Chinook Therapeutics Provides Business Update and Reports First Quarter 2022 Financial Results

May 12, 2022

SEATTLE, May 12, 2022 (GLOBE NEWSWIRE) -- Chinook Therapeutics, Inc. (Nasdaq: KDNY), a biopharmaceutical company focused on the discovery, development and commercialization of precision medicines for kidney diseases, today provided a business update and reported financial results for the first quarter ended March 31, 2022.

“During the first quarter of 2022, we made strong progress advancing our pipeline of clinical, research and discovery programs for rare, severe chronic kidney diseases. We continue to enroll patients in the phase 3 ALIGN and phase 2 AFFINITY trials for atrasentan as well as the phase 1/2 trial of BION-1301, and we are pleased to have recently initiated the phase 1 healthy volunteer trial of CHK-336, our first internally-discovered program for the treatment of primary and idiopathic hyperoxaluria,” said Eric Dobmeier, president and chief executive officer of Chinook Therapeutics. “We look forward to the upcoming 59th ERA Congress being held May 19th – 22nd, where we will present clinical data from both our lead programs, atrasentan and BION-1301, in patients with IgA nephropathy (IgAN).”

Recent Accomplishments and Updates

Atrasentan
Atrasentan is a potent and selective endothelin A (ET_A) receptor antagonist that has the potential to provide 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 of atrasentan is currently enrolling patients with IgAN, and the phase 2 AFFINITY basket trial of atrasentan is currently enrolling patients with proteinuric glomerular diseases.

- Enrollment of the phase 3 ALIGN trial of atrasentan continues to advance with the activation of new trial sites and expansion into additional countries. Chinook expects to report topline data from the six-month interim proteinuria endpoint analysis in 2023 to support an application for accelerated approval under Subpart H in the United States.

- Chinook plans to present data from the IgAN patient cohort of the phase 2 AFFINITY trial in an oral presentation at the 59th ERA Congress on May 20, 2022, and provide a program update on atrasentan during an investor conference call and webcast at 4:15 pm EDT that day. Chinook has completed enrollment of the IgAN patient cohort of this trial, and continues to enroll the other three cohorts, including patients with focal segmental glomerulosclerosis (FSGS), Alport syndrome and diabetic kidney disease in combination with SGLT2 inhibitors.

- Chinook will deliver a mini-oral presentation at the 59th ERA Congress on May 19, 2022 on preclinical mechanistic work describing atrasentan’s effect to block mesangial cell injury and the pathogenic transcriptional networks driving IgAN progression in a model system.

- In March 2022, Chinook presented an overview of the phase 2 AFFINITY clinical trial at the 4th Annual Chronic Kidney Disease (CKD) Drug Development Summit.

- In February 2022, Chinook delivered an encore trials-in-progress presentations on the phase 3 ALIGN and phase 2 AFFINITY clinical trials at the ISN World Congress of Nephrology 2022.

BION-1301
BION-1301 is a novel anti-APRIL monoclonal antibody currently in phase 1/2 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) to prevent the formation of pathogenic immune complexes has been demonstrated preclinically as well as clinically in both healthy volunteers and patients with IgAN.

- Chinook will present additional data from Cohort 1 of Part 3 in a mini-oral presentation at the 59th ERA Congress on May 19, 2022. After at least 24 weeks of treatment, all eight patients in Cohort 1 transitioned from IV dosing at 450 mg every two weeks to SC dosing at 600 mg every two weeks.

- Enrollment of Cohort 2 of Part 3 of the ongoing phase 1/2 trial of BION-1301 is ongoing. Patients in Cohort 2 receive a SC dose of 600 mg of BION-1301 every two weeks. Data from Cohort 2 is expected in the second half of 2022.

- Chinook will present a trials-in-progress mini-oral presentation at the 59th ERA Congress on May 19, 2022 on the ongoing phase 1/2 trial of BION-1301.

- In March 2022, Chinook presented a detailed overview of the BION-1301 program at the 4th Annual CKD Drug Development Summit.

- In February 2022, Chinook delivered encore presentations on data from Cohort 1 of Part 3 as well as a trials-in-progress of the ongoing phase 1/2 trial of BION-1301 at the ISN World Congress of Nephrology 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), secondary hyperoxaluria due to increased endogenous oxalate production and idiopathic stone formation.

- In April 2022, Chinook initiated dosing in a phase 1 clinical trial evaluating CHK-336 in healthy volunteers. Data from this trial is expected in the first half of 2023.

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 will deliver an oral presentation at the 59th ERA Congress on May 20, 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.

- In March 2022, Chinook participated in a panel on the challenges and opportunities in drug development for rare kidney diseases at the 4th Annual CKD Drug Development Summit.

Corporate

- In April 2022, Chinook announced an outreach initiative in collaboration with the IgA Nephropathy Foundation and Komodo Health, 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.

- In March 2022, Chinook announced the appointment of Dr. Mahesh Krishnan, group vice president of research and development at DaVita Inc., to its Board of Directors.

- In January 2022, Chinook announced the appointment of Dr. Charlotte Jones-Burton as senior vice president of product development and strategy.

First Quarter 2022 Financial Results

- **Cash Position –** Cash, cash equivalents and marketable securities totaled $330.0 million at March 31, 2022, compared to $355.1 million at December 31, 2021.

- **Revenue –** Revenue for the quarter ended March 31, 2022 was $2.7 million compared to $0.4 million for the same period in 2021. The increase was primarily due to revenue recognized under Chinook's license agreement with SanReno.

- **Expenses –**

    - Research and development expenses for the quarter ended March 31, 2022 were $26.3 million compared to $25.7 million for the same period in 2021. The increase was primarily due to higher employee-related costs from increased staff to build out our clinical and development capabilities; increased spending for consulting and outside services; and an increase in facilities and other costs. These increases were partially offset by a decrease in licensing and contract research and manufacturing costs. The decrease resulted from an upfront fee of $3.3 million to Evotec International GmbH included in the quarter ended March 31, 2021 and lower costs from clinical trials initiated in 2021.

    - General and administrative expenses for the quarter ended March 31, 2022 were $7.9 million compared to $9.5 million for the same period in 2021. The decrease was primarily due to lower consulting and other professional services costs; lower employee-related costs; and a decrease in facilities and other costs. These decreases were partially offset by an increase in stock-based compensation expense resulting from new grants.

- The change in fair value of contingent consideration and contingent value rights liabilities for the quarter ended March 31, 2022 was a benefit of $1.0 million compared to expense of $1.8 million for the same period in 2021. The decrease in these non-cash expenses primarily resulted from a change in estimate of the potential future proceeds derived from the Merck collaboration.

- **Other –**

  - A $10.0 million development milestone under the Merck collaboration was earned in the fourth quarter of 2021 and received in the first quarter of 2022. We expect to pay this milestone, net of taxes and expenses, to the CVR holders in the second quarter of 2022.

- **Net Loss –** Net loss for the first quarter of 2022 was $31.7 million, or $0.54 per basic share, compared to a net loss of $37.2 million, or $0.88 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 other 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 healthy volunteer trial. In addition, Chinook is advancing research programs for other rare, severe chronic kidney diseases. Chinook is building its pipeline by leveraging insights in kidney single cell RNA sequencing, human-derived organoids and new translational models, to discover and develop therapeutics with differentiating mechanisms of action 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. 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, whether results of early clinical trials or preclinical studies will be indicative of the results of future trials, 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 COVID-19 on our clinical programs and business operations. 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.

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

	Three Months Ended March 31,	
	2022	**2021**
Collaboration and license revenue	$ 2,697	$ 351
Operating expenses:		
Research and development	26,252	25,697
General and administrative	7,868	9,543
Change in fair value of contingent consideration and contingent value rights liabilities	(1,038)	1,839
Amortization of intangible assets	429	420
Total operating expenses	33,511	37,499
Loss from operations	(30,814)	(37,148)
Other expense, net	(95)	(67)
Loss before income taxes and share of net loss of equity method investment	(30,909)	(37,215)
Share of net loss of equity method investment	(775)	—
Net loss	$ (31,684)	$ (37,215)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.54)	$ (0.88)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	58,340	42,136

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

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 103,500	$ 181,724
Marketable securities	172,599	105,113
Accounts receivable	2,947	10,061
Prepaid expenses and other current assets	6,727	3,741
Total current assets	285,773	300,639
Marketable securities	53,933	68,215
Property and equipment, net	18,263	18,935
Restricted cash	2,074	2,074
Operating lease right-of-use assets	53,922	55,385
Investment in equity securities	41,200	41,200
Equity method investment	7,201	8,205
Intangible assets, net	25,580	26,009
In-process research & development	36,550	36,550
Goodwill	117	117
Other assets	6,657	6,474
Total assets	$ 531,270	$ 563,803
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	9,039	8,580
Accrued and other current liabilities	12,946	17,104
Operating lease liabilities	4,581	4,401
Contingent value rights liability	10,000	10,000
Total current liabilities	36,566	40,085
Contingent value rights liability - non-current	23,963	24,591
Contingent consideration liability	4,750	5,160
Deferred tax liabilities	735	735
Operating lease liabilities, net of current maturities	38,461	39,589
Total liabilities	104,475	110,160
Stockholders' equity	426,795	453,643
Total liabilities and stockholders' equity	$ 531,270	$ 563,803

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