



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

August 8, 2022

SEATTLE, Aug. 08, 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 quarter and six months ended June 30, 2022.

"During the second quarter of 2022, we executed well on advancing our pipeline of clinical and preclinical programs for rare, severe chronic kidney diseases. We continue to ramp up enrollment of patients in the phase 3 ALIGN trial for atrasentan, and the data we presented at ERA from the ongoing phase 2 AFFINITY trial of atrasentan demonstrated consistent and clinically meaningful proteinuria reductions in patients with IgAN," said Eric Dobmeier, president and chief executive officer of Chinook Therapeutics. "For BION-1301, the additional data presented at ERA from the ongoing phase 1/2 trial reaffirms its disease-modifying potential in IgAN by demonstrating durable reductions in mechanistic biomarkers and corresponding impressive proteinuria reductions. We look forward to advancing BION-1301 into a phase 3 study for patients with IgAN in 2023. We are also continuing to make progress with dose escalation in the ongoing phase 1 trial of CHK-336 in healthy volunteers and expect to report data in the first half of 2023."

Recent Accomplishments and Updates

Atrasentan

Atrasentan is a potent and selective endothelin A (ETA) 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 presented data from the IgAN patient cohort of the phase 2 AFFINITY trial in an oral presentation at the 59th ERA Congress in May 2022, demonstrating consistent and clinically meaningful proteinuria reductions at weeks six, 12 and 24 of treatment in patients with IgAN already on a maximally tolerated and stable dose of a RAS inhibitor. Specifically, atrasentan demonstrated a 38.0% geometric mean reduction in 24-hour urine protein creatinine ratio (UPCR) in 20 patients at six weeks of treatment, 49.9% geometric mean reduction in 24-hour UPCR in 18 patients at 12 weeks of treatment and 58.5% geometric mean reduction in 24-hour UPCR in 11 patients at 24 weeks of treatment. After 24 weeks of treatment, ten of the 11 patients (91%) who had completed this visit had greater than a 40% cumulative 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. There were no increases in BNP or mean bodyweight, suggesting minimal fluid retention. As of the April 22, 2022 data cutoff, atrasentan was well-tolerated in patients with IgAN, with no treatment-related serious adverse events.
- Chinook has completed enrollment of the IgAN patient cohort of the AFFINITY 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 plans to report additional data from the AFFINITY trial in the second half of 2022, as well as during 2023.
- Chinook delivered a mini-oral presentation at the 59th ERA Congress on preclinical mechanistic data describing atrasentan's effect to block mesangial cell injury and the pathogenic transcriptional networks driving IgAN progression in a model system.

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.

- Enrollment of up to 30 patients in 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. Chinook expects to report initial data from Cohort 2 in the second half of 2022.

- Based on the data generated to date in the ongoing phase 1/2 study and after consulting with an expert advisory panel, Chinook has decided to advance BION-1301 into phase 3 utilizing the current Cohort 2 dose of 600 mg SC every two weeks, and will not move forward with the optional Cohort 3. Chinook is currently finalizing trial design, conducting site and country feasibility and pursuing regulatory interactions to enable initiation of a global phase 3 trial of BION-1301 in 2023.
- Chinook presented additional interim data from Cohort 1 of Part 3 in a mini-oral presentation at the ERA Congress in May 2022, further demonstrating its disease-modifying potential in IgAN by generating durable reductions in mechanistic biomarkers and corresponding impressive proteinuria reductions within three months of initiating treatment. After at least 24 weeks of treatment, patients in Cohort 1 transitioned from IV dosing at 450 mg every two weeks to SC dosing at 600 mg every two weeks. BION-1301 treatment resulted in steady-state reductions in Gd-IgA1 in the range of 70–80%, demonstrating depletion of the pathogenic IgA variant, and establishing the potentially disease-modifying mechanism of BION-1301 by directly targeting the initial pathway in the pathogenesis of IgAN. Additionally, BION-1301 demonstrated a 48.8% geometric mean reduction in 24-hour UCPR in all eight patients at six months of treatment, a 70.9% geometric mean reduction in 24-hour UPCr in six patients at one year of treatment and a 69.1% geometric mean reduction in 24-hour UPCr in two patients at 1.5 years of treatment. As of the May 6, 2022 data cutoff, BION-1301 was well-tolerated, with no serious adverse events or treatment discontinuations due to adverse events.
- 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), 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 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

- In May 2022, Chinook completed an underwritten public offering of 7.6 million shares of common stock at a price to the public of \$14.00 per share, including the exercise in full of the underwriters' option to purchase an additional 1.1 million shares of common stock. As part of the offering, Chinook sold to certain investors pre-funded warrants to purchase up to an aggregate of 1.1 million shares of common stock at a purchase price of \$13.9999 per pre-funded warrant. The underwritten public offering resulted in gross proceeds to Chinook of \$120.7 million.
- 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.

Quarter and Six Months Ended June 30, 2022 Financial Results

- **Cash Position** – Cash, cash equivalents and marketable securities totaled \$405.2 million at June 30, 2022, compared to \$355.1 million at December 31, 2021.
- **Revenue** – Revenue for the quarter and six months ended June 30, 2022 was \$0.4 million and \$3.1 million, respectively, compared to less than \$0.1 million and \$0.4 million for the same periods 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 and six months ended June 30, 2022 were \$30.0 million and \$56.3 million, respectively, compared to \$22.8 million and \$48.5 million, respectively, for the same periods in 2021. The increase was primarily due to higher employee-related costs, including stock-based compensation expense, consulting and outside services fees, as well as facilities and other costs to continue progression of our research and clinical programs. The increase in the three months ended June 30, 2022 also included an increase in licensing and contract research and manufacturing costs. The increase in the six months ended June 30, 2022, was partially offset by a decrease resulting from an upfront fee of \$3.3 million to Evotec International GmbH recognized in the same period in 2021.
- General and administrative expenses for the quarter and six months ended June 30, 2022 were \$8.6 million and \$16.5 million, respectively, compared to \$7.8 million and \$17.3 million, respectively, for the same periods in 2021. The increase during the quarter ended June 30, 2022 was primarily due to higher consulting and outside services costs to support our operations and an increase in stock-based compensation expense, partially offset by lower facilities and other costs. The decrease during the six months ended June 30, 2022 was primarily due to lower employee-related costs and facilities and other costs, partially offset by an increase in stock-based compensation expense.
- The change in fair value of contingent consideration and contingent value rights liabilities for the quarter and six months ended June 30, 2022 was a benefit of \$2.0 million and \$3.0 million, respectively, compared to expense of \$19.6 million and \$21.4 million for the same periods in 2021. The decrease in these non-cash expenses was primarily due to a change in the fair value in the second quarter of 2021 to include the impact of Merck intending to evaluate MK-5890 in a phase 2 clinical study for a new indication and the sale of certain of our non-renal assets in exchange for preferred shares in Sairopa B.V.

• **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 paid this milestone, net of taxes and expenses, to the CVR holders in the second quarter of 2022.

- **Net Loss –** Net loss for the quarter and six months ended June 30, 2022 was \$37.6 million, or \$0.61 per share, and \$69.3 million, or \$1.15 per share, respectively. Net loss for the quarter and six months ended June 30, 2021 was \$42.6 million, or \$0.97 per share, and \$79.8 million, or \$1.86 per share, respectively.

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, including the timing of the results of our phase 3 ALIGN trial and phase 2 AFFINITY trial of atrasentan and submission for potential accelerated approval. 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.

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Collaboration and license revenue	\$ 418	\$ 34	\$ 3,115	\$ 385
Operating expenses:				
Research and development	30,023	22,787	56,275	48,484
General and administrative	8,635	7,768	16,503	17,311
Change in fair value of contingent consideration and contingent value rights liabilities	(1,984)	19,557	(3,022)	21,396
Amortization of intangible assets	429	422	858	842
Total operating expenses	37,103	50,534	70,614	88,033
Gain on sale of assets to equity method investment	—	7,227	—	7,227
Loss from operations	(36,685)	(43,273)	(67,499)	(80,421)
Other income (expense), net	767	(39)	672	(106)
Loss before income taxes and share of net loss of equity method investment	(35,918)	(43,312)	(66,827)	(80,527)
Income tax benefit	—	741	—	741
Share of net loss of equity method investment	(1,730)	—	(2,505)	—
Net loss	<u>\$ (37,648)</u>	<u>\$ (42,571)</u>	<u>\$ (69,332)</u>	<u>\$ (79,786)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.61)</u>	<u>\$ (0.97)</u>	<u>\$ (1.15)</u>	<u>\$ (1.86)</u>
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	<u>61,983</u>	<u>43,861</u>	<u>60,175</u>	<u>43,004</u>

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

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 145,927	\$ 181,724
Marketable securities	216,687	105,113
Accounts receivable	3,115	10,061
Prepaid expenses and other current assets	5,670	3,741
Total current assets	371,399	300,639
Marketable securities	42,587	68,215
Property and equipment, net	17,500	18,935
Restricted cash	2,074	2,074
Operating lease right-of-use assets	52,277	55,385
Investment in equity securities	41,200	41,200
Equity method investment	5,345	8,205
Intangible assets, net	25,151	26,009
In-process research & development	36,550	36,550
Goodwill	117	117
Other assets	7,042	6,474
Total assets	<u>\$ 601,242</u>	<u>\$ 563,803</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	4,907	8,580
Accrued and other current liabilities	17,373	17,104
Operating lease liabilities	4,701	4,401
Contingent value rights liability	2,500	10,000
Total current liabilities	29,481	40,085
Contingent value rights liability - non-current	22,509	24,591
Contingent consideration liability	4,220	5,160
Deferred tax liabilities	735	735
Operating lease liabilities, net of current maturities	37,166	39,589

Total liabilities	94,111	110,160
Stockholders' equity	507,131	453,643
Total liabilities and stockholders' equity	<u>\$ 601,242</u>	<u>\$ 563,803</u>

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Source: Chinook Therapeutics, Inc.