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

May 12, 2021

SEATTLE, May 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 first quarter ended March 31, 2021.

“During the first quarter of 2021, Chinook made strong progress with its pipeline of programs for kidney diseases, including initiating the phase 3 ALIGN and phase 2 AFFINITY trials of atrasentan, presenting encouraging clinical data from the BION-1301 program and entering into a strategic collaboration with Evotec,” said Eric Dobmeier, president and chief executive officer of Chinook Therapeutics. “We are well-capitalized and resourced to execute across our programs to generate additional data catalysts and continue building Chinook into a leading kidney disease company.”

Recent Highlights

- Presented Gd-IgA1 biomarker data in healthy volunteers from Part 1 (single ascending dose) and Part 2 (multiple ascending dose) of the ongoing phase 1b 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, demonstrating our ability to transition to subcutaneous administration of BION-1301 in cohort 2 of the ongoing phase 1b and future studies.

- 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). Chinook expects to report data from initial patient cohorts of this study in 2022.

- Enrolled the first patient with IgA nephropathy (IgAN) in the phase 3 ALIGN trial of atrasentan, (see www.clinicaltrials.gov, identifier NCT04573478). Chinook expects to report top-line proteinuria data from this study in 2023 to support potential accelerated approval from the FDA.

- Entered into a strategic collaboration with Evotec to discover and develop novel precision medicine therapies for lupus nephritis, IgAN, polycystic kidney disease (PKD) and other primary glomerular diseases by leveraging the National Unified Renal Translational Research Enterprise (NURTuRE) patient biobank and Evotec’s proprietary PanHunter multi-omics platform.

- Received rare pediatric disease designation from the U.S. Food and Drug Administration (FDA) for CHK-336, an investigational oral small molecule inhibitor of lactate dehydrogenase A (LDHA), for primary hyperoxaluria (PH).

Anticipated Upcoming Catalysts

- Part 3 of Chinook's phase 1b study of BION-1301 is currently enrolling IgAN patients in an open-label setting, and Chinook expects to present a small subset of interim patient data in an oral presentation at the 58th ERA-EDTA Congress in June, as well as additional patient data at the ASN Kidney Week 2021 in November.

- CHK-336 is currently in IND-enabling studies and advancing towards an expected IND submission in late 2021 or early 2022 for the treatment of primary hyperoxaluria.

First Quarter 2021 Financial Results

- **Cash Position –** Cash, cash equivalents and marketable securities totaled $222.6 million at March 31, 2021, compared to $250.4 million at December 31, 2020.

- **Revenue –** Total revenue increased by $0.4 million for the first quarter of 2021 compared to the same period 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 $25.7 million for the first quarter of 2021 compared to $2.8 million for the same period 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 our clinical and development capabilities; increased spending for consulting and outside services; and higher facilities and other costs. The three months ended March 31, 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 $9.5 million for the first quarter of 2021 compared to $1.3 million for the same period 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 our public-company infrastructure; higher legal, consulting and outside services costs; and an increase in facilities and other costs.

- Expenses due to change in fair value of contingent consideration and amortization of intangibles were $2.3 million for the first quarter of 2021 compared to nil for the same period in 2020. These non-cash expenses are due to the quarterly revaluation of assets and liabilities related to the merger with Aduro.

- **Net Loss –** Net loss for the first quarter of 2021 was $37.2 million or $0.88 per share compared to net loss of $5.1 million or $1.25 per share for the same period in 2020.

- **Cash Used in Operations –** For the first quarter ended March 31, 2021, cash used in operations totaled $28.1 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.
Consolidated Statements of Operations
(In thousands, except per share amounts)

	Three Months Ended March 31,	
	2021	2020
Collaboration and license revenue	$ 351	$ -
Operating expenses:		
Research and development	25,697	2,818
General and administrative	9,543	1,271
Change in fair value of contingent consideration	1,839	-

Amortization of intangible assets	420	-
Total operating expenses	37,499	4,089
Loss from operations	(37,148)	(4,089)
Other expense, net	67	1,060
Net loss	$ (37,215)	$ (5,149)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.88)	$ (1.25)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	42,136	4,104

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

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 168,092	$ 187,750
Marketable securities	51,478	59,622
Accounts receivable	256	262
Prepaid expenses and other current assets	6,174	6,447
Total current assets	226,000	254,081
Marketable securities	2,999	3,000
Property and equipment, net	19,860	20,626
Restricted cash	1,750	1,750
Operating lease right-of-use assets	54,420	55,673
Intangible assets, net	27,277	27,696
In process research & development	39,295	39,295
Goodwill	22,441	22,441
Other assets	4,731	4,440
Total assets	$ 398,773	$ 429,002
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	7,363	3,995
Accrued and other current liabilities	14,486	15,674
Operating lease liabilities	3,135	3,045
Deferred revenue	—	95
Total current liabilities	24,984	22,809
Contingent value right liability	15,589	13,780
Contingent consideration related to acquisition	1,830	1,800
Deferred tax liabilities	16,377	16,377
Operating lease liabilities	37,966	38,709
Other long-term liabilities	1,508	905
Total liabilities	98,254	94,380
Stockholders' equity	300,519	334,622
Total liabilities and stockholders' equity	$ 398,773	$ 429,002

CHINOOK THERAPEUTICS

Source: Chinook Therapeutics, Inc.