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): May 9, 2023

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 May 9, 2023, Chinook Therapeutics, Inc. ("Chinook") announced certain financial results for the first quarter ended March 31, 2023. A copy of Chinook's press release, titled "Chinook Therapeutics Reports First Quarter 2023 Financial Results and Provides Corporate Updates" 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 May 9, 2023, titled "Chinook Therapeutics Reports First Quarter 2023 Financial Results and Provides Corporate Updates"
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: May 9, 2023

Chinook Therapeutics, Inc.

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

Chinook Therapeutics Reports First Quarter 2023 Financial Results and Provides Corporate Updates

SEATTLE May 9, 2023 – Chinook Therapeutics, Inc. (Nasdaq: KDNY), a biopharmaceutical company focused on the discovery, development and commercialization of precision medicines for kidney diseases, today reported financial results for the first quarter ended March 31, 2023 and provided corporate updates.

“During the first quarter of 2023, we continued to advance our pipeline of clinical and preclinical programs for rare, severe chronic kidney diseases. We recently completed full enrollment of the phase 3 ALIGN clinical trial, are on track to initiate the phase 3 BION-1301 IgAN clinical trial mid-year and expect to report topline ALIGN results in the fourth quarter of this year,” said Eric Dobmeier, president and chief executive officer of Chinook Therapeutics. “We also look forward to the upcoming 60th European Renal Association (ERA) Congress being held June 15th - 18th, where we will present clinical data from the phase 1/2 trial of BION-1301 as well as the phase 1 trial of CHK-336 in healthy volunteers.”

Recent Accomplishments and Updates

Atrasentan
Atrasentan is a potent and selective endothelin A (ET_A) receptor antagonist that has potential therapeutic 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 is evaluating atrasentan in patients with IgAN and the phase 2 AFFINITY basket trial is evaluating atrasentan in patients with proteinuric glomerular diseases.

- Chinook has completed enrollment of the phase 3 ALIGN trial, including 320 patients in the main stratum and 64 patients in the SGLT2 inhibitor (SGLT2i) combination stratum. Following a Type D meeting with the U.S. Food and Drug Administration (FDA), Chinook has agreed to change the primary proteinuria endpoint in the ALIGN study to be evaluated at 36 weeks, and plans to report topline data from this endpoint in the fourth quarter of 2023 to potentially support an application for accelerated approval with the FDA.

- Chinook has completed enrollment of the first four cohorts of the AFFINITY trial, including patients with IgAN, focal segmental glomerulosclerosis (FSGS), Alport syndrome and diabetic kidney disease in combination with SGLT2 inhibitors, and is continuing to enroll the fifth cohort of FSGS patients at a 1.5 mg dose of atrasentan. Chinook plans to present data from one or more additional cohorts of the AFFINITY trial in the second half of 2023.

- Chinook is preparing to initiate the phase 2 ASSIST trial evaluating atrasentan in patients with IgAN on stable doses of a renin-angiotensin system inhibitor (RASi) and an SGLT2i. The goal of the ASSIST trial is to generate proteinuria data with the combination that will be available at the time of atrasentan’s launch. More details of the ASSIST trial design will be presented in June at the ERA Congress in Milan.

BION-1301 (Zigakibart)
BION-1301 is a novel anti-APRIL monoclonal antibody currently in phase 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 clinically in both healthy volunteers and patients with IgAN.

- Chinook has finalized trial design and is completing site and country feasibility and global regulatory interactions to enable initiation of the phase 3 BEYOND trial of BION-1301 in mid-2023. More details of the BEYOND trial design will be presented in June at the ERA Congress in Milan.

- Chinook has completed enrollment of 30 patients in Cohort 2 of Part 3 of the ongoing phase 1/2 trial of BION-1301. Patients in Cohort 2 receive a subcutaneous (SC) dose of 600 mg of BION-1301 every two weeks. Chinook plans to report additional data from Cohorts 1 and 2 in June at the ERA Congress in Milan as well as in the second half of 2023.

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) and other kidney stone disorders driven by endogenous overproduction of oxalate.

- In April 2022 Chinook initiated a phase 1 single ascending dose (SAD) and multiple ascending dose (MAD) clinical trial in healthy volunteers evaluating the safety, tolerability and pharmacokinetic profile of CHK-336. Initial data from this trial will be presented in June at the ERA Congress in Milan.

- In April 2023 Chinook voluntarily paused dosing in the phase 1 clinical trial of CHK-336 in healthy volunteers to allow for a thorough investigation of a serious adverse event that occurred in a single subject following the first dose in the 125 mg MAD group. Based on information available thus far, we believe the subject may have had a hypersensitivity reaction shortly after receiving their first dose of 125 mg of CHK-336. Comprehensive follow-up of this subject is ongoing, and Chinook is determining next steps for the program.

Corporate

- Chinook recently announced the appointment of Robert W. Azelby to its Board of Directors. Mr. Azelby brings more than 20 years of executive leadership and commercial experience in the biopharmaceutical industry to Chinook, including chief executive officer roles at Eliem Therapeutics and Alder Biopharmaceuticals, as well as chief commercial officer at Juno Therapeutics and commercial positions across Amgen's nephrology and oncology business units.

- In November 2022, Sairopa B.V., in which Chinook owns approximately a 36 percent equity interest, entered into an exclusive license and option agreement with Exelixis, Inc. for the development of ADU-1805, a monoclonal antibody targeting SIRPα. Under this agreement, Sairopa received an upfront payment of $40.0 million and an additional $35.0 million milestone payment when the FDA cleared Sairopa's Investigational New Drug (IND) Application for a phase 1 trial of ADU-1805 in adults with advanced solid tumors in the first quarter of 2023.

First Quarter 2023 Financial Results

- **Cash Position –** Cash, cash equivalents and marketable securities totaled $357.4 million at March 31, 2023, compared to $385.3 million at December 31, 2022.

- **Revenue –** Revenue for the quarter ended March 31, 2023 was $1.8 million compared to $2.7 million for the same period in 2022. The decrease was primarily due to revenue recognized under Chinook's license agreement with SanReno.
- **Expenses –**
    - Research and development expenses for the quarter ended March 31, 2023 were $50.9 million compared to $26.3 million for the same period in 2022. The increase was primarily due to higher licensing, contract research and manufacturing costs, employee-related costs, including stock-based compensation expense, as well as spending for consulting, outside services and other costs. These higher costs primarily resulted from completing enrollment of the phase 3 ALIGN trial, startup activities for additional atrasentan and BION-1301 clinical trials and an increase in hiring to support our clinical programs.
    - General and administrative expenses for the quarter ended March 31, 2023 were $11.4 million compared to $7.9 million for the same period in 2022. The increase was primarily due to higher employee-related costs, including stock-based compensation expense, and higher consulting and outside services costs.
    - The change in fair value of contingent consideration and contingent value rights liabilities for the quarter ended March 31, 2023 was an expense of $0.5 million compared to a benefit of $1.0 million for the same period in 2022. The increase in this non-cash expense primarily resulted from a change in estimate of the potential future proceeds derived from the Merck collaboration.
- **Net Loss –** Net loss for the first quarter of 2023 was $60.2 million, or $0.85 per basic share, compared to a net loss of $31.7 million, or $0.54 per share for the same period in 2022.

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 in phase 1 development. In addition, Chinook's research and discovery efforts are focused on building a pipeline of precision medicines for rare, severe chronic kidney diseases with defined genetic and molecular drivers. Chinook is leveraging insights from kidney single cell RNA sequencing and large CKD patient cohorts that have been comprehensively panomically phenotyped, with retained biosamples and prospective clinical follow-up, to discover and develop therapeutic candidates with mechanisms of action targeted 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, phase 3 clinical trial of BION-1301, phase 1/2 trial of BION-1301, phase 1 clinical trial of CHK-336, and submission for potential accelerated approval for atrasentan. 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 or other strategic collaborations, whether results of early clinical trials or preclinical studies will be indicative of the results of future trials, including our phase 3 ALIGN trial, 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 macroeconomic conditions on our business operations, including rising interest rates and inflation. 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.

Investor Contact:
Noopur Liffick
Senior Vice President, Investor Relations & Corporate Communications
investors@chinooktx.com

Media Contact:
Kelly North
Senior Manager, Investor Relations & Corporate Communications
media@chinooktx.com

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

	Three Months Ended March 31,	
	2023	2022
Collaboration and license revenue	$ 1,828	$ 2,697
Operating expenses:		
Research and development	50,883	26,252
General and administrative	11,404	7,868
Change in fair value of contingent consideration and contingent value rights liabilities	526	(1,038)
Amortization of intangible assets	433	429
Total operating expenses	63,246	33,511
Loss from operations	(61,418)	(30,814)
Investment and other income (expense), net	3,102	(95)
Loss before income taxes and equity method investment loss	(58,316)	(30,909)
Equity method investment loss	(1,861)	(775)
Net loss	$ (60,177)	$ (31,684)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.85)	$ (0.54)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	70,703	58,340

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

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 118,495	$ 115,438
Marketable securities	231,881	262,887
Accounts receivable	2,444	1,091
Prepaid expenses and other current assets	5,824	6,176
Total current assets	358,644	385,592
Marketable securities	7,002	6,989
Property and equipment, net	16,974	16,908
Restricted cash	2,074	2,074
Operating lease right-of-use assets	47,345	48,970
Investment in equity securities	41,200	41,200
Equity method investment	2,653	4,071
Intangible assets, net	23,854	24,287
In-process research & development	36,550	36,550
Goodwill	117	117
Other assets	7,462	7,326
Total assets	$ 543,875	$ 574,084
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	9,774	9,751
Accrued and other current liabilities	33,605	33,636
Operating lease liabilities	5,085	4,948
Contingent value rights liability	2,500	2,500
Total current liabilities	50,964	50,835
Contingent value rights liability - non-current	37,794	37,318
Contingent consideration liability	4,470	4,420
Deferred tax liabilities	5,076	5,076
Operating lease liabilities, net of current maturities	33,178	34,494
Total liabilities	131,482	132,143
Stockholders' equity	412,393	441,941
Total liabilities and stockholders' equity	$ 543,875	$ 574,084