UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 17, 2022

Chinook Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-37345	**94-3348934**
(Commission File No.)	**(IRS Employer Identification No.)**

400 Fairview Avenue North, Suite 900
Seattle, WA
(Address of principal executive offices)

98109
(Zip Code)

Registrant's telephone number, including area code: (206) 485-7241

Not applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	KDNY	The Nasdaq Stock Market LLC (The Nasdaq Global Select Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On March 17, 2022, Chinook Therapeutics, Inc. ("Chinook") announced certain financial results for the fourth quarter and year ended December 31, 2021. A copy of Chinook's press release, titled "Chinook Therapeutics Provides Business Update and Reports Fourth Quarter and Full Year 2021 Financial Results" is furnished pursuant to Item 2.02 as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
99.1	Press Release, dated March 17, 2022, titled "Chinook Therapeutics Provides Business Update and Reports Fourth Quarter and Full Year 2021 Financial Results"
104	Cover Page Interactive File (the cover page tags are embedded within the Inline XBRL document)

The information in this report, including the exhibit hereto, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by Chinook Therapeutics, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: March 17, 2022

Chinook Therapeutics, Inc.

By: /s/ Eric L. Dobmeier
Eric L. Dobmeier
President and Chief Executive Officer

Chinook Therapeutics Provides Business Update and Reports Fourth Quarter and Full Year 2021 Financial Results

SEATTLE March 17, 2022 – 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 fourth quarter and year ended December 31, 2021.

“2021 was a very productive year for Chinook, as we initiated the phase 3 ALIGN and phase 2 AFFINITY trials for atrasentan, presented compelling phase 1/2 data in patients with IgA nephropathy for BION-1301, successfully completed IND-enabling studies for CHK-336, continued to advance multiple programs within our research pipeline and executed notable strategic partnerships including our Evotec research collaboration, formation of Sairopa B.V. for the development of non-renal assets and establishment of the SanReno Therapeutics joint venture in China,” said Eric Dobmeier, president and chief executive officer of Chinook Therapeutics. “With the recent milestones we have achieved and our strong financial position, Chinook is well-positioned to continue building the leading company addressing unmet medical needs in kidney disease. During 2022, we look forward to presenting additional data from both our atrasentan and BION-1301 programs, initiating our phase 1 trial of CHK-336 and continuing to advance our preclinical pipeline for rare, severe chronic kidney diseases.”

2021 and Recent Accomplishments

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 IgA nephropathy (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 has completed enrollment of the IgAN patient cohort of the phase 2 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 present data from the IgAN patient cohort of this study in an oral presentation at the ERA Congress in May 2022, with data from one or more additional cohorts expected in the second half of 2022.

- Several abstracts on atrasentan were delivered as poster presentations at nephrology conferences throughout 2021, including:

    - Data demonstrating endothelin pathway activation in the kidneys of patients with IgAN has a strong association with clinical progression. Atrasentan was also shown to inhibit endothelin-1 mediated transcriptional networks, including cell proliferation, inflammation and fibrosis in human mesangial cells. This translational research was conducted in collaboration with the laboratory of Matthias Kretzler, M.D., Professor of Nephrology and Professor of Computational Medicine & Bioinformatics at

University of Michigan Medical School, and supports the therapeutic potential of ETA receptor blockade with atrasentan in patients with IgAN at high risk of progression. (ASN Kidney Week 2021)

- Analysis of three separate single-dose, randomized phase 1 studies of atrasentan demonstrating consistent and predictable safety, tolerability and pharmacokinetic profiles in healthy Chinese, Japanese and North American adults of non-Asian descent. The consistent profile of atrasentan across these ethnicities and geographic regions, supports the inclusion of patients with IgAN in Asia, where there is an increased prevalence and potentially accelerated disease progression, in the ongoing global phase 3 ALIGN study. (ASN Kidney Week 2021)

- Data demonstrating atrasentan's effect to rapidly reduce albuminuria and downregulate intra-renal transcriptional proliferative, inflammatory and fibrotic signaling in the gddY mouse IgAN model, supporting the therapeutic potential of atrasentan in patients with IgAN to reduce proteinuria and kidney inflammation and fibrosis, key drivers of IgAN progression. (ISN WCN 2021)

- Data demonstrating atrasentan's effect to attenuate human renal mesangial cell activation induced by endothelin-1 or IgAN patient immune-derived immune complexes in a translational model system, supporting the therapeutic potential of atrasentan in patients with IgAN, not only via its well characterized effect of reducing proteinuria, but also by potentially reducing mesangial cell activation, a hallmark of IgAN. (ISN WCN 2021)

- Atrasentan was granted orphan drug designation for the treatment of primary IgAN by the European Commission.

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) has been demonstrated preclinically as well as clinically in both healthy volunteers and patients with IgAN.

- Chinook presented data from the BION-1301 phase 1 intravenous (IV) to subcutaneous (SC) bioavailability study in healthy volunteers at the ISN World Congress of Nephrology 2021, demonstrating the ability to transition to SC administration of BION-1301 in the ongoing phase 1/2 study of BION-1301.

- Chinook completed enrollment of Cohort 1 of Part 3 of the ongoing phase 1/2 study of BION-1301 and presented additional patient data and follow-up from this cohort at ASN Kidney Week 2021, indicating BION-1301 was well-tolerated and caused durable reductions in Gd-IgA1, IgA, IgM, and to a lesser extent, IgG levels in patients with IgAN. BION-1301 demonstrated a greater than 50% geometric mean reduction in 24-hour urine protein creatinine ratio (UPCR) after three (n=6) to six (n=4) months of treatment, with further reductions in two patients through one year of treatment. After at least 24 weeks of treatment, patients in Cohort 1 are transitioning 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 study of BION-1301 is ongoing. Patients in Cohort 2 receive a SC dose of 600 mg of BION-1301 every two weeks.

- Chinook plans to present additional data from Cohort 1 of Part 3 in a mini-oral presentation at the ERA Congress in May 2022, with data from Cohort 2 of Part 3 expected in the second half of 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.

- Chinook has completed IND-enabling studies, submitted an IND and is advancing CHK-336 towards planned initiation of a phase 1 clinical trial in healthy volunteers in the first half of 2022.

- CHK-336 has received rare pediatric disease designation from the U.S. Food and Drug Administration (FDA) for PH.

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.

Corporate

- In April 2021, Chinook entered into an agreement for Sairopa B.V. 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 Chinook and the CVR holders until October 4, 2030, after which 100 percent of the value will accrue to Chinook.

- In November 2021, Chinook closed a $183.5M public offering, which included the exercise in full of the underwriters' option to purchase additional shares of common stock.

- Also in November 2021, Chinook formed SanReno Therapeutics, a 50/50 joint venture with an investor syndicate led by Frazier Healthcare Partners and Pivotal bioVenture Partners China, to develop, manufacture and commercialize kidney disease therapies in mainland China, Hong Kong, Macau, Taiwan and Singapore.

Fourth Quarter and Full Year 2021 Financial Results

- **Cash Position –** Cash, cash equivalents and marketable securities totaled $355.1 million at December 31, 2021, compared to $250.4 million at December 31, 2020. The increase is primarily due to net proceeds from our public offering in November 2021 and at-the-market (ATM) sales of common stock under our existing ATM facility in the second quarter of 2021, partially offset by cash used in operations.

- **Revenue –** Total revenue increased by $50.4 million and $50.8 million for the quarter and year ended December 31, 2021, respectively, compared to the same periods in 2020. The increase was primarily due to non-cash revenue of $41.2 million recognized under Chinook's license agreement with SanReno and from a development

milestone of $10.0 million recognized under the Exclusive Patent and Know-How License and Research Collaboration Agreement with Merck for MK-5890, an anti-CD27 agonist.

- **Expenses –**

    - Research and development expenses for the quarter and year ended December 31, 2021 were $24.9 million and $97.0 million, respectively, compared to $21.8 million and $36.1 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 from increased staff to build out our clinical and development capabilities; and an increase in facilities and other costs. Research and development expenses for the year ended December 31, 2021 also included an upfront fee under a collaboration agreement with Evotec.

    - General and administrative expenses for the quarter and year ended December 31, 2021 were $7.7 million and $31.9 million, respectively, compared to $11.0 million and $19.1 million, respectively, for the same periods in 2020. The decrease in the quarter ended December 31, 2021 compared to same period in 2020 was primarily due to higher costs related to the merger with Aduro in 2020. The increase in the year ended December 31, 2021 compared to the prior year was primarily due to higher employee-related costs from increased staff to build out our public-company infrastructure and an increase in facilities and other costs.

    - Expenses due to the change in fair value of contingent consideration and contingent value rights liabilities for the quarter and year ended December 31, 2021 were $5.8 million and $27.3 million, respectively, compared to $1.5 million for the same periods in 2020. These non-cash expenses are due to the quarterly revaluation of liabilities related to the Sairopa transaction and under the Merck collaboration. During the quarter ended December 31, 2021, we were notified of the achievement of a development milestone under the agreement with Merck, which resulted in an increase to the fair value of the CVR liability.

- **Other –**
    - The sale of non-renal assets to Sairopa in the second quarter of 2021 resulted in a $7.2 million gain for the year ended December 31, 2021.

    - The development milestone received under the Merck collaboration, net of permitted deductions, will be paid to CVR holders in the second quarter of 2022.

- **Net Loss –** Net income for the fourth quarter of 2021 was $7.5 million, or $0.15 per basic share, compared to a net loss of $49.9 million, or $1.24 per share for the same period in 2020. Net loss for the year ended December 31, 2021 was $102.9 million, or $2.26 per share, compared to a net loss of $81.6 million, or $6.20 per share for the same period in 2020.

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. 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 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.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Collaboration and license revenue	$ 51,236	$ 827	$ 51,625	$ 827
Operating expenses:				
Research and development	24,930	21,788	96,987	36,051
General and administrative	7,741	11,023	31,899	19,071
Change in fair value of contingent consideration and contingent value rights liabilities	5,754	1,510	27,317	1,510
Amortization of intangible assets	422	422	1,687	422
Total operating expenses	38,847	34,743	157,890	57,054
Gain on sale of assets to equity method investment	—	—	7,227	—
Income (loss) from operations	12,389	(33,916)	(99,038)	(56,227)
Other income (expense):				
Other income (expense), net	5	163	(170)	298
Change in fair value of redeemable convertible preferred stock tranche liability	—	(18,163)	—	(27,696)
Income (loss) before income taxes and share of net loss of equity method investment	12,394	(51,916)	(99,208)	(83,625)
Income tax (expense) benefit	(3,297)	2,003	(2,093)	2,003
Share of net loss of equity method investment	(1,552)	—	(1,636)	—
Net income (loss)	$ 7,545	$ (49,913)	$ (102,937)	$ (81,622)
Net income (loss) per share attributable to common stockholders:				
Basic	$ 0.15	$ (1.24)	$ (2.26)	$ (6.20)
Diluted	$ 0.14	$ (1.24)	$ (2.26)	$ (6.20)
Weighted-average shares used in computing net income (loss) per share attributable to common stockholders:				
Basic	51,675	40,327	45,607	13,168
Diluted	53,690	40,327	45,607	13,168

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

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 181,724	$ 187,750
Marketable securities	105,113	59,622
Accounts receivable	10,061	262
Prepaid expenses and other current assets	3,741	6,447
Total current assets	300,639	254,081
Marketable securities	68,215	3,000
Property and equipment, net	18,935	20,626
Restricted cash	2,074	1,750
Operating lease right-of-use assets	55,385	55,673
Investment in equity securities	41,200	—
Equity method investment	8,205	—
Intangible assets, net	26,009	27,696
In-process research & development	36,550	39,295
Goodwill	117	22,441
Other assets	6,474	4,440
Total assets	$ 563,803	$ 429,002
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 8,580	$ 3,995
Accrued and other current liabilities	17,104	15,674
Operating lease liabilities	4,401	3,045
Contingent value rights liability	10,000	—
Deferred revenue	—	95
Total current liabilities	40,085	22,809
Contingent value rights liability - non-current	24,591	13,780
Contingent consideration liability	5,160	1,800
Deferred tax liabilities	735	16,377
Operating lease liabilities, net of current maturities	39,589	38,709
Other long-term liabilities	—	905
Total liabilities	110,160	94,380
Stockholders' equity	453,643	334,622
Total liabilities and stockholders' equity	$ 563,803	$ 429,002