is being evaluated in a phase 1 clinical trial in healthy volunteers. In addition, Chinook's research and discovery efforts are focused on building a pipeline of precision medicines for rare, severe chronic kidney diseases with defined genetic and molecular drivers. Chinook is leveraging insights from kidney single cell RNA sequencing and large CKD patient cohorts that have been comprehensively panomically phenotyped, with retained biosamples and prospective clinical follow-up, to discover and develop therapeutic candidates with mechanisms of action targeted against key kidney disease pathways. To learn more, visit www.chinooktx.com.

Cautionary Note on Forward-Looking Statements
Certain of the statements made in this press release are forward looking, including those relating to Chinook's business, future operations, advancement of its product candidates and product pipeline, clinical development of its product candidates, including expectations regarding cash forecasts and timing of initiation and results of clinical trials, and regulatory submissions, including the timing of the results of our phase 3 ALIGN trial and phase 2 AFFINITY trial of atrasentan, phase 3 clinical trial of BION-1301, phase 1/2 trial of BION-1301, phase 1 clinical trial of CHK-336, and submission for potential accelerated approval for atrasentan. In some cases, you can identify these statements by forward-looking words such as "may," "will," "continue," "anticipate," "intend," "could," "project," "expect" or the negative or plural of these words or similar expressions. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including, but not limited to, our ability to develop and commercialize our product candidates, including initiation of clinical trials of our existing product candidates or those developed as part of the Evotec collaboration or other strategic collaborations, whether results of early clinical trials or preclinical studies will be indicative of the results of future trials, including our phase 3 ALIGN trial, our ability to obtain and maintain regulatory approval of our product candidates, our ability to operate in a competitive industry and compete successfully against competitors that may be more advanced or have greater resources than we do, our ability to obtain and adequately protect intellectual property rights for our product candidates, and the effects of macroeconomic conditions on our business operations, including rising interest rates and inflation. Many of these risks are described in greater detail in our filings with the SEC. Any forward-looking statements in this press release speak only as of the date of this press release. Chinook assumes no obligation to update forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

Contact:
Noopur Liffick
Senior Vice President, Investor Relations & Corporate Communications

CHINOOK THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Collaboration and license revenue	$ 512	$ 51,236	$ 6,128	$ 51,625
Operating expenses:				
Research and development	42,952	24,930	141,211	96,987
General and administrative	9,765	7,741	36,291	31,899
Change in fair value of contingent consideration and contingent value rights liabilities	7,268	5,754	11,987	27,317
Amortization of intangible assets	433	422	1,722	1,687
Total operating expenses	60,418	38,847	191,211	157,890
Gain on sale of assets to equity method investment	—	—	—	7,227
Income (loss) from operations	(59,906)	12,389	(185,083)	(99,038)
Investment and other income (expense), net	2,447	5	4,809	(170)
Income (loss) before income taxes and equity method investment loss	(57,459)	12,394	(180,274)	(99,208)
Income tax expense	(4,341)	(3,297)	(4,341)	(2,093)

Equity method investment loss	(754)	(1,552)	(3,250)	(1,636)
Net income (loss)	$ (62,554)	$ 7,545	$ (187,865)	$ (102,937)
Net income (loss) per share attributable to common stockholders:				
Basic	$ (0.90)	$ 0.15	$ (2.92)	$ (2.26)
Diluted	$ (0.90)	$ 0.14	$ (2.92)	$ (2.26)
Weighted-average shares used in computing net income (loss) per share attributable to common stockholders:				
Basic	69,217	51,675	64,370	45,607
Diluted	69,217	53,690	64,370	45,607

CHINOOK THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(In thousands)
(Unaudited)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 115,438	$ 181,724
Marketable securities	262,887	105,113
Accounts receivable	1,091	10,061
Prepaid expenses and other current assets	6,176	3,741
Total current assets	385,592	300,639
Marketable securities	6,989	68,215
Property and equipment, net	16,908	18,935
Restricted cash	2,074	2,074
Operating lease right-of-use assets	48,970	55,385
Investment in equity securities	41,200	41,200
Equity method investment	4,071	8,205
Intangible assets, net	24,287	26,009
In-process research & development	36,550	36,550
Goodwill	117	117
Other assets	7,326	6,474
Total assets	$ 574,084	$ 563,803
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 9,751	$ 8,580
Accrued and other current liabilities	33,636	17,104
Operating lease liabilities	4,948	4,401
Contingent value rights liability	2,500	10,000
Total current liabilities	50,835	40,085
Contingent value rights liability - non-current	37,318	24,591
Contingent consideration liability	4,420	5,160
Deferred tax liabilities	5,076	735
Operating lease liabilities, net of current maturities	34,494	39,589
Total liabilities	132,143	110,160
Stockholders' equity	441,941	453,643
Total liabilities and stockholders' equity	$ 574,084	$ 563,803

investors@chinooktx.com
media@chinooktx.com

Source: Chinook Therapeutics, Inc.