Chinook Therapeutics Provides Business Update and Reports Second Quarter 2021 Financial Results

August 12, 2021

SEATTLE, Aug. 12, 2021 (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 second quarter ended June 30, 2021.

“During the second quarter of 2021, we made strong progress across our pipeline of programs for kidney diseases, including driving enrollment in the phase 3 ALIGN and phase 2 AFFINITY trials of atrasentan, presenting interim clinical data for BION-1301 demonstrating initial proof-of-concept in patients with IgA nephropathy and advancing key IND-enabling studies for CHK-336,” said Eric Dobmeier, president and chief executive officer of Chinook Therapeutics. “Our solid cash position and resourcing enable us to continue executing on key priorities to advance our pipeline and build Chinook into a leading kidney disease company.”

Recent Highlights

- Enrolled the first patient in the phase 2 AFFINITY basket trial of atrasentan, a highly potent and selective endothelin A receptor (ETA) antagonist (see www.clinicaltrials.gov, identifier NCT04573920).
- Presented interim data from the first several patients with IgA nephropathy (IgAN) enrolled in Cohort 1 of Part 3 of the ongoing phase 1/2 study of BION-1301 at the 58th ERA-EDTA conference, demonstrating durable reductions in Gd-IgA1, IgA, IgM, and to a lesser extent, IgG levels, as well as clinically meaningful reductions in 24-hour proteinuria (UPCR), providing initial proof-of-concept for BION-1301 in IgAN.
- Presented Gd-IgA1 biomarker data in healthy volunteers from Part 1 (single ascending dose) and Part 2 (multiple ascending dose) of the ongoing phase 1/2 study of BION-1301 at the ISN World Congress of Nephrology 2021, showing dose-dependent and durable reductions in Gd-IgA1 levels following administration of BION-1301.
- Presented data from the BION-1301 phase 1 intravenous to subcutaneous bioavailability study in healthy volunteers at the ISN World Congress of Nephrology 2021.
- Entered into an agreement for Sairopa B.V., or Sairopa, to acquire certain of Chinook’s non-renal assets in exchange for a 44 percent preferred equity position in Sairopa. Any future proceeds resulting from this transaction will be shared equally between the CVR holders and Chinook until October 4, 2030, after which 100 percent of the value will accrue to Chinook.
- Announced promotions of Tom Frohlich to Chief Operating Officer and Andrew King, D.V.M., Ph.D., to Chief Scientific Officer.

Anticipated Upcoming Catalysts

- Chinook expects to complete enrollment in Cohort 1 of Part 3 of the ongoing phase 1/2 study of BION-1301 in the third quarter of 2021 and to present additional patient data from this cohort at the ASN Kidney Week 2021 in November.
- Chinook expects to initiate enrollment in Cohort 2 of Part 3 of the ongoing phase 1/2 study of BION-1301 in the third quarter of 2021. Patients in Cohort 2 will receive a subcutaneous dose of 600 mg of BION-1301 every two weeks for up to 52 weeks. Chinook expects to present patient data from Cohort 2 and provide an update on planned later-stage clinical trials of BION-1301 in the first half of 2022.
- Chinook expects to present interim data from one or more patient cohorts of the ongoing phase 2 AFFINITY basket trial of atrasentan in the first half of 2022.
- CHK-336 is currently in IND-enabling studies and is advancing towards expected initiation of a phase 1 clinical study in healthy volunteers in the first quarter of 2022 for the treatment of primary hyperoxaluria.

Second Quarter 2021 Financial Results

- **Cash Position –** Cash, cash equivalents and marketable securities totaled $229.8 million at June 30, 2021, compared to $250.4 million at December 31, 2020.

- **Revenue –** Total revenue increased by less than $0.1 million for the second quarter of 2021 and increased by $0.4 million for the six months ended June 30, 2021, compared to the same periods in 2020 due to revenue recognized related to research and development services provided under the collaboration agreement with Lilly, which was acquired under the merger with Aduro.

- **Expenses –**

    - Research and development expenses were $22.8 million for the second quarter of 2021 and $48.5 million for the six months ended June 30, 2021, compared to $3.9 million and $6.7 million, respectively, for the same periods in 2020. The increase was primarily due to external clinical and manufacturing expenses related to the atrasentan and BION-1301 clinical programs; higher employee-related costs, including salaries, benefits and stock-based compensation expense associated with hiring staff to build out Chinook's clinical and development capabilities; increased spending for consulting and outside services; and an increase in facilities and other costs. The six months ended June 30, 2021 also includes an upfront fee of $3.3 million due to Evotech International GmbH under a research collaboration and license agreement entered into in February 2021.

    - General and administrative expenses were $7.8 million for the second quarter of 2021 and $17.3 million for the six months ended June 30, 2021, compared to $3.9 million and $5.2 million, respectively, for the same periods in 2020. The increase was primarily due to higher employee-related costs, including salaries, benefits and stock-based compensation expense associated with the addition of administrative staff to buildout Chinook's public-company infrastructure; higher legal, consulting and outside services costs; and an increase in facilities and other costs.

    - Expenses due to the change in fair value of contingent consideration and contingent value rights liabilities were $19.6 million for the second quarter of 2021 and $21.4 million for the six months ended June 30, 2021, compared to nil for the same periods in 2020. These non-cash expenses are due to the quarterly revaluation of assets and liabilities related to the Sairopa transaction and an updated valuation of Chinook's CVR liability under the Merck collaboration, as a result of the merger with Aduro. In the second quarter of 2021, Merck informed Chinook that it intends to explore the potential benefit of the product candidate MK-5890, previously out-licensed to Merck by Aduro, in a phase 2 clinical study for a new indication. This may result in potential milestone and royalty payments for the benefit of CVR holders.

- **Other –**

    - The sale of certain of Chinook's non-renal assets to Sairopa in the second quarter of 2021 resulted in a $7.2 million gain.

- **Net Loss –** Net loss for the second quarter of 2021 was $42.6 million or $0.97 per share and $79.8 million or $1.86 per share for the six months ended June 30, 2021, compared to net loss of $7.7 million or $1.87 per share and $12.9 million or $3.12 per share, respectively, for the same periods in 2020.

- **Cash Used in Operations –** For the six months ended June 30, 2021, cash used in operations totaled $55.5 million.

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 1b trial for IgA nephropathy. In addition, Chinook is advancing CHK-336, an oral small molecule LDHA inhibitor for the treatment of primary hyperoxaluria, as well as 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. 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Collaboration and license revenue	$ 34	$ —	$ 385	$ —
Operating expenses:				
Research and development	22,787	3,870	48,484	6,688
General and administrative	7,768	3,879	17,311	5,150
Change in fair value of contingent consideration and contingent value rights liabilities	19,557	—	21,396	—
Amortization of intangible assets	422	—	842	—
Total operating expenses	50,534	7,749	88,033	11,838
Gain on sale of assets to equity method investment	7,227	—	7,227	—
Loss from operations	(43,273)	(7,749)	(80,421)	(11,838)
Other income (expense), net	(39)	(4)	(106)	115
Change in fair value of redeemable convertible preferred stock tranche liability	—	10	—	(1,169)
Loss before income taxes	(43,312)	(7,743)	(80,527)	(12,892)
Income tax benefit	741	—	741	—
Net loss	$ (42,571)	$ (7,743)	$ (79,786)	$ (12,892)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.97)	$ (1.87)	$ (1.86)	$ (3.12)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	43,861	4,151	43,004	4,128

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

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 135,466	$ 187,750
Marketable securities	61,684	59,622
Accounts receivable	467	262
Prepaid expenses and other current assets	5,710	6,447
Total current assets	203,327	254,081
Marketable securities	32,682	3,000
Property and equipment, net	19,359	20,626
Restricted cash	2,074	1,750
Operating lease right-of-use assets	53,157	55,673
Equity method investment	9,972	—
Intangible assets, net	26,854	27,696
In process research & development	36,550	39,295
Goodwill	18,541	22,441

Other assets	5,349	4,440
Total assets	$ 407,865	$ 429,002
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	9,221	3,995
Accrued and other current liabilities	11,269	15,674
Operating lease liabilities	3,280	3,045
Deferred revenue	—	95
Total current liabilities	23,770	22,809
Contingent value rights liability	29,050	13,780
Contingent consideration liability	4,780	1,800
Deferred tax liabilities	15,635	16,377
Operating lease liabilities	37,147	38,709
Other long-term liabilities	754	905
Total liabilities	111,136	94,380
Stockholders' equity	296,729	334,622
Total liabilities and stockholders' equity	$ 407,865	$ 429,002

CHINOOK THERAPEUTICS

Source: Chinook Therapeutics, Inc.