Chinook Therapeutics Provides Business Update and Reports Fourth Quarter and Full Year 2020 Financial Results

April 7, 2021

SEATTLE, April 07, 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 full year ended December 31, 2020.

“We are executing well on our goal of building Chinook into a leading kidney disease company. 2020 was a very busy and productive year, as we in-licensed atrasentan from AbbVie, closed a $115 million financing, brought BION-1301 into our pipeline through the merger with Aduro, unveiled CHK-336, our first internally-developed program, and bolstered our precision medicine discovery and research efforts,” said Eric Dobmeier, president and chief executive officer of Chinook Therapeutics. “We are excited to have recently initiated our atrasentan phase 3 ALIGN and phase 2 AFFINITY trials and announced our collaboration with Evotec. We look forward to multiple data announcements from our BION-1301 program this year, as well as continuing to move CHK-336 towards the clinic.”

Mr. Dobmeier continued, “Our team has grown over 300 percent since the beginning of 2020, and we’re continuing to execute on our hiring plans to ensure we have strong resourcing in place to advance our pipeline. Our solid cash position, which we expect to fund our operations to the middle of 2023, enables us to achieve key milestones across our programs.”

2020 and Recent Accomplishments

Atrasentan

- 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 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, which could support accelerated approval from the FDA.
- Delivered an oral presentation at the 3rd Annual Chronic Kidney Disease Drug Development (CKD3) Summit on selective ET_A receptor antagonist atrasentan for the treatment of primary glomerular diseases.
- Entered into a license agreement with Morehouse School of Medicine for patents supporting the development of therapies in kidney diseases that disproportionately affect people of West African descent and underserved communities, including focal segmental glomerulosclerosis (FSGS) and HIV-associated nephropathy (HIVAN).
- Delivered a poster presentation at the American Society of Nephrology (ASN) Kidney Week 2020 Reimagined on the phase 3 ALIGN trial design for atrasentan.
- Entered into a license agreement with AbbVie for worldwide, exclusive rights to atrasentan.

BION-1301

- Completed enrollment and analysis of a phase 1 intravenous (IV) to subcutaneous (SC) bioavailability study of BION-1301, a novel anti-APRIL monoclonal antibody, in healthy volunteers.
- Dosed the first patient with IgAN in Part 3 of the ongoing phase 1 study of BION-1301.
- Delivered a poster presentation at the 57th ERA-EDTA Virtual Congress and ASN Kidney Week 2020 Reimagined on healthy volunteer data from Part 1 (single ascending dose) and Part 2 (multiple ascending dose) of the ongoing phase 1 study of BION-1301.
- Delivered a poster presentation at the 57th ERA-EDTA Virtual Congress on nonclinical toxicology studies of BION-1301 evaluating IV administration for up to six months and SC administration for up to one month.

CHK-336

- 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).

- Delivered a preclinical poster presentation at the ASN Kidney Week 2020 Reimagined unveiling CHK-336 with the potential to treat all subtypes of PH and other disorders arising from excess oxalate.

Precision Medicine Research & Discovery

- Participated in an expert panel discussion at the 3rd Annual CKD3 Summit on executing precision medicine in clinical trials.

- Entered into a strategic collaboration with Evotec to discover and develop novel precision medicine therapies for polycystic kidney disease (PKD), lupus nephritis, IgAN and other proteinuric glomerular diseases by leveraging the National Unified Renal Translational Research Enterprise (NURTuRE) patient biobank and Evotec's proprietary PanHunter multi-omics platform.
- Presented an oral abstract at the ASN Kidney Week 2020 Reimagined on a single cell transcriptomic atlas of human autosomal dominant polycystic kidney disease (ADPKD) through Chinook's academic collaboration with the laboratory of Benjamin Humphreys, M.D., Ph.D., Joseph Friedman Professor of Renal Diseases in Medicine and Chief of Nephrology at Washington University School of Medicine in St. Louis.

Corporate

- Appointed healthcare financial expert, Eric Bjerkholt, as chief financial officer.

- Appointed the following life sciences industry veterans to the Board of Directors: William M. Greenman, president and chief executive officer of Cerus Corporation; Michelle Griffin, director and audit committee chair for Adaptive Biotechnologies, Acer Therapeutics and HTG Molecular Diagnostics, Inc.; Ross Haghighat, founder, chairman and managing partner of Triton Systems, Inc.; and Dolca Thomas, M.D., executive vice president, head of research and development and chief medical officer of Equillium, Inc.

- Closed the merger with Aduro Biotech, Inc. on October 5, 2020 and began trading on the Nasdaq Global Select Market under the symbol "KDNY."

- Completed a $115 million private placement financing with top-tier healthcare investors concurrent with the merger closing.

Anticipated Upcoming Catalysts

- Chinook expects to present 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 in April.

- Chinook expects to present data from the BION-1301 phase 1 IV to SC bioavailability study in healthy volunteers at the ISN World Congress of Nephrology 2021 in April. Results from the study demonstrate the potential to transition to SC administration of BION-1301 in the long-term extension and phase 2 studies.

- 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.

Fourth Quarter and Full Year Financial Results

- **Cash Position –** Cash, cash equivalents and marketable securities totaled $250.4 million at December 31, 2020, compared to $11.2 million at December 31, 2019.

- **Revenue –** Total revenue increased by $0.8 million for both the fourth quarter of 2020 and year ended December 31, 2020 as compared to the fourth quarter of 2019 and year ended December 31, 2019. The increase was due to revenue recognized related to research and development services provided under the collaboration agreement with Lilly.

- **Expenses –**

- Research and development expenses were $21.8 million for the fourth quarter of 2020 and $36.1 million for the year ended December 31, 2020, compared to $9.2 million and $17.0 million, respectively, for the same periods in 2019. For the quarter and year ended December 31, 2020, the increases were primarily due to external clinical and manufacturing expenses related to the atrasentan and BION-1301 clinical programs; higher personnel expenses, including salaries, benefits and stock-based compensation expense associated with hiring staff to build out our clinical and development capabilities; and increased spending for consulting and outside services. The year-over-year increase was partially offset by expenses in the prior year period for the in-license of atrasentan, the purchase of intellectual property and know-how from a related party to support the CHK-336 program and discovery research activities.

- General and administrative expenses were $11.0 million for the fourth quarter of 2020 and $19.1 million for the year ended December 31, 2020, compared to $0.7 million and $3.0 million, respectively, for the same periods in 2019. For the quarter and year ended December 31, 2020, costs increased primarily due to legal, consulting and accounting costs related to the merger; an increase in personnel costs, including salaries, benefits and stock-based compensation expense due to the addition of administrative staff to buildout our public-company infrastructure; and an increase in facilities and other costs.

- **Net Loss –** Net loss for the fourth quarter of 2020 was $49.9 million or $1.24 per share and $81.6 million or $6.20 per share for the year ended December 31, 2020, compared to net loss of $34.2 million or $14.65 per share and $46.5 million or $25.48 per share, respectively, for the same periods in 2019.

- **Cash Used in Operations –** For the fourth quarter ended December 31, 2020, cash used in operations totaled $41.3 million, of which $20.1 million were non-recurring expenses related to the merger and integration with Aduro Biotech.

About Chinook Therapeutics, Inc.
Chinook Therapeutics, Inc. is a clinical-stage biotechnology 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 share and per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Revenue:				
Collaboration and license revenue	$ 827	$ —	$ 827	$ —
Total revenue	827	—	827	—

Operating expenses:				
Research and development	21,788	9,195	36,051	17,010
General and administrative	11,023	695	19,071	2,956
Change in fair value of contingent consideration	1,510	—	1,510	—
Amortization of intangible assets	422	—	422	—
Total operating expenses	34,743	9,890	57,054	19,966
Net loss from operations	(33,916)	(9,890)	(56,227)	(19,966)
Other income (expense):				
Interest expense – related party	(2)	(7)	(15)	(33)
Other income (expense), net	165	44	313	299
Change in fair value of redeemable convertible preferred stock tranche liability	(18,163)	(24,352)	(27,696)	(26,819)
Loss before income tax benefit	(51,916)	(34,205)	(83,625)	(46,519)
Income tax benefit	2,003	—	2,003	—
Net loss	$ (49,913)	$ (34,205)	$ (81,622)	$ (46,519)
Net loss per common share, basic and diluted	$ (1.24)	$ (14.65)	$ (6.20)	$ (25.48)
Shares used in computing net loss per common share, basic and diluted	40,326,568	2,334,877	13,168,143	1,825,716

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

	December 31,	
	2020	**2019**
Assets		
Current assets:		
Cash and cash equivalents	$ 187,750	$ 11,203
Restricted cash	—	154
Marketable securities	59,622	—
Accounts receivable	262	—
Prepaid expenses and other current assets	6,447	1,174
Total current assets	254,081	12,531
Marketable securities	3,000	—
Property and equipment, net and finance right-of-use asset	20,626	1,311
Restricted cash	1,750	—
Operating lease right-of-use assets	55,673	1,880
Intangible assets, net	27,696	—
IPR&D	39,295	—
Goodwill	22,441	—
Other assets	4,440	—
Total assets	$ 429,002	$ 15,722
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable (including amounts due to related party of $9 and $250 at December 31, 2020 and 2019, respectively)	$ 3,995	$ 939
Accrued and other current liabilities (including amounts due to related party of $192 and $489 at December 31, 2020 and 2019, respectively)	15,674	1,250
Operating lease liabilities (including amounts due to related party of $0 and $163 at December 31, 2020 and 2019, respectively)	3,045	163
Finance lease liabilities – related party	—	75
Deferred revenue	95	—
Total current liabilities	22,809	2,427
Redeemable convertible preferred stock tranche liability	—	32,733
Contingent value right liability	13,780	—
Contingent consideration related to acquisition	1,800	—
Deferred tax liabilities	16,377	—
Operating lease liabilities, net of current maturities (including amounts due to related party of $0 and $1,732 at December 31, 2020 and 2019, respectively)	38,709	1,732

Finance lease liabilities, net of current maturities – related party	—	114
Other long-term liabilities	905	—
Total liabilities	94,380	37,006
Commitments and contingencies		
Redeemable convertible preferred stock, $0.0001 par value; none and 65,000,000 shares authorized as of December 31, 2020 and 2019, respectively; none and 7,596,886 shares issued and outstanding as of December 31, 2020 and 2019, respectively; liquidation preference $0 and $26,000 as of December 31, 2020 and 2019, respectively	—	19,835
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 and no shares authorized as of December 31, 2020 and 2019, respectively; no shares issued and outstanding as of December 31, 2020 and 2019	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized as of December 31, 2020 and 2019; 42,282,381 and 4,501,885 shares issued and outstanding as of December 31, 2020 and 2019, respectively	4	—
Additional paid-in capital	463,436	6,095
Accumulated deficit	(128,829)	(47,207)
Accumulated other comprehensive income (loss)	11	(7)
Total stockholders' equity (deficit)	334,622	(41,119)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 429,002	$ 15,722

CHINOOK THERAPEUTICS

Source: Chinook Therapeutics, Inc.