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 8, 2021

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) 485-7051

1600 Fairview Avenue East, Suite 100
Seattle, WA 98102
(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 240.13e-4(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 8, 2021, Chinook Therapeutics, Inc. ("Chinook") announced certain financial results for the third quarter ended September 30, 2021. A copy of Chinook's press release, titled "Chinook Therapeutics Provides Business Update and Reports Third Quarter 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 November 8, 2021, titled "Chinook Therapeutics Provides Business Update and Reports Third Quarter 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: November 8, 2021

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 2021 Financial Results

SEATTLE November 8, 2021 – 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 third quarter ended September 30, 2021.

“During the third quarter of 2021, we focused on execution and advancement of our lead clinical programs, atrasentan and BION-1301 for IgA nephropathy, a serious progressive disease for which there are no approved therapies. We are advancing enrollment in the ALIGN and AFFINITY studies of atrasentan, and the data we recently presented at ASN from the ongoing phase 1/2 study of BION-1301 in patients with IgAN shows consistent mechanistic biomarker responses and clinically meaningful reductions in proteinuria within three months of initiating treatment, demonstrating its potential as a novel disease-modifying therapy,” said Eric Dobmeier, president and chief executive officer of Chinook Therapeutics. “We’re enthusiastic about the potential of precision medicine to provide new treatments for kidney disease, and we look forward to continuing to advance our other pipeline programs, including initiating a phase 1 study of CHK-336 next year and making progress on our research and discovery programs.”

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 progress 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 U.S.

- Chinook continues to enroll all four cohorts of the phase 2 AFFINITY basket trial, including patients with lower proteinuria IgAN (between 0.5 and 1.0 g/day), focal segmental glomerulosclerosis (FSGS), Alport syndrome and diabetic kidney disease in combination with SGLT2 inhibitors. Chinook expects to present data from the IgAN patient cohort of this study in the first half of 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 ASN Kidney Week 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.

- Analysis of three separate single-dose, randomized phase 1 studies of atrasentan demonstrated 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.

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 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.

- Chinook recently initiated enrollment of Cohort 2 of Part 3 of the ongoing phase 1/2 study of BION-1301. Patients in Cohort 2 will receive a subcutaneous dose of 600 mg of BION-1301 every two weeks for up to 52 weeks.

- Chinook expects to present additional data from the ongoing phase 1/2 trial of BION-1301 in patients with IgAN and provide an update on planned later-stage clinical trials of BION-1301 in the first 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, secondary hyperoxaluria due to increased endogenous oxalate production and idiopathic stone formation.

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

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.

Third Quarter 2021 Financial Results

- **Cash Position –** Cash, cash equivalents and marketable securities totaled $204.8 million at September 30, 2021, compared to $250.4 million at December 31, 2020.

- **Revenue –** Total revenue increased by less than $0.1 million for the third quarter of 2021 and increased by $0.4 million for the nine months ended September 30, 2021, compared to the same periods in 2020 due to revenue recognized related to research and development services provided under the collaboration agreement with Lilly, which was acquired under the merger with Aduro.

- **Expenses –**

    - Research and development expenses were $23.6 million for the third quarter of 2021 and $72.1 million for the nine months ended September 30, 2021, compared to $7.6 million and $14.3 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, including salaries, benefits and stock-based compensation expense associated with hiring staff to build out Chinook's clinical and development capabilities; increased spending for consulting and outside services; costs related to our collaboration with Evotec; and an increase in facilities and other costs.

    - General and administrative expenses were $6.8 million for the third quarter of 2021 and $24.2 million for the nine months ended September 30, 2021, compared to $2.9 million and $8.0 million, respectively, for the same periods in 2020. The increase was primarily due to higher employee-related costs, including salaries, benefits and stock-based compensation expense associated with the addition of administrative staff to build out Chinook's public-company infrastructure; higher legal, consulting and outside services costs; and an increase in facilities and other costs.

    - Expenses due to the change in fair value of contingent consideration and contingent value rights liabilities were $0.2 million for the third quarter of 2021 and $21.6 million for the nine months ended September 30, 2021, compared to nil for the same periods in 2020. These non-cash expenses are due to the quarterly revaluation of assets and liabilities related to the Sairopa transaction and an updated valuation of Chinook's CVR liability under the Merck collaboration, as a result of the merger with Aduro. In the second quarter of 2021, Merck informed Chinook that it intends to explore the potential benefit of the product candidate MK-5890 in a phase 2 clinical study for a new indication, which may result in potential milestone and royalty payments under the Merck collaboration for the benefit of CVR holders.

- **Other –**
    - The sale of certain of Chinook's non-renal assets to Sairopa in the second quarter of 2021 resulted in a $7.2 million gain for the nine months ended September 30, 2021.

- **Net Loss –** Net loss for the third quarter of 2021 was $30.7 million or $0.69 per share and $110.5 million or $2.54 per share for the nine months ended September 30, 2021, compared to net loss of $18.8 million or $4.50 per share and $31.7 million or $7.65 per share, respectively, for the same periods in 2020.

- **Cash Used in Operations –** For the nine months ended September 30, 2021, cash used in operations totaled $80.2 million.

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. 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.

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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Collaboration and license revenue	$ 4	$ —	$ 389	$ —
Operating expenses:				
Research and development	23,573	7,575	72,057	14,263
General and administrative	6,847	2,898	24,158	8,048
Change in fair value of contingent consideration and contingent value rights liabilities	167	—	21,563	—
Amortization of intangible assets	423	—	1,265	—
Total operating expenses	31,010	10,473	119,043	22,311
Gain on sale of assets to equity method investment	—	—	7,227	—
Loss from operations	(31,006)	(10,473)	(111,427)	(22,311)
Other income (expense):				
Other income (expense), net	(69)	20	(175)	135
Change in fair value of redeemable convertible preferred stock tranche liability	—	(8,364)	—	(9,533)
Loss before income taxes and share of net loss of equity method investment	(31,075)	(18,817)	(111,602)	(31,709)
Income tax benefit	463	—	1,204	—
Share of net loss of equity method investment	(84)	—	(84)	—
Net loss	$ (30,696)	$ (18,817)	$ (110,482)	$ (31,709)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.69)	$ (4.50)	$ (2.54)	$ (7.65)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	44,661	4,185	43,563	4,147

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

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 108,522	$ 187,750
Marketable securities	75,513	59,622
Accounts receivable	11	262
Prepaid expenses and other current assets	2,496	6,447
Total current assets	186,542	254,081
Marketable securities	20,739	3,000
Property and equipment, net	19,327	20,626
Restricted cash	2,074	1,750
Operating lease right-of-use assets	56,948	55,673
Equity method investment	9,888	—
Intangible assets, net	26,432	27,696
In-process research & development	36,550	39,295
Goodwill	18,541	22,441
Other assets	6,243	4,440
Total assets	$ 383,284	$ 429,002
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	5,511	3,995
Accrued and other current liabilities	13,867	15,674
Operating lease liabilities	4,194	3,045
Deferred revenue	—	95
Total current liabilities	23,572	22,809
Contingent value rights liability	29,327	13,780
Contingent consideration liability	4,670	1,800
Deferred tax liabilities	15,172	16,377
Operating lease liabilities	40,763	38,709
Other long-term liabilities	—	905
Total liabilities	113,504	94,380
Stockholders' equity	269,780	334,622
Total liabilities and stockholders' equity	$ 383,284	$ 429,002