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): November 10, 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 November 10, 2022, Chinook Therapeutics, Inc. ("Chinook") announced certain financial results for the third quarter ended September 30, 2022. A copy of Chinook's press release, titled "Chinook Therapeutics Provides Business Update and Reports Third Quarter 2022 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 November 10, 2022, titled "Chinook Therapeutics Provides Business Update and Reports Third Quarter 2022 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: November 10, 2022

Chinook Therapeutics, Inc.

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

Chinook Therapeutics Provides Business Update and Reports Third Quarter 2022 Financial Results

SEATTLE November 10, 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 quarter and nine months ended September 30, 2022.

"During the third quarter of 2022, we continued advancing our pipeline of clinical and preclinical programs for rare, severe chronic kidney diseases. We are pleased with the strong data presented at ASN Kidney Weekend 2022 from both our lead programs, atrasentan and BION-1301, in IgA nephropathy (IgAN), as well as from CHK-336 and our preclinical research approach," said Eric Dobmeier, president and chief executive officer of Chinook Therapeutics. "We look forward to 2023, when we plan to initiate a phase 3 study of BION-1301 in patients with IgAN, present data from the ongoing phase 1 clinical trial of CHK-336 in healthy volunteers in the first half and report topline proteinuria data from the ongoing phase 3 ALIGN study of atrasentan in the third quarter."

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 of atrasentan is currently enrolling patients with 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 at more than 160 sites in 21 countries. Chinook expects to report topline data from the six-month interim proteinuria endpoint analysis in the third quarter of 2023 to support a New Drug Application under the Subpart H accelerated approval pathway in the United States.

- In November 2022, the United States Patent and Trademark Office (USPTO) issued U.S. Patent No. 11,491,137, titled, "Methods of Improving Renal Function," which includes claims directed to methods of treating patients with IgAN with atrasentan, and expires in 2039 absent any patent term extensions.

- Chinook presented updated interim data from the IgAN patient cohort of the phase 2 AFFINITY trial in a poster presentation at ASN Kidney Week 2022 in November, demonstrating consistent and clinically meaningful proteinuria reductions in patients with IgAN already on a maximally tolerated and stable dose of a RAS inhibitor. Specifically, atrasentan demonstrated mean reductions in 24-hour urine protein creatinine ratio (UPCR) of 38.1% at six weeks of treatment, 48.3% at 12 weeks of treatment and 54.7% at 24 weeks of treatment. After 24 weeks of treatment, 15 of the 19 patients (79%) who had completed this visit had greater than a 40% reduction in UPCR. There were no meaningful changes in blood pressure or acute eGFR effects, suggesting proteinuria reductions were not primarily due to hemodynamic effects of atrasentan, and there were no increases in BNP or mean bodyweight, suggesting minimal fluid retention. Atrasentan was well-tolerated, with no treatment-related serious adverse events.

- Chinook has completed enrollment of the IgAN patient cohort of the AFFINITY trial, and continues to enroll the other cohorts, including patients with focal segmental glomerulosclerosis (FSGS), Alport syndrome and diabetic

- kidney disease in combination with SGLT2 inhibitors. Chinook plans to report additional data from the AFFINITY trial in 2023.

- Chinook presented a preclinical research poster at ASN Kidney Week 2022 on single-cell RNA-seq of a mouse model of IgAN, revealing a prominent expansion of failed repair proximal tubular epithelial cells, which was reversed by atrasentan but not by ACE inhibition.

BION-1301

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) to prevent the formation of pathogenic immune complexes has been demonstrated clinically in both healthy volunteers and patients with IgAN.

- Chinook is currently finalizing trial design, conducting site and country feasibility and pursuing regulatory interactions to enable initiation of a global phase 3 trial of BION-1301 in 2023.

- Enrollment of up to 30 patients in Cohort 2 of Part 3 of the ongoing phase 1/2 trial of BION-1301 is ongoing. Patients in Cohort 2 receive a subcutaneous (SC) dose of 600 mg of BION-1301 every two weeks.

- Chinook presented additional interim data from Cohorts 1 and 2 in a poster presentation at ASN Kidney Week 2022 in November, further demonstrating BION-1301's disease-modifying potential in IgAN by generating rapid and durable reductions in mechanistic biomarkers and corresponding clinically meaningful proteinuria reductions within three months of initiating treatment, which was consistent across both cohorts.

  In Cohort 1, patients transitioned from intravenous (IV) dosing at 450 mg every two weeks to SC dosing at 600 mg every two weeks after at least 24 weeks of treatment. Reductions in IgA and Gd-IgA1 were maintained beyond 52 weeks of treatment. Reductions in IgM, and to a lesser extent IgG, were also observed. BION-1301 demonstrated mean reductions in 24-hour UPCR of 30.4% in seven patients at 12 weeks of treatment, 48.8% in all eight patients at 24 weeks of treatment, 66.9% in all eight patients at 52 weeks of treatment, 67.4% in four patients at 76 weeks of treatment and 71.0% in two patients at 100 weeks of treatment.

  In Cohort 2, SC BION-1301 treatment resulted in rapid and sustained reductions in IgA and Gd-IgA1, IgM, and to a lesser extent IgG, through 24 weeks of treatment, highly consistent with Cohort 1. BION-1301 demonstrated mean reductions in 24-hour UPCR of 28.7% in 15 patients at 12 weeks of treatment and 53.8% in 9 patients at 24 weeks of treatment, similar to reductions observed at the same timepoints in Cohort 1.

  In both cohorts, BION-1301 was well-tolerated, with no serious adverse events or treatment discontinuations due to adverse events, and no anti-drug antibodies were observed.

- BION-1301 was granted orphan drug designation for the treatment of primary IgAN by the European Commission in July 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) and secondary hyperoxalurias driven by endogenous overproduction of oxalate.

- Chinook presented a poster on CHK-336 at ASN Kidney Week 2022, demonstrating preclinical efficacy in PH1 and PH2 mouse models, and the potential for benefit in non-genetic hyperoxalurias caused by oxalate overproduction was also described.

- The phase 1 single ascending dose (SAD) and multiple ascending dose (MAD) clinical trial evaluating CHK-336 in healthy volunteers is ongoing, and data from this trial is expected in the first half of 2023.

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.

- Chinook delivered an oral presentation at ASN Kidney Week 2022 in November on a multi-omics approach to the characterization of IgAN in the NURTuRE cohort, integrating clinical, histological, transcriptomic and serum proteomic data to gain deeper insights into patient stratification and IgAN disease pathogenesis.

- Chinook presented a poster in collaboration with Evotec at ASN Kidney Week 2022 in November on a human data-driven, patient-centric and multi-omics-enabled target identification framework focused on common cellular and molecular mechanisms of CKD by leveraging the NURTuRE and QUOD patient cohorts.

Corporate

- In April 2021, Chinook partnered with Van Herk Investments to create and fund a new company called Sairopa B.V. to advance the research and development of the non-renal antibodies generated through Aduro Biotech's B-Select platform. As of September 30, 2022 Chinook owns approximately a 36% interest in Sairopa and has one seat on its board of directors. Chinook will hold its shares in Sairopa until there is a liquidation event, at which time, in accordance with the CVR agreement, 50% of any net proceeds will accrue to the benefit of the CVR holders, net of deductions permitted, including taxes and certain other expenses.

- On November 1, 2022, Sairopa entered into an exclusive agreement with Exelixis, Inc. for the development of ADU-1805, a monoclonal antibody that targets SIRPα. Under the terms of the agreement, Sairopa will receive an upfront payment of $40 million from Exelixis and additional near-term milestones. Sairopa is eligible to receive additional payments if Exelixis exercises its option and upon achievement of specified clinical, commercial and net sales milestones, as well as tiered royalties on net sales worldwide.

Quarter and Nine Months Ended September 30, 2022 Financial Results

- **Cash Position –** Cash, cash equivalents and marketable securities totaled $397.7 million at September 30, 2022, compared to $355.1 million at December 31, 2021.

- **Revenue –** Revenue for the quarter and nine months ended September 30, 2022 was $2.5 million and $5.6 million, respectively, compared to less than $0.1 million and $0.4 million for the same periods in 2021. The

increase was primarily due to revenue recognized under Chinook's license agreement with SanReno Therapeutics and collaboration agreement with Lilly.

- **Expenses –**
    - Research and development expenses for the quarter and nine months ended September 30, 2022 were $42.0 million and $98.3 million, respectively, compared to $23.6 million and $72.1 million, respectively, for the same periods in 2021. The increase was primarily due to an increase in licensing and contract research and manufacturing costs, higher employee-related costs, including stock-based compensation expense, consulting and outside services fees, as well as facilities and other costs to continue the progression of our research and clinical programs.
    - General and administrative expenses for the quarter and nine months ended September 30, 2022 were $10.0 million and $26.5 million, respectively, compared to $6.8 million and $24.2 million, respectively, for the same periods in 2021. The increase was primarily due to higher employee-related costs, including stock-based compensation expense, and higher consulting and outside services costs to support our operations. The increase in the nine months ended September 30, 2022 was partially offset by a decrease in facilities costs.
    - The change in fair value of contingent consideration and contingent value rights liabilities for the quarter and nine months ended September 30, 2022 was expense of $7.7 million and $4.7 million, respectively, compared to expense of $0.2 million and $21.6 million, respectively, for the same periods in 2021. The increase in these non-cash expenses in the quarter ended September 30, 2022 was due to an increase in the fair value of the contingent value rights liability, primarily resulting from remeasuring the value of our preferred shares in Sairopa at estimated fair value, which resulted primarily from the Sairopa license agreement for ADU-1805. The decrease in the nine months ended September 30, 2022 was primarily due to a change in the fair value in the second quarter of 2021 to include the impact of Merck intending to evaluate MK-5890 in a phase 2 clinical study for a new indication, partially offset by an increase in the fair value of the contingent value rights liability primarily resulting from remeasuring the value of our preferred shares in Sairopa at estimated fair value.
- **Net Loss –** Net loss for the quarter and nine months ended September 30, 2022 was $56.0 million, or $0.83 per share, and $125.3 million, or $2.00 per share, respectively. Net loss for the quarter and nine months ended September 30, 2021 was $30.7 million, or $0.69 per share, and $110.5 million, or $2.54 per share, respectively.

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 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 being evaluated in a phase 1 clinical trial in healthy volunteers. In addition, Chinook is advancing 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, including the timing of the results of our phase 3 ALIGN trial and phase 2 AFFINITY trial of atrasentan, phase 1 clinical trial of CHK-336, and submission for potential accelerated approval. 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, 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 and macroeconomic conditions 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.

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Collaboration and license revenue	$ 2,501	$ 4	$ 5,616	$ 389
Operating expenses:				
Research and development	41,984	23,573	98,259	72,057
General and administrative	10,023	6,847	26,526	24,158
Change in fair value of contingent consideration and contingent value rights liabilities	7,741	167	4,719	21,563
Amortization of intangible assets	431	423	1,289	1,265
Total operating expenses	60,179	31,010	130,793	119,043
Gain on sale of assets to equity method investment	—	—	—	7,227
Loss from operations	(57,678)	(31,006)	(125,177)	(111,427)
Other income (expense), net	1,690	(69)	2,362	(175)
Loss before income taxes and equity method investment gain (loss)	(55,988)	(31,075)	(122,815)	(111,602)
Income tax benefit	—	463	—	1,204
Equity method investment gain (loss)	9	(84)	(2,496)	(84)
Net loss	$ (55,979)	$ (30,696)	$ (125,311)	$ (110,482)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.83)	$ (0.69)	$ (2.00)	$ (2.54)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	67,779	44,661	62,736	43,563

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

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 126,072	$ 181,724
Marketable securities	247,211	105,113
Accounts receivable:	2,919	10,061
Prepaid expenses and other current assets	5,468	3,741
Total current assets	381,670	300,639
Marketable securities	24,412	68,215
Property and equipment, net	16,827	18,935
Restricted cash	2,074	2,074
Operating lease right-of-use assets	50,546	55,385
Investment in equity securities	41,200	41,200
Equity method investment	5,118	8,205
Intangible assets, net	24,720	26,009
In-process research & development	36,550	36,550
Goodwill	117	117
Other assets	7,102	6,474
Total assets	$ 590,336	$ 563,803
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	11,843	8,580
Accrued and other current liabilities	25,583	17,104
Operating lease liabilities	4,810	4,401
Contingent value rights liability	2,500	10,000
Total current liabilities	44,736	40,085
Contingent value rights liability - non-current	30,430	24,591
Contingent consideration liability	4,040	5,160
Deferred tax liabilities	735	735
Operating lease liabilities, net of current maturities	35,759	39,589
Total liabilities	115,700	110,160
Stockholders' equity:	474,636	453,643
Total liabilities and stockholders' equity	$ 590,336	$ 563,803