# 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): August 8, 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 August 8, 2022, Chinook Therapeutics, Inc. ("Chinook") announced certain financial results for the second quarter ended June 30, 2022. A copy of Chinook's press release, titled "Chinook Therapeutics Provides Business Update and Reports Second 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 August 8, 2022, titled "Chinook Therapeutics Provides Business Update and Reports Second 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: August 8, 2022

**Chinook Therapeutics, Inc.**

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

**Chinook Therapeutics Provides Business Update and Reports Second Quarter 2022 Financial Results**

SEATTLE August 8, 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 six months ended June 30, 2022.

“During the second quarter of 2022, we executed well on advancing our pipeline of clinical and preclinical programs for rare, severe chronic kidney diseases. We continue to ramp up enrollment of patients in the phase 3 ALIGN trial for atrasentan, and the data we presented at ERA from the ongoing phase 2 AFFINITY trial of atrasentan demonstrated consistent and clinically meaningful proteinuria reductions in patients with IgAN,” said Eric Dobmeier, president and chief executive officer of Chinook Therapeutics. “For BION-1301, the additional data presented at ERA from the ongoing phase 1/2 trial reaffirms its disease-modifying potential in IgAN by demonstrating durable reductions in mechanistic biomarkers and corresponding impressive proteinuria reductions. We look forward to advancing BION-1301 into a phase 3 study for patients with IgAN in 2023. We are also continuing to make progress with dose escalation in the ongoing phase 1 trial of CHK-336 in healthy volunteers and expect to report data in the first half of 2023.”

**Recent Accomplishments and Updates**

***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 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 presented data from the IgAN patient cohort of the phase 2 AFFINITY trial in an oral presentation at the 59th ERA Congress in May 2022, demonstrating consistent and clinically meaningful proteinuria reductions at weeks six, 12 and 24 of treatment in patients with IgAN already on a maximally tolerated and stable dose of a RAS inhibitor. Specifically, atrasentan demonstrated a 38.0% geometric mean reduction in 24-hour urine protein creatinine ratio (UPCR) in 20 patients at six weeks of treatment, 49.9% geometric mean reduction in 24-hour UPCR in 18 patients at 12 weeks of treatment and 58.5% geometric mean reduction in 24-hour UPCR in 11 patients at 24 weeks of treatment. After 24 weeks of treatment, ten of the 11 patients (91%) who had completed this visit had greater than a 40% cumulative 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. There were no increases in BNP or mean bodyweight, suggesting minimal fluid retention. As of the April 22, 2022 data cutoff, atrasentan was well-tolerated in patients with IgAN, 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 three 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 the second half of 2022, as well as during 2023.

- Chinook delivered a mini-oral presentation at the 59th ERA Congress on preclinical mechanistic data describing atrasentan's effect to block mesangial cell injury and the pathogenic transcriptional networks driving IgAN progression in a model system.

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

- 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 SC dose of 600 mg of BION-1301 every two weeks. Chinook expects to report initial data from Cohort 2 in the second half of 2022.

- Based on the data generated to date in the ongoing phase 1/2 study and after consulting with an expert advisory panel, Chinook has decided to advance BION-1301 into phase 3 utilizing the current Cohort 2 dose of 600 mg SC every two weeks, and will not move forward with the optional Cohort 3. 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.

- Chinook presented additional interim data from Cohort 1 of Part 3 in a mini-oral presentation at the ERA Congress in May 2022, further demonstrating its disease-modifying potential in IgAN by generating durable reductions in mechanistic biomarkers and corresponding impressive proteinuria reductions within three months of initiating treatment. After at least 24 weeks of treatment, patients in Cohort 1 transitioned from IV dosing at 450 mg every two weeks to SC dosing at 600 mg every two weeks. BION-1301 treatment resulted in steady-state reductions in Gd-IgA1 in the range of 70–80%, demonstrating depletion of the pathogenic IgA variant, and establishing the potentially disease-modifying mechanism of BION-1301 by directly targeting the initial pathway in the pathogenesis of IgAN. Additionally, BION-1301 demonstrated a 48.8% geometric mean reduction in 24-hour UCPR in all eight patients at six months of treatment, a 70.9% geometric mean reduction in 24-hour UPCR in six patients at one year of treatment and a 69.1% geometric mean reduction in 24-hour UPCR in two patients at 1.5 years of treatment. As of the May 6, 2022 data cutoff, BION-1301 was well-tolerated, with no serious adverse events or treatment discontinuations due to adverse events.

- 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), secondary hyperoxaluria due to increased endogenous oxalate production and idiopathic stone formation.

- In April 2022, Chinook initiated dosing in a phase 1 clinical trial evaluating CHK-336 in healthy volunteers. 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 the 59th ERA Congress in May 2022 on the approach used in collaboration with Evotec to leverage the NURTuRE CKD biobank to generate mechanistic disease understanding for patient-centric, integrated target and biomarker discovery that will enable the development of novel precision treatments for CKD patient subsets.

***Corporate***

- In May 2022, Chinook completed an underwritten public offering of 7.6 million shares of common stock at a price to the public of $14.00 per share, including the exercise in full of the underwriters' option to purchase an additional 1.1 million shares of common stock. As part of the offering, Chinook sold to certain investors pre-funded warrants to purchase up to an aggregate of 1.1 million shares of common stock at a purchase price of $13.9999 per pre-funded warrant. The underwritten public offering resulted in gross proceeds to Chinook of $120.7 million.

- In April 2022, Chinook announced an outreach initiative in collaboration with the IgA Nephropathy Foundation and Komodo Health, leveraging data and technology to drive awareness of IgAN and engage key medical providers at nephrology practices across the U.S., with the goal of ensuring patients have access to optimal support and treatment options earlier in their disease journey.

**Quarter and Six Months Ended June 30, 2022 Financial Results**

- **Cash Position –** Cash, cash equivalents and marketable securities totaled $405.2 million at June 30, 2022, compared to $355.1 million at December 31, 2021.

- **Revenue –** Revenue for the quarter and six months ended June 30, 2022 was $0.4 million and $3.1 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.

- **Expenses –**

    - Research and development expenses for the quarter and six months ended June 30, 2022 were $30.0 million and $56.3 million, respectively, compared to $22.8 million and $48.5 million, respectively, for the same periods in 2021. The increase was primarily due to higher employee-related costs, including stock-based compensation expense, consulting and outside services fees, as well as facilities and other costs to continue progression of our research and clinical programs. The increase in the three months ended June 30, 2022 also included an increase in licensing and contract research and manufacturing costs. The increase in the six months ended June 30, 2022, was partially offset by a decrease resulting from an upfront fee of $3.3 million to Evotec International GmbH recognized in the same period in 2021.

    - General and administrative expenses for the quarter and six months ended June 30, 2022 were $8.6 million and $16.5 million, respectively, compared to $7.8 million and $17.3 million, respectively, for the same periods in 2021. The increase during the quarter ended June 30, 2022 was primarily due to higher consulting and outside services costs to support our operations and an increase in stock-based compensation expense, partially offset by lower facilities and other costs. The decrease during the six months ended June 30, 2022 was primarily due to lower employee-related costs and facilities and other costs, partially offset by an increase in stock-based compensation expense.

    - The change in fair value of contingent consideration and contingent value rights liabilities for the quarter and six months ended June 30, 2022 was a benefit of $2.0 million and $3.0 million, respectively, compared to expense of $19.6 million and $21.4 million for the same periods in 2021. The decrease in these non-cash expenses 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 and the sale of certain of our non-renal assets in exchange for preferred shares in Sairopa B.V.

- **Other –**

    - A $10.0 million development milestone under the Merck collaboration was earned in the fourth quarter of 2021 and received in the first quarter of 2022. We paid this milestone, net of taxes and expenses, to the CVR holders in the second quarter of 2022.

- **Net Loss –** Net loss for the quarter and six months ended June 30, 2022 was $37.6 million, or $0.61 per share, and $69.3 million, or $1.15 per share, respectively. Net loss for the quarter and six months ended June 30, 2021 was $42.6 million, or $0.97 per share, and $79.8 million, or $1.86 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 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 being evaluated in a phase 1 healthy volunteer trial. 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 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, 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.**
**Condensed Consolidated Statements of Operations**
**(In thousands, except per share amounts)**
**(Unaudited)**

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Collaboration and license revenue | $ 418 | $ 34 | $ 3,115 | $ 385 |
| Operating expenses: | | | | |
| Research and development | 30,023 | 22,787 | 56,275 | 48,484 |
| General and administrative | 8,635 | 7,768 | 16,503 | 17,311 |
| Change in fair value of contingent consideration and contingent value rights liabilities | (1,984) | 19,557 | (3,022) | 21,396 |
| Amortization of intangible assets | 429 | 422 | 858 | 842 |
| Total operating expenses | 37,103 | 50,534 | 70,614 | 88,033 |
| Gain on sale of assets to equity method investment | — | 7,227 | — | 7,227 |
| Loss from operations | (36,685) | (43,273) | (67,499) | (80,421) |
| Other income (expense), net | 767 | (39) | 672 | (106) |
| Loss before income taxes and share of net loss of equity method investment | (35,918) | (43,312) | (66,827) | (80,527) |
| Income tax benefit | — | 741 | — | 741 |
| Share of net loss of equity method investment | (1,730) | — | (2,505) | — |
| Net loss | $ (37,648) | $ (42,571) | $ (69,332) | $ (79,786) |
| Net loss per share attributable to common stockholders, basic and diluted | $ (0.61) | $ (0.97) | $ (1.15) | $ (1.86) |
| Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted | 61,983 | 43,861 | 60,175 | 43,004 |

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

| | June 30, 2022 | December 31, 2021 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 145,927 | $ 181,724 |
| Marketable securities | 216,687 | 105,113 |
| Accounts receivable | 3,115 | 10,061 |
| Prepaid expenses and other current assets | 5,670 | 3,741 |
| Total current assets | 371,399 | 300,639 |
| Marketable securities | 42,587 | 68,215 |
| Property and equipment, net | 17,500 | 18,935 |
| Restricted cash | 2,074 | 2,074 |
| Operating lease right-of-use assets | 52,277 | 55,385 |
| Investment in equity securities | 41,200 | 41,200 |
| Equity method investment | 5,345 | 8,205 |
| Intangible assets, net | 25,151 | 26,009 |
| In-process research & development | 36,550 | 36,550 |
| Goodwill | 117 | 117 |
| Other assets | 7,042 | 6,474 |
| Total assets | $ 601,242 | $ 563,803 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | 4,907 | 8,580 |
| Accrued and other current liabilities | 17,373 | 17,104 |
| Operating lease liabilities | 4,701 | 4,401 |
| Contingent value rights liability | 2,500 | 10,000 |
| Total current liabilities | 29,481 | 40,085 |
| Contingent value rights liability - non-current | 22,509 | 24,591 |
| Contingent consideration liability | 4,220 | 5,160 |
| Deferred tax liabilities | 735 | 735 |
| Operating lease liabilities, net of current maturities | 37,166 | 39,589 |
| Total liabilities | 94,111 | 110,160 |
| Stockholders' equity | 507,131 | 453,643 |
| Total liabilities and stockholders' equity | $ 601,242 | $ 563,803 |