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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2022

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number 001-37345

CHINOOK THERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**94-3348934**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

400 Fairview Avenue North, Suite 900
Seattle, WA 98109
(Address of principal executive offices including zip code)

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

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)

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☒ NO ☐

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
		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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the Registrant's common stock held by non-affiliates as of June 30, 2022, based on the closing price of the shares of common stock on the Nasdaq Stock Market for such date, was $896,480,697.

The number of shares of Registrant's Common Stock outstanding as of February 17, 2023 was 65,846,156.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement for its 2023 Annual Meeting of Stockholders, or the 2023 Proxy Statement, to be filed within 120 days of the Registrant's fiscal year ended December 31, 2022, are incorporated by reference in Part III, Items 10 through 14 of this Annual Report on Form 10-K. Except with respect to information specifically incorporated by reference in this Annual Report on Form 10-K, the 2023 Proxy Statement is not deemed to be filed as part hereof.

Auditor Firm Id:	238	Auditor Name:	PricewaterhouseCoopers LLP	Auditor Location:	Seattle, Washington, United States

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Corporate Information

Chinook Therapeutics, Inc. (the "Company", "Chinook", "we", "our", or "us) is a clinical-stage biopharmaceutical company. On October 5, 2020, Aduro Biotech, Inc. ("Aduro") completed its merger with Chinook Therapeutics U.S., Inc. ("Private Chinook"), pursuant to the terms of a merger agreement dated as of June 1, 2020, and amended on August 17, 2020, by which a wholly owned subsidiary of Aduro merged with and into Private Chinook, with Private Chinook continuing as a wholly owned subsidiary of Aduro (the "Merger"). Immediately following the Merger, Aduro changed its name to "Chinook Therapeutics, Inc." and the business conducted by Private Chinook became the primary business conducted by the Company.

Forward Looking Statements

This Annual Report on Form 10-K contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements, other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future financial condition, business strategy and plans, and objectives of management for future operations, are forward-looking statements. In some cases you can identify these statements by forward-looking words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect" or the negative or plural of these words or similar expressions. These forward-looking statements include, but are not limited to, statements concerning the following:

- our ability to develop and commercialize our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our ability to fund our working capital needs for at least the next twelve months;
- our ability to use and expand our technologies to build a pipeline of product candidates;
- the potential of our technologies and our ability to execute on our corporate strategy;
- the strength and breadth of our patent portfolio;
- the potential for receipt of additional milestone payments;
- our ability to obtain and adequately protect intellectual property rights for our product candidates;
- our continued reliance on third parties for manufacturing our product candidates, conducting our clinical trials and certain research activities;
- our ability to in-license, acquire or invest in complementary businesses, technologies, products or assets to further expand or complement our portfolio of product candidates;
- expected timing of our clinical trials;
- the timing and availability of results of our clinical trials and those of our collaborators;
- general economic and market conditions, including rising interest rates and inflation and the economic impact of the war in Ukraine; and
- our ability to extend our operating capital.

These statements are only current predictions and are subject to known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. We discuss many of these risks in greater detail under the heading "Risk Factors" and elsewhere in this Annual Report on Form 10-K. You should not rely upon forward-looking statements as predictions of future events. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risks and uncertainties.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, after the date of this report, we are under no duty to update or revise any of the forward-looking statements, whether as a result of new information, future events or otherwise.

We obtained industry, market and competitive position data in this report from our own internal estimates and research as well as from industry and general publications and research surveys and studies conducted by third parties. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such information or estimates.

PART I

Item 1. Business.

Overview

Chinook is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing precision medicines for kidney diseases. Our pipeline is focused on rare, severe chronic kidney diseases with well-defined clinical pathways. Our lead clinical program is atrasentan, a potent and selective endothelin A receptor antagonist. We are currently conducting the phase 3 ALIGN trial of atrasentan for IgA nephropathy, or IgAN, and the phase 2 AFFINITY basket trial for proteinuric glomerular diseases. We most recently presented interim data from the IgAN patient cohort of the AFFINITY trial at the American Society of Nephrology, or ASN, Kidney Week in November 2022. In addition, enrollment in the ALIGN trial to date exceeds 270 patients. The interim proteinuria endpoint analysis will be performed on the first 270 patients enrolled, and we expect to report topline data from this analysis in the second half of 2023 to potentially support an application for accelerated approval under Subpart H in the United States. Our second product candidate, BION-1301, is an anti-APRIL monoclonal antibody also in phase 2 development for patients with IgAN. We most recently presented interim results from the ongoing phase 1/2 trial at ASN Kidney Week in November 2022. Our third product candidate is CHK-336, an oral small molecule lactate dehydrogenase, or LDHA, inhibitor for the treatment of primary and idiopathic hyperoxaluria that is currently in a phase 1 clinical trial in healthy volunteers. In addition, we are conducting research programs in several other rare, severe chronic kidney diseases. We seek to build our pipeline by leveraging insights from kidney single cell RNA sequencing and large chronic kidney disease, or 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 support these efforts, we have an ongoing strategic collaboration with Evotec SE, or Evotec, to jointly identify, characterize and validate novel mechanisms and discover precision medicines for lupus nephritis, IgAN, polycystic kidney disease, or PKD, and other primary glomerular diseases. We also continue to evaluate opportunities to in-license kidney disease programs to bolster our pipeline. In November 2021, we established SanReno Therapeutics, or SanReno, a joint venture to develop, manufacture and commercialize kidney disease therapies in mainland China, Hong Kong, Macau, Taiwan and Singapore. We believe that a strong local presence in East Asia may allow us to accelerate the clinical development and maximize the commercial potential of atrasentan and BION-1301, the two programs licensed to SanReno, in the region.

Chronic kidney disease is a large and growing problem globally, with few approved therapies and a large unmet medical need. Nearly one-in-ten people globally suffer from chronic kidney disease. In the United States alone, it is estimated that over $130 billion is spent annually on managing and treating kidney diseases, much of which is dedicated to dialysis, transplant and supportive care after a patient's kidneys have already failed. Despite the large unmet medical need, there are few drugs approved to prevent the progression of kidney disease. Drug development in nephrology has historically been hindered by categorization of disease based on clinical presentation or kidney pathology, rather than underlying molecular mechanism or genetics. This has resulted in the development of drugs with non-specific mechanisms to address broad indications that contain heterogeneous patient populations with a variety of distinct disease drivers. Complicating matters, large, lengthy and expensive clinical outcome-based clinical trials have been required to establish proof of concept and regulatory approval for new drugs.

We believe now is an opportune time for precision medicine to be applied in kidney disease, since many of the historical barriers can be overcome. The field is rapidly changing as an increased understanding of underlying disease biology has led to new and validated drug targets, novel translational platforms, and patient stratification tools. Importantly, regulators have recently accepted biomarkers such as proteinuria and eGFR as registration endpoints in certain well-characterized disease populations, potentially reducing the time and cost previously associated with clinical trials in nephrology.

Our approach to precision medicines leverages recent advances in identifying targeted kidney therapies linked to mechanistic biomarkers by the application of systems biology approaches in nephrology. The application of this approach in nephrology has advanced over the past decade through the study of multiple patient groups across a wide variety of kidney diseases and their associated multilevel data sets, including genome, transcriptome, proteome, metabolome, pathology and prospective long-term clinical characteristics and outcomes. A key objective of these investigations is to define kidney diseases in molecular terms to drive the development of targeted treatments. We believe we are well-positioned to exploit the insights provided into the key molecular drivers and classifiers of kidney diseases by the application of these systems biology tools to nephrology. Our strategy is to use these mechanistic insights to select compelling drug targets and deliver novel and differentiated product candidates for rare and severe kidney diseases with high unmet medical need.

We believe our research and discovery approach provides significant insights into human disease mechanisms and allows us to select and validate key targets that are central drivers of human kidney diseases.

Atrasentan

Our lead product candidate is atrasentan, a potent and selective endothelin A receptor, or ET_A receptor, antagonist that we are developing for the treatment of proteinuric glomerular diseases. In March 2021 we initiated a phase 3 trial of atrasentan called ALIGN for IgAN, and in April 2021 we initiated a phase 2 basket trial called AFFINITY for proteinuric glomerular diseases.

IgAN is the leading cause of primary glomerulonephritis worldwide, with an estimated incidence of 1.3 per 100,000 individuals per year in the United States. The global incidence of IgAN is approximately 2.5 per 100,000 individuals per year. Variations in disease incidence and prevalence are, in part, due to regional differences in urine screening, referral patterns and indications for biopsy.

We estimate that IgAN is associated with progressive loss of kidney function leading to end-stage kidney disease, or ESKD, in approximately 30% to 45% of IgAN patients over 20 to 25 years, representing a significant unmet need for new treatment options. Galactose-deficient immunoglobulin A1, or Gd-IgA1, is recognized as a critical autoantigen to which IgAN patients develop circulating autoantibodies, resulting in the formation and deposition of immune complexes in the glomeruli of the kidney. This process initiates an inflammatory cascade that damages the glomeruli, resulting in proteinuria or hematuria. Ultimately the filtration function of the kidney is impaired, reducing the ability to remove waste products from the blood. As the disease progresses, these waste products accumulate and can result in potentially life-threatening complications that often lead to the need for dialysis or kidney transplant. Sustained proteinuria is the most widely studied and the strongest predictor for the rate of progression to ESKD in IgAN.

Activation of the ET_A receptor has been implicated as a key driver of proteinuria, renal cell injury, including podocyte dysfunction and mesangial cell activation, along with promoting kidney inflammation and fibrosis, all resulting in the progression of IgAN. Atrasentan, by blocking ET_A, 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. We in-licensed atrasentan in December 2019 from AbbVie, which previously developed atrasentan for diabetic kidney disease, or DKD, through multiple clinical trials, including the phase 3 SONAR trial, which evaluated atrasentan in over 5,000 DKD patients. We presented new preclinical data elucidating the mechanism of action of atrasentan in IgAN at multiple nephrology congresses in 2021 and 2022, including most recently at ASN Kidney Week in November 2022. In preclinical studies, atrasentan rapidly reduced albuminuria and downregulated intra-renal transcriptional proliferative, inflammatory and fibrotic signaling in the gddY mouse IgAN model. The data also showed that atrasentan attenuated human renal mesangial cell activation induced by endothelin-1 or IgAN patient immune-derived immune complexes in a translational model system. Additionally, preclinical data presented at ASN Kidney Week in November 2022 on single-cell RNA-seq of a mouse model of IgAN, revealed a prominent expansion of failed repair proximal tubular epithelial cells, which was reversed by atrasentan but not ACE inhibition.

In 2015, AbbVie made a strategic decision to exit kidney disease drug development and ultimately discontinued the SONAR trial in 2017 when less than half of the planned events had occurred due to a lower than predicted annual occurrence of the primary renal outcome. Clinical investigators closed the trial per protocol during which time further events accrued, and in April 2019 the data was reported at the WCN and simultaneously published in *The Lancet*. At that time, after only 184 out of a planned 425 events had been observed, the trial showed a statistically significant p-value of 0.029 on its primary endpoint of a composite of hard kidney outcomes, consisting of time to first occurrence of progression to ESKD or doubling of serum creatinine. In the SONAR trial, atrasentan also demonstrated statistically significant reductions in proteinuria as well as improvements in the estimated glomerular filtration rate, or eGFR, both of which are measures of kidney function. Trial results showed atrasentan having well-characterized and manageable safety results in this high-risk DKD patient population. Fluid retention-related adverse events were more frequent in the atrasentan group than in the placebo group; however, these adverse events are a known class effect of endothelin receptor antagonists, and they were anticipated and generally well-managed in this high-risk diabetic population.

Based on the encouraging data from SONAR and strong mechanistic rationale, we initiated the phase 3 ALIGN trial of atrasentan in patients with IgAN at high risk of kidney function decline in March 2021. We chose IgAN as the lead indication for evaluation of atrasentan due to the role of endothelin activation and proteinuria in disease progression, potential improved tolerability of atrasentan in this patient population, high unmet need and the possibility of submitting a new drug application, or NDA, seeking accelerated approval based on surrogate endpoints, including proteinuria. In April 2021 we initiated the phase 2 AFFINITY trial in proteinuric glomerular diseases, including cohorts of patients with lower proteinuria IgAN, focal segmental glomerosclerosis, or FSGS, and Alport syndrome, as well as DKD combined with sodium glucose co-transporter 2, or SGLT2, inhibitors, such as canagliflozin, dapagliflozin or empagliflozin, which have recently been shown to provide clinical benefit in patients with multiple types of chronic kidney disease.

We most recently presented interim data from the IgAN patient cohort of the AFFINITY trial in a poster presentation at ASN Kidney Week in November 2022 where atrasentan demonstrated 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. As of the October 19, 2022 data cutoff, atrasentan demonstrated mean reductions in 24-hour urine protein creatinine ratio, or 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 proteinuria. Atrasentan was well-tolerated, with no treatment-related serious or severe adverse events. The mean treatment duration was 45 weeks, with time on treatment ranging from 13 to 52 weeks. 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 brain natriuretic peptide, or BNP, or mean bodyweight, suggesting minimal fluid retention.

We plan to present data from additional cohorts of the AFFINITY trial during the second half of 2023. In addition, enrollment in the ALIGN trial to date exceeds 270 patients. . The interim proteinuria endpoint analysis will be performed on the first 270 patients enrolled, and we expect to report topline data from this analysis in the second half of 2023 to potentially support an application for accelerated approval under Subpart H in the United States.

BION-1301

We are also developing BION-1301, an investigational humanized IgG4 monoclonal antibody that blocks APRIL, a TNF-family cytokine involved in B-cell signaling that is believed to be implicated in IgAN and other indications, from binding to its receptors.

Patients with IgAN have significantly higher levels of APRIL than healthy individuals, and higher APRIL levels in these patients correlate with poor prognosis in the form of increased Gd-IgA1, increased proteinuria and decreased eGFR. Published literature has demonstrated that APRIL critically drives IgA class switching, the survival of IgA-producing plasma cells and the secretion of Gd-IgA1 (Hit 1 in the multi-hit pathogenesis of IgAN). Blocking APRIL with BION-1301 is a distinct approach to treating IgAN by reducing circulating levels of Gd-IgA1, which is considered to be the pathogenic variant of IgA in IgAN. We believe BION-1301 represents a novel potential disease-modifying treatment for IgAN.

A phase 1/2 clinical trial of BION-1301 is currently underway. Parts 1 and 2 of this trial evaluating the safety and tolerability of BION-1301 in healthy volunteers have been completed, and Part 3 of this trial evaluating BION-1301 in patients with IgAN is ongoing. We most recently presented interim data from Cohorts 1 and 2 of Part 3 of this trial at ASN Kidney Week in November 2022. Patients in Cohort 1 started treatment at an intravenous, or IV, BION-1301 dose of 450 mg every two weeks, and after at least 24 weeks of treatment, all patients transitioned to subcutaneous, or SC, dosing at 600 mg every two weeks. In Cohort 2, patients started treatment at a SC BION-1301 dose of 600 mg every two weeks. In both cohorts, patients can receive treatment for up to a total of two years.

The data presented at ASN demonstrated 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, 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. In Cohort 1, 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 also 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.

Based on the data generated to date in the ongoing phase 1/2 study, we plan to advance BION-1301 into a phase 3 trial with the current Cohort 2 dose of 600 mg SC every two weeks. We have finalized our trial design, are conducting site and country feasibility assessments, pursuing regulatory interactions and manufacturing drug product for the trial, with a plan of initiating a global phase 3 trial of BION-1301 in mid-2023. We also have received orphan drug designation for BION-1301 for the treatment of primary IgAN from the European Commission.

CHK-336

Our third product candidate is CHK-336, a liver-targeted oral small molecule LDHA inhibitor, which we are developing for the treatment of primary hyperoxaluria, or PH, and idiopathic hyperoxaluria. Hyperoxalurias, including PH, are diseases caused by excess oxalate, a potentially toxic metabolite typically filtered by the kidneys and excreted as a waste product in urine. Symptoms of PH include recurrent kidney stones, which when left untreated, can result in kidney failure requiring dialysis or dual kidney/liver transplantation. In patients with hyperoxalurias, excess oxalate combines with calcium to form calcium oxalate crystals that deposit in the kidney, resulting in the formation of painful kidney stones and driving progressive kidney damage over time. PH1, PH2 and PH3 are a group of ultra-rare diseases caused by genetic mutations that result in excess oxalate, and in their most severe forms, can lead to ESKD at a young age. We presented a poster on CHK-336 at ASN Kidney Week in November 2022, demonstrating preclinical efficacy in PH1 and PH2 mouse models, and describing the potential for benefit in non-genetic hyperoxalurias caused by oxalate overproduction. We are currently conducting a phase 1 single ascending dose and multiple ascending dose clinical trial in healthy volunteers evaluating the safety, tolerability and pharmacokinetic profile of CHK-336, and we expect to report initial data from this trial in the first half of 2023. We have also received rare pediatric disease designation from the U.S. Food and Drug Administration, or FDA, for CHK-336 for the treatment of PH.

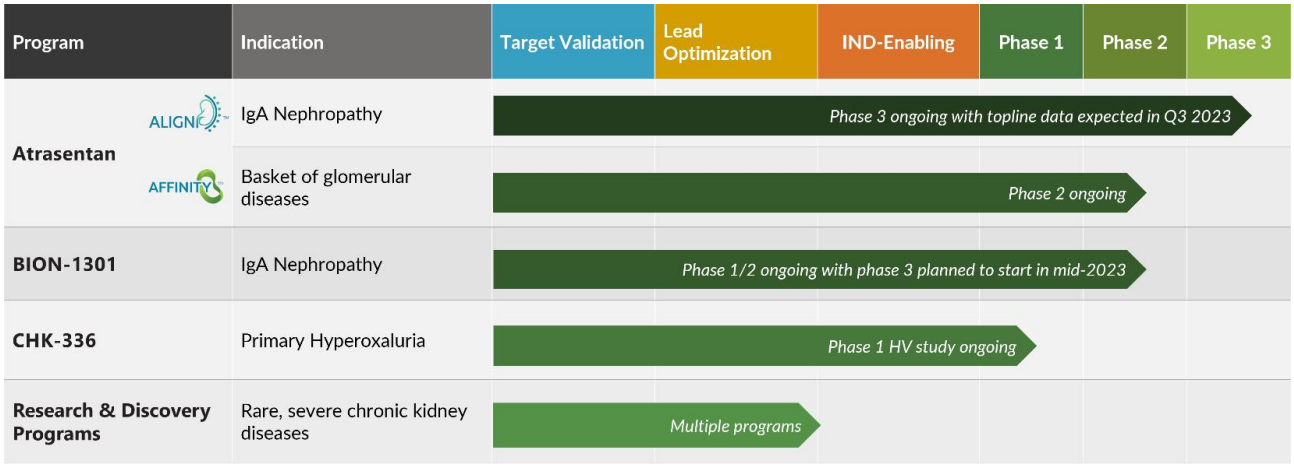
Research and Discovery Programs

Beyond CHK-336, we have active research and discovery efforts focused on other rare, severe kidney diseases. Our precision medicine research approach focuses on developing product candidates targeting the most promising molecular pathways identified as key disease drivers in collaboration with key scientific advisors. Our scientific advisors provide valuable guidance on target selection, prioritization and validation strategies, as well as access to technology platforms that support target validation efforts through biological insights into human disease mechanisms and translational cellular and animal model systems.

In March 2021, we announced a strategic collaboration with Evotec focused on the joint identification, characterization and validation of novel mechanisms as well as the discovery of precision medicines for lupus nephritis, IgAN, PKD and other primary glomerular diseases. The collaboration leverages access to the National Unified Renal Translational Research Enterprise, or NURTuRE, patient biobank for chronic kidney diseases and nephrotic syndrome as well as Evotec's proprietary PanOmics platform, which combines enhanced throughput proteomics, high throughput transcriptomics and cell imaging with PanHunter, Evotec's unique data analysis platform.

Our Pipeline

We have assembled a portfolio of precision medicine product candidates designed to address rare, severe chronic kidney diseases with potentially well-defined and efficient clinical pathways. We intend to further enhance our portfolio by identifying novel kidney disease targets for research and development and in-licensing promising product candidates for kidney diseases. Our development programs consist of the following:



Our Strategy

Our goal is to be a leader in the discovery, development and commercialization of precision medicines to treat kidney diseases. Our strategy includes the following key components:

Continue to advance the phase 3 ALIGN trial of atrasentan for IgAN towards an expected topline data readout from the interim proteinuria endpoint analysis in the second half of 2023, and present data from additional cohorts of the phase 2 AFFINITY basket trial for proteinuric glomerular diseases beginning in the second half of 2023. In March 2021 we initiated the phase 3 ALIGN trial of our lead product candidate, atrasentan, for IgAN. We received feedback from the FDA, and the European Medicines Agency, or the EMA, on the design of our phase 3 trial, which utilizes reduction in proteinuria after 24 weeks of treatment as the primary endpoint to support an application for accelerated approval under Subpart H in the United States, and reduction in eGFR decline following 2.5 years of treatment followed by a wash-out period as the potential confirmatory endpoint for full approval, if accelerated approval is granted. Enrollment in the ALIGN trial to date exceeds 270 patients. The interim proteinuria endpoint analysis will be performed on the first 270 patients enrolled, and we expect to report topline data from this analysis in the second half of 2023. We believe the hemodynamic, anti-fibrotic and anti-inflammatory properties of atrasentan, as well as its impact to reduce mesangial cell activation, could provide significant clinical benefit on top of standard-of-care renin-angiotensin inhibitors, or RASis, for patients with IgAN. In April 2021 we initiated the phase 2 AFFINITY basket trial in proteinuric glomerular diseases. We most recently presented interim data from the IgAN patient cohort of the AFFINITY trial in a poster presentation at ASN Kidney Week in November 2022, and we plan to present data from additional cohorts of the AFFINITY trial during the second half of 2023.

Initiate a global phase 3 trial of BION-1301 for IgAN in 2023. Based on the data generated to date in the ongoing phase 1/2 study, we plan to advance BION-1301 into a phase 3 trial with the current Cohort 2 dose of 600 mg SC every two weeks. We have finalized our trial design, are conducting site and country feasibility and pursuing regulatory interactions, with a plan of initiating a global phase 3 trial of BION-1301 in mid-2023.

Report data on CHK-336 from the phase 1 trial in healthy volunteers and initiate phase 2 POC trials for patients with primary and idiopathic hyperoxaluria. We are currently conducting a phase 1 single ascending dose and multiple ascending dose clinical trial in healthy volunteers evaluating the safety, tolerability and pharmacokinetic profile of CHK-336, and we expect to report initial data from this trial in the first half of 2023. We believe CHK-336 could represent an important new treatment option for patients with diseases caused by excess oxalate production and will continue to advance CHK-336 into proof-of-concept, or POC, trials for both primary and idiopathic hyperoxaluria.

Identify and validate novel targets and utilize translational platforms to develop a pipeline of product candidates for rare, severe chronic kidney diseases. Our chemistry and biology teams have partnered with our academic founders and key opinion leaders, to identify, validate and develop precision medicines to add to our preclinical pipeline. Our lead program from these internal research efforts is CHK-336 for hyperoxalurias, and we also have multiple active research programs underway in other rare, severe chronic kidney diseases. Our collaboration with Evotec will supplement our internal efforts to define the molecular drivers of kidney diseases, identify novel targets for drug development in selected patient sub-populations and continue to build the foundation for our precision medicine approach.

Enhance our product portfolio by identifying novel disease targets and in-licensing promising product candidates for kidney diseases. We are actively evaluating and pursuing novel targets, intellectual property and product candidates for acquisition and in-licensing to supplement our internal research efforts and continue to build our pipeline of precision medicines for kidney disease. Through our team's focus and expertise in kidney disease, as well as our connections within the nephrology community, we are positioning the company as a partner of choice for promising renal programs. We believe continued advances in the biological understanding of kidney diseases will provide opportunities to further expand our portfolio with preclinical and/or clinical product candidates.

Maintain broad commercial rights to our product candidates. We plan to maintain commercial rights for atrasentan and BION-1301 in North America and possibly Europe. In November 2021, we also established SanReno Therapeutics, a joint venture in China to develop, manufacture and commercialize kidney disease therapies in mainland China, Hong Kong, Macau, Taiwan and Singapore. There is a large unmet medical need due to the higher incidence and prevalence of IgAN among east-Asian populations, and we believe it is important to have a strong local presence that may allow us to accelerate the clinical development and maximize the commercial potential of atrasentan and BION-1301 in the region. As we continue to advance our programs, we may pursue additional strategic collaborations to share risk and supplement our resources at the appropriate time, especially in regions outside of North America.

Continue to strengthen and expand our intellectual property portfolio. We have an intellectual property portfolio that includes issued and pending claims for atrasentan and BION-1301, as well as pending claims relating to CHK-336, in the United States and other countries. We will also look to in-license any third-party patents relating to our pipeline programs as needed. Our proprietary position is reinforced by additional technical know-how and trade secrets. We continually assess and refine our intellectual property strategy and will file additional patent applications as appropriate.

Chronic Kidney Disease Background

CKD is a large and growing problem globally. In 2017, the global prevalence of CKD was 9.4 percent (697.3 million cases) and CKD has risen from the 29th leading cause of global disability-adjusted life-years, or DALYs, in 1990 for all ages to the 18th leading cause in 2019. Overall, nearly one in ten people around the world have CKD. In the United States alone, the health care system spends over $130 billion annually on kidney disease, much of which is dedicated to dialysis and transplant after a patient's kidneys have already failed. There have been few new drugs developed and approved for chronic kidney diseases over the past several decades. Current management of CKD largely consists of supportive care, focused mainly on controlling high blood pressure with medications. Therefore, there is a large unmet medical need for therapies that can delay or prevent progression of kidney disease, preserve kidney function and improve quality of life for people living with kidney disease. We are focused initially on developing atrasentan and BION-1301 in IgAN and other proteinuric glomerular diseases.

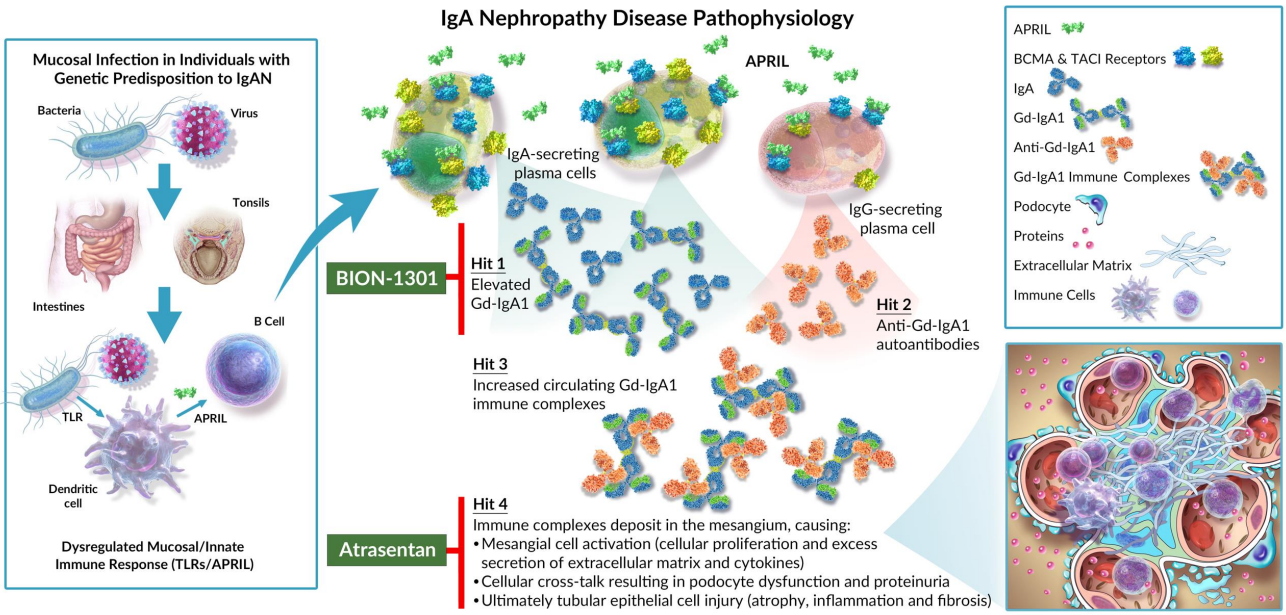
Immunoglobulin A Nephropathy (IgAN)

IgAN is the most common primary glomerular disease in the developed world and a leading cause of CKD and ESKD, requiring dialysis or kidney transplantation. Although the disease may follow a benign clinical course in many patients, it is estimated that up to 45 percent of IgAN patients will develop ESKD, requiring dialysis or kidney transplant, over a period of 20 to 25 years. IgAN is most

commonly diagnosed in the second or third decade of life and more commonly affects males in North America and Europe, while having equal gender prevalence in Asia. There is considerable regional and ethnic variation in the epidemiology of IgAN, with a higher incidence in Caucasians and Asians and a lower incidence in individuals of African descent. Worldwide, the incidence of IgAN has been estimated at 2.5 per 100,000. Limited data from population-based studies in the United States indicate that the annual incidence of biopsy-proven disease is approximately 1.3 per 100,000, giving rise to a lifetime risk of approximately one per 1,400 adults.

Recent research has suggested that an abnormal mucosal immune response stimulating the production of Gd-IgA1 (Hit 1), which is recognized as an autoantigen by circulating autoantibodies (Hit 2), may be the initiating event causing IgAN. As demonstrated in the figure below, immune recognition results in the formation of pathogenic immune complexes (Hit 3) that deposit in the kidney and activate mesangial cells (Hit 4), which are key cells in the kidney that provide structural support to the glomerulus. Activated mesangial cells proliferate and produce excess amounts of extracellular matrix components, such as cytokines and chemokines. Mesangial cell-podocyte crosstalk results in proteinuria, which is a key driver of disease progression and subsequent kidney function loss.

Excessive tubular reabsorption of filtered proteins is thought to stimulate a pro-inflammatory response in tubular epithelial cells that results in the secretion of cytokines, chemokines, growth factors and vasoactive molecules into the tubulointerstitial space. This results in interstitial inflammation and fibrosis, which drives kidney function decline.



The clinical presentation of IgAN is heterogenous and can range from intermittent hematuria and low-level proteinuria with a benign clinical course over time and a low risk of progression to ESKD, to a more aggressive form with high levels of proteinuria and rapid loss of kidney function. Given the variable disease course, a major advance in the care of IgAN patients is the recognition of prognostic factors that can identify patients at greater risk of progression to ESKD. These prognostic markers include the presence of hypertension, evidence of reduced eGFR, and the presence of sustained proteinuria of more than one gram per day. These factors, in addition to biopsy histologic characteristics, prior medication use and race/ethnicity, have given rise to a risk prediction tool that can stratify newly diagnosed patients into risk groups. Of these various factors, the strongest risk factor for rapid progression, identified through multivariate analyses, is sustained proteinuria. The importance of this factor was demonstrated in multiple studies showing that proteinuria over one gram per day was associated with more rapid kidney function loss in a dose-dependent fashion, and that interventions that reduce proteinuria to below one gram per day led to decreased risk of kidney failure. Therefore, clinical management of IgAN is focused on reduction of proteinuria in order to slow progression of kidney function loss.

Importantly, in patients whose proteinuria at diagnosis was greater than three grams per day, treatments that resulted in proteinuria reduction to less than one gram per day generally led to slowing of kidney function loss to a rate that was comparable to those with less than one gram per day proteinuria values at diagnosis. It is estimated that for every one-gram per day increase in proteinuria over a baseline of one gram per day there is a 10 to 25-fold higher risk of kidney failure.

The primary focus of patient management is to control glomerular pressure through the administration of hypertension medications, such as angiotensin converting enzyme inhibitors, or ACE inhibitors, and angiotensin II receptor blockers, or ARBs, as well as lifestyle management such as dietary salt restriction, smoking cessation, weight control and exercise. Patients who fail conservative management and continue to have levels of proteinuria greater than one gram per day have limited established safe and effective treatment options. Current treatment guidelines suggest that a six-month course of glucocorticoids can be administered to these patients, although the potential for toxicity needs to be carefully considered. There are only two drugs approved for the treatment of IgAN: Tarpeyo (budesonide), a corticosteroid, and Filspari (sparsentan), a dual ARB/endothelin receptor antagonist. Both drugs received accelerated approval based on a reduction in proteinuria for patients at risk of rapid progression, which is defined as those generally having UPCR > 1.5g/g. It has not yet been established whether either Tarpeyo or Filspari slow kidney function decline in patients with IgAN.

Other Proteinuric Glomerular Diseases

Many glomerular diseases, such as FSGS, Alport syndrome, membranous nephropathy and sickle cell nephropathy, include proteinuria as an important feature in disease progression. These glomerular diseases currently have very limited treatment options that often involve immunosuppressive therapy. For example, FSGS is an important cause of ESKD. There are currently no FDA-approved pharmacologic treatments for FSGS, and off-label treatments are limited to ACE inhibitors and ARBs, steroids and other immunosuppressant agents, which are effective in only a subset of patients. The global incidence of FSGS has been estimated at eight per million people and we estimate that there are approximately 40,000 FSGS patients in the United States and a similar number in Europe. Additionally, Alport syndrome is a rare, genetic form of CKD caused by mutations in the genes encoding type IV collagen, which is a major structural component of the glomeruli in the kidney. Patients with Alport syndrome experience a progressive worsening of the kidney's capacity to filter waste products out of the blood, which can lead to ESKD and the need for chronic dialysis treatment or a kidney transplant. Alport syndrome affects both children and adults. In patients with the most severe forms of the disease, approximately 50 percent progress to dialysis by age 25, 90 percent by age 40, and nearly 100 percent by age 60. According to the Alport Syndrome Foundation, the disease affects approximately 30,000 to 60,000 people in the United States. There are currently no approved therapies to treat Alport syndrome, and current management focuses on blood pressure control.

Our Product Candidates

Atrasentan

Our lead product candidate is atrasentan, a potent and selective endothelin A receptor antagonist that we are developing for the treatment of proteinuric glomerular diseases. Atrasentan is designed to reduce proteinuria and slow the progression of IgAN. In March 2021 we initiated a phase 3 trial of atrasentan called ALIGN for the treatment of IgAN, and in April 2021, we initiated a phase 2 basket trial called AFFINITY for the treatment of proteinuric glomerular diseases.

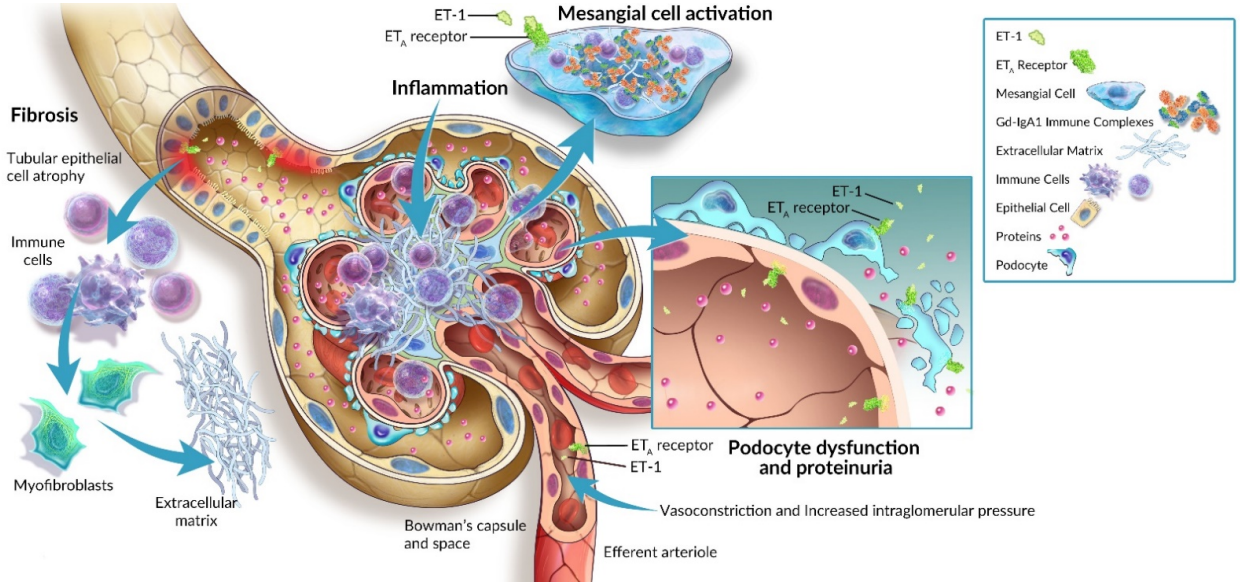
Endothelin System in Chronic Kidney Disease

The endothelin, or ET, system consists of three peptides, ET-1, ET-2 and ET-3, which typically act locally. ET-1 is considered of most biological relevance to kidney physiology and disease. Two ET receptors, ET_A and ET_B, mediate the effects of the ET peptides. ET_A receptor activation typically results in blood vessel constriction, cellular proliferation and extracellular matrix deposition, whereas ET_B activation generally opposes these effects producing blood vessel dilation, antiproliferative and antifibrotic responses.

In kidney physiology, the ET system modulates regional kidney blood flow, mesangial cell and podocyte function and tubular acid/base handling. The ET system also regulates sodium and water excretion, so blockade of ET receptors can be accompanied by fluid retention, which is a known clinical observation with this class of agents.

The kidney ET system is activated in virtually all causes of experimental and human CKD in which it has been investigated, irrespective of the initiating cause. Activation of the ET_A receptor by ET-1 has been implicated as a key driver of proteinuria, renal

cell injury, including podocyte dysfunction and mesangial cell activation, along with promoting kidney inflammation and fibrosis, all resulting in the progression of CKD. The key effects of ET_A activation in CKD are shown in the figure below.



ET-1 is a potent vasoconstrictor and its effects contribute to systemic and local increases in blood pressure in the kidney that support the progression of CKD. While this effect can help maintain glomerular filtration rate, or GFR, in the short term, ultimately, it is maladaptive and a central driver of kidney damage and CKD progression.

ET_A activation also appears to have additional direct negative effects in CKD, independent of its effects on blood pressure. These additional effects include increased permeability of the glomerular filtration barrier to proteins leading to proteinuria, mesangial cell activation and kidney inflammation and fibrosis. Pharmacological studies indicate that these pathogenic effects are primarily mediated by the ET_A receptor. Combined, these observations have encouraged the investigation of ET_A inhibition as a potential therapeutic strategy in CKD.

ET pathway activation has been documented in patients with IgAN. High kidney levels of ET-1 are often seen in patients with IgAN with high levels of proteinuria, and predict rapid progression of IgAN.

Mechanism of Action of Atrasentan

Atrasentan is designed to be a potent, selective blocker of the ET_A receptor to reduce proteinuria, kidney inflammation and fibrosis, and delay the progression of kidney function loss. In preclinical studies, atrasentan has shown substantially more potency as an ET_A receptor antagonist than ET_B, with an ET_A inhibition constant [Ki] = 0.034 nanomolar, or nM, more than 1,800-fold selective over ET_B ([Ki] = 63.3 nM). We believe atrasentan has the required selectivity profile for therapeutic benefit in CKD, while minimizing the potential for fluid retention.

Previous Clinical Development of Atrasentan

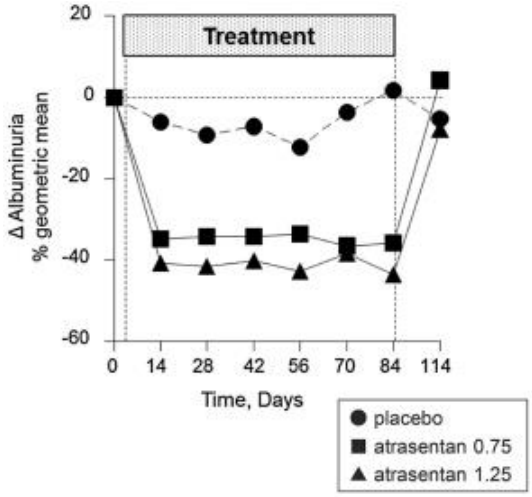
We in-licensed atrasentan from Abbvie in late 2019. Before AbbVie made the strategic decision to terminate development of atrasentan, it had been investigated in multiple phase 1, 2 and 3 clinical trials involving approximately 622 healthy volunteers, 2,000 patients with prostate cancer and more than 5,000 patients with DKD. Atrasentan is designed to be orally bioavailable, readily absorbed with linear dose proportionality and administered once daily. Dedicated pharmacokinetic studies in special populations have demonstrated that no dose adjustment was needed based on race, degree of renal impairment, or mild or moderate hepatic impairment. Population pharmacokinetic studies have shown that the only factor significantly affecting atrasentan exposure was body weight. In prior trials, the recommended dose for evaluating atrasentan in patients with DKD was determined to be 0.75 mg daily, which resulted in the greatest proteinuria reduction with least fluid retention.

Atrasentan demonstrated a statistically significant and clinically meaningful reduction in proteinuria, as assessed by urine albumin to creatinine ratio, or UACR, in multiple phase 2 and phase 3 trials in patients with DKD. In these trials, the change in UACR was generally observed within the first two weeks after treatment initiation and remained stable thereafter for the duration of chronic

administration. Across phase 2 and phase 3 trials, the placebo-adjusted mean reduction in proteinuria was approximately 30 to 35 percent, although considerable intra-subject and inter-subject variability has been observed.

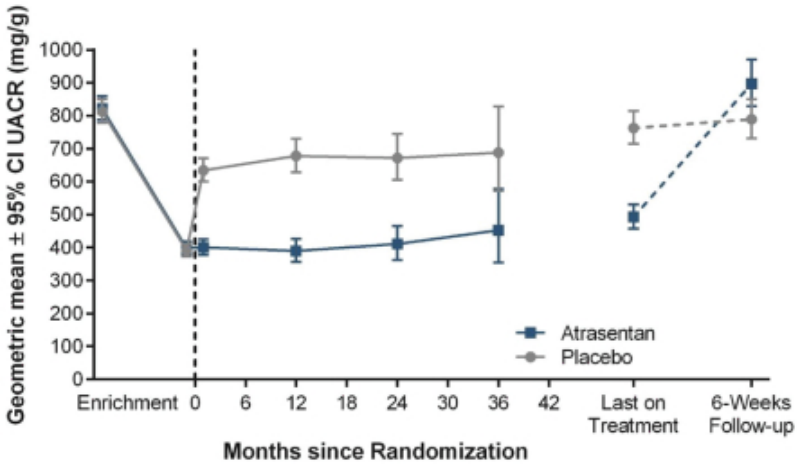
From 2013 to 2017, AbbVie conducted the global phase 3 SONAR trial, which was a randomized, double-blind, parallel, placebo-controlled, multicenter study designed to assess the effects of atrasentan on renal outcomes in patients with type 2 diabetes and CKD while they continued to be treated with the current standard of care. Despite early termination of the trial by AbbVie in 2017 for strategic reasons and due to a lower than anticipated accrual of primary endpoint events, patients who remained on trial and reached the primary endpoint of at least a 30 percent reduction in UACR following an initial six-week open label enrichment period with daily atrasentan experienced a clinically important and statistically significant improvement on the primary composite renal endpoint of time to doubling of serum creatinine or progression to ESKD (p-value=0.029). A similarly favorable trend was also observed in a smaller cohort of patients with a less than 30 percent UACR reduction in response to atrasentan following the six-week enrichment period (p-value=0.15).

The following figure shows mean UACR change from baseline to recovery for the placebo, 0.75 milligrams per day, or mg/d, atrasentan, and 1.25 mg/d atrasentan groups in AbbVie's phase 2b RADAR trial. The RADAR trial was a randomized, double-blind, placebo-controlled trial completed in 2012 that tested in 161 patients the effects of atrasentan on albuminuria reduction in patients with type 2 diabetes and nephropathy who were treated with the maximum tolerated labeled dose of a Renin Angiotensin System, or RAS, inhibitor.



The following figure shows the mean UACR levels in SONAR among the patients that experienced at least a 30 percent reduction in UACR following the initial six-week open label enrichment period. Among these 2,648 patients, UACR decreased from

baseline by an average of 51.8 percent during the enrichment period. During the double-blind period, UACR increased in the placebo group as compared to the atrasentan group (a difference of 33.6 percent, p-value<0.0001).



We believe the observed reduction in UACR across multiple clinical trials, as well as the favorable results observed on long-term renal outcomes, provide strong rationale for clinical evaluation of atrasentan in IgAN, a disease in which clinical management is centered around proteinuria reduction.

The most common and consistent safety findings across clinical studies of atrasentan in the DKD patient population were fluid retention and associated manifestations and dilutional anemia. In the phase 3 SONAR trial, fluid retention events were reported in approximately 26 percent of atrasentan-treated patients within the first six weeks. During the double-blind period, events of fluid retention were higher in the atrasentan groups (36.6 percent) than placebo groups (32.3 percent); however, across the population, atrasentan was associated with less than a one-kilogram increase in body weight and a six percent increase in brain natriuretic peptide levels, which is a peptide that is associated with fluid retention. In the phase 3 SONAR trial for patients with DKD, atrasentan was associated with a numerically higher, but not statistically significantly increased risk of heart failure hospitalizations due to fluid retention. Over time, anemia events were reported in approximately 18 percent of atrasentan patients compared with ten percent of placebo treated patients, with mean change in hemoglobin between groups of approximately one g/dL; these findings are consistent with mechanism-based hemodilution. Notably, there were no significant differences in adverse events leading to discontinuation during the double-blind treatment period between atrasentan and the placebo group. Importantly, no liver toxicity signal has been observed in over 5,000 patients with DKD treated for up to five years in the phase 3 SONAR study and nearly 2,000 prostate cancer patients at much higher doses. We currently have accumulated a total of over 5,000 patient years of treatment with atrasentan across all trials.

As a class, endothelin receptor antagonists have a well-characterized embryo-fetal toxicity profile, resulting in Risk Evaluation and Mitigation Strategies, or REMS, programs and mandatory birth control for women of child-bearing age. Filspari (sparsentan), a dual ARB/endothelin receptor antagonist that was granted accelerated approval by the FDA in February 2022 for adult patients with IgAN at risk of rapid progression, has a black box warning for embryo-fetal toxicity and is only available through the Filspari REMS. The black box warning states that based on animal data, Filspari can cause major birth defects if used during pregnancy. Pregnancy testing is required before, during and after treatment with Filspari. Patients who can become pregnant must use effective contraception prior to initiation of treatment, during treatment and for one month after treatment with Filspari. We expect the FDA to require similar restrictions on the use of atrasentan, if approved. The endothelin system is also known to play a role in spermatogenesis, and although atrasentan was linked to reduced sperm concentrations in a small study (n=17) evaluating the effect of atrasentan on sperm concentration, sperm concentrations subsequently recovered in the four affected patients to within the normal range following drug discontinuation. The impact of long-term atrasentan treatment on spermatogenesis and male fertility is not known.

Due to the differences in IgAN and DKD, we expect that the patient population in the phase 3 ALIGN trial of atrasentan will be younger and have fewer cardiovascular co-morbidities than in the SONAR study. Though patients in each clinical trial have a unique set of baseline characteristics, the median age of patients in the atrasentan phase 2 AFFINITY IgAN cohort was 45 years old and the mean ages of patients in Cohort 1 and Cohort 2 of the phase 1/2 trial of BION-1301 in IgAN were 42 and 40 years old respectively, while the mean age of patients in the SONAR trial was 65 years old. Additionally, patients with DKD are at greater risk of myocardial infarction, congestive heart failure and stroke than the non-diabetic population.

The diuretic effects achieved with SGLT2 inhibitors may offset the fluid retention effects of atrasentan, while the effects on albuminuria and kidney protection of both drug classes may be complementary due to distinct mechanisms of action. A third-party post-hoc analysis of the SONAR trial showed that in 14 patients with type 2 diabetes and CKD, six-weeks of treatment with atrasentan combined with an SGLT2 inhibitor versus atrasentan alone decreased body weight, a surrogate for fluid retention, and further decreased albuminuria. We believe this data and the increasing use of SGLT2 inhibitors in the non-diabetic CKD population provide rationale for the exploration of the long-term efficacy and safety of atrasentan in combination with SGLT2 inhibitors in IgAN.

Rationale for Atrasentan Development in IgAN

Chronic proteinuric kidney diseases, including IgAN and other proteinuric glomerular diseases, are characterized by progressive renal function loss, accompanied by excessive levels of urinary protein excretion, and have been proposed to progress by a final common pathway, irrespective of initiating cause. Glomerular hypertension, a maladaptive response to reduced kidney function, along with increased glomerular permeability results in the increased filtration of plasma proteins, which causes proteinuria. The consequent excess exposure of protein to glomerular and tubular epithelial cells has been shown preclinically to play a key pathogenic role in the progression of CKD. Kidney cells exposed to an excessive protein load release pro-fibrotic factors that can act locally to drive glomerulosclerosis. In vitro and in vivo studies have been used to develop a model of the final common pathway whereby excessive tubular reabsorption of filtered proteins stimulates a pro-inflammatory response that results in the secretion of cytokines, chemokines, growth factors and vasoactive molecules into the tubulointerstitial space. This results in interstitial inflammation and fibrosis, which drive renal function decline.

Clinical evidence consistent with proteinuria as a causal factor in CKD pathogenesis includes the observation that proteinuria is an independent predictor of disease progression. In IgAN, there appears to be a dose-dependent effect of proteinuria on the risk of renal progression, beginning at a urinary protein excretion rate of greater than one gram per day, with increasing levels of proteinuria associated with increased risk of ESKD. Sustained proteinuria has demonstrated to be the most important predictor of the rate of kidney progression in IgAN and sustained improvements in proteinuria to less than one gram per day are associated with an excellent long-term prognosis. The finding that the rate of eGFR decline correlates negatively with proteinuria reduction and positively with residual proteinuria provides further evidence for the pathogenetic role of proteinuria in CKD progression.

In preclinical studies, atrasentan has protected the kidney in nondiabetic CKD and has also been shown to reduce proteinuria and reduce the risk of progression to ESKD clinically in type 2 diabetics with CKD. In addition, a different ET_A antagonist significantly reduced proteinuria, diminished glomerular hypercellularity and prevented the loss of kidney function in a mouse model of IgAN. Further, in a randomized, double-blind, placebo and active controlled study in proteinuric CKD subjects already achieving optimal RAS inhibition, over half of which had biopsy-proven IgAN, selective ET_A antagonist sitaxsentan significantly reduced proteinuria and substantially reduced measured GFR and effective filtration fraction, consistent with a reduction in intraglomerular hypertension. In February 2022, the FDA granted accelerated approval to a treatment called Filspari (sparsentan), a dual ARB/endothelin receptor antagonist for adult patients with IgAN at risk of rapid progression. The effect of Filspari on proteinuria was assessed in a randomized, double-blind, active-controlled, multicenter, global study (PROTECT, NCT03762850) in adults with biopsy-proven IgAN, eGFR ≥30 mL/min/1.73 m^2 and total urine protein ≥r1.0 g/day on a maximized stable dose of RAS inhibitor treatment that was at least 50% of maximum labeled dose. Adjusted geometric mean percent change from baseline in UPCR at week 36 (95% CI) was -45% (-51%, 38%) in the Filspari arm and -15% (-24%, -4%) in the irbesartan control arm.

We are investigating atrasentan in IgAN based on the scientific rationale for targeting endothelin signaling, the strong association between high levels of protein excretion in IgAN and kidney function loss, the extent of clinical data demonstrating protein-lowering effects of atrasentan and other endothelin antagonists, the potential for a better tolerated dosing regimen in the IgAN patient population, and the clear unmet medical need for specific therapies to slow disease progression to ESKD.

Proteinuria as a Surrogate Marker for IgAN

CKD trials have historically relied on clinical outcomes for the primary endpoint, such as time to first occurrence of doubling of serum creatinine or ESKD (dialysis or transplantation). This generally requires very large trials of long duration, which have proved challenging in IgAN. The Kidney Health Initiative, or KHI, a partnership between the American Society of Nephrology and the FDA launched a project in 2016 to identify surrogate endpoints that could serve as reliable predictors of a treatment's effect on long-term kidney outcomes in IgAN and be used as a basis for accelerated approval. Surrogate endpoints are used in clinical trials as a substitute for a direct measure of how a patient feels, functions or survives and although they do not measure the clinical benefit of primary interest, they are expected to predict that clinical benefit. The KHI project focused on proteinuria reduction as the most widely recognized and studied risk factor for progression to ESKD in IgAN and found a consistent relationship between the level and duration of proteinuria and loss of kidney function from epidemiologic studies. In addition, trial-level analyses of 13 randomized IgAN clinical trials showed a strong association between treatment effects on percent reduction of proteinuria at approximately nine months (measurements ranged from seven to 12 months) and treatment effects on a composite of time to doubling of serum creatinine, ESKD, or death. The analyses also indicated that the reduction of proteinuria must be sustained to confer protection against

progressive loss of GFR. The KHI project concluded that proteinuria reduction is a surrogate endpoint reasonably likely to predict a treatment's effect on progression to ESKD in IgAN. In the United States, surrogate endpoints reasonably likely to predict clinical benefit can be used as a basis for accelerated approval of therapies intended to treat serious or life-threatening conditions, such as IgAN. The predicted clinical benefit of products granted accelerated approval must be verified in a post-marketing confirmatory trial.

A meta-analysis of 12 randomized clinical trials in IgAN to compare treatment effects on change in proteinuria to change in eGFR slope provides new evidence supporting the use of early reduction in proteinuria as a surrogate endpoint for studies of CKD progression in IgAN.

Ongoing Phase 3 ALIGN Trial of Atrasentan for the Treatment of IgAN

The ALIGN study, a phase 3, randomized, double-blind, placebo-controlled study of atrasentan in patients with IgAN at risk of progressive loss of kidney function, is designed to evaluate change from baseline in proteinuria and eGFR in 320 patients with IgAN. We have designed the trial in collaboration with a steering committee composed of leading global experts in glomerular diseases and are evaluating atrasentan at 0.75 mg daily, the dose used in the SONAR trial. The primary endpoint of the trial is change from baseline in proteinuria in the first 270 patients at 24 weeks following randomization. The key secondary endpoint is change from baseline in eGFR after all 320 patients have completed approximately two and half years of treatment. This global study is being conducted in over 20 countries on four continents at approximately 170 investigative sites. We initiated the trial in March 2021 and have enrolled over 270 patients to date. The interim proteinuria endpoint analysis will be performed on the first 270 patients enrolled, and we expect to report topline data from this analysis in the second half of 2023 to support potential accelerated approval.

We have held a Type B End of phase 2 meeting with the FDA to discuss the design of the ALIGN trial and, if the data from the trial are positive, we plan to seek approval of an NDA under the Subpart H accelerated approval pathway in the United States. Additionally, we have also received feedback on the study design from the EMA and the Pharmaceuticals and Medical Devices Agency, or PMDA, in Japan. Based upon this feedback, we believe that upon completion, the ALIGN trial could serve as the basis of a successful marketing authorization application, or MAA, in European countries, Japan, China and other countries.

At the ERA Congress in June 2022, we announced our two-pronged approach to evaluating atrasentan in combination with SGLT2 inhibitors. Our market research indicates that physician uptake of SGLT2 inhibitors is increasing. In addition, we believe the proteinuria and kidney protection benefits of the ET_A receptor antagonist and SGLT2 inhibitor drug classes have the potential to be complementary due to their distinct mechanisms of action, and the diuretic effects of SGLT2 inhibitors may offset the potential fluid retention of atrasentan. Data from a SONAR post-hoc analysis showed that in patients with DKD, six weeks of treatment with atrasentan combined with SGLT2 inhibitors vs. atrasentan alone further decreased albuminuria by 27.6% and decreased body weight, a surrogate for fluid retention, by 1.2 kilograms.

Due to its low hemodynamic effect and because it is not an immunosuppressive agent, we believe atrasentan is well-positioned to be combined with SGLT2 inhibitors. Therefore, we plan to include a combination stratum of patients who receive atrasentan on top of their stable dose of SGLT2 inhibitor in the ongoing phase 3 ALIGN study. In addition, we plan to initiate a phase 2 study of atrasentan in combination with an SGLT2 inhibitor in patients with IgAN in the first half of 2023.

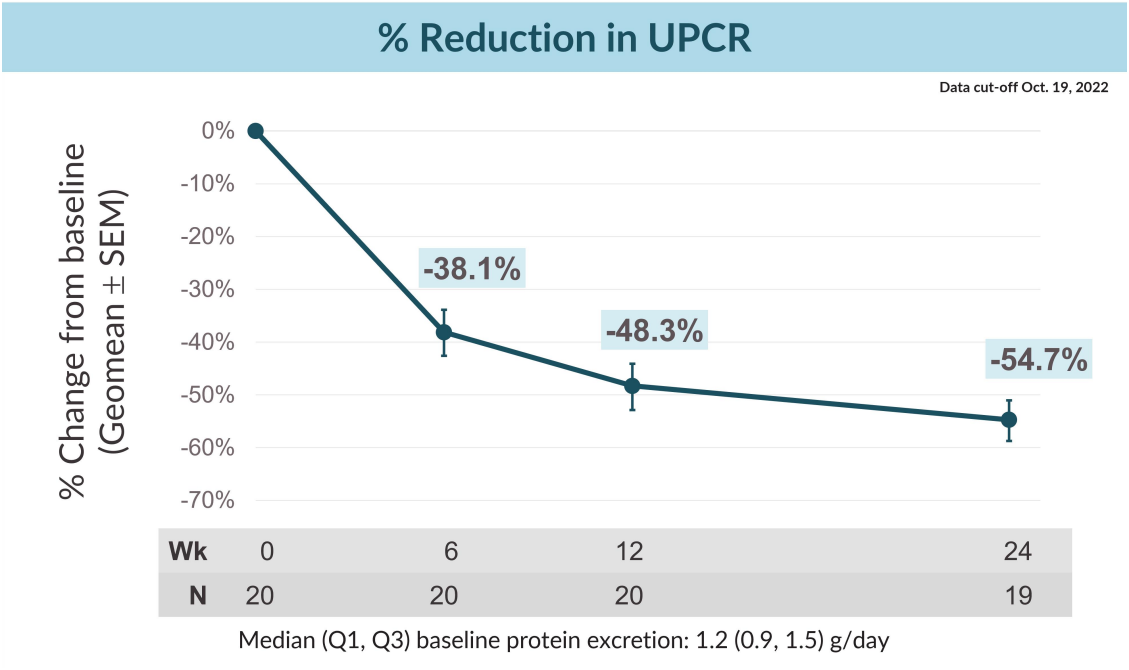
We believe our two-pronged approach will enable us to determine whether atrasentan may be combined with SGLT2 inhibitors. We have executed a protocol amendment to the ALIGN trial to enable the enrollment of a stratum of patients who are on a stable dose of an SGLT2 inhibitor. This will allow for a safety and efficacy exploratory analysis of the combination stratum for UPCR at 24 weeks and eGFR at 136 weeks, without any change to our enrollment timelines or the primary analysis for ALIGN. We are also planning to initiate a phase 2 study of atrasentan in combination with SGLT2 inhibitors that will enroll patients with IgAN at high risk for progression despite being on a stable optimized dose of RASi and an SGLT2 inhibitor. Patients will be randomized to placebo or atrasentan, and the primary endpoint will be change in UPCR from baseline to 12 weeks. This study will not be part of our regulatory package for approval of atrasentan, but it will provide additional data to inform potential future use of atrasentan. We plan to initiate this study in the first half of 2023.

In response to review of the statistical analysis plan for the ALIGN trial, we received correspondence from the FDA in February 2023 recommending that evaluation of the interim proteinuria endpoint analysis for accelerated approval in the ALIGN trial be delayed from week 24 to week 36. The FDA referenced the likelihood that the later timepoint would allow for a greater amount of eGFR data to be evaluated at the time of accelerated approval. We plan to engage with the FDA as soon as possible to discuss their advice. If we shift the interim proteinuria endpoint analysis of the ALIGN trial to 36 weeks, topline proteinuria data would be expected in the fourth quarter of 2023. Therefore, we are updating our timing to report topline proteinuria data from the ALIGN trial to the second half of 2023.

Ongoing Phase 2 AFFINITY Basket Trial for the Treatment of Proteinuric Glomerular Diseases

In April 2021 we initiated a phase 2 basket study of atrasentan called AFFINITY in several populations of proteinuric glomerular disease patients. Four initial cohorts will include IgAN patients with lower levels of proteinuria (UPCR >0.5g/g <1.0 g/g urine protein/creatinine), FSGS, Alport syndrome, and DKD combined with an SGLT2 inhibitor. Approximately 20 patients are being treated with open-label atrasentan in each cohort. The primary endpoint for each cohort is change in UPCR from baseline to week 12 from two 24-hour urine collections at each time point.

We most recently presented interim data from the IgAN patient cohort of the AFFINITY trial in a poster presentation at ASN Kidney Week in November 2022 where atrasentan demonstrated 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. As of the October 19, 2022 data cutoff, atrasentan demonstrated mean reductions in 24-hour urine protein creatinine ratio, or 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 proteinuria. Atrasentan was well-tolerated, with no treatment-related serious or severe adverse events. The mean treatment duration was 45 weeks, with time on treatment ranging from 13 to 52 weeks. 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 brain natriuretic peptide, or BNP, or mean bodyweight, suggesting minimal fluid retention.



We plan to present data from additional cohorts of the AFFINITY trial during the second half of 2023.

BION-1301

Our second product candidate, BION-1301, is an investigational humanized IgG4 monoclonal antibody that blocks APRIL binding to its receptors and is being developed as a novel disease-modifying therapy for IgAN. BION-1301 is currently in an ongoing phase 1/2 clinical trial for patients with IgAN and we are preparing to initiate a global phase 3 trial of BION-1301 in mid-2023.

We believe the key attributes of our BION-1301 product candidate include:

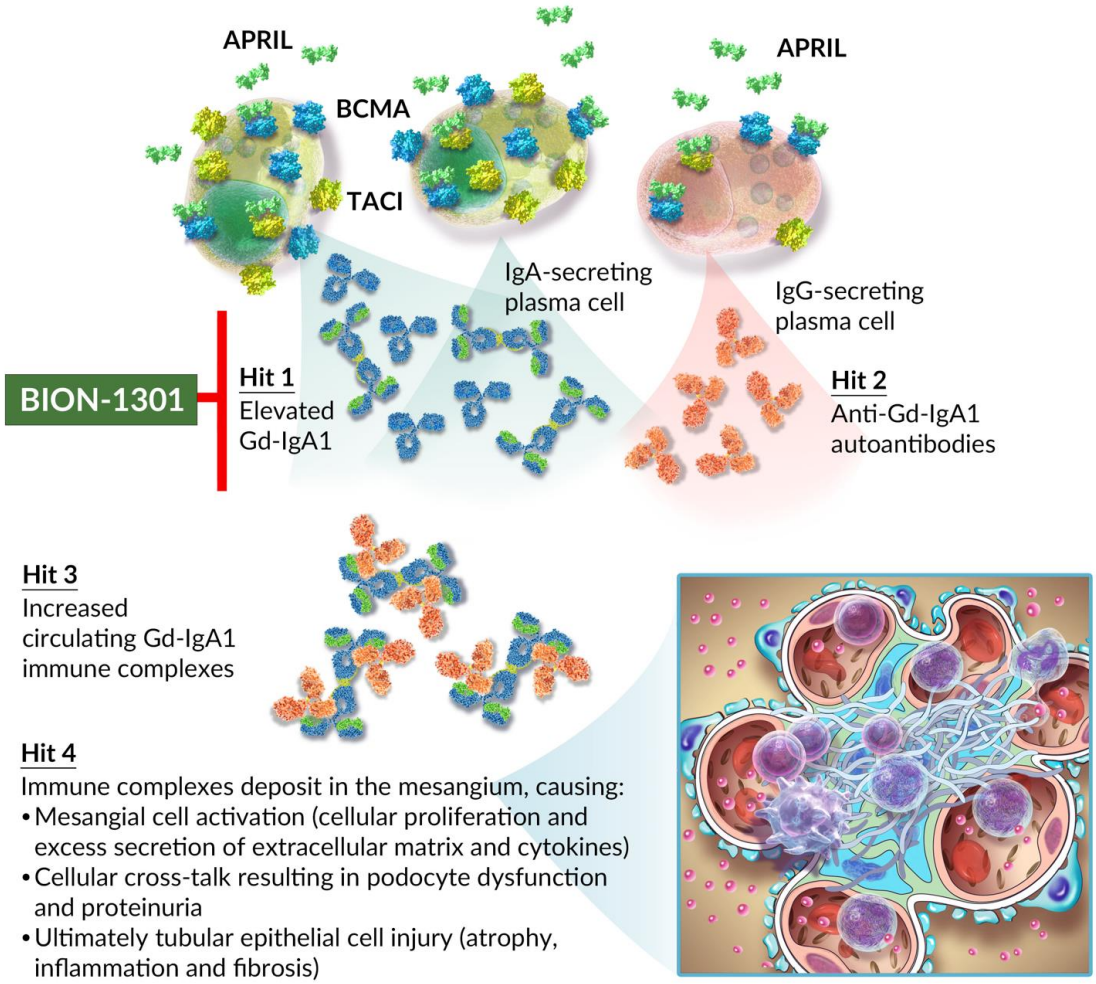
- *Early Evidence of Potency.* BION-1301, a humanized antibody that blocks APRIL from binding to both its receptors, has been shown in preclinical studies in mice and non-human primates to reduce serum IgA levels, and to reduce IgA as well as Gd-IgA1 levels in healthy volunteers, demonstrating compelling rationale for its use in patients with IgAN.
- *Novel Mechanism.* Blocking APRIL is a distinct approach to reduce circulating levels of IgA and Gd-IgA1, with disease-modifying potential in patients with IgAN.

- *Versatility.* APRIL is implicated in the pathogenesis of multiple indications including IgAN and other diseases that involve plasma cells.
- *Ease of Manufacture.* BION-1301 is a biologic that can be manufactured through well-established processes.
- *Broad Applicability.* BION-1301 is a monoclonal antibody, an established therapeutic class to treat cancer as well as autoimmune diseases.

Patients with IgAN have significantly higher levels of APRIL than healthy individuals, and higher APRIL levels in these patients correlate with poor prognosis in the form of increased Gd-IgA1, increased proteinuria and decreased eGFR. We know from published literature that APRIL critically drives IgA class switching, the survival of IgA-producing plasma cells and the secretion of Gd-IgA1 (Hit 1 in the multi-hit pathogenesis of IgAN). Our preclinical experiments demonstrate that blocking APRIL inhibits the survival of and immunoglobulin production by human plasma cells. We have also demonstrated that IgA-producing plasma cells are more sensitive to immunomodulation by BION-1301, with a lesser effect observed on IgG, providing the potential to deplete IgA with BION-1301, while tempering effects on IgG and minimizing the potential for immunosuppression associated with IgG depletion. Blocking APRIL with BION-1301 is a distinct approach to IgAN by reducing circulating levels of Gd-IgA1 which is considered to be the pathogenic variant of IgA in IgAN. We believe BION-1301 represents a novel potential disease-modifying treatment for IgAN.

Preclinical studies have demonstrated that BION-1301 binds to a specifically defined epitope on APRIL, resulting in complete blockade of APRIL-induced receptor activation. In a preclinical study of BION-1301 in non-human primates, we observed a significant reduction of blood IgA levels and a favorable safety profile. Additional preclinical studies demonstrated that APRIL transgenic mice produce rising levels of IgA as well as IgA deposits in the kidney. Administration of mouse anti-human APRIL was shown to reduce levels of IgA in both the serum and the kidney. In patients with IgAN, BION-1301 has been shown to neutralize

APRIL and deplete Gd-IgA1, resulting in clinically meaningful reductions in proteinuria. The illustration below shows the potential reduction of Gd-IgA1 in the kidneys by BION-1301 and its effect in IgAN.



In May 2019, we initiated a phase 1/2 clinical trial evaluating BION-1301 in healthy volunteers and patients with IgAN. The phase 1/2 multi-center trial evaluated the safety and tolerability of BION-1301 in 63 healthy volunteers in double-blinded, placebo-controlled single-ascending dose, or SAD, and multiple-ascending dose, or MAD, settings. Parts 1 and 2 of this trial in healthy volunteers have been completed. Healthy volunteers in the SAD portion of the study (Part 1) received placebo or a single IV dose of BION-1301 ranging from 10 mg to 1350 mg on day 1. Healthy volunteers in the MAD portion of the study (Part 2) received placebo or IV doses of BION-1301 ranging from 50 mg to 450 mg on days 1, 15 and 29 (three doses total).

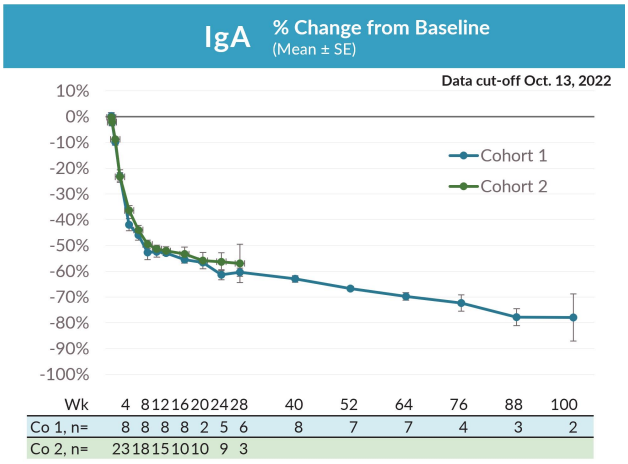
In healthy volunteers, BION-1301 was well-tolerated, with no significant adverse events, treatment discontinuations or events meeting stopping criteria, across a wide range of doses. Non-neutralizing ADAs occurred in less than 10 percent of subjects with no correlation to dose. The PK profile of BION-1301 was well-behaved, generally dose proportional, and had a half-life of approximately 33 days, suggesting the potential for an extended dosing interval. BION-1301 demonstrated a dose-dependent increase in target engagement as measured by free APRIL levels in serum; over 90 percent target engagement was achieved with a single 450 mg dose. BION-1301 dose-dependently and durably reduced IgA and IgM levels, and to a lesser extent, IgG levels. Approximately 50 to 60 percent reduction in IgA levels was achieved with 150 mg to 450 mg of BION-1301. At all doses tested, IgG levels remained in the normal lab range, thereby providing a PD window to potentially exploit reductions in IgA, while tempering reductions in IgG. BION-

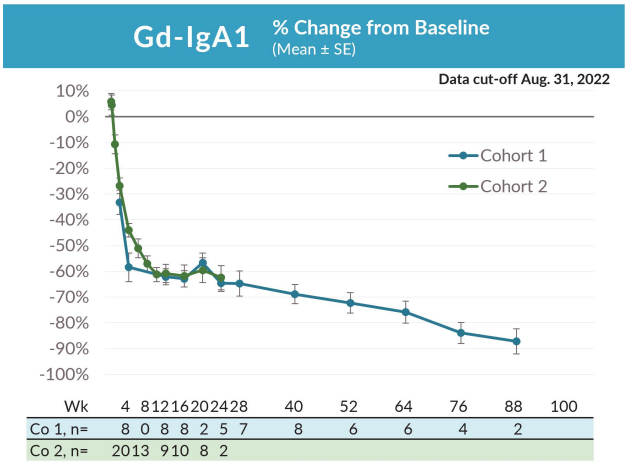
1301 produced dose-dependent reductions in serum Gd-IgA1 levels that were greater in magnitude than reported for total IgA concentrations.

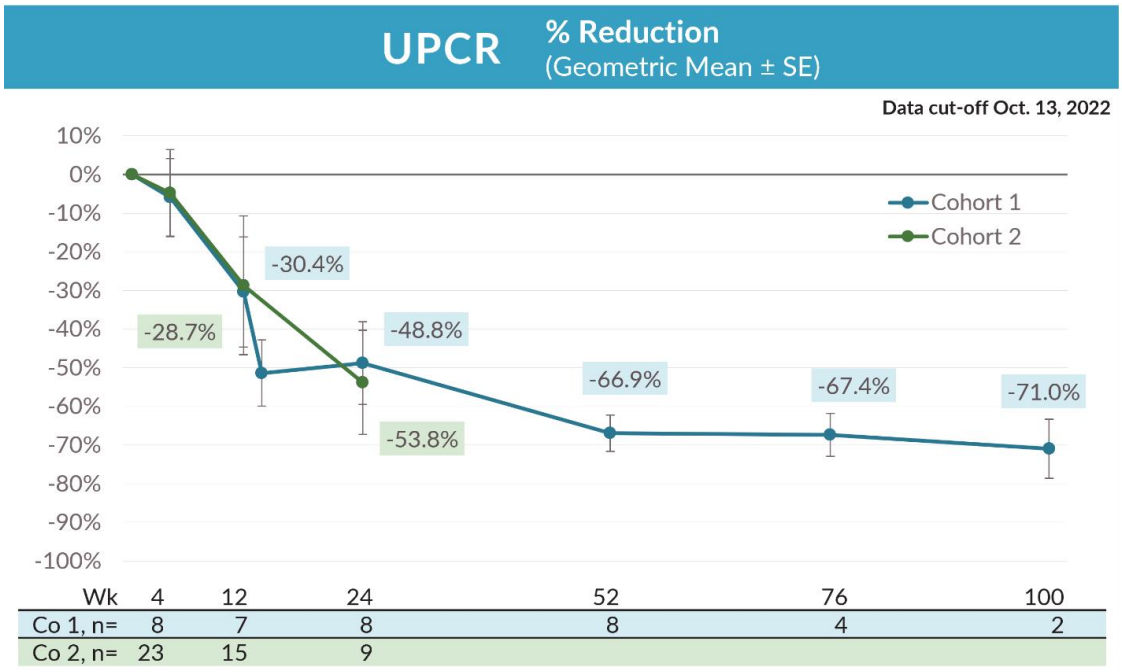
In addition, a phase 1 IV to SC bioavailability study in healthy volunteers has been completed. In this study, BION-1301 was well-tolerated when administered by both IV and SC routes in healthy volunteers, the pharmacokinetic profile of BION-1301 was consistent with previous clinical studies, the absorption rate of BION-1301 was typical of a monoclonal antibody and the magnitude of pharmacodynamic responses were largely retained with SC dosing compared to IV dosing.

We have completed enrollment of 10 patients with IgAN in Cohort 1 and 30 patients with IgAN in Cohort 2 of Part 3 of the ongoing phase 1/2 trial of BION-1301. We most recently presented interim data from both cohorts at ASN Kidney Week in November 2022. Patients in Cohort 1 started treatment at an intravenous, or IV, BION-1301 dose of 450 mg every two weeks, and after at least 24 weeks of treatment, all patients transitioned to subcutaneous, or SC, dosing at 600 mg every two weeks. In Cohort 2, patients started treatment at a SC BION-1301 dose of 600 mg every two weeks. In both cohorts, patients can receive treatment for up to a total of two years.

The data presented at ASN demonstrated 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, 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. In Cohort 1, 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 also 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.







Median (min, max) baseline protein excretion: Cohort 1, 1.2 (0.7, 6.5) g/day ; Cohort 2, 1.0 (0.6, 2.7) g/day

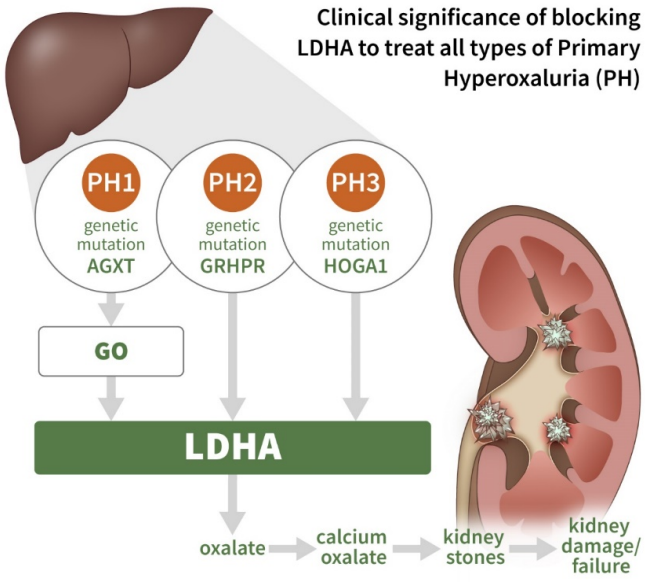
Based on the data generated to date in the ongoing phase 1/2 study, we plan to advance BION-1301 into a phase 3 trial with the current Cohort 2 dose of 600 mg SC every two weeks. We have finalized our trial design, are conducting site and country feasibility and pursuing regulatory interactions, with a plan of initiating a global phase 3 trial of BION-1301 in mid-2023. We also have received orphan drug designation for BION-1301 for the treatment of primary IgAN from the European Commission.

CHK-336

Our third product candidate is CHK-336, a liver-targeted oral small molecule LDHA inhibitor, which we are developing for the treatment of PH and idiopathic hyperoxaluria. Hyperoxalurias, including PH, are diseases caused by excess oxalate, a potentially toxic metabolite typically filtered by the kidneys and excreted as a waste product in urine. Symptoms of PH include recurrent kidney stones, which when left untreated, can result in kidney failure requiring dialysis or dual kidney/liver transplantation. In patients with hyperoxalurias, excess oxalate combines with calcium to form calcium oxalate crystals that deposit in the kidney, resulting in the formation of painful kidney stones and driving progressive kidney damage over time. PH1, PH2 and PH3 are a group of ultra-rare diseases caused by genetic mutations that result in excess oxalate, and in their most severe forms, can lead to ESKD at a young age. We also believe CHK-336 may have potential in the treatment of patients with idiopathic hyperoxaluria which is more common. Idiopathic hyperoxaluria is an acquired condition, potentially resulting from increased endogenous oxalate overproduction, particularly in association with metabolic diseases. We are currently conducting a phase 1 single ascending dose and multiple ascending dose clinical trial in healthy volunteers evaluating the safety, tolerability and pharmacokinetic profile of CHK-336, and we expect to report initial data from this trial in the first half of 2023.

As seen in the illustration below, LDHA catalyzes the terminal step in the production of oxalate from glyoxylate in the liver, therefore LDHA inhibition has the potential to treat all forms of PH – PH1, PH2 and PH3 – as well as other disorders arising from excess oxalate. This is a point of differentiation for CHK-336 since inhibition using small molecules or silencing using small-interfering RNAs (siRNAs) of glycolate oxidase (GO), the enzyme involved in the production of glyoxylate from glycolate, is limited to the treatment of PH1 only. An oral, liver-targeted LDHA small molecule inhibitor has the potential for robust efficacy by rapidly

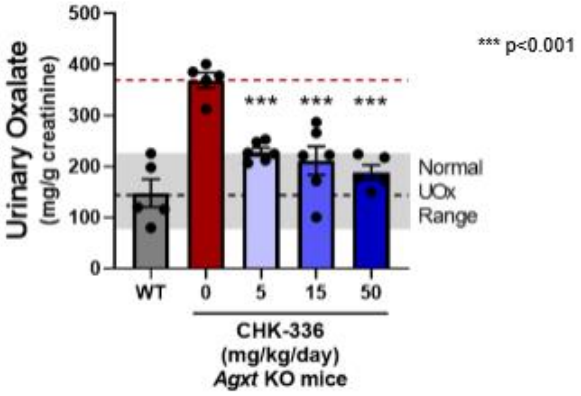
distributing to the site of oxalate production, while minimizing systemic exposures and potential for off-target activity, to facilitate a favorable tolerability profile required in this chronic disease.



With the goal of developing a best-in-class treatment applicable to all types of PH, our research team designed, synthesized and characterized hundreds of LDHA inhibitors to engineer the required properties of potent and selective LDHA inhibition with a liver-targeted tissue-distribution profile. We designed CHK-336 to demonstrate a promising preclinical pharmacokinetic and safety profile.

In preclinical studies, CHK-336 has demonstrated tight LDHA binding and a slow enzyme off-rate, potentially extending the duration of action and enabling the potential of a once-daily oral dose in humans. In order to maximize efficacy and reduce the potential for any systemic toxicities as is observed with complete loss-of-function of LDHA, our team engineered into CHK-336 a liver-targeted tissue distribution profile by incorporating moieties that result in liver-selective OATP transporter uptake and simultaneously reducing non-specific passive permeability.

To evaluate efficacy, we generated a novel mouse model of PH1 using CRISPR-Cas9 gene editing to delete the AGXT gene responsible for PH1 in humans, which created mice with significantly elevated urinary oxalate excretion compared to normal wild-type (WT) control mice. CHK-336 was dosed orally at three different dose levels, once-daily for seven days and urinary oxalate excretion was compared to a control group of PH mice treated with vehicle. As demonstrated in the figure below, CHK-336 demonstrated significant dose-dependent reductions in urinary oxalate levels, with the majority of CHK-336 treated mice reaching the normal range seen in WT mice.



We 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. We are currently conducting a phase 1 single ascending dose and multiple ascending dose clinical trial in healthy volunteers evaluating the safety, tolerability and pharmacokinetic profile of CHK-336, and we expect to report initial data from this trial in the first half of 2023. Following completion of the phase 1 trial, we will advance CHK-336 towards initiation of phase 2 POC trials for patients with both primary and idiopathic hyperoxalurias. We believe clinical POC for CHK-336 can be achieved efficiently in small studies using urinary oxalate as a validated surrogate biomarker and primary endpoint with the potential for full approval of this program in PH. We have also received rare pediatric disease designation from the FDA for CHK-336 for the treatment of PH.

Preclinical Product Candidates

In addition to our lead product candidates, we are also conducting research and discovery efforts to develop a pipeline of product candidates in other rare, severe chronic kidney diseases.

We have initiated drug discovery programs against promising biological targets across kidney disease indications with high unmet medical need selected in alignment with our guiding precision medicine principles:

- Focus on key pathways driving kidney disease, especially where definitive genetic evidence of a causal, pathogenic role exists;
- Design novel, differentiated molecules;
- Utilize new and efficient translational approaches to speed research and development; and
- Execute clinical trials in defined patient populations with rapid, robust endpoints.

Our experienced research and discovery team has partnered with academic founders and key opinion leaders to identify targets and utilize novel translational technologies to develop precision medicines for kidney diseases. One of the key challenges in defining molecular mechanisms of kidney disease has been the cellular heterogeneity of the kidney, with nearly 30 distinct cell types arranged in the complex three-dimensional structure of the nephron. This cellular diversity and structure have made it difficult to understand the specific mechanisms associated with loss in kidney function. The recent development of genome-wide single-cell RNA sequencing of cell populations harvested from the kidney presents a new opportunity to dissect molecular mechanisms of kidney function and disease. We utilize single-cell RNA sequencing techniques developed by one of our academic founders to gain high resolution molecular insights into kidney disease mechanisms.

The cellular heterogeneity of the kidney has historically presented barriers to developing translationally relevant in-vitro cellular models of human kidney diseases. Recently, pluripotent stem cell, or PSC, derived kidney organoids along with patient derived three-dimensional cellular systems have emerged as advanced preclinical models to study kidney disease.

To supplement our internal research efforts, we have entered into a strategic collaboration with Evotec focused on the discovery and development of novel precision medicine therapies for patients with chronic kidney diseases. Based on Evotec's proprietary comprehensive molecular datasets from thousands of patients across chronic kidney diseases of multiple underlying etiologies, we and Evotec will jointly identify, characterize and validate novel mechanisms and discover precision medicines for lupus nephritis, IgAN, PKD, and other primary glomerular diseases. The collaboration will also involve further characterization of pathways and patient stratification strategies for programs currently in Chinook's clinical and preclinical pipeline.

Gaining access to the NURTuRE cohort study and other proprietary patient biobanks, along with Evotec's multi-omics integration platform, enables us to characterize the molecular drivers of kidney diseases, identify and validate novel targets and drive patient stratification strategies in kidney disease. With a focus on comprehensive molecular disease classification, combined with prospective clinical outcomes, we believe we have the opportunity to potentially deliver targeted therapies to the right patient populations.

We believe our research and discovery approach provides significant insights into human disease mechanisms and allows us to select and validate key targets that are central drivers of human kidney diseases.

License Agreements

AbbVie

In December 2019, we entered into an agreement with AbbVie, through its affiliate AbbVie Ireland Unlimited Company for an exclusive, sublicensable, worldwide license to atrasentan, along with claims in several issued patents and associated know-how, to manufacture, have manufactured, use and sell defined licensed products for use within the field of all human and non-human diagnostic, prophylactic, and therapeutic uses. Under the terms of this license, we paid an initial licensing fee and issued AbbVie 1,999,415 shares of common stock. The license agreement requires us to pay potential milestone payments totaling up to $135 million upon the achievement of certain developmental, regulatory and commercial milestones, as well as royalties ranging from the high single digits to the high teens based on annual thresholds for net sales of licensed products by us, our affiliates and our sublicensees.

Under the AbbVie license, we have a continuing obligation to use commercially reasonable efforts to develop, obtain regulatory approvals and commercialize licensed products. The license agreement is effective on a per-country basis until the later of: (i) the last expiration of a claim in a licensed patent that covers the licensed product in such country, (ii) the expiration of any period of regulatory exclusivity for a licensed product that bars the entry of generic competitors in such country, or (iii) a specified period after the first commercial sale of the licensed product. Each party has the right to terminate the license for the other party's material breach or in the event of the other party's bankruptcy or insolvency, subject to specified notice and cure periods. Additionally, AbbVie can terminate the license if we challenge claims in licensed patents or fail to meet our diligence obligations with respect to licensed products. Upon any termination of the license, we may grant AbbVie an exclusive, sublicenseable license to any improvements that we make to the licensed technology, including those that we license from third parties, subject to a mutually agreed royalty.

Manufacturing

We currently contract with third parties to manufacture our products and anticipate using third parties for our clinical and commercial manufacturing. We do not own or operate facilities for product manufacturing, packaging, storage and distribution, or testing. We have internal personnel and utilize consultants with extensive technical, manufacturing, analytical and quality experience to oversee contract manufacturing and testing activities. We will continue to expand and strengthen our network of third-party providers but may also consider investing in internal manufacturing capabilities in the future if there is a technical need, or a strategic or financial benefit.

Manufacturing is subject to extensive regulations that impose procedural and documentation requirements. At a minimum these regulations govern record keeping, manufacturing processes and controls, personnel, quality control and quality assurance. Our systems, procedures and contractors are required to be in compliance with these regulations and are assessed through regular monitoring and formal audits.

Atrasentan. Under our license agreement with AbbVie, we received a substantial amount of drug product and drug substance to support clinical trials of atrasentan. We are resupplying our clinical trials and preparing for future commercial launch with additional manufacturing campaigns conducted by AbbVie. We believe that the synthesis from regulatory starting material to drug substance can be manufactured at scale, resulting in a commercially competitive cost of goods.

BION-1301. We rely on third-party contract manufacturing organizations, or CMOs, to manufacture product for clinical use based on engineered cell lines that express and secrete the antibody product candidate. We have contracted with several CMOs to develop, produce and release drug substance and drug product for use in the ongoing phase 1/2 clinical trial and the upcoming phase 3

clinical trial. We expect to continue to rely on CMOs for further manufacturing of BION-1301, including the development and manufacturing of alternative formulations.

CHK-336. In 2022, we continued manufacturing activities for CHK-336 to support the initiation of our healthy volunteer study of CHK-336 and expect to continue to rely on CMOs for further manufacturing of CHK-336.

Sales and Marketing

We do not currently have sales and marketing infrastructure to support commercial launch of our products. We intend to build such capabilities in North America prior to launch of atrasentan. Outside of North America, we may rely on licensing, co-sale and co-promotion agreements with strategic partners for the commercialization of our products, including the recently formed joint venture, SanReno Therapeutics, in East Asia. If we build a commercial infrastructure to support marketing in North America, such commercial infrastructure could be expected to include a targeted sales force supported by sales management, internal sales support, an internal marketing group and distribution support. To develop the appropriate commercial infrastructure internally, we would have to invest financial and management resources, some of which would have to be deployed prior to any confirmation that atrasentan will be approved.

Coverage & Reimbursement

The regulations that govern pricing and reimbursement for new drugs vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription biopharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, a drug company can obtain regulatory approval for a product in a country, but then be subject to price regulations that delay commercial launch of that product.

A drug company’s ability to successfully commercialize any products will also depend on the extent to which coverage and adequate reimbursement for these products will be available from government authorities, private health insurers and other organizations. Even if one or more products are successfully brought to the market, these products may not be considered cost effective, and the amount reimbursed for such products may be insufficient to allow them to be sold on a competitive basis. Third-party payors who reimburse patients or healthcare providers, such as government plans, are requiring that drug companies provide them with predetermined discounts from list prices and are seeking to reduce the prices charged or the amounts reimbursed for biopharmaceutical products.

Significant delays can occur in obtaining reimbursement for newly-approved drugs or therapeutic biologics, and coverage may be more limited than the purposes for which the drug or therapeutic biologic is approved by the FDA or similar foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be reimbursed in all cases or at a rate that covers a drug company’s costs, including research, development, manufacture, sale and distribution.

Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover a drug company’s costs and may not be made permanent. Reimbursement rates may be based on payments allowed for lower cost drugs or therapeutic biologics that are already reimbursed, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drugs or therapeutic biologics may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs or therapeutic biologics from countries where they may be sold at lower prices than in the United States. Further, no uniform policy for coverage and reimbursement exists in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement can differ significantly from payor to payor.

Competition

The biotechnology and biopharmaceutical industries are characterized by rapid evolution of technologies, fierce competition and vigorous defense of intellectual property. Any product candidates that we successfully develop and commercialize will have to compete with existing and future new therapies. While we believe that our technology, development experience and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies, and public and private research institutions.

If our lead product candidate atrasentan is approved for the treatment of IgAN, it may compete with other products used to treat this disease. To our knowledge, there are only two FDA-approved drugs for IgAN, the corticosteroid treatment Tarpeyo (budesonide) from Calliditas Therapeutics AB and Filspari (sparsentan), a dual ARB/endothelin receptor antagonist from Travere Therapeutics,

Inc., but there are a variety of additional treatments utilized, including RASis, steroids, chemotherapy drugs and immunomodulatory approaches. In addition, there are a number of competitors in clinical development for the treatment of IgAN at a similar stage of development or more advanced than us, including Alnylam Pharmaceuticals, Inc., AstraZeneca PLC, Ionis Pharmaceuticals, Inc., F. Hoffman-La Roche Ltd., Novartis AG, Omeros Corporation, Vera Therapeutics, RemeGen, Alpine Immune Sciences, Inc. and Otsuka Pharmaceutical Co., Ltd.

Many of our potential competitors, alone or with strategic partners, may have substantially greater financial, technical and other resources than we do, such as larger research and development, clinical, marketing and manufacturing organizations. Accordingly, our competitors may be more successful than us in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining approval for treatments and achieving widespread market acceptance, rendering our treatments obsolete or non-competitive. Mergers and acquisitions in the biotechnology and biopharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials and acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or less expensive than any product candidates that we may develop. In geographies that are critical to our commercial success, competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our products, which could result in our competitors establishing a strong market position before we are able to enter the market, if ever. The key competitive factors affecting the success of all of our programs are likely to be their efficacy, safety, convenience and availability of reimbursement. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic drugs.

Intellectual Property

We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to our business, including obtaining, maintaining and defending patent rights, whether developed internally or licensed from third parties. Our policy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements, platforms and product candidates that are important to the development and implementation of our business. Our patent portfolio, including in-licensed patents and patent applications, is intended to cover, but is not limited to, our technology platforms, product candidates and components thereof, their methods of use and processes for their manufacture, and any other inventions that are commercially important to our business. We also rely on trade secret protection of our confidential information and know-how relating to our proprietary technology, platforms and product candidates, continuing innovation, and in-licensing opportunities to develop, strengthen, and maintain our position in our platform and product candidates. Our commercial success may depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions and improvements; to preserve the confidentiality of our trade secrets; to maintain our licenses to use intellectual property owned or controlled by third parties; to defend and enforce our proprietary rights, including our patents; to defend against challenges and assertions by third parties of their purported intellectual property rights; and to operate without infringement of valid and enforceable patents and other proprietary rights of third parties.

With respect to atrasentan, we have exclusively licensed issued U.S. and foreign patents and pending U.S. and foreign patent applications that cover formulations and methods of use related directly to atrasentan from AbbVie. These exclusively licensed patents included seven issued U.S. patents, one issued foreign patent and four pending foreign patent applications. These patents, and any patents that issue from the pending applications, that we have licensed from AbbVie are anticipated to expire between 2028 and 2034, absent any patent term adjustments or extensions.

Separately, we have filed U.S. and foreign patent applications with claims that are intended to cover additional methods of treatment and combinations of atrasentan with other therapies in kidney disease. We have one issued U.S. patent relating to methods of treatment with atrasentan. This patent, and any patents that may issue from these currently pending patent applications, which include PCT international applications, U.S. patent applications, and foreign patent applications, are expected to expire in 2040, absent any patent term adjustments or extensions.

With respect to BION-1301, we have seven issued U.S. patents, twenty-four issued foreign patents (not including European country validations), at least twenty pending U.S. and foreign patent applications, that cover the composition of matter of BION-1301, as well as methods of use. These patents, and any patents that issue from the pending applications are anticipated to expire between 2030 and 2041, absent any patent term adjustments or extensions.

With respect to CHK-336, we have in-licensed issued U.S. and foreign patents and have filed U.S. and foreign patent applications with claims that cover the composition of matter of CHK-336 and other related compounds, as well as methods of use. As

of December 31, 2022, any patents that may issue from these currently pending patent applications, which include PCT international applications, U.S. patent applications, and foreign patent applications, are expected to expire between 2035 and 2041, absent any patent term adjustments or extensions.

The term of individual patents depends upon the laws of the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing of a non-provisional patent application. However, the term of United States patents may be extended for delays incurred due to compliance with the FDA requirements or by delays encountered during prosecution that are caused by the United States Patent and Trademark Office, or the USPTO. For example, for drugs that are regulated by the FDA under the Hatch-Waxman Act, it is permitted to extend the term of a patent that covers such drug for up to five years beyond the normal expiration date of the patent. For more information on patent term extensions, see "*—Government regulation—The Hatch-Waxman Act—Patent term extension*." In the future, if and when our biopharmaceutical product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those product candidates. We intend to seek patent term extensions to any of our issued patents in any jurisdiction where these are available; however, there is no guarantee that the applicable authorities, including the USPTO and FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. Our currently issued patents will likely expire on dates ranging from 2028 to 2041, unless we receive patent term extension. If patents are issued on our pending patent applications, the resulting patents are projected to expire on dates ranging from 2036 to 2041, unless we receive patent term extension or patent term adjustment, or both. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, specific claims issues, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. The patent situation outside of the United States is even more uncertain. Changes in the patent laws and rules, either by legislation, judicial decisions, or regulatory interpretation in the United States and other countries may diminish our ability to protect our inventions and enforce our intellectual property rights, and more generally could affect the value of our intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell, importing or otherwise commercializing any of our patented inventions, either directly or indirectly, will depend in part on our success in obtaining, defending and enforcing patent claims that cover our technology, inventions, and improvements. With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our platform and product candidates and the methods used to manufacture them. Moreover, our issued patents and those that may issue in the future may not guarantee us the right to practice our technology in relation to the commercialization of our platform's product candidates. The area of patent and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties, and third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and practicing our proprietary technology. The USPTO and FDA are currently collaborating regarding the patent prosecution practice for biotechnology patents. The outcome of that collaboration may impact biotechnology patent assets, including ours. Our issued patents and those that may issue in the future may be challenged, narrowed, circumvented or invalidated, which could limit our ability to stop competitors from marketing related platforms or product candidates or limit the length of the term of patent protection that we may have for our product candidates. In addition, the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or third parties may seek to develop our clinical candidates in countries where we do not have patent protection. This risk may also affect our ability to partner rights in those countries. For these reasons, we may have competition for our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before any product candidate can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent. For this and other risks related to our proprietary technology, inventions, improvements, platforms and product candidates, please see the section titled "*Risk Factors—Risks Related to Our Intellectual Property*."

We have filed for trademark protection of the "Chinook Therapeutics" mark with the USPTO and foreign trademark registries. We intend to register and maintain the trademark "Chinook Therapeutics" in the USPTO and in numerous other jurisdictions, including, but not limited to, the European Union (EU), China, India, Switzerland, the United Kingdom, or UK, and Canada.

We also rely on trade secret protection for our confidential and proprietary information. Although we take steps to protect our confidential and proprietary information as trade secrets, including through contractual means with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements under the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the individual's relationship with us is to be kept confidential

and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In many cases our confidentiality and other agreements with consultants, outside scientific collaborators, sponsored researchers and other advisors require them to assign or grant us licenses to inventions they invent as a result of the work or services they render under such agreements or grant us an option to negotiate a license to use such inventions. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches.

We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. Although we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. To the extent that our employees, contractors, consultants, collaborators and advisors use intellectual property owned by others in their work for us, disputes may arise as to the rights in relation to the resulting know-how or inventions. For more information, please see the section titled "*Risk Factors—Risks Related to Our Intellectual Property*."

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA, the Federal Food, Drug, and Cosmetic Act, or FD&C Act, and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of pharmaceutical products. Pharmaceutical products—such as small molecule drugs and biological products, or biologics—used for the prevention, treatment, or cure of a disease or condition of a human being—are subject to regulation under the FD&C Act, with the exception that the section of the FD&C Act which governs the approval of drugs via New Drug Applications, or NDAs, does not apply to the approval of biologics. In contrast, biologics are approved for marketing under provisions of the Public Health Service Act, or PHS Act, via a Biologics License Application, or BLA. However, the application process and requirements for approval of BLAs are very similar to those for NDAs. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as clinical hold, FDA refusal to approve pending NDAs or BLAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the United States typically involves preclinical laboratory and animal tests, the submission to the FDA of an IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including Good Laboratory Practices, or GLP. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with Good Clinical Practices, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, and ethics committee for approval. The IRB will also monitor the clinical trial until completed. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial.

Clinical trials to support NDAs and BLAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence of effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks. If a drug demonstrates evidence of effectiveness and an acceptable safety profile in phase 2 evaluations, phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug or biologic and to provide adequate information for the labeling of the drug or biologic. In most cases the FDA requires two adequate and well-controlled phase 3 clinical trials to demonstrate the efficacy of the drug or biologic. A single phase 3 trial may be sufficient in rare instances, including (1) where the trial is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible or (2) when in conjunction with other confirmatory evidence.

The manufacturer of an investigational drug or biologic in a phase 2 or 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access to such investigational drug or biologic.

After completion of the required clinical testing, an NDA or BLA is prepared and submitted to the FDA. FDA approval of the NDA or BLA is required before marketing of the product may begin in the United States. The NDA or BLA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls.

The cost of preparing and submitting an NDA or BLA is substantial. The submission of most NDAs or BLAs is additionally subject to a substantial application user fee, currently exceeding $3,200,000 for Fiscal Year 2023 for an application containing clinical data. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication. The applicant under an approved NDA or BLA is also subject to annual program fees, currently exceeding $390,000 for each prescription product. The FDA adjusts the user fees on an annual basis, and the fees typically increase annually.

The FDA reviews each submitted NDA or BLA before it determines whether to file it and may request additional information. The FDA must make a decision on whether to file an NDA or BLA within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the submission is filed, the FDA begins an in-depth review of the NDA or BLA. The FDA has agreed to certain performance goals in the review of NDAs or BLAs. Most applications for standard review drug products are reviewed within ten to twelve months; most applications for priority review drugs or biologics are reviewed in six to eight months. Priority review can be applied to drugs or biologics that the FDA determines may offer significant improvement in safety or effectiveness compared to marketed products or where no adequate therapy exists. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission. The FDA does not always meet its goal dates for standard and priority NDAs or BLAs, and the review process can be extended by FDA requests for additional information or clarification.

The FDA may also refer applications for novel drug and biologic products, or drug and biologic products that present difficult questions of safety or efficacy, to an outside advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA or BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with Good Manufacturing Practices, or cGMP, requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also typically inspects clinical trial sites to ensure compliance with GCP requirements and the integrity of the data supporting safety and efficacy.

After the FDA evaluates the NDA or BLA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter, or CRL, generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application, such as additional clinical data, additional pivotal clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a CRL is issued, the applicant may resubmit the NDA or BLA addressing all of the deficiencies identified in the letter, withdraw the application, engage in formal dispute resolution or request an opportunity for a hearing. The FDA has committed to reviewing resubmissions in two or six months depending on the type of information included. Even if such data and information are submitted, the FDA may decide that the NDA or BLA does not satisfy the criteria for approval.

If, or when, the deficiencies identified in the CRL have been addressed to FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug or biologic with specific prescribing information for specific indications. As a condition of NDA or BLA approval, the FDA may require a REMS to help ensure that the benefits of the drug or biologic outweigh the potential risks to patients. A REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug or biologic. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the safety or efficacy of the drug or biologic. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of an NDA or BLA supplement or, in some case, a new NDA or BLA, before the change can be implemented. An NDA or BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA and BLA supplements as it does in reviewing NDAs and BLAs.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Expedited Development and Review Programs

The FDA is required to facilitate the development, and expedite the review, of drugs and biologics that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition.

Fast Track Designation

Fast track designation may be granted for a product that is intended to treat a serious or life-threatening disease or condition for which preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. The sponsor of an investigational drug product may request that the FDA designate the drug candidate for a specific indication as a fast track drug concurrent with, or after, the submission of the IND for the product candidate. The FDA must determine if the product candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's NDA or BLA before the application is complete. This rolling review is available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. At the time of NDA or BLA filing, the FDA will determine whether to grant priority review designation. Additionally, fast track designation may be withdrawn if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Accelerated Approval

Accelerated approval may be granted for a product that is intended to treat a serious or life-threatening condition and that generally provides a meaningful therapeutic advantage to patients over existing treatments. A product eligible for accelerated approval may be approved on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on

irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. The accelerated approval pathway is contingent on a sponsor's agreement to conduct additional post-approval confirmatory studies to verify and describe the product's clinical benefit. These confirmatory trials must be completed with due diligence and, in some cases, the FDA may require that the trial be designed, initiated, and/or fully enrolled prior to approval. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA. The Food and Drug Omnibus Reform Act, or FDORA, was recently enacted, which included provisions related to the accelerated approval pathway. Pursuant to FDORA, the FDA is authorized to require a post-approval study to be underway prior to approval or within a specified time period following approval. FDORA also requires the FDA to specify conditions of any required post-approval study, which may include milestones such as a target date of study completion and requires sponsors to submit progress reports for required post-approval studies and any conditions required by the FDA not later than 180 days following approval and not less frequently than every 180 days thereafter until completion or termination of the study. FDORA enables the FDA to initiate criminal prosecutions for the failure to conduct with due diligence a required post-approval study, including a failure to meet any required conditions specified by the FDA or to submit timely reports.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologics intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States but for which there is no reasonable expectation that the cost of developing and making the product for this type of disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the drug or biologic and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The first NDA or BLA applicant to receive FDA approval for a particular active moiety to treat a rare disease for which it has such designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug or biologic for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care, or in instances of drug supply issues. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Other benefits of orphan drug designation include tax credits for certain research and an exemption from the NDA user fee.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs or BLAs or supplements to NDAs or BLAs must contain data to assess the safety and effectiveness of the drug or biologic for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug or biologic is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug or biologic for an indication for which orphan designation has been granted, with certain exceptions.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA or BLA holders a six-month extension of any exclusivity—patent or nonpatent—for a drug, and nonpatent for a biologic, if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug or biologic in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Rare Pediatric Disease Vouchers

The Rare Pediatric Disease Voucher Program is intended to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Although there are existing incentive programs to encourage the development and study of drugs and biologics for rare diseases, pediatric populations, and unmet medical needs, this program provides an additional incentive for the development of drugs and biologics for rare pediatric diseases, which may be used alone or in combination with other incentive programs. A rare pediatric disease is defined as a disease that is a serious or life-threatening disease

in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; and is a rare disease or condition as defined in the FD&C Act, which includes diseases and conditions that affect fewer than 200,000 persons in the United States and diseases and conditions that affect a larger number of persons and for which there is no reasonable expectation that the costs of developing and making available the product in the United States can be recovered from sales of the product in the United States.

The sponsor of a human drug application for a rare pediatric disease drug or biologic product may be eligible for a voucher that can be used (or sold) to obtain a priority review for a subsequent human drug application submitted under section 505(b)(1) of the FD&C Act or section 351 of the PHS Act after the date of approval of the rare pediatric disease drug product. The rare pediatric disease priority review voucher program was most recently re-authorized by Congress in the Consolidated Appropriations Act of 2021, extending the rare pediatric disease program through September 30, 2024, with the potential for priority review vouchers to be granted through September 30, 2026.

Additional Controls for Biologics

To help reduce the increased risk of the introduction of adventitious agents, the PHS Act emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHS Act also provides authority to the FDA to immediately suspend biologics licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases within the United States.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the lot manufacturing history and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before allowing the manufacturer to release the lots for distribution. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. As with drugs, after approval of a BLA, biologics manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

Post-Approval Requirements

Once an NDA or BLA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs and biologics, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs and biologics may be marketed only for the approved indications and in a manner consistent with the approved labeling.

Adverse event reporting and submission of periodic reports are required following FDA approval of an NDA or BLA. The FDA also may require post-marketing testing, known as phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, manufacturing, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug and biologic manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the Agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

The Hatch-Waxman Amendments

Orange Book Listing

Under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch Waxman Amendments, NDA applicants are required to identify to the FDA each patent whose claims cover the applicant’s drug or approved method of using the drug. Upon approval of a drug, the applicant must update its listing of patents to the NDA in timely fashion and each of the patents listed in the application for the drug is then published in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book.

Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredient(s), strength, route of administration, and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. An approved ANDA product is considered to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, pre-clinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved under the ANDA pathway are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug pursuant to each state's laws on drug substitution.

The ANDA applicant is required to certify to the FDA concerning any patents identified for the reference listed drug in the Orange Book. Specifically, the applicant must certify to each patent in one of the following ways: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. For patents listed that claim an approved method of use, under certain circumstances the ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents through a Paragraph IV certification, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA-holder and patentee(s) once the ANDA has been accepted for filing by the FDA (referred to as the "notice letter"). The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice letter. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months from the date the notice letter is received, expiration of the patent, the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed, or a decision in the patent case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired. In some instances, an ANDA applicant may receive approval prior to expiration of certain non-patent exclusivity if the applicant seeks, and the FDA permits, the omission of such exclusivity-protected information from the ANDA prescribing information.

Drug Exclusivity

Upon NDA approval of a new chemical entity, or NCE, which is a drug that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which the FDA cannot receive any ANDA seeking approval of a generic version of that drug unless the application contains a Paragraph IV certification, in which case the application may be submitted one year prior to expiration of the NCE exclusivity. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA for a generic version of the drug may be filed before the expiration of the exclusivity period.

Certain changes to an approved drug, such as the approval of a new indication, the approval of a new strength, and the approval of a new condition of use, are associated with a three-year period of exclusivity from the date of approval during which the FDA cannot approve an ANDA for a generic drug that includes the change. In some instances, an ANDA applicant may receive approval prior to expiration of the three-year exclusivity if the applicant seeks, and the FDA permits, the omission of such exclusivity-protected information from the ANDA package insert.

Patent Term Extension

The Hatch Waxman Amendments permit a patent term extension as compensation for patent term lost during the FDA regulatory review process. Patent term extension, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. After NDA approval, owners of relevant drug patents may apply for the extension. The allowable patent term extension is calculated as half of the drug's testing phase (the time between IND application and NDA submission) and all of the review phase (the time between NDA submission and approval) up to a maximum of five years. The time can be reduced for any time the FDA determines that the applicant did not pursue approval with due diligence.

The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. However, the USPTO may not grant an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than requested.

The total patent term after the extension may not exceed 14 years, and only one patent per product can be extended. The application for the extension must be submitted prior to the expiration of the patent, and for patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Biologic Exclusivity

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, which was enacted as part of the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, created an abbreviated approval pathway for biological products that are demonstrated to be "biosimilar" or "interchangeable" with an FDA-licensed reference biological product. Biosimilarity sufficient to reference a prior FDA-licensed product requires that there be no differences in conditions of use, route of administration, dosage form, and strength, and no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. Biosimilarity must be shown through analytical studies, animal studies, and at least one clinical study, absent a waiver from the Secretary of the U.S. Department of Health and Human Services. In order to meet the higher hurdle of interchangeability, a sponsor must demonstrate that the biosimilar product can be expected to produce the same clinical result as the reference product, and for a product that is administered more than once, that the risk of switching between the reference product and biosimilar product is not greater than the risk of maintaining the patient on the reference product. The first biosimilar product was approved under the BPCIA in 2015, and the first interchangeable product was approved in 2021. Complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being evaluated by the FDA. A reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product and no application for a biosimilar can be submitted for four years from the date of licensure of the reference product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against a finding of interchangeability for other biologics for the same condition of use for the lesser of (i) one year after first commercial marketing of the first interchangeable biosimilar, (ii) eighteen months after the first interchangeable biosimilar is approved if there is not patent challenge, (iii) eighteen months after resolution of a lawsuit over the patents of the reference biologic in favor of the first interchangeable biosimilar applicant, or (iv) 42 months after the first interchangeable biosimilar's application has been approved if a patent lawsuit is ongoing within the 42-month period.

Other Healthcare Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain general business and marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes, false claims statutes and other healthcare laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully offering, soliciting or receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers, among others, on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. In addition, a person or entity does not need to have actual knowledge of the Anti-Kickback Statute or specific intent to violate it in order to commit a violation.

Federal civil and criminal false claims laws, including the federal civil False Claims Act, prohibit any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. This includes claims made to programs where the federal government reimburses, such as Medicare and Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Additionally, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Most states also have statutes or regulations similar to the federal Anti-Kickback Statute and civil False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offeror or payor knows or should know is likely to influence the beneficiary to order a receive a reimbursable item or service from a particular supplier, and the additional federal criminal statutes created by the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations or promises of any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to commit a violation.

Further, pursuant to the ACA, the Centers for Medicare & Medicaid Services, or CMS, has issued a final rule that requires manufacturers of prescription drugs or biologics to collect and report information on certain payments or transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, certain types of advance practice nurses and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. The reported data is made available in searchable form on a public website on an annual basis. Failure to submit required information may result in civil monetary penalties.

In addition, several states now require prescription drug and biologic companies to report certain expenses relating to the marketing and promotion of drug or biologic products and to report gifts and payments to individual healthcare practitioners in these states. Other states prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals. Still other states require the posting of information relating to clinical studies and their outcomes. Some states require the reporting of certain drug or biologic pricing information, including information pertaining to and justifying price increases. In addition, certain states require pharmaceutical companies to implement compliance programs and/or marketing codes. Certain states and local jurisdictions also require the registration of pharmaceutical sales and medical representatives. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties.

Efforts to ensure that business arrangements with third parties comply with applicable healthcare laws and regulations involve substantial costs. If a drug company’s operations are found to be in violation of any such requirements, it may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of its operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other federal or state government healthcare programs, including Medicare and Medicaid, integrity oversight and reporting obligations, imprisonment, and reputational harm. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action for an alleged or suspected violation can cause a drug company to incur significant legal expenses and divert management’s attention from the operation of the business, even if such action is successfully defended.

U.S. Healthcare Reform

Healthcare reforms that have been adopted, and that may be adopted in the future, could result in further reductions in coverage and levels of reimbursement for pharmaceutical products, increases in rebates payable under U.S. government rebate programs and additional downward pressure on pharmaceutical product prices. On September 9, 2021, the Biden administration published a wide-ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. The U.S. Department of Health and Human Services, or HHS, plan includes, among other reform measures, proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. These initiatives recently culminated in the enactment of the Inflation Reduction Act, or IRA, in August 2022, which will, among other things, allow HHS to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics) can be selected by CMS for negotiation. Because the negotiated price takes effect two years after the selection year, no drug or biologic will be subject to a negotiated price prior to 9 or 13 years after approval, respectively. The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price. Beginning in October 2023, the IRA will also penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges.

Data Privacy & Security Laws

Numerous local, state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of personal information, including health-related information. In the United States, numerous local, federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations, govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, imposes privacy, security and breach notification obligations on certain health care providers, health plans, and health care clearinghouses, known as covered entities, as well as their business associates that perform certain services involving creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities.

Even when HIPAA does not apply, according to the Federal Trade Commission, or FTC, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

In addition, certain state and non-U.S. laws, notably the California's Privacy Rights Act, or CPRA, the EU's General Data Protection Regulation, or GDPR, and Canada's Personal Information Protection and Electronic Documents Act, or PIPEDA, govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, the CPRA, which went into effect January 1, 2023, provides for among other things, new data privacy obligations for covered companies and new privacy rights to California residents, including the right to opt out of disclosure and sale of their information. The CPRA also creates a private right of action with statutory damages for certain data breaches of personal information, thereby potentially increasing risks associated with a data breach. Colorado, Utah, Connecticut and Virginia have also recently enacted comparable consumer privacy regimes that have and will take effect in 2023, and as of January 2023, four states (Michigan, Ohio, New Jersey and Pennsylvania) have active bills under review relating to consumer privacy. In Europe, the GDPR went into effect in May 2018 and introduced strict requirements for processing the personal data of individuals within the European Economic Area, or EEA. In addition, the GDPR increases the scrutiny of transfers of personal data from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission does not recognize as having "adequate" data protection laws, and imposes substantial fines for breaches and violations. In Canada, PIPEDA and similar provincial laws impose obligations on companies with respect to processing personal information, including health-related information. PIPEDA requires companies to obtain an individual's consent when collecting, using or disclosing that individual's personal information. Individuals in certain jurisdictions have the right to access and correct the accuracy of their personal information held by an organization, and personal information may only be used for the purposes for which it was collected. If an organization intends to use personal information for another purpose, it must give notice of the new use, and in certain circumstances, again obtain that individual's consent. Failure to comply with PIPEDA could result in significant fines and penalties.

Domestic laws in all 50 states have laws requiring businesses to provide notice to customers, in certain circumstances whose personally identifiable information was been disclosed as a result of unauthorized access or data breach, in addition to requirements under foreign and federal laws. The laws and respective regulations are not consistent and frequently amended.

Employees and Human Capital Resources

As of December 31, 2022, we had 214 employees, of which 59 held a Ph.D. or M.D. We have not experienced any work stoppages. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

Corporate Information

On October 5, 2020, Chinook Therapeutics U.S., Inc. completed its business combination with Aduro Biotech, Inc., a publicly held company. In connection with the Merger, Aduro Biotech, Inc. changed its name to Chinook Therapeutics, Inc. For additional

information regarding this business combination, refer to Note 3, “Reverse Merger and Contingent Value Rights” within Part II, Item 8, “Financial Statements and Supplementary Data” in this Annual Report on Form 10-K. Aduro Biotech, Inc. was incorporated in Delaware in June 2011. Chinook Therapeutics U.S., Inc. (prior to its business combination with Aduro Biotech, Inc.) was incorporated in Delaware in November 2018.

Our principal executive offices are located at 400 Fairview Avenue North, Suite 900, Seattle, WA 98109 and our telephone number is (206) 485-7241. Our website address is www.chinooktx.com. Information contained on or accessible through our website is not a part of this Annual Report on Form 10-K.

Chinook Therapeutics, the Chinook logo and other trade names, trademarks or service marks of Chinook appearing in this Annual Report on Form 10-K are the property of Chinook. Trade names, trademarks and service marks of other companies appearing in this report are the property of their respective holders.

Available Information

The following filings are available through the SEC, which maintains an Internet site at www.sec.gov, and through our website as soon as reasonably practicable after we file them with the SEC: Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, as well as any amendments to such reports and all other filings pursuant to Section 13(a) or 15 (d) of the Securities Act. We will make available on our website www.chinooktx.com, free of charge, copies of these reports and other information as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The contents of the websites referred to above are not incorporated into this filing. Further, our references to the URLs for these websites are intended to be inactive textual references only.

Item 1A. Risk Factors.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risks and all of the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and related notes and the section "Management's Discussion and Analysis of Financial Condition and Results of Operations," before investing in our common stock. While we believe that the risks and uncertainties described below are the material risks currently facing us, additional risks that we do not yet know of or that we currently think are immaterial may also arise and materially affect our business. If any of the following risks materialize, our business, financial condition and results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose some or all of your investment.

Summary of Risk Factors

Our business is subject to a number of risks and uncertainties, including those immediately following this summary. Some of these risks are:

- We have a history of operating losses, and may not achieve or sustain profitability. We anticipate that we will continue to incur losses for the foreseeable future. If we fail to obtain additional funding to conduct our planned research and development efforts, we could be forced to delay, reduce or eliminate our product development programs or commercial development efforts.
- We expect to need to raise additional funding before we can become profitable from any potential future sales of atrasentan or our other product candidates.
- As reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, we previously had material weaknesses in our internal control over financial reporting. While we remediated these material weaknesses as of the fiscal year ended December 31, 2022 and concluded that our internal control over financial reporting was effective as of December 31, 2022, such remediation does not guarantee that our remediated controls will continue to operate properly, or that we will not experience another material weakness in the future.
- We may attempt to secure U.S. Food and Drug Administration, or FDA, approval of atrasentan and our other product candidates through the accelerated approval pathway. If we are unable to obtain accelerated approval, we may be required to conduct additional clinical trials beyond those that we currently contemplate.
- If we are unable to develop, obtain regulatory approval for and commercialize atrasentan or any other future product candidates, or if we experience significant delays in doing so, our business will be materially harmed.
- Success in preclinical studies and earlier clinical trials for our product candidates may not be indicative of the results that may be obtained in later clinical trials, including our phase 3 clinical trial for atrasentan, which may delay or prevent obtaining regulatory approval.
- Atrasentan and our other product candidates may cause undesirable and/or unforeseen side effects or be perceived by the public as unsafe, which could delay or prevent their advancement into clinical trials or regulatory approval, limit the commercial potential or result in significant negative consequences.
- Certain of the diseases we seek to treat have low prevalence and it may be difficult to identify patients with these diseases, which may lead to delays in enrollment for our trials or slower commercial revenue if atrasentan or our other product candidates are approved.
- The commercial success of our product candidates, including atrasentan, will depend upon their degree of market acceptance by providers, patients, patient advocacy groups, third-party payors and the general medical community.
- We face significant competition in an environment of rapid technological change and the possibility that our competitors may achieve regulatory approval before us or develop therapies that are more advanced or effective than ours.
- The manufacture of drugs is complex, and our third-party manufacturers may encounter difficulties in production.
- Actual or perceived failure to comply with privacy and data protection laws or to adequately secure the personal information we hold could result in significant legal liability or reputational harm, and, in turn, create a material adverse effect on our potential future revenue and research & testing efforts.
- Our success depends in part on our ability to obtain, maintain and protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

- The continued presence of COVID-19, or the outbreak of a similar public health crises, could have a material adverse impact on our business, financial condition and results of operations, including the execution of our planned clinical trials and could cause potential supply chain disruptions.

Risks Related to Our Financial Position

We have a history of operating losses, and may not achieve or sustain profitability. We anticipate that we will continue to incur losses for the foreseeable future. If we fail to obtain additional funding to conduct our planned research and development efforts, we could be forced to delay, reduce or eliminate our product development programs or commercial development efforts.

We are a clinical-stage biotechnology company with a limited operating history. Biotechnology product development is a highly speculative undertaking and involves a substantial degree of risk. Our operations to date have been limited primarily to organizing and staffing the Company, business planning, raising capital, acquiring and developing product and technology rights, manufacturing, and conducting research and development activities for our product candidates. We have never generated any revenue from product sales. We have not obtained regulatory approvals for any of our product candidates and have funded our operations to date through proceeds from sales of preferred stock and common stock.

We have incurred net losses in each year since our inception. We incurred a net loss of $187.9 million for the year ended December 31, 2022. As December 31, 2022, we had an accumulated deficit of $419.6 million. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses over the next several years and for the foreseeable future as we intend to continue to conduct research and development, clinical testing, regulatory compliance activities, manufacturing activities, and, if any of our product candidates are approved, sales and marketing activities that, together with anticipated general and administrative expenses, will likely result in us incurring significant losses for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We expect to need to raise additional funding before we become profitable from any potential future sales of atrasentan or our other product candidates. This additional financing may not be available on acceptable terms or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

We will require substantial future capital in order to complete planned and future preclinical and clinical development for atrasentan and other product candidates and potentially commercialize these product candidates. Based upon our current operating plan, we believe that our existing cash, cash equivalents, and marketable securities held as of December 31, 2022 will enable us to fund our operating expenses and capital expenditure requirements into 2025. We expect our spending levels to increase in connection with our preclinical studies and clinical trials of our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant expenses related to commercial launch, product sales, medical affairs, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations before any commercial revenue may occur.

Additional capital might not be available when we need it and our actual cash requirements might be greater than anticipated. If we require additional capital at a time when investment in our industry or in the marketplace in general is limited, we may not be able to raise funding on favorable terms, if at all. If we are not able to obtain financing when needed or on terms favorable to us, we may need to delay, reduce or eliminate certain research and development programs or other operations, sell some or all of our assets or merge with another entity.

Our operations have consumed significant amounts of cash since inception. Our future capital requirements will depend on many factors, including:

- the costs associated with the scope, progress and results of discovery, preclinical development, laboratory testing and clinical trials for our product candidates;
- the costs associated with the manufacturing of our product candidates;
- the costs related to the extent to which we enter into partnerships or other arrangements with third parties to further develop our product candidates;
- the costs and fees associated with the discovery, acquisition or in-license of product candidates or technologies;
- our ability to establish collaborations on favorable terms, if at all;
- the costs of future commercialization activities, if any, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;

- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval; and
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

Our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of product candidates that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives, which may not be available to us on acceptable terms, or at all.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are a clinical-stage biotechnology company and our operations to date have been limited to organizing and staffing the Company, business planning, raising capital, acquiring our technology, identifying potential product candidates, undertaking research and preclinical studies of our product candidates, manufacturing, and establishing licensing arrangements. We have limited experience in conducting clinical trials and have not yet demonstrated the ability to successfully complete clinical trials of our product candidates, obtain marketing approvals, manufacture a commercial scale product or conduct sales and marketing activities necessary for commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

As reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, we previously had material weaknesses in our internal control over financial reporting. While we remediated these material weaknesses as of the fiscal year ended December 31, 2022 and concluded that our internal control over financial reporting was effective as of December 31, 2022, such remediation does not guarantee that our remediated controls will continue to operate properly, or that we will not experience another material weakness in the future.

Internal controls are critical to maintaining adequate internal control over financial reporting. As disclosed in Part II, Item 9A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on March 17, 2022, in preparing our consolidated financial statements as of and for the years ended December 31, 2021 and 2020, our management identified certain material weaknesses in our internal control over financial reporting. While these material weaknesses were remediated as of the year ended December 31, 2022, and we concluded that our internal control over financial reporting was effective as of December 31, 2022, we cannot assure you that we will not identify material weaknesses in the future. If material weaknesses are identified in our internal controls then the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with Section 404 of the Sarbanes-Oxley Act, securities law requirements regarding the timely filing of periodic reports or the Nasdaq listing requirements, investors may lose confidence in our financial reporting, and our share price could decline. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Additionally, our management is required to report on the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. However, we recognize that maintaining adequate internal control over financial reporting will continue to require significant management attention and expense.

Risks Related to Our Product Development and Regulatory Approval

If we are unable to develop, obtain regulatory approval for and commercialize atrasentan or any other future product candidates, or if we experience significant delays in doing so, our business will be materially harmed.

We plan to invest a substantial amount of our efforts and financial resources in our current lead product candidates, atrasentan, a potent and selective endothelin receptor antagonist, and BION-1301, an anti-APRIL monoclonal antibody. With atrasentan, we are currently conducting the ALIGN phase 3 clinical trial for the treatment of IgAN and the phase 2 AFFINITY clinical trial for certain proteinuric glomerular diseases. With BION-1301, we are currently conducting a phase 1/2 clinical trial for the treatment of IgAN, and planning to initiate a global phase 3 trial in mid-2023. We are also developing CHK-336 for the treatment of kidney stone disease, or hyperoxaluria, and have received rare pediatric disease designation from the FDA for CHK-336 for the treatment of primary hyperoxaluria. In addition, we are conducting research programs in several other rare, severe chronic kidney diseases. Our ability to generate product revenue will depend heavily on the successful development and eventual commercialization of atrasentan and our other product candidates, which may never occur. We currently generate no revenue from sales of any product, and we may never be able to develop or commercialize a marketable product.

Each of our programs and product candidates will require further clinical and/or preclinical development, regulatory approval in multiple jurisdictions, obtaining preclinical, clinical and commercial manufacturing supply, capacity and expertise, building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenue from product sales. Atrasentan and our other product candidates must be authorized for marketing by the FDA, the Health Products and Food Branch of Health Canada, or HPFB, the EMA, and certain other foreign regulatory agencies before we may commercialize any of our product candidates.

The success of atrasentan and our other product candidates depends on multiple factors, including:

- successful completion of preclinical studies, including those compliant with GLP, or GLP toxicology studies, biodistribution studies and minimum effective dose studies in animals, and successful enrollment and completion of clinical trials compliant with current GCPs;
- effective investigational new drug applications, or INDs, and Clinical Trial Authorizations, or CTAs, that allow commencement of our planned clinical trials or future clinical trials for our product candidates in relevant territories;
- establishing and maintaining relationships with contract research organizations, or CROs, and clinical sites for the clinical development of our product candidates, both in the United States and internationally;
- maintenance of arrangements with third-party contract manufacturing organizations, or CMOs, for key materials used in our manufacturing processes and to establish backup sources for clinical and large-scale commercial supply;
- positive results from our clinical programs that are supportive of safety and efficacy and provide an acceptable risk-benefit profile for our product candidates in the intended patient populations;
- receipt of regulatory approvals from applicable regulatory authorities, including those necessary for pricing and reimbursement of our product candidates;
- establishment and maintenance of patent and trade secret protection and regulatory exclusivity for our product candidates;
- commercial launch of our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of our product candidates, if and when approved, by patients, patient advocacy groups, third-party payors and the general medical community;
- our effective competition against other therapies available in the market;
- establishment and maintenance of adequate reimbursement from third-party payors for our product candidates;
- our ability to acquire or in-license additional product candidates;
- prosecution, maintenance, enforcement and defense of intellectual property rights and claims;
- maintenance of a continued acceptable safety profile of our product candidates following approval, including meeting any post-marketing commitments or requirements imposed by or agreed to with applicable regulatory authorities;
- political factors surrounding the approval process, such as government shutdowns or political instability; or
- disruptions in enrollment of our clinical trials due to the COVID-19 pandemic.

If we do not succeed in one or more of these factors in a timely manner or at all, then we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

Success in preclinical studies and earlier clinical trials for our product candidates may not be indicative of the results that may be obtained in later clinical trials, including our phase 3 clinical trial for atrasentan, which may delay or prevent obtaining regulatory approval.

Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Success in preclinical studies and early clinical trials may not be predictive of results in later-stage clinical trials, and successful results from early or small clinical trials may not be replicated or show as favorable an outcome in later-stage or larger clinical trials, even if successful. We will be required to demonstrate through adequate and well-controlled clinical trials that our product candidates are safe and effective for their intended uses before we can seek regulatory approvals for their commercial sale. The conduct of phase 3 trials and the submission of an NDA, or BLA is a complicated process. We have limited experience in conducting clinical trials and preparing, submitting and supporting regulatory filings, and have not previously submitted an NDA or BLA. Consequently, we may be unable to successfully and efficiently execute and complete

necessary clinical trials and other requirements in a way that leads to NDA or BLA submission and approval of any product candidate we are developing.

We in-licensed atrasentan from AbbVie. Atrasentan was previously investigated in a phase 3 clinical trial evaluating the effects of atrasentan on progression of kidney disease in patients with DKD, referred to as the SONAR trial. While patients receiving atrasentan in the SONAR trial had a lower rate of primary composite renal events than patients receiving placebo, the trial accrued measurable primary endpoints at a slower rate than expected, and AbbVie decided to close the study early for corporate strategic reasons. We believe the results of the SONAR trial support further evaluation of atrasentan in IgAN. Although the SONAR trial was not terminated due to safety concerns, further safety issues could be discovered in our phase 2 and phase 3 trials. Based on the data from the SONAR trial, we believe that atrasentan, combined with current standard of care, may have benefits compared to treatment with current standard of care. However, we cannot assure that any potential advantages that we believe atrasentan may have for treatment of patients with proteinuric glomerular diseases will be substantiated by our planned clinical trials or included in the product's labeling should we obtain approval. Without head-to-head data, we will not be able to make comparative claims with respect to any other treatments. In addition, the patient populations under investigation with atrasentan have many co-morbidities that may cause severe illness or death, which may be attributed to atrasentan in a manner that negatively affects its safety profile. If the results of our clinical trials for atrasentan are inconclusive with respect to efficacy, if we do not meet our clinical endpoints with statistical significance, or if there are unanticipated safety concerns or adverse events that emerge during clinical trials, we may have to conduct further preclinical studies and/or clinical trials before obtaining marketing approval, or we may be prevented from or delayed in obtaining marketing approval.

Though atrasentan has been evaluated by AbbVie in late-stage clinical trials, our other product candidates, such as BION-1301 and CHK-336, have only been evaluated in early-stage clinical trials, and we may experience unexpected or negative results in the future as our other product candidates are evaluated in clinical trials. Any positive results we have observed in preclinical animal models may not be predictive of our future clinical trials in humans, as animal models carry inherent limitations relevant to all preclinical studies. Our product candidates may also fail to show the desired safety and efficacy in later stages of clinical development even if they successfully advance through initial clinical trials. Even if our clinical trials demonstrate acceptable safety and efficacy of atrasentan or our other product candidates and such product candidates receive regulatory approval, the labeling we obtain through negotiations with the FDA or foreign regulatory authorities may not include data on secondary endpoints and may not provide us with a competitive advantage over other products approved for the same or similar indications.

Many companies in the biotechnology industry have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and there is a high failure rate for product candidates proceeding through clinical trials. In addition, different methodologies, assumptions and applications we utilize to assess particular safety or efficacy parameters may yield different statistical results. Even if we believe the data collected from clinical trials of our product candidates are promising, these data may not be sufficient to support approval by the FDA or foreign regulatory authorities. Preclinical and clinical data can be interpreted in different ways. Accordingly, the FDA or foreign regulatory authorities could interpret these data in different ways from us or our partners, which could delay, limit or prevent regulatory approval. If our study data do not consistently or sufficiently demonstrate the safety or efficacy of any of our product candidates, including atrasentan, to the satisfaction of the FDA or foreign regulatory authorities, then the regulatory approvals for such product candidates could be significantly delayed as we work to meet approval requirements, or, if we are not able to meet these requirements, such approvals could be withheld or withdrawn.

Even if we complete the necessary preclinical studies and clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize a product candidate and the approval may be for a narrower indication than we seek.

Prior to commercialization, atrasentan and our other product candidates must be approved by the FDA pursuant to an NDA or BLA in the United States and pursuant to similar marketing applications by the HPFB, European Medicines Agency, or the EMA, and similar regulatory authorities outside the United States. The process of obtaining marketing approvals, both in the United States and abroad, is expensive and takes many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market atrasentan or any of our other product candidates from regulatory authorities in any jurisdiction. We have no experience in submitting and supporting the applications necessary to gain marketing approvals, and, in the event regulatory authorities indicate that we may submit such applications, we may be unable to do so as quickly and efficiently as desired. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. Regulatory authorities have substantial discretion in the approval process and may refuse to accept or file any application or may decide if our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate.

Approval of atrasentan and our other product candidates may be delayed or refused for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate, to the satisfaction of the FDA or comparable foreign regulatory authorities, that our product candidates are safe and effective for any of their proposed indications;
- the populations studied in clinical trials may not be sufficiently broad or representative to assure efficacy and safety in the populations for which we seek approval;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate our product candidates' clinical and other benefits outweigh their safety risks;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA, BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the facilities of third-party manufacturers with which we contract or procure certain service or raw materials, may not be adequate to support approval of our product candidates; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Even if our product candidates meet their pre-specified safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner and may not consider the clinical trial results sufficient to grant, or we may not be able to obtain, regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process. For example, in response to review of the statistical analysis plan for the ALIGN trial, we received correspondence from the FDA in February 2023 recommending that evaluation of the interim proteinuria endpoint analysis for accelerated approval in the ALIGN trial be delayed from week 24 to week 36. The FDA referenced the likelihood that the later timepoint would allow for a greater amount of eGFR data to be evaluated at the time of accelerated approval. We plan to engage in discussions with the FDA as soon as possible regarding this advice, but we may not be able to come to agreement regarding the appropriate timing for the primary proteinuria endpoint and/or may experience additional delays or potential rejection of our application for approval from the FDA or similar regulatory agencies.

Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings, contraindications or a risk evaluation and mitigation strategy, or REMS. These regulatory authorities may also grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and adversely affect our business, financial condition, results of operations and prospects.

Atrasentan and our other product candidates may cause undesirable and/or unforeseen side effects or be perceived by the public as unsafe, which could delay or prevent their advancement into clinical trials or regulatory approval, limit the commercial potential or result in significant negative consequences.

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with our product candidates' use. For example, in the phase 3 SONAR trial, the most common adverse events of atrasentan included fluid retention and anemia. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. If any such adverse events occur, our clinical trials could be suspended or terminated and the FDA, the HPFB, the European Commission, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. Even if we can demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may adversely affect our business, financial condition, results of operations and prospects significantly. Other treatments for kidney diseases that utilize an ET_A receptor antagonist or similar mechanism of action could also generate data that could adversely affect the clinical, regulatory or commercial perception of atrasentan and our other product candidates.

Additionally, if any of our product candidates receives marketing approval, the FDA could require us to adopt a REMS to ensure that the benefits of the product outweigh its risks, which may include, for example, a Medication Guide outlining the risks of the product for distribution to patients and a communication plan to health care practitioners, or other elements to assure safe use of the product. For example, other approved endothelin A receptor antagonists, or ERAs, have been required to include a REMS for women of child-bearing age regarding the risk of embryo-fetal toxicity and/or hepatotoxicity. Filspari (sparsentan), which was approved in February 2022, has a black box warning on its label for hepatotoxicity and embryo-fetal toxicity and is only available through a restricted distribution program called the Filspari REMS. Furthermore, if we or others later identify undesirable side effects caused by our product candidates, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings in the labeling;
- we may be required to change the way a product candidate is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly.

Certain of the diseases we seek to treat have low prevalence, and it may be difficult to identify patients with these diseases, which may lead to delays in enrollment for our trials or slower commercial revenue growth if atrasentan or our other product candidates are approved.

While chronic kidney diseases represent a large market, primary glomerular kidney diseases, including IgAN, to which our lead product candidate is targeted, have relatively low incidence and prevalence. We estimate that IgAN affects approximately 1.3 per 100,000 individuals per year in the United States. The global incidence of IgAN is approximately 2.5 per 100,000 individuals per year. Variations in disease incidence and prevalence are, in part, due to regional differences in urine screening, referral patterns and indications for biopsy. We estimate that IgAN is associated with progressive loss of kidney function leading to ESKD in approximately 30% to 45% of IgAN patients over 20 to 25 years, representing a significant unmet need for new treatment options. We are also developing CHK-336 for the treatment of primary hyperoxaluria, which is an ultra-orphan disease with an even smaller number of patients. We have received rare pediatric disease designation from the FDA for CHK-336 for the treatment of PH. Small target patient populations could pose obstacles to the timely recruitment and enrollment of a sufficient number of eligible patients in our trials, or limit a product candidate's commercial potential. Patient enrollment may be affected by other factors including:

- the ability to identify and enroll patients that meet study eligibility criteria in a timely manner for clinical trials;
- the severity of the disease under investigation;
- design of the study protocol;
- the perceived risks, benefits and convenience of administration of the product candidate being studied;
- the patient referral practices of providers;
- the proximity and availability of clinical trial sites to prospective patients; and
- the availability of approved or investigational alternative treatment options.

Our inability to enroll a sufficient number of patients with these diseases for our clinical trials would result in significant delays and could cause us to not initiate or abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased time to potential approval and development costs for our product candidates, which would cause the value of the Company to decline and limit our ability to obtain additional financing.

Additionally, our projections of both the number of people who have IgAN and other proteinuric glomerular diseases, as well as the people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates derived from a commissioned market research study, which may not accurately identify the size of the market for our product candidates. The total addressable market opportunity for atrasentan and our other product candidates will ultimately depend upon, among other things, the final labeling for our product candidates, if our product candidates are approved for sale in our target indications, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients globally may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidates, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

Moreover, in light of the limited number of potential patients impacted by proteinuric glomerular diseases, our per-patient therapy pricing of atrasentan, if approved, may need to be high in order to recover our development and manufacturing costs, fund additional research and achieve profitability. We may also need to fund patient support programs upon the marketing of a product candidate, which would negatively affect our product revenue. We may be unable to maintain or obtain sufficient therapy sales volumes at a price high enough to justify our development efforts and our sales, marketing and manufacturing expenses.

We may not be successful in our efforts to expand our pipeline of product candidates and develop marketable products.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. Our business depends on our successful development and commercialization of the limited number of internal product candidates we are researching or have in preclinical development. Even if we are successful in continuing to build our pipeline, development of the potential product candidates that we identify will require substantial investment in additional clinical development, management of clinical, preclinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply capability, building a commercial organization, and significant marketing efforts before we generate any revenue from product sales. Furthermore, such product candidates may not be suitable for clinical development, including as a result of their harmful side effects, limited efficacy or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we cannot develop further product candidates, we may not be able to obtain product revenue in future periods, which would adversely affect our business, prospects, financial condition and results of operations.

Although our pipeline includes multiple programs, we are primarily focused on our lead product candidates, atrasentan, BION-1301 and CHK-336, and we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities and our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. Our understanding and evaluation of biological targets for the discovery and development of new product candidates may fail to identify challenges encountered in subsequent preclinical and clinical development. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

Any product candidate for which we obtain marketing approval will be subject to extensive post-marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to penalties if it fails to comply with regulatory requirements or if it experiences unanticipated problems with our product candidates, when and if any of them are approved.

Our product candidates and the activities associated with their development and potential commercialization, including their testing, manufacturing, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other U.S. and international regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, including current Good Manufacturing Practices, or cGMPs, quality control, quality assurance and corresponding maintenance of records and documents, including periodic inspections by the FDA and other regulatory authorities and requirements regarding the distribution of samples to providers and recordkeeping. In addition, manufacturers of drug and biological products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMPs.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of any approved product. The FDA closely regulates the post-approval marketing and promotion of drugs and biologics to ensure that they are marketed in a manner consistent with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products. If we promote our product candidates in a manner inconsistent with FDA-approved labeling or otherwise not in compliance with FDA regulations, we may be subject to enforcement action. Violations of the Federal Food, Drug, and Cosmetic Act, or FD&C Act, relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws and similar laws in international jurisdictions.

In addition, later discovery of previously unknown adverse events or other problems with our product candidates, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such product candidates, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;

- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of any approved product from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of product candidates;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our product candidates;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity. The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we have obtained, and we may not achieve or sustain profitability.

Non-compliance with Canadian and European requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with Canada's or Europe's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidates outside the United States.

To market and sell atrasentan and our other product candidates in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time and data required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Failure to obtain foreign regulatory approvals or non-compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries.

If we fail to comply with the regulatory requirements in international markets and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval of any of our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business prospects could decline.

Risks Related to Commercialization and Manufacturing

The commercial success of our product candidates, including atrasentan, will depend upon their degree of market acceptance by providers, patients, patient advocacy groups, third-party payors and the general medical community.

Even with the requisite approvals from the FDA, the HPFB, the EMA and other regulatory authorities internationally, the commercial success of our product candidates will depend, in part, on the acceptance of providers, patients and third-party payors of drugs designed to act as a selective blocker of the ET_A receptor in particular for atrasentan, and our product candidates in general, as medically necessary, cost-effective and safe. In addition, we may face challenges in seeking to establish and grow sales of atrasentan or our other product candidates. Any product that we commercialize may not gain acceptance by providers, patients, patient advocacy groups, third-party payors and the general medical community. If these products do not achieve an adequate level of acceptance, we

may not generate significant product revenue and may not become profitable. The degree of market acceptance of atrasentan and our other product candidates, if approved for commercial sale, will depend on several factors, including:

- the efficacy, durability of treatment effect and safety of such product candidates as demonstrated in clinical trials;
- the potential and perceived advantages of product candidates over alternative treatments;
- the cost of treatment relative to alternative treatments;
- the clinical indications for which the product candidate is approved by the FDA, the HPFB or the European Commission;
- the willingness of providers to prescribe new therapies;
- the willingness of the target patient population to try new therapies;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA, the HPFB, EMA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- the quality of our relationships with patient advocacy groups;
- publicity concerning our product candidates or competing products and treatments; and
- sufficient third-party payor coverage and adequate reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be fully known until after it is launched.

The pricing, insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate product revenue.

Our target indications, including IgAN and other proteinuric glomerular diseases, are indications with relatively small patient populations. For product candidates that are designed to treat smaller patient populations to be commercially viable, the reimbursement for such product candidates must be higher, on a relative basis, to account for the lack of volume. Accordingly, we will need to implement a coverage and reimbursement strategy for any approved product candidate that accounts for the smaller potential market size. If we are unable to establish or sustain coverage and adequate reimbursement for our product candidates from third-party payors, the adoption of those product candidates and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved.

We expect that coverage and reimbursement by third-party payors will be essential for most patients to be able to afford these treatments. Accordingly, sales of atrasentan and our other product candidates will depend substantially, both domestically and internationally, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers and other third-party payors. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered and reimbursed. The Medicare program covers certain individuals aged 65 or older, disabled or suffering from ESKD. The Medicaid program, which varies from state-to-state, covers certain individuals and families who have limited financial means. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. One payor's determination to provide coverage for a drug or biological product, however, does not assure that other payors will also provide coverage for the product. Further, a payor's decision to provide coverage for a drug or biological product does not imply that an adequate reimbursement rate will be approved.

In addition to government and private payors, professional organizations such as the American Medical Association, or the AMA, can influence decisions about coverage and reimbursement for new products by determining standards for care. In addition, many private payors contract with commercial vendors who sell software that provide guidelines that attempt to limit utilization of,

and therefore reimbursement for, certain products deemed to provide limited benefit to existing alternatives. Such organizations may set guidelines that limit reimbursement or utilization of our product candidates. Even if favorable coverage and reimbursement status is attained for one or more product candidates for which our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the EU, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, the prices of products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payors, in the United States and internationally, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of certain third-party payors, such as health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market. Recently there have been instances in which third-party payors have refused to reimburse treatments for patients for whom the treatment is indicated in the FDA-approved product labeling. Even if we are successful in obtaining FDA approvals to commercialize our product candidates, we cannot guarantee that we will be able to secure reimbursement for all patients for whom treatment with our product candidates is indicated.

If third parties on which we depend to conduct our preclinical studies or clinical trials, do not perform as contractually required, fail to satisfy regulatory or legal requirements or miss expected deadlines, our development program could be delayed with adverse effects on our business, financial condition, results of operations and prospects.

We rely on third party CROs, CMOs, consultants and others to design, conduct, supervise and monitor key activities relating to, discovery, manufacturing, preclinical studies and clinical trials of our product candidates, and we intend to do the same for future activities relating to existing and future programs. Because we rely on third parties and do not have the ability to conduct all required testing, discovery, manufacturing, preclinical studies or clinical trials independently, we have less control over the timing, quality and other aspects of discovery, manufacturing, preclinical studies and clinical trials than we would if we conducted them on our own. These investigators, CROs, CMOs and consultants are not our employees, and we have limited control over the amount of time and resources that they dedicate in our programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties we contract with might not be diligent, careful or timely in conducting our discovery, manufacturing, preclinical studies or clinical trials, resulting in testing, discovery, manufacturing, preclinical studies or clinical trials being delayed or unsuccessful, in whole or in part.

If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, satisfy legal and regulatory requirements for the conduct of preclinical studies or clinical trials or meet expected deadlines, our clinical development programs could be delayed and otherwise adversely affected. In all events, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the general investigational plan and protocols for the trial, as well as in accordance with GLP, GCP and other applicable laws, regulations and standards. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. The FDA and other regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If the Company or any of these third parties fails to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials have complied with GCPs. In addition, our clinical trials must be conducted with product produced in accordance with cGMPs. Our failure to comply with these regulations may require us to repeat clinical trials,

which could delay or prevent the receipt of regulatory approvals. Any such event could have an adverse effect on our business, financial condition, results of operations and prospects.

We expect some of the product candidates we develop will be regulated as biological products, or biologics, and therefore they may be subject to competition sooner than anticipated.

The Biologics Price Competition and Innovation Act, or BPCIA, was enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the ACA, to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement the BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our product candidates.

We believe that if any of our product candidates is approved as a biological product under a BLA, such as BION-1301, it should qualify for the 12-year period of exclusivity. However, there is a risk that the FDA will not consider any of our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Additionally, this period of regulatory exclusivity does not apply to companies pursuing regulatory approval via their own traditional BLA, rather than via the abbreviated pathway. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. There has been public discussion of efforts to incentivize and increase biosimilar drug development including by potentially decreasing the period of exclusivity from the current 12 years. In September 2021, the Biden administration released its prescription drug pricing reform plans, which included proposals to reassess exclusivity periods, streamline biosimilar licensure, force disclosure of inactive ingredients, and other measures to increase biosimilar drug development. If such changes and reforms were to be enacted, our product candidates, if approved, could have a shorter period of exclusivity than anticipated or face increased competition from biosimilar drug products. We continue to evaluate executive, legislative and judicial efforts to modify aspects of the law, and the extent to which any such changes may impact our business or financial condition.

We face significant competition in an environment of rapid technological change and it is possible that our competitors may achieve regulatory approval before us or develop therapies that are more advanced or effective than ours, which may harm our business, financial condition and our ability to successfully market or commercialize atrasentan and our other product candidates.

The biotechnology and pharmaceutical industries are characterized by rapidly changing technologies, competition and a strong emphasis on intellectual property. We are aware of several companies focused on developing proteinuric glomerular disease treatments in various indications as well as several companies addressing other treatments for rare, severe chronic kidney diseases. We may also face competition from large and specialty pharmaceutical and biotechnology companies, academic research institutions, government agencies and public and private research institutions that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing and commercialization.

Although several companies are focused on developing treatments on IgAN and other proteinuric glomerular diseases, there are currently limited treatment options for proteinuric glomerular diseases. To our knowledge, there are only two FDA-approved drugs for IgAN, Tarpeyo (budesonide) from Calliditas Therapeutics AB and Filspari (sparsentan) from Travere Therapeutics, Inc. In addition, there are a variety of additional treatments utilized that include RASis, steroids, chemotherapy drugs and immunomodulatory approaches. In addition, there are a number of competitors in clinical development for the treatment of IgAN at a similar stage of development or more advanced than us, including Alnylam Pharmaceuticals, Inc., AstraZeneca PLC, Ionis Pharmaceuticals, Inc., F. Hoffman-La Roche Ltd., Novartis AG, Omeros Corporation, Vera Therapeutics, Inc., RemeGen, Alpine Immune Sciences, Inc., and Otsuka Pharmaceutical Co., Ltd.

Many of our potential competitors, alone or with their strategic partners, may have substantially greater financial, technical and other resources than we do, such as larger research and development, clinical, marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors. Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any product candidates that we may develop. Competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our products, which could result in our competitors establishing a strong market position before we are able to enter the market, if ever. Additionally, new or advanced technologies developed by our competitors may render

our current or future product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors.

To become and remain profitable, we must develop and eventually commercialize product candidates with significant market potential, which will require us to be successful in a range of challenging activities. These activities include, among other things, completing preclinical studies and initiating and completing clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those products that are approved and satisfying any post marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenues that are significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue operations. A decline in the value of the Company also could cause you to lose all or part of your investment.

The manufacture of pharmaceutical products is complex, and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide supply of atrasentan or our other product candidates for clinical trials, our ability to obtain marketing approval, or our ability to provide supply of our product candidates for patients, if approved, could be delayed or stopped.

We have and intend to continue to establish manufacturing relationships with a limited number of suppliers to manufacture raw materials, the drug substance and finished product of any product candidate for which we are responsible for preclinical or clinical development. Pursuant to our license agreement with AbbVie, we received a substantial amount of drug product and drug substance to support initiation of our clinical trials of atrasentan; however, we do not yet have a long-term commercial manufacturing agreement for atrasentan with AbbVie or any other CMO. We will need to establish manufacturing relationships for the production of sufficient atrasentan for any potential commercialization. Each supplier may require licenses to manufacture such components if such processes are not owned by the supplier or in the public domain. As part of any marketing approval, a manufacturer and our processes are required to be qualified by the FDA prior to regulatory approval. If supply from the approved vendor is interrupted, there could be a significant disruption in commercial supply. An alternative vendor would need to be qualified through an NDA or BLA supplement which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if a new supplier is relied upon for commercial production. Switching vendors may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

The process of manufacturing pharmaceutical products is complex, highly-regulated and subject to multiple risks. The manufacture of drugs and biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered at the facilities of our manufacturers, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. Moreover, if the FDA determines that our CMOs are not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may deny regulatory approval until the deficiencies are corrected or we replace the manufacturer in our regulatory approvals with a manufacturer that is in compliance. In addition, approved products and the facilities at which they are manufactured are required to maintain ongoing compliance with extensive FDA requirements and the requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to cGMP requirements. As such, our CMOs are subject to continual review and periodic inspections to assess compliance with cGMPs. Furthermore, although we do not have day-to-day control over the operations of our CMOs, we are responsible for ensuring compliance with applicable laws and regulations, including cGMPs.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency and timely availability of raw materials. Even if our collaborators obtain regulatory approval for any of our product candidates, there is no assurance that manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and prospects.

We believe that we will rely upon a limited number of manufacturers for our product candidates, including atrasentan, for which we have identified single-source suppliers for the various steps of manufacture. This reliance on a limited number of manufacturers and the complexity of drug manufacturing and the difficulty of scaling up a manufacturing process could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and

prevent us from commercializing our product candidates successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production in a timely manner at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell atrasentan and our other product candidates, we may be unable to generate any revenues.

We currently do not have an organization for the sales, marketing and distribution of atrasentan, BION-1301, CHK-336 and our other product candidates, and the expense of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. To market any products that may be approved, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. With respect to certain of our current programs as well as future programs, we may rely completely on an alliance partner for sales and marketing. In addition, although we intend to establish a sales organization if we are able to obtain approval to market any product candidates, we may enter into strategic alliances with third parties to develop and commercialize atrasentan and other product candidates, including in markets outside of the United States or for other large markets that are beyond our resources, such as the joint venture, SanReno Therapeutics, we formed for the development and commercialization of atrasentan and BION-1301 in China and certain other East-Asian countries. This will reduce the revenue generated from the sales of these products.

Any future strategic alliance partners may not dedicate sufficient resources to the commercialization of our product candidates or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective alliances to enable the sale of our product candidates to healthcare professionals and in geographical regions, including the United States, that will not be covered by our marketing and sales force, or if our potential future strategic alliance partners do not successfully commercialize the product candidates, our ability to generate revenues from product sales will be adversely affected.

If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

We may not be successful in finding strategic collaborators for continuing development of certain of our future product candidates or successfully commercializing or competing in the market for certain indications.

In the future, we may decide to collaborate with non-profit organizations, universities and pharmaceutical and biotechnology companies for the development and potential commercialization of existing and new product candidates. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our expense. If we elect to increase our expenditures to fund development or commercialization activities on our product candidates, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

The success of any potential collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead

to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of such collaboration arrangements. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

Risks Related to Government Regulation

A Fast Track Designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval.

While we do not intend to seek Fast Track Designation for atrasentan, we may seek such designation for our other product candidates. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the drug or biologic demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply to the FDA for Fast Track Designation. The FDA has broad discretion whether to grant this designation. Even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. The FDA may also withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Even if we receive Fast Track Designation for any of our product candidates, such product candidates may not experience faster development, review or approval processes compared to conventional FDA procedures. Many drugs and biologics that have received Fast Track Designation have failed to obtain approval.

We may attempt to secure FDA approval of atrasentan and our other product candidates through the accelerated approval pathway. If we are unable to obtain accelerated approval, we may be required to conduct additional clinical trials beyond those that we currently contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals.

We are developing certain product candidates for the treatment of serious conditions, and therefore intend to seek approval of such product candidates under the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it is designed to treat a serious or life-threatening disease or condition and provides a meaningful therapeutic benefit over existing treatments based upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability of or lack of alternative treatments. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit.

The accelerated approval pathway may be used in cases in which the advantage of a new product over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug or biologic's anticipated effect on irreversible morbidity or mortality or other clinical benefit. In some cases, the FDA may require that the trial be designed, initiated, and/or fully enrolled prior to approval. If the sponsor fails to conduct such studies in a timely manner, or if such post-approval studies fail to verify the drug or biologic's predicted clinical benefit, or if other evidence demonstrates that the product candidate is not shown to be safe and effective under the conditions of use, the FDA may withdraw its approval of the drug or biologic on an expedited basis.

We intend to use reduction in proteinuria as a surrogate endpoint in our phase 3 ALIGN trial of atrasentan. However, atrasentan may not show a sufficient treatment benefit on the expected surrogate endpoint to satisfy the FDA that the anticipated benefit on loss of renal function will be confirmed in the planned post-marketing phase of the trial. If we decide to submit an NDA seeking accelerated approval or receive an expedited regulatory designation for atrasentan or any of our other product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. If the standard of care were to evolve or if any of our competitors were to receive full approval for an indication for which we are seeking accelerated approval before we receive accelerated approval, the indication we are seeking may no longer qualify as a condition for which there is an unmet medical need and accelerated approval of our product candidate would not occur without a showing of benefit over available therapy.

In addition, the FDA may terminate the accelerated approval program or change the standards under which accelerated approvals are considered and granted in response to public pressure or other concerns regarding the accelerated approval program. Changes to or termination of the accelerated approval program could prevent or limit our ability to obtain accelerated approval of any of our clinical development programs. Recently, the accelerated approval pathway has come under scrutiny within the FDA and by Congress. The FDA has put increased focus on ensuring that confirmatory studies are conducted with diligence and, ultimately, that

such studies confirm the benefit. Congress has also considered various proposals to potentially make changes to the accelerated approval pathway, including proposals to increase the likelihood of withdrawal of approval in such circumstances. The Food and Drug Omnibus Reform Act, or FDORA, was recently enacted, which included provisions related to the accelerated approval pathway. Pursuant to FDORA, the FDA is authorized to require a post-approval study to be underway prior to approval or within a specified time period following approval. FDORA also requires the FDA to specify conditions of any required post-approval study and requires sponsors to submit progress reports for required post-approval studies. FDORA enables the FDA to initiate criminal prosecutions for the failure to conduct with due diligence a required post-approval study, including a failure to meet any required conditions specified by the FDA or to submit timely reports.

Failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidates would result in a longer time period to commercialization of such product candidate, if any, and could increase the cost of development of such product candidate and harm our competitive position in the marketplace.

We may be unsuccessful in obtaining Orphan Drug Designation for our product candidates or transfer of designations obtained by others for future product candidates, and, even if we obtain such designation, we may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity, for atrasentan or our other product candidates.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs intended to treat relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug in the United States will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting for regulatory approval. In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for tax credits for qualified clinical research costs and exemption from prescription drug user fees. Similarly, in the EU, the European Commission grants Orphan Drug Designation after receiving the opinion of the EMA's Committee for Orphan Medicinal Products on an Orphan Drug Designation application. In the EU, Orphan Drug Designation is intended to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the EU and for which no satisfactory method of diagnosis, prevention or treatment has been authorized (or the product would be a significant benefit to those affected). In the EU, Orphan Drug Designation entitles a party to financial incentives such as reduction of fees or fee waivers.

Generally, if a drug with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA or EMA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. If a competitor is able to obtain orphan drug exclusivity prior to us for a product that constitutes the same active moiety and treats the same indications as our product candidates, we may not be able to obtain approval of our drug by the applicable regulatory authority for a significant period of time unless we are able to show that our drug is clinically superior to the approved drug. The applicable period is seven years in the United States and ten years in the EU. The EU exclusivity period can be reduced to six years if a drug no longer meets the criteria for Orphan Drug Designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

We have obtained Orphan Drug Designation for atrasentan and BION-1301 for IgAN in the EU and may seek Orphan Drug Designation for these product candidates for this indication in the United States and other countries. However, we may not obtain Orphan Drug Designation and even if we do, Orphan Drug Designation does not guarantee future orphan drug marketing exclusivity.

Even after an orphan drug is approved, the FDA can also subsequently approve a later application for the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer in a substantial portion of the target populations, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

We may be unsuccessful in obtaining Rare Pediatric Disease Designation for our product candidates or for future product candidates, and, even if we obtain such designation, we may be unable to maintain the benefits associated with such designation, including the potential for use or sale of a future priority review voucher.

The Rare Pediatric Disease Voucher Program is intended to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Although there are existing incentive programs to encourage the

development and study of drugs and biologics for rare diseases, pediatric populations, and unmet medical needs, this program provides an additional incentive for the development of drugs and biologics for rare pediatric diseases, which may be used alone or in combination with other incentive programs. A rare pediatric disease is defined as a disease that is a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; and is a rare disease or condition as defined in the FD&C Act, which includes diseases and conditions that affect fewer than 200,000 persons in the United States and diseases and conditions that affect a larger number of persons and for which there is no reasonable expectation that the costs of developing and making available the product in the United States can be recovered from sales of the product in the United States.

The sponsor of an application for a rare pediatric disease drug product may be eligible for a voucher that can be used or sold to obtain a priority review for a subsequent application submitted under section 505(b)(1) of the FD&C Act or section 351 of the PHS Act after the date of approval of the rare pediatric disease drug product. The rare pediatric disease priority review voucher program was most recently re-authorized by Congress, extending the rare pediatric disease program through September 30, 2024, with the potential for priority review vouchers to be granted through September 30, 2026. Although we have obtained designation of CHK-336 for the treatment of PH as a rare pediatric disease, we may not meet the eligibility requirements for a priority voucher at the time we seek approval of CHK-336 or we may not meet the current deadline for receiving a priority review voucher, in which case we would not be able to use priority review for a subsequent product of ours or be able to sell such voucher to a third party, unless Congress further reauthorizes the program. Additionally, designation of a drug for a rare pediatric disease does not guarantee that a drug will meet the other eligibility criteria for a rare pediatric disease priority review voucher at the time the application is approved. Finally, a rare pediatric disease designation does not necessarily lead to faster development or regulatory review of the product or increase the likelihood that it will receive marketing approval.

Enacted and future legislation may increase the difficulty and cost for us to commercialize and obtain marketing approval of our product candidates and may affect the prices we may set.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. For example, the FDA may require additional trials in indications for which similar products to ours were previously approved based on smaller clinical trials or less stringent clinical outcome requirements. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

With regard to the healthcare and pharmaceutical pricing, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the Affordable Care Act, or ACA, was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

There have been executive, legislative and judicial efforts to modify, repeal or otherwise invalidate all or certain aspects of the ACA. By way of example, the Tax Cuts and Jobs Act, or the TCJA, was enacted and included, among other things, effective January 1, 2019, a provision repealing the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In June 2021, the U.S. Supreme Court held that plaintiffs did not have standing to challenge constitutionality of the individual mandate. Thus, the ACA remains in effect in its current form. It is unclear whether there may be other judicial or congressional efforts to challenge, repeal or replace the ACA. We are continuing to monitor any changes to the ACA that, in turn, may potentially impact our business in the future. In addition, other legislative changes have been proposed and adopted since the ACA was enacted to reduce healthcare expenditures, including aggregate reductions to Medicare payments to providers of 2 percent per fiscal year, which went into effect April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2031. The Medicare reductions phased back in starting with a 1% reduction in effect from April 1, 2022 to June 30, 2022 before increasing to the full 2% reduction. In addition, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several presidential executive orders, Congressional inquiries, and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare, and reform government program reimbursement methodologies for drug products.

On September 9, 2021, the Biden administration published a wide-ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. The U.S. Department of Health and Human Services, or HHS, plan includes, among other reform measures, proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. These initiatives recently culminated in the enactment of the Inflation Reduction Act, or IRA, in August 2022, which will, among other things, allow HHS to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics) can be selected by CMS for negotiation. Because the negotiated price takes effect two years after the selection year, no drug or biologic will be subject to a negotiated price prior to 9 or 13 years after approval, respectively. The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price. Beginning in October 2023, the IRA will also penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges. The full economic impact of the IRA is unknown at this time, but the law's passage may affect the pricing of our products and product candidates. The adoption of restrictive price controls in new jurisdictions, more restrictive controls in existing jurisdictions or the failure to obtain or maintain timely or adequate pricing could also adversely impact revenue. We expect pricing pressures will continue globally.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or companion diagnostics or additional pricing pressures.

We expect that the ACA and IRA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn and Matthew Bellina Right to Try Act of 2017 was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA authorization under an FDA expanded access program; however, manufacturers are not obligated to provide investigational new drug products under the current federal right to try law. We may choose to seek an expanded access program for our product candidates, or to utilize comparable rules in other countries that allow the use of a drug, on a named patient basis or under a compassionate use program.

The FDA's ability to review and approve new products may be hindered by a variety of factors, including budget and funding levels, ability to hire and retain key personnel, statutory, regulatory and policy changes and global health concerns.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities.

The ability of the FDA and other government agencies to properly administer their functions is highly dependent on the levels of government funding and the ability to fill key leadership appointments, among various factors. Delays in filling or replacing key positions could significantly impact the ability of the FDA and other agencies to fulfill their functions and could greatly impact healthcare and the pharmaceutical industry.

Our operations and relationships with future customers, providers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties including criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with providers, third-party payors and customers will subject us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any product candidates for which we obtain marketing approval.

Restrictions under applicable U.S. federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;
- federal false claims laws, including the federal False Claims Act, imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal Physician Payment Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report payments and other transfers of value provided during the previous year to physicians, as defined by such law, physician assistants, certain types of advance practice nurses, and teaching hospitals, as well as certain ownership and investment interests held by such physicians and their immediate family, which includes annual data collection and reporting obligations;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and
- some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of product candidates from government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. If any of the physicians or other

healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Risks Related to Our Intellectual Property

Our success depends in part on our ability to obtain, maintain and protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our commercial success will depend in large part on obtaining and maintaining patent, trademark, trade secret and other intellectual property protection of our proprietary technologies and product candidates, which include atrasentan and the other product candidates we have in development, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending our patents and other intellectual property rights against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell, importing or otherwise commercializing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. If we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop may be adversely affected.

The patenting process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development activities before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and may be reliant on our licensors or licensees to do so. Our pending and future patent applications may not result in issued patents. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we hold or in-license may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether any of our platform advances and product candidates will be protectable or remain protected by valid and enforceable patents. In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technologies.

We depend on intellectual property licensed from third parties, and our licensors may not always act in our best interest. If we fail to comply with our obligations under our intellectual property licenses, if the licenses are terminated, or if disputes regarding these licenses arise, we could lose significant rights that are important to our business.

We are dependent on patents, know-how and proprietary technology licensed from others. Our licenses to such patents, know-how and proprietary technology may not provide exclusive rights in all relevant fields of use and in all territories in which we may wish to develop or commercialize our products in the future. The agreements under which we license patents, know-how and proprietary technology from others are complex, and certain provisions in such agreements may be susceptible to multiple interpretations.

For example, we are a party to a license agreement with AbbVie, pursuant to which we in-license worldwide, exclusive rights to atrasentan, including responsibility for our development and commercialization. This agreement imposes various diligence, milestone payment, royalty, insurance and other obligations on us. If we, or our sublicensees, fail to comply with these obligations, AbbVie may have the right to terminate our license, in which event we would not be able to develop or market atrasentan or any other technology or product candidates covered by the intellectual property licensed under this agreement. In addition, we may need to obtain additional licenses from our existing licensors and others to advance our research or allow commercialization of product candidates we may develop. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. In either event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology or product candidates.

If our licensors fail to adequately protect our licensed intellectual property, our ability to commercialize product candidates could suffer. We do not have complete control over the maintenance, prosecution and litigation of our in-licensed patents and patent applications and may have limited control over future intellectual property that may be in-licensed. For example, we cannot be certain that activities such as the maintenance and prosecution by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. It is possible that our

licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves or may not be conducted in accordance with our best interests.

In addition, the resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant patents, know-how and proprietary technology, or increase what we believe to be our financial or other obligations under the relevant agreement. Disputes that may arise between us and our licensors regarding intellectual property subject to a license agreement could include disputes regarding:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates and what activities satisfy those diligence obligations;
- royalty, milestone or other payment obligations that may result from the advancement or commercial sale of any of our product candidates; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected technology or product candidates.

Our owned and in-licensed patents and patent applications may not provide sufficient protection of our atrasentan product candidate and our other product candidates or result in any competitive advantage.

We have in-licensed issued U.S. patents and foreign patent applications that cover formulations and methods of use related directly to atrasentan from AbbVie and own an issued U.S. patent related to methods of use of atrasentan. We have filed patent applications intended to specifically cover additional methods of use and combinations of atrasentan with other therapies in kidney disease. We cannot be certain that any of these patent applications will issue as patents, and if they do, that such patents will cover or adequately protect atrasentan or that such patents will not be challenged, narrowed, circumvented, invalidated or held unenforceable.

In addition to claims directed toward the technology underlying atrasentan, our owned and in-licensed patents and patent applications contain claims directed to compositions of matter on the active pharmaceutical ingredients, or APIs, in BION-1301, CHK-336 and our other product candidates, as well as methods-of-use directed to the use of such APIs for a specified treatment. Composition-of-matter patents on the API in prescription drug products provide protection without regard to any particular method of use of the API used. Method-of-use patents do not prevent a competitor or other third party from developing or marketing an identical product for an indication that is outside the scope of the patented method. Patents covering methods-of-use are not available in certain foreign countries, in which case we may not be able to prevent competitors or third parties from marketing our product candidates in those countries. Moreover, with respect to method-of-use patents, even if competitors or other third parties do not actively promote their product for our targeted indications or uses for which we may obtain patents, providers may recommend that patients use these products off-label, or patients may do so themselves. Although off-label use may infringe or contribute to the infringement of method-of-use patents, the practice is common, and this type of infringement is difficult to prevent or prosecute.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. For example, while our patent applications are pending, we may be subject to a third party preissuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or become involved in interference or derivation proceedings, or equivalent proceedings in foreign jurisdictions. Even if patents do successfully issue, third parties may challenge their inventorship, validity, enforceability or scope, including through opposition, revocation, reexamination, post-grant and *inter partes* review proceedings. An adverse determination in any such submission, proceeding or litigation may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. Moreover, some of our owned and in-licensed patents and patent applications may be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors

could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in development, testing, and regulatory review of new product candidates, the period of time during which we could market our product candidates under patent protection would be reduced or eliminated.

Since patent applications in the United States and other countries are confidential for a period of time after filing, at any moment in time, we cannot be certain that we were in the past or will be in the future the first to file any patent application related to our product candidates. In addition, some patent applications in the United States may be maintained in secrecy until the patents are issued. As a result, there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim, and we may be subject to priority disputes. We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that, if challenged, our patents would be declared by a court, patent office or other governmental authority to be valid or enforceable or that even if found valid and enforceable, a competitor's technology or product would be found by a court to infringe our patents. We may analyze patents or patent applications of our competitors that we believe are relevant in our activities, and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, that block our efforts or potentially result in our product candidates or our activities infringing such claims. It is possible that our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to our own products or technology. Those patent applications may have priority over our owned and in-licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. The possibility also exists that others will develop products that have the same effect as our product candidates on an independent basis that do not infringe our patents or other intellectual property rights, or will design around the claims of patents that we have had issued that cover our product candidates or their use.

Likewise, our currently owned and in-licensed patents and patent applications, if issued as patents, directed to our proprietary technologies and our product candidates are expected to expire from 2028 through 2041, without taking into account any possible patent term adjustments or extensions. Our earliest in-licensed patents may expire before, or soon after, our first product achieves marketing approval in the United States or foreign jurisdictions. Additionally, we cannot be assured that the USPTO or relevant foreign patent offices will grant any of the pending patent applications we own or in-license currently or in the future. Upon the expiration of our current patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could also have a similar material adverse effect on our business, financial condition, results of operations and prospects.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use compounds that are similar to the active compositions of our product candidates but that are not covered by the claims of our patents;
- the APIs in our current product candidates will eventually become commercially available in generic drug products, and no patent protection may be available with regard to formulation or method of use;
- our licensors, as the case may be, may fail to meet our obligations to the U.S. government regarding any in-licensed patents and patent applications funded by U.S. government grants, leading to the loss or unenforceability of patent rights;
- our licensors, as the case may be, might not have been the first to file patent applications for certain inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our currently pending or future patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our owned or in-licensed patents, as the case may be, or parts of our owned or in-licensed patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished patent applications or patent applications maintained in secrecy that may later issue with claims covering our product candidates or technology similar to ours;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;

- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not adequately cover our product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes that design around our patents, or become hostile to the Company or the patents or patent applications on which they are named as inventors;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable or such omitted individuals may grant licenses to third parties;
- we have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing products that are outside the scope of our patent claims;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates or diagnostic tests we develop may be covered by third parties' patents or other exclusive rights; or
- the patents of others may have an adverse effect on our business.

Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Our strategy of obtaining rights to key technologies through in-licenses may not be successful.

The future growth of our business will depend in part on our ability to in-license or otherwise acquire the rights to additional product candidates and technologies. Although we have succeeded in licensing technology from AbbVie and others in the past, we cannot assure you that we will be able to in-license or acquire the rights to any product candidates or technologies from third parties on acceptable terms or at all.

For example, our agreements with certain of our third-party research partners provide that improvements developed in the course of our relationship may be owned solely by either us or our third-party research partner, or jointly between us and the third party. If we determine that exclusive rights to such improvements owned solely by a research partner or other third party with whom we collaborate are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain an exclusive license from such third party in order to use the improvements and continue developing, manufacturing or marketing our product candidates. We may not be able to obtain such a license on an exclusive basis, on commercially reasonable terms, or at all, which could prevent us from commercializing our product candidates or allow our competitors or others the opportunity to access technology that is important in our business. We also may need the cooperation of any co-owners of our intellectual property in order to enforce such intellectual property against third parties, and such cooperation may not be provided to us.

In addition, in-licensing and acquisition of these technologies is a highly competitive area, and a number of more established companies are also pursuing strategies to license or acquire product candidates or technologies that we may consider attractive. These established companies may have a competitive advantage over the Company due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive the Company to be a competitor may be unwilling to license rights to the Company. Furthermore, we may be unable to identify suitable product candidates or technologies within our area of focus. If we are unable to successfully obtain rights to suitable product candidates or technologies, our business and prospects could be materially and adversely affected.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to patent protection, we rely upon know-how and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable.

It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with the Company. These agreements provide that all confidential information concerning our research and development, business, or financial affairs developed or made known to the individual or entity during the course of the party's relationship with Chinook Therapeutics are to be kept

confidential and not disclosed to third parties, except in certain specified circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and that are related in our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information (or as otherwise permitted by applicable law), are our exclusive property. In the case of consultants and other third parties, the agreements provide that all inventions conceived in connection with the services provided are our exclusive property. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We have also adopted policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our secrets. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information through other appropriate precautions, such as physical and technological security measures. However, trade secrets and know-how can be difficult to protect. These measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and any recourse we might take against this type of misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent us from receiving legal recourse. If any of our confidential or proprietary information, such as the Company's trade secrets, were to be disclosed or misappropriated, such as through a data breach, or if any of that information was independently developed by a competitor, our competitive position could be harmed. Additionally, certain trade secrets and proprietary information may be required to be disclosed in submissions to regulatory authorities. If such authorities do not maintain the confidential basis of such information or disclose it as part of the basis of regulatory approval, our competitive position could be adversely affected.

In addition, courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. Even if we are successful, these types of lawsuits may consume our time and other resources. Although we take steps to protect our proprietary information and trade secrets, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology, through legal or illegal means. As a result, we may not be able to meaningfully protect the Company's trade secrets. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Third-party claims of intellectual property infringement may prevent, delay or otherwise interfere with our product discovery and development efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property or other proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, inter partes review, post grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications that are owned by third parties exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our field, third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

If a third party claims that we infringe, misappropriate or otherwise violate our intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims that, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages plus the patent owner's attorneys' fees;

- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third-party licenses its product rights or proprietary technology to us, which it is not required to do, on commercially reasonable terms or at all;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our product candidates;
- the requirement that we redesign our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time; and
- there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, financial condition, results of operations and prospects.

Third parties may assert that we are employing their proprietary technology without authorization, including by enforcing its patents against us by filing a patent infringement lawsuit against the Company. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof.

There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents.

If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, or materials used in or formed during the manufacturing process, or any final product itself, the holders of those patents may be able to block our ability to commercialize our product candidate unless we obtain a license under the applicable patents, or until those patents were to expire or those patents are finally determined to be invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of that patent may be able to block our ability to develop and commercialize the product candidate unless we obtain a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, a license may not be available on commercially reasonable terms, or at all, particularly if such patent is owned or controlled by one of our primary competitors. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to the Company. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee time and resources from our business. In the event of a successful claim of infringement against the Company, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any license of this nature would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates and we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could significantly harm our business.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful and could result in a finding that such patents are unenforceable or invalid.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court

may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question.

In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. These types of mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). These types of proceedings could result in revocation or amendment to our patents such that they no longer cover our product candidates. The outcome for any particular patent following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Defense of these types of claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Conversely, we may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings), or we may choose to challenge a third party's patent in patent opposition proceedings in the Canadian Intellectual Property Office, or CIPO, the European Patent Office, or EPO, or another foreign patent office. Even if successful, the costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, CIPO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates or proprietary technologies.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common stock. Any of the foregoing could have a material adverse effect on our business financial condition, results of operations and prospects.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We currently have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. For example, patents covering methods-of-use are not available in certain foreign countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we do not have or have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our product candidates in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at universities or other biopharmaceutical or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. We may then have to pursue litigation to defend against these claims. If we fail in defending any claims of this nature, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these types of claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities, and we may not have sufficient financial or other resources to adequately conduct this type of litigation or proceeding. For example, some of our competitors may be able to sustain the costs of this type of litigation or proceeding more effectively than we can because of their substantially greater financial resources. In any case, uncertainties resulting from the initiation and continuation of intellectual property litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

The growth of our business may depend in part on our ability to acquire, in-license or use third-party proprietary rights. For example, our product candidates may require specific formulations to work effectively and efficiently, we may develop product candidates containing pre-existing pharmaceutical compounds, or we may be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our product candidates, any of which could require us to obtain rights to use intellectual property held by third parties. In addition, with respect to any patents we may co-own with third parties, we may require licenses to such co-owners' interest in such patents. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties we identify as necessary or important in our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, which means our competitors may also receive access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution’s rights in technology resulting from the collaboration. Even if we hold such an option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. There can be no assurance that we will be able to successfully complete these types of negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to develop or market. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of certain programs and our business financial condition, results of operations and prospects could suffer.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign patent agencies also require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable laws and rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. Were a noncompliance event to occur, our competitors might be able to enter the market, which would have a material adverse effect on our business financial condition, results of operations and prospects.

Changes in patent law in the United States and in non-U.S. jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain.

Past or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. For example, in March 2013, under the Leahy-Smith America Invents Act, or America Invents Act, the United States moved from a “first to invent” to a “first-to-file” patent system. Under a “first-to-file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The effects of these changes continue to evolve as the USPTO continues to promulgate new regulations and procedures in connection with the America Invents Act and many of the substantive changes to patent law, including the “first-to-file” provisions, only became effective in March 2013. In addition, the courts have yet to address many of these provisions and the applicability of the act and new regulations on the specific patents discussed in this filing have not been determined and would need to be reviewed. Moreover, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Additionally, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the case, *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to DNA molecules are not patent-eligible.

Similarly, other cases by the U.S. Supreme Court have held that certain methods of treatment or diagnosis are not patent-eligible. U.S. law regarding patent-eligibility continues to evolve. While we do not believe that any of our owned or in-licensed patents will be found invalid based on these changes to U.S. patent law, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse changes in the patent laws of other jurisdictions could also have a material adverse effect on our business, financial condition, results of operations and prospects.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after we or our partners commercialize those candidates. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to our products.

If we do not obtain patent term extension for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during clinical trials and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent per product may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. U.S. and ex-U.S. law concerning patent term extensions and foreign equivalents continue to evolve. Even if we were to seek a patent term extension, it may not be granted because of, for example, the failure to exercise due diligence during the testing phase or regulatory review process, the failure to apply within applicable deadlines, the failure to apply prior to expiration of relevant patents, or any other failure to satisfy applicable requirements. Moreover, the applicable time period of extension or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than it requests, our competitors may obtain approval of competing products following our patent expiration sooner than expected, and our business, financial condition, results of operations and prospects could be materially harmed.

Some intellectual property that we have in-licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.

Inventions contained within some of our in-licensed patents and patent applications may have been made using U.S. government funding or other non-governmental funding. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980, or Bayh-Dole Act, and implementing regulations. We rely on our licensors to ensure compliance with applicable obligations arising from such funding, such as timely reporting, an obligation associated with in-licensed patents and patent applications. The failure of our licensors to meet their obligations may lead to a loss of rights or the unenforceability of relevant patents. For example, the government could have certain rights in such in-licensed patents, including a non-exclusive license authorizing the government to use the invention or to have others use the invention on its behalf for non-commercial purposes. In addition, our rights in such in-licensed government-funded inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any of the foregoing could harm our business, financial condition, results of operations and prospects significantly.

Risks Related to Employee Matters, Managing Growth and Other Risks Related to Our Business

We expect to expand our development and regulatory capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of product candidate development, growing our capability to conduct clinical trials, and, if approved, through commercialization of our product candidates. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel, or contract with third parties to provide these capabilities for us. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Future acquisitions or strategic alliances could disrupt our business and harm our financial condition and results of operations.

We may acquire additional businesses or drugs, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new drugs resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction. The risks we face in connection with acquisitions, include:

- diversion of management time and focus from operating our business to addressing acquisition integration challenges;
- coordination of research and development efforts;
- retention of key employees from the acquired company;

- changes in relationships with strategic partners as a result of product acquisitions or strategic positioning resulting from the acquisition;
- cultural challenges associated with integrating employees from the acquired company into our organization;
- the need to implement or improve controls, procedures and policies at a business that prior to the acquisition may have lacked sufficiently effective controls, procedures and policies;
- liability for activities of the acquired company before the acquisition, including intellectual property infringement claims, violation of laws, commercial disputes, tax liabilities and other known liabilities;
- unanticipated write-offs or charges; and
- litigation or other claims in connection with the acquired company, including claims from terminated employees, customers, former stockholders or other third parties.

Our failure to address these risks or other problems encountered in connection with our past or future acquisitions or strategic alliances could cause us to fail to realize the anticipated benefits of these transactions, cause us to incur unanticipated liabilities and harm the business generally. There is also a risk that future acquisitions will result in the incurrence of debt, contingent liabilities, amortization expenses or incremental operating expenses, any of which could harm our financial condition or results of operations.

Our employees, principal investigators, CROs, CMOs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Our business entails a significant risk of product liability and our ability to obtain sufficient insurance coverage could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We will face an inherent risk of product liability exposure related to the testing of atrasentan and our other product candidates in clinical trials and will face an even greater risk if we commercialize any of our product candidates. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in a product, negligence, strict liability or breach of warranty. Claims could also be asserted under U.S. state consumer protection acts. If we cannot successfully defend ourselves against claims of our product candidates caused injuries, then we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant time and costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- termination of our collaboration relationships or disputes with our collaborators;
- voluntary product recalls, withdrawals or labeling restrictions; and
- the inability to commercialize any product candidates that we may develop.

While we currently have insurance that we believe is appropriate for our stage of development, we may need to obtain higher levels prior to clinical development or marketing atrasentan or any of our future product candidates. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Our ability to utilize our net operating loss carryforwards may be subject to limitations.

To the extent our taxable income exceeds any current year operating losses, we plan to use our net operating loss carryforwards to offset income that would otherwise be taxable. Under Section 382 of the Code, changes in a company's ownership may limit the amount of net operating loss carryforwards and tax credit carryforwards that could be utilized annually to offset its future taxable income, if any. This limitation generally applies in the event of a cumulative change in ownership of more than 50 percent within a three-year period. Aduro experienced and Private Chinook likely experienced an ownership change under Section 382 as a result of the Merger. Any such limitation may significantly reduce our ability to utilize net operating loss carryforwards and tax credit carryforwards before they expire. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of Private Chinook's or Aduro's net operating loss carryforwards and other tax attributes, which could have a material adverse effect on our cash flow and results of operations. There is also a risk that due to regulatory changes, such as suspensions on the use of net operating losses, or NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

Under the TCJA, as modified by the CARES Act, NOLs and other carryforwards generated in tax years that began after December 31, 2017 may offset no more than 80 percent of current taxable income annually for taxable years beginning after December 31, 2020. Accordingly, we, Private Chinook or Aduro, as applicable, generated or will generate NOLs after the tax year ended December 31, 2017, and we might have to pay more federal income taxes in a subsequent year as a result of the 80 percent taxable income limitation than we would have had to pay under the law in effect before the Tax Act as modified by the CARES Act.

Risks Related to the CVRs

Our outstanding CVRs may expire valueless.

The right of the holders of our contingent value rights, or CVRs, issued prior to the closing of the Merger will be contingent solely upon the occurrence of certain events described in the CVR Agreement and the consideration received being greater than the amounts that could be deducted by us under the CVR Agreement. In 2022, we paid $7.5 million to CVR holders following receipt of a development milestone under our license agreement with Merck for MK-5890. In April 2021, prior to the disposition period set forth in the CVR Agreement, we entered into an agreement with Sairopa, a private company created by Van Herk Royalty B.V. and D.S. Chahal to acquire certain of our non-renal assets in exchange for stock in Sairopa. We will hold our equity interests in Sairopa until there is a liquidity event, upon which 50% of any proceeds, net of deductions permitted under the CVR Agreement, including taxes and certain other expenses, will be distributed to CVR holders, provided such liquidity event occurs during the 10-year CVR period. If no additional events described within the CVR Agreement occur within the 10-year CVR period specified in the CVR Agreement or the consideration received is not greater than the amounts that could be deducted by us, no additional payments will be made under the CVR Agreement, and the CVRs will expire valueless.

We do not have any obligation to develop the non-renal assets, or to expend any effort or resources to divest or otherwise monetize the non-renal assets. Furthermore, the CVRs are unsecured obligations of us and all payments under the CVRs, all other obligations under the CVR Agreement and the CVRs and any rights or claims relating thereto may be subordinated in right of payment to the prior payment in full of all current or future senior obligations of us.

The tax treatment of the CVRs is unclear.

The U.S. federal income tax treatment of the CVRs is unclear. There is no legal authority directly addressing the U.S. federal income tax treatment of the receipt of, and payments under, the CVRs, and there can be no assurance that the IRS would not assert, or that a court would not sustain, a position that could result in adverse U.S. federal income tax consequences to holders of the CVRs.

For example, Aduro did not report the issuance of the CVRs as a current distribution of property with respect to its common stock, but it is possible that the IRS could assert that CVR recipients are treated as having received a distribution of property equal to the fair market value of the CVRs on the date the CVRs are distributed, which could be taxable to such recipients without the corresponding receipt of cash. In addition, it is possible that the IRS or a court could determine that the issuance of the CVRs (and/or any payments thereon) and the reverse stock split constitute a single "recapitalization" for U.S. federal income tax purposes with the CVRs constituting taxable "boot" received in such recapitalization exchange. In such case, the tax consequences of the CVRs and the

reverse stock split would differ from those described in the Merger proxy statement, including with respect to the timing and character of income.

Risks Related to our Common Stock

The market price of our common stock is expected to be volatile, and the market price of the common stock may drop in the future.

The market price of our common stock is subject to significant fluctuations. Some of the factors that may cause the market price of our common stock to fluctuate include:

- results of clinical trials, including our ALIGN trial for atrasentan, and preclinical studies of our product candidates, or those of our competitors or our existing or future collaborators;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about the combined business, or if they issue adverse or misleading opinions regarding our business and common stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions or market conditions in the pharmaceutical and biotechnology sectors, including rising interest rates and inflation;
- sales of securities by us or our securityholders in the future;
- if we fail to raise an adequate amount of capital to fund our operations and continued development of our product candidates;
- trading volume of our common stock;
- announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to precision medicine product candidates, including with respect to other products in such markets;
- the introduction of technological innovations or new therapies that compete with our potential products; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In addition, a recession, depression or other sustained adverse market event resulting from the spread of COVID-19 or otherwise could materially and adversely affect our business and the value of our common stock. Furthermore, the trading price of our common stock may be adversely affected by third-parties trying to drive down the market price. Short sellers and others, some of whom post anonymously on social media, may be positioned to profit if our stock declines and their activities can negatively affect our stock price. In the past, following periods of volatility in the market price of a company’s securities, stockholders have often instituted class action securities litigation against such companies. Furthermore, market volatility may lead to increased shareholder activism if we have a market valuation that activists believe is not reflective of our intrinsic value. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition.

We will incur additional costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies.

We will incur significant legal, accounting and other expenses as a public company that we did not incur as a private company, including costs associated with public company reporting obligations under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our management team consists, among others, of the executive officers of Private Chinook prior to the Merger, some of whom have not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise related to public company reporting requirements and compliance with applicable laws and regulations to ensure that we comply with all of these requirements. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on the board of directors or on board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

We will no longer be a smaller reporting company in 2023, and will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results.

We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition as well as other disclosure and corporate governance requirements. For 2023 we will no longer be a smaller reporting company nor qualify for certain exemptions from disclosure requirements applicable to smaller reporting companies and non-accelerated filers. As a result, we will be required to comply with certain additional legal and regulatory requirements applicable to public companies and may incur significant legal, accounting and other expenses to do so. If we are not able to comply with the requirements in a timely manner or at all, our financial condition or the market price of our common stock may be harmed. For example, if we or our independent auditor identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, we could face additional costs to remedy those deficiencies, the market price of our stock could decline or we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Provisions in our charter documents and under Delaware law could make an acquisition more difficult and may discourage any takeover attempts the company stockholders may consider favorable, and may lead to entrenchment of management.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws could delay or prevent changes in control or changes in management without the consent of the board of directors. These provisions include the following:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- a prohibition on stockholder action by written consent, which means that all stockholder action must be taken at an annual or special meeting of the stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the Chief Executive Officer or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to the board of directors;
- a requirement that no member of the board of directors may be removed from office by stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of voting stock to amend any bylaws by stockholder action or to amend specific provisions of the certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, these provisions would apply even if we were to receive an offer that some stockholders may consider beneficial.

We are also subject to the anti-takeover provisions contained in Section 203 of the DGCL, or Section 203. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15 percent or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Our certificate of incorporation and bylaws provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, and that federal district court is the exclusive forum for any actions arising under the Exchange Act, which could limit your ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our certificate of incorporation and bylaws provides that the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on the Company's behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against it arising pursuant to any provisions of the DGCL, its certificate of incorporation or its bylaws, or any action asserting a claim against it that is governed by the internal affairs doctrine. The exclusive forum provision does not apply to actions arising under the Exchange Act. The amended and restated bylaws will also provide that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action under the Securities Act. The provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with the Company or its directors, officers or other employees, which may discourage such lawsuits against the Company and its directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in the certificate of incorporation and bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially and adversely affect our business, financial condition and results of operations.

We do not expect to pay any cash dividends in the foreseeable future.

Our current expectation is that we will retain future earnings, if any, to fund the growth of our business as opposed to paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain, if any, for the foreseeable future.

Our executive officers, directors and principal stockholders have the ability to control or significantly influence all matters submitted to the Company's stockholders for approval.

Our executive officers, directors and principal stockholders, in the aggregate, beneficially own a significant portion of our outstanding shares of common stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of us on terms that other stockholders may desire.

General Risk Factors

Unfavorable global economic conditions could adversely affect our business, financial condition, stock price and results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, a global economic downturn, whether due to terrorism, armed conflict (such as the current conflict between Russia and Ukraine), natural disasters or health crises (such as COVID-19) could cause extreme volatility and disruptions in the capital and credit markets, as well as rising interest rates and inflation. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive such difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. Furthermore, our stock price may decline due in part to the volatility of the stock market and any general economic downturn.

If we fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also may produce hazardous waste

products. We generally anticipate contracting with third parties for the disposal of these materials and wastes. We will not be able to eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from any use by us of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities.

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We or the third parties upon whom we depend may be adversely affected by natural disasters and other calamities, including pandemics, such as the global outbreak of COVID-19, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, fire, hurricane, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters or other offices, that damaged critical infrastructure, such as our suppliers' manufacturing facilities, or that otherwise disrupted operations, such as data storage, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time.

Occurrences of epidemics or pandemics, depending on their scale, may cause different degrees of damage to the national and local economies within our geographic focus. Global economic conditions may be disrupted by widespread outbreaks of infectious or contagious diseases, and such disruption may adversely affect clinical development plans. For example, the COVID-19 pandemic could have an adverse effect on the coordination of research and development, our capital raising efforts, and the financial condition of our business, as well as the ability of us to retain key personnel and continue to expand product candidate development and conduct clinical trials.

The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. For example, as a result of the COVID-19 pandemic, we may experience reduction in research and development, clinical testing, regulatory compliance activities, and manufacturing activities, and are unable at this time to estimate the extent of the effect of COVID-19 on our business. Further, the extent and duration of the current economic slowdown or other adverse effects attributable to COVID-19 remain uncertain at this time. A continued significant economic slowdown could have a substantial adverse effect on our financial condition, liquidity, and results of operations. If these conditions persist for an extended term, it could have a material adverse effect on our future revenue and sales.

The continued presence of the COVID-19 pandemic, or the outbreak of a similar public health crisis, could have a material adverse impact on our business, financial condition and results of operations, including the execution of our clinical trials and could cause potential supply chain disruptions.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. The measures taken in response to the COVID-19 pandemic have had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, facilities and production have been suspended, and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The extent to which COVID-19 impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19 and the actions to contain the virus or treat its impact.

For instance, our phase 2 and phase 3 clinical trials of atrasentan and our phase 1/2 clinical trial of BION-1301 have been and may continue to be affected by the pandemic. Site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis for our clinical trials has been and may continue to be delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. Additionally, some participants and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to conduct our clinical trials. Any delays in our phase 3 ALIGN clinical trial for atrasentan and the clinical trials for our other product candidates could impact the use and sufficiency of our existing cash reserves, and we may be required to raise additional capital earlier than we

had previously planned. We may be unable to raise additional capital if and when needed, which may result in further delays or suspension of our development plans.

Further, infections and deaths related to COVID-19 have disrupted certain healthcare and healthcare regulatory systems globally. Such disruptions could divert healthcare resources away from, or materially delay review by, the FDA and comparable foreign regulatory agencies. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially adversely affect the development and study of our product candidates.

We currently utilize third parties to, among other things, manufacture raw materials and our product candidates, components, parts, and consumables, and to perform quality testing. If either we or any third-party in the supply chain for materials used in the production of our product candidates are adversely impacted by restrictions resulting from the COVID-19 pandemic, our supply chain may be disrupted, limiting our ability to manufacture product candidates for our clinical trials.

In response to the COVID-19 pandemic, we have at times limited access to our offices and have undertaken safety precautions to reduce the risk of transmission in our workforce. Due to mandated local travel restrictions, such as quarantine requirements, third parties conducting clinical or manufacturing activities may not be able to access laboratory or manufacturing space, and our core activities may be significantly limited or curtailed, possibly for an extended period of time.

While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and may continue to cause, significant disruption of global financial markets and the trading prices of biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the global effort to control COVID-19 infections could materially and adversely affect our business.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on the Company's business, our planned clinical trials, healthcare systems or the global economy as a whole. However, these effects could have a material adverse impact on our business, financial condition and results of operations.

We have broad discretion in the use of our cash and cash equivalents and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.

We have broad discretion over the use of our cash and cash equivalents. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. Our failure to apply these resources effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. You may not have the opportunity to influence our decisions on how to use our cash resources.

We must attract and retain highly skilled employees to succeed.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan, harm our results of operations and increase our capabilities to successfully commercialize atrasentan and other product candidates. In particular, we believe that our future success is highly dependent upon the contributions of our senior management, particularly our President and Chief Executive Officer, Eric Dobmeier. The loss of services of Mr. Dobmeier or any of our senior management could delay or prevent the successful development of our product pipeline, completion of our clinical trials or the commercialization of our product candidates, if approved. The competition for qualified personnel in the biotechnology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover and develop product candidates and our business will be limited.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about the Company, its business or its market, its stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of

research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on it regularly, demand for our common stock could decrease, which in turn could cause its stock price or trading volume to decline.

Our internal computer and information systems, or those used by our CROs, CMOs or other contractors or consultants, may fail or suffer security incidents (e.g., cyber-attacks), which could result in a material disruption of our development programs and may result in extensive and costly legal compliance requirements.

Despite the implementation of appropriate security measures, our internal computer and information systems and those of our current and any future CROs, CMOs and other contractors or consultants may become vulnerable to damage from security incidents (such as data breaches, viruses or other malicious code, coordinated attacks, data loss, phishing attacks, ransomware, denial of service attacks, or other security or information technology incidents caused by threat actors, technological vulnerabilities or human error), unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of data from completed or future preclinical studies or clinical trials could result in significant delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be significantly delayed. System failures or outages, including any potential disruptions due to significantly increased global demand on certain cloud-based systems during the COVID-19 pandemic, could compromise our ability to perform our day-to-day operations, which could harm our ability to conduct business or delay our financial reporting. Such failures could materially adversely affect our operating results and financial condition.

Although we devote resources designed to protect our information systems, we realize that cyberattacks resulting in a security incident are a threat, and there can be no assurance of our efforts will prevent information security breaches that would result in business, legal, financial, or reputational harm to the Company, or would have a material adverse effect on our results of operations and financial condition. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including personal and financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. The COVID-19 pandemic is generally increasing the attack surface available to criminals, as more companies and individuals work online and work remotely, and as such, the risk of a cybersecurity incident potentially occurring, and our investment in risk mitigations against such an incident, is increasing.

Federal, state, and foreign laws and government requirements include obligations of companies to notify regulators and/or individuals, in certain circumstances, of security breaches involving personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Even though we may have contractual protections with such vendors, contractors, or other organizations, notifications and follow-up actions related to a security breach could impact our reputation and cause us to incur significant costs. Any failure to prevent or mitigate security breaches or improper access to, use, disclosure or other misappropriation of our data or consumers' personal data could result in significant contractual and legal liability, such as under state breach notification laws, federal law (including HIPAA/Health Information Technology for Economic and Clinical Health Act, or HITECH), and international law (e.g., GDPR). Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous, expensive and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules and possible government oversight. Our failure to comply with such laws or to adequately secure the information we hold could result in significant liability and/or reputational harm and, in turn, a material adverse effect on our future client base, member base and revenue.

We are subject to a variety of privacy and data security laws, and our failure to comply with them could harm our business.

We maintain a large quantity of sensitive information, including confidential business and patient health information in connection with our preclinical and clinical studies, and are subject to laws and regulations governing the privacy and security of such information. Privacy laws, rules and regulations evolve frequently, and their scope may continually change through new legislation, amendments to existing legislation, and changes in enforcement, and may be inconsistent from one jurisdiction to another. The interpretation and application of consumer, health-related and data protection laws, especially with respect to genetic samples and data, in the United States, the European Union and elsewhere, are often uncertain, contradictory and in flux. We cannot provide assurance that current or future legislation will not prevent us from generating or maintaining personal data or that patients will consent to the use of their personal data (as necessary); either of these circumstances may prevent us from undertaking or publishing essential research and development, manufacturing, and commercialization, which could have a material adverse effect on our business, results of operations, financial condition and prospects. Complying with these various laws and regulations could cause us to

incur substantial costs or require us to change our business practices, systems, and compliance procedures in a manner adverse to our business. Any violations of these rules by us could subject us to civil and criminal penalties and adverse publicity and could harm our ability to initiate and complete clinical trials.

In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including health information privacy laws, security breach notification laws, and consumer protection laws. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data), that are subject to privacy and security requirements under HIPAA/HITECH. Entities that are found to be in violation of HIPAA/HITECH as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Further, entities that knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA may be subject to criminal penalties. Additionally, governmental agencies like the FTC have adopted, or are considering adopting, laws and regulations concerning personal data and data security. The FTC may also take action against companies for unfair acts or practices for failing to keep promises made in public statements, such as privacy policies. We make public statements about our use and disclosure of personal data through our privacy policy, information described on our website, and in press statements. Although we endeavor to ensure that our public statements are complete and accurate, any failure (real or perceived) by us to comply with our privacy and security commitments could be considered an “unfair and deceptive” act by the FTC resulting in an FTC consent decree that may include fines and sustained government-mandated audits for a period of 20 years. State Attorneys General may enforce comparable state law statutes covering unfair and deceptive practices with similar resulting consequences.

Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. California recently enacted legislation, the California Privacy Rights Act, or CPRA, which went into effect January 1, 2023. The CPRA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of the sale and disclosure of their information and receive detailed information about how their personal information is used. The CPRA provides for civil penalties for violations, as well as a private right of action for data breaches, in certain circumstances, that is expected to increase data breach litigation. The CPRA may increase our compliance costs and potential liability. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CPRA. Potential uncertainty surrounding the CPRA may increase our compliance costs and potential liability, particularly in the event of a data breach, and could have a material adverse effect on our business. Other states have followed California’s lead. The Virginia Consumer Data Protection Act, or VCDPA, which went into effect on January 1, 2023, gives new data protection rights to Virginia residents and imposes additional obligations on controllers and processors of personal data. Colorado, Utah and Connecticut have passed similar laws which will go into effect in 2023. As of January 2023, four states have active consumer privacy legislation under review, which if enacted would add additional costs and expense of resources to maintain compliance.

In Canada, the Personal Information Protection and Electronic Documents Act, or PIPEDA, and similar provincial laws may impose obligations with respect to processing personal information, including health-related information. PIPEDA requires companies to obtain an individual’s consent when collecting, using, or disclosing that individual’s personal information. Individuals have the right to access and challenge the accuracy of their personal information held by an organization, and personal information may only be used for the purposes for which it was collected. If an organization intends to use personal information for another purpose, it must again obtain that individual’s consent. Failure to comply with PIPEDA could result in significant fines and penalties.

In May 2018, the General Data Protection Regulation, or the GDPR, took effect in the European Economic Area, the EEA. The GDPR governs the collection, use, disclosure, transfer, or other processing of personal data of natural persons. Among other things, the GDPR imposes strict obligations on the ability to process health-related and other personal data of data subjects in the EEA, including in relation to use, collection, analysis, and transfer (including cross-border transfer) of such personal data. The GDPR includes requirements relating to the consent of the individuals to whom the personal data relates, including detailed notices for clinical trial subjects and investigators. The GDPR also includes certain requirements regarding the security of personal data and notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects as well as requirements for establishing a lawful basis on which personal data can be processed and a right to lodge a complaint with the government.

The GDPR, as well as law in the United Kingdom, or the UK, and Switzerland, also prohibits the international transfer of personal data from the EEA/UK/Switzerland to countries outside of those jurisdictions unless made to a country deemed to have adequate data privacy laws by the European Commission or where a data transfer mechanism has been put in place. We rely on Standard Contracts Clauses, or SCCs, to transfer personal data to countries outside of the EEA, Switzerland, and the UK, including to the United States and are continuing to evaluate the guidance and mechanisms required to establish adequate safeguards for personal data. In July 2020 the Court of Justice of the European Union, or CJEU, declared the Privacy Shield to be invalid; however, the Biden administration recently announced the United States has agreed to new terms for protecting EU residents’ data which may potentially

result in the revised EU Privacy Shield being resurrected as an adequate method of transferring data to the US. The CJEU upheld the validity of the SCCs as a legal mechanism to transfer personal data but companies relying on SCCs will continually be subject to guidance from regulators in the EEA and need to evaluate and implement supplementary measures that provide privacy protections additional to those provided under SCCs. In turn, the findings of the CJEU will have significant implications for cross-border data flows. On June 4, 2021, the European Commission adopted new SCCs to apply to international transfers of data. We had until December 27, 2022 to update any existing agreements, or any new agreements executed before September 27, 2021, that rely on the former SCCs. If we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we conduct our operations, and we may find it necessary to establish systems in the EEA, Switzerland, and the UK to maintain personal data originating from the EEA and the UK, which may involve substantial expense and distraction from other aspects of our business. As supervisory authorities continue to issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used and/or what safeguards must be implemented, or start taking enforcement action, there will be uncertainty as to how we comply with EEA, Switzerland, and UK privacy and security laws and we could suffer additional costs, complaints, or regulatory investigations or fines. For example, German and Irish supervisory authorities have indicated that the SCCs alone provide inadequate protection for EU-U.S. data transfers. Use of the data transfer mechanisms must now be assessed on a case-by-case basis, taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals. We may need to implement additional safeguards to further enhance the security of data transferred out of the EEA/Switzerland/UK, conduct data transfer impact assessments, and review existing agreements which could increase our compliance costs, expose us to further regulatory scrutiny and liability, and adversely affect our business. Further, the GDPR provides that countries in the EEA may establish their own laws and regulations further restricting the processing of certain personal data, including genetic data, biometric data, and health data.

Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4 percent of the annual global revenues of the noncompliant company, whichever is greater. Additionally, following the UK's withdrawal from the EU and the EEA, companies must comply with the GDPR and the GDPR as incorporated into UK national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4 percent of global turnover. Companies that violate the GDPR in the EEA and UK can also face prohibitions on data processing and other corrective action, such as class action lawsuits brought by classes of data subjects or by consumer protection organizations authorized at law to represent their interests.

Further, as a consequence of the UK's departure from the EU, the UK is free to diverge from EU data privacy laws. The UK's Data Reform Bill, containing proposals for the UK GDPR to diverge from the EU GDPR is currently paused while ministers consider how to replace EU GDPR. We may, in the future, be subject to separate and additional data protection obligations to those that we are already subject to. This may result in substantial costs and may necessitate changes to our business practices, which in turn may adversely affect our business, reputation, legal exposures, and financial condition.

Some countries (including some outside the EEA), also are considering or have passed legislation requiring local storage and processing of data, or similar requirements, which could increase the cost and complexity of delivering our products and services if we were to operate in those countries. If we are required to implement additional measures to transfer data from the EEA, this could increase our compliance costs, and could adversely affect our business, financial condition and results of operations.

We create contractual obligations with third parties with whom we depend in relation to the operation of our business, a number of which process personal data on our behalf. With each such provider we attempt to mitigate the associated risks of using third parties by performing security assessments and detailed due diligence, entering into contractual arrangements to ensure that providers only process personal data according to our instructions, and that they have sufficient technical and organizational security measures in place. Where we transfer personal data outside the EEA, the UK, or Switzerland to such third parties, we do so while considering the relevant data export requirements, as described above. There is no assurance that these contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, storage, and transmission of such information. Any violation of data or security laws by our third-party processors could have a material adverse effect on our business and result in the fines and penalties outlined above.

If our operations are found to be in violation of any of the privacy and data protection laws described above or any other laws that apply to us, we may be subject to penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in government healthcare programs, injunctions, private qui tam actions brought by individual whistleblowers in the name of the government, class action litigation and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corrective action plan or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our results of operations. When such events occur (or even alleged), our reputation may be harmed, we may lose current and potential users and the competitive positions of our brand might be diminished, any or all of which could materially adversely affect our business, reputation, operating results, and financial condition.

U.S. federal income tax reform and changes in other tax laws could adversely affect us.

Changes in U.S. (federal or state) or foreign tax laws and regulations, or their interpretation and application, including those with retroactive effect, could result in increases in our tax expense and affect future cash flows. For example, in December 2017, the TCJA, was signed into law, significantly reforming the Code. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of business interest, allows for the expensing of capital expenditures, puts into effect the migration from a "worldwide" system of taxation to a partial "territorial" system, and modifies or repeals many business deductions and credits. Beginning in 2022, the TCJA also eliminated the option to deduct research and development expenditures immediately in the year incurred and requires taxpayers to amortize such expenditures over five years for tax purposes.

In addition, new legislation or regulation which could affect our tax burden could be enacted by any governmental authority. We cannot predict the timing or extent of such tax-related developments which could have a negative impact on our financial results. Additionally, we use our best judgment in attempting to quantify and reserve for these tax obligations. However, a challenge by a taxing authority, our ability to utilize tax benefits such as carryforwards or tax credits, or a deviation from other tax-related assumptions could have a material adverse effect on our business, results of operations or financial condition.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We lease approximately 23,000 square feet of office space in Vancouver, Canada that has a remaining lease term expiring on August 31, 2027.

In addition, we lease approximately 26,000 square feet of office space in Seattle, Washington, which we are using for our corporate headquarters, and that has a remaining lease term expiring April 30, 2026.

In connection with the Merger in 2020, we assumed a facility lease for approximately 112,000 square feet of office and laboratory space in Berkeley, California that has a remaining lease term expiring on December 31, 2029. We have the right to further extend the lease term for up to two renewal terms of five years each, provided that the rental rate would be subject to market adjustment at the beginning of each renewal term. We are subleasing this facility, which covers the entire leased premises and expires at the same time as the underlying lease.

We believe that our existing facilities are adequate to meet our current needs, and that suitable additional or alternative spaces will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Price of Common Stock

Our common stock is traded on the Nasdaq Global Select Market under the symbol "KDNY." From April 15, 2015 to October 5, 2020 our common stock was traded under the symbol "ADRO."

On February 17, 2023, the last reported sale price of our common stock on the Nasdaq Global Select Market was $23.21 per share.

Holders of Record

As of February 17, 2023, we had 89 stockholders of record of our common stock. This number of stockholders of record does not include stockholders whose shares are held in street names by brokers and other nominees, or may be held in trust by other entities. Therefore, the actual number of stockholders is greater than this number of stockholders of record.

Dividend Policy

We have not declared or paid cash dividends on our common stock since our inception. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors.

Recent Sales of Unregistered Securities

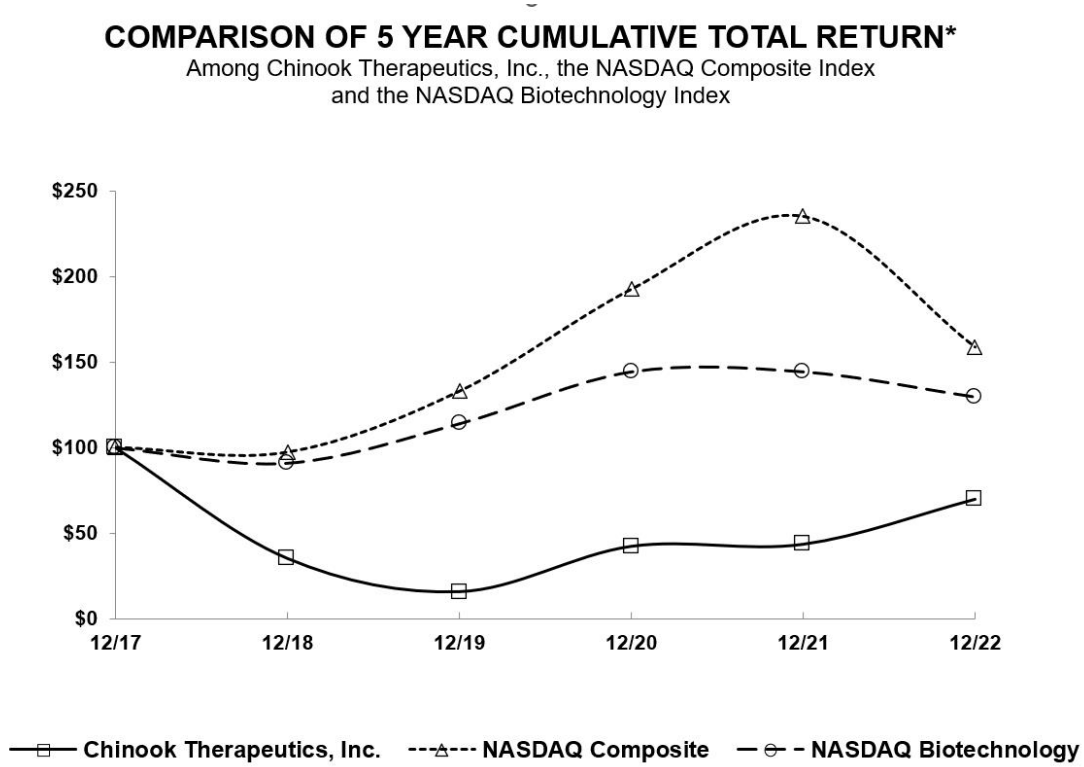
None.

Repurchases of Shares or of Company Equity Securities

None.

Stock Performance Graph (1)

The graph below shows the cumulative total return to our stockholders during the period from December 31, 2017 through December 31, 2022 in comparison to the indicated indices. The results assume that $100 was invested on December 31, 2017 in our common stock and each of the indicated indexes, including reinvestment of dividends, if any. Additionally, on October 5, 2020, Aduro Biotech, Inc. ("Aduro") completed its merger with Chinook Therapeutics U.S., Inc. ("Private Chinook"), pursuant to the terms of a merger agreement dated as of June 1, 2020, and amended on August 17, 2020, by which a wholly owned subsidiary of Aduro merged with and into Private Chinook, with Private Chinook continuing as a wholly owned subsidiary of Aduro (the "Merger"). Immediately following the Merger, Aduro changed its name to "Chinook Therapeutics, Inc." and the business conducted by Private Chinook became the primary business conducted by the Company. Accordingly, our common stock is traded on the Nasdaq Global Select Market under the symbol "KDNY." From April 15, 2015 to October 5, 2020 our common stock was traded under the symbol "ADRO."



This information under "Stock Performance Graph" shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Exchange Act or incorporated by reference into any filing of Chinook Therapeutics, Inc. under the Securities Act or the Exchange Act, except to the extent we specifically incorporate it by reference into such filing. The past performance of our common stock is not an indication of future performance.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this report contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations and intentions. As a result of many factors, including those factors set forth in the "Risk Factors" section of this report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

Chinook is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing precision medicines for kidney diseases. Our pipeline is focused on rare, severe chronic kidney diseases with well-defined clinical pathways. Our lead clinical program is atrasentan, a potent and selective endothelin A receptor antagonist. We are currently conducting the phase 3 ALIGN trial of atrasentan for IgA nephropathy, or IgAN, and the phase 2 AFFINITY basket trial for proteinuric glomerular diseases. We most recently presented interim data from the IgAN patient cohort of the AFFINITY trial at the American Society of Nephrology, or ASN, Kidney Week in November 2022. In addition, enrollment in the ALIGN trial to date exceeds 270 patients. The interim proteinuria endpoint analysis will be performed on the first 270 patients enrolled and we expect to report topline data from this analysis in the second half of 2023 to potentially support an application for accelerated approval under Subpart H in the United States. Our second product candidate, BION-1301, is an anti-APRIL monoclonal antibody also in phase 2 development for patients with IgAN. We most recently presented interim results from the ongoing phase 1/2 trial at ASN Kidney Week in November 2022. Our third product candidate is CHK-336, an oral small molecule LDHA inhibitor for the treatment of primary and idiopathic hyperoxaluria that is currently in a phase 1 clinical trial in healthy volunteers. In addition, we are conducting research programs in several other rare, severe chronic kidney diseases. We seek to build our pipeline by leveraging insights from kidney single cell RNA sequencing and large chronic kidney disease, or 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 support these efforts, we have an ongoing strategic collaboration with Evotec SE, or Evotec, to jointly identify, characterize and validate novel mechanisms and discover precision medicines for lupus nephritis, IgAN, polycystic kidney disease, or PKD, and other primary glomerular diseases. We also continue to evaluate opportunities to in-license kidney disease programs to bolster our pipeline. In November 2021, we established SanReno Therapeutics, or SanReno, a joint venture to develop, manufacture and commercialize kidney disease therapies in mainland China, Hong Kong, Macau, Taiwan and Singapore. We believe that a strong local presence in East Asia may allow us to accelerate the clinical development and maximize the commercial potential of atrasentan and BION-1301, the two programs licensed to SanReno, in the region.

Our approach to precision medicines leverages recent advances in identifying targeted kidney therapies linked to mechanistic biomarkers by the application of systems biology approaches in nephrology. The application of this approach in nephrology has advanced over the past decade through the study of multiple patient groups across a wide variety of kidney diseases and their associated multilevel data sets, including genome, transcriptome, proteome, metabolome, pathology and prospective long-term clinical characteristics and outcomes. A key objective of these investigations is to define kidney diseases in molecular terms to drive the development of targeted treatments. We believe we are well-positioned to exploit the insights provided into the key molecular drivers and classifiers of kidney diseases by the application of these systems biology tools to nephrology. Our strategy is to use these mechanistic insights to select compelling drug targets and deliver novel and differentiated product candidates for rare and severe kidney diseases with high unmet medical need.

For additional information regarding our product candidates, clinical development candidates and other research and discovery programs, refer to "Overview" within Part I, Item 1. Business in this Annual Report on Form 10-K.

Components of Operating Results

Collaboration and License Revenue

We have not generated any revenue from product sales. Our revenue to date has been primarily derived from our collaboration and license agreements.

SanReno Therapeutics

In November 2021, we entered into a License Agreement with SanReno, or the China License Agreement. The China License Agreement includes the transfer of intellectual property rights in the form of a development and commercialization license in the Territory; manufacturing and supply services; and participation in opt-in global studies with the collaboration party. The terms of the China License Agreement also include potential payments to us for the following: progress-dependent milestone payment; royalties on the net sales of a licensed product and reimbursement for certain expenses incurred. As of December 31, 2022, these potential payments are not considered probable of being achieved and they relate to promised goods or services for which revenue will be recognized upon our satisfaction of the underlying performance obligations.

Pre-existing Collaboration Agreements

Prior to the completion of the Merger, Aduro generated revenue from collaboration and license agreements. These collaboration agreements may have included the transfer of intellectual property rights in the form of licenses, promises to provide research and development services and promises to participate on certain development committees with the collaboration party. The terms of such agreements included payment to Aduro of one or more of the following: nonrefundable upfront fees, payment for research and development services, development, regulatory and commercial milestone payments, and royalties on net sales of licensed products.

Potential milestone payments related to development, regulatory or commercial milestone payments may be earned in the future under these pre-existing agreements, but all such payments are uncertain and beyond our or our collaborators' control and would be recorded as revenue upon receipt or over a period following receipt, such as under the CAPM model, if and when such payments are earned. We evaluated the remaining performance obligations under these pre-existing agreements and concluded that we do not expect to recognize material revenue under these pre-existing agreements in the near term.

For additional information, refer to Note 11 "Collaboration and License Agreements" of the Notes to the Consolidated Financial Statements under Part II, Item 8, "Financial Statements and Supplementary Data" in this Annual Report on Form 10-K.

Research and Development Expenses

The largest component of our operating expenses is our investment in research and development activities, including the clinical development of our product candidates. Research and development expenses represent costs incurred to conduct research, such as the discovery and development of our product candidates, as well as the development of product candidates pursuant to Aduro's pre-existing collaboration and license agreements. Research and development costs include employee-related costs; licensing costs; materials and supplies; contracted research and manufacturing; consulting arrangements; allocated costs, such as facility costs; and other expenses incurred to advance our research and development activities. Employee-related costs consist of salaries, bonuses, severance and benefits. We recognize all research and development costs as they are incurred. Clinical trial costs, contract manufacturing and other development costs incurred by third parties are expensed as the contracted work is performed.

We expect our research and development expenses to increase in the future as we advance our product candidates into and through clinical trials and pursue regulatory approval of our product candidates. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming. The probability of success for our product candidates and technologies may be affected by a variety of factors including: the quality of our product candidates, early clinical data, investment in our clinical programs, competition, manufacturing capability and commercial viability. We may never succeed in obtaining regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates.

General and Administrative Expenses

General and administrative expenses include employee-related costs, expenses for consulting and outside services, allocated costs, such as facility costs, and other costs. Employee-related costs consist of salaries, bonuses, severance and benefits. Consulting and outside services consist of legal, accounting and audit services, insurance expenses, investor relations activities, administrative services and other consulting fees. Allocated costs consist of rent expense related to our offices and research and development facility.

Change in Fair Value of Contingent Consideration and Contingent Value Rights Liabilities

At the effective time of the Merger, we also entered into an agreement, or CVR Agreement, pursuant to which Aduro's common stockholders of record as of the close of business on October 2, 2020 received one contingent value right, or CVR, for each outstanding share of Aduro common stock held by such stockholder on such date. Each CVR represents the contractual right to receive payments from us upon the receipt of consideration resulting from certain events described in the CVR Agreement, such as milestones and royalties from certain pre-existing agreements and the disposition or licensing of certain of Aduro's non-renal assets, net of deductions permitted under the CVR Agreement, including taxes and certain other expenses. Change in the fair value of the contingent consideration and CVR liabilities at each reporting period consists of the changes in the values of these contractual rights.

Amortization of Intangible Assets

Amortization of intangible assets, excluding goodwill results from the amortization of finite-lived intangible assets acquired in the Merger. Amortization is over periods of 9 to 17 years, with an original weighted average period of 16.7 years.

Gain on Sale of Assets to Equity Method Investment

In 2021 we entered into an agreement with Sairopa B.V., or Sairopa, to acquire certain of our non-renal assets in exchange for preferred stock in Sairopa. The sale of the non-renal assets to Sairopa resulted in a $7.2 million gain, which is the difference between the fair value of the equity received and the carrying value of the non-renal assets. The gain is reported in our consolidated statements of operations and comprehensive loss for the year ended December 31, 2021.

Investment and Other Income (Expense), Net

Investment and other income (expense), net consists primarily of interest income, foreign currency gains and losses, and various income or expense items of a non-recurring nature.

Income Tax (Expense) Benefit

We are subject to income taxes in the United States and foreign jurisdictions in which we do business. These foreign jurisdictions have statutory tax rates different from those in the United States. Accordingly, our effective tax rates will vary depending on the relative proportion of foreign to U.S. income, the availability of research and development tax credits, changes in the valuation of our deferred tax assets and liabilities and changes in tax laws. We regularly assess the likelihood of adverse outcomes resulting from the examination of our tax returns by the Internal Revenue Service, or IRS, and other tax authorities to determine the adequacy of our income tax reserves and expense. Should actual events or results differ from our current expectations, charges or credits to our income tax expense may become necessary.

Equity Method Investment Gain (Loss)

Equity method investment gain (loss) represents our share of net loss of the Sairopa investment, which is reported in our consolidated statements of operations and comprehensive loss on a one quarter lag. Additionally, equity method investment gain (loss) includes gains or losses of our equity method investment due to changes in our ownership interest, if any.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

	Year Ended December 31,		
	2022	2021	Change
	(in thousands)		
Collaboration and license revenue	$ 6,128	$ 51,625	$ (45,497)
Operating expenses:			
Research and development	141,211	96,987	44,224
General and administrative	36,291	31,899	4,392
Change in fair value of contingent consideration and contingent value rights liabilities	11,987	27,317	(15,330)
Amortization of intangible assets	1,722	1,687	35
Total operating expenses	191,211	157,890	33,321
Gain on sale of assets to equity method investment	—	7,227	(7,227)
Loss from operations	(185,083)	(99,038)	(86,045)
Investment and other income (expense), net	4,809	(170)	4,979
Loss before income taxes and equity method investment loss	(180,274)	(99,208)	(81,066)
Income tax expense	(4,341)	(2,093)	(2,248)
Equity method investment loss	(3,250)	(1,636)	(1,614)
Net loss	$ (187,865)	$ (102,937)	$ (84,928)

Collaboration and License Revenue

Total collaboration and license revenue was $6.1 million for the year ended December 31, 2022, a decrease of $45.5 million compared to $51.6 million for the year ended December 31, 2021. The decrease was primarily due to $41.2 million of non-cash revenue recognized under our license agreement with SanReno and a development milestone of $10.0 million recognized under our agreement with Merck and Co, Inc., or Merck, in 2021. This decrease was offset by $4.2 million related to services provided under our license agreement with SanReno and $1.9 million from the achievement of a development milestone under our collaboration agreement with Lilly, which were both recognized in revenue in 2022.

Research and development expenses

The following tables summarize our research and development expenses by program and by category incurred during the years ended December 31, 2022 and 2021:

	Year Ended December 31,		
	2022	2021	Change
	(in thousands)		
Product candidates:			
Atrasentan	$ 56,930	$ 41,606	$ 15,324
BION-1301	31,781	12,928	18,853
CHK-336	8,292	9,141	(849)
Other discovery, research and development programs	12,367	17,334	(4,967)
Subtotal	109,370	81,009	28,361
Stock-based compensation expense	10,510	6,007	4,503
Facility and depreciation costs	6,526	4,046	2,480
Other general research and development expenses	14,805	5,925	8,880
Total research and development expenses	$ 141,211	$ 96,987	$ 44,224

	Year Ended December 31,		
	2022	2021	Change
	(in thousands)		
Licensing and contract research and manufacturing	$ 62,403	$ 51,248	$ 11,155
Employee-related costs	42,702	24,904	17,798
Supplies used in research and development	2,107	2,882	(775)
Stock-based compensation expense	10,510	6,007	4,503
Facility and depreciation costs	6,526	4,046	2,480
Consulting and outside services	12,890	6,531	6,359
Other	4,073	1,369	2,704
Total research and development expenses	$ 141,211	$ 96,987	$ 44,224

Research and development expenses were $141.2 million for the year ended December 31, 2022, an increase of $44.2 million compared to $97.0 million for the year ended December 31, 2021. The increase in research and development expenses was primarily due to higher employee-related costs, including salaries, benefits and stock-based compensation expense which resulted from increased headcount to support our clinical programs; an increase in licensing and contract research and manufacturing costs; increased spending for consulting and outside services costs, and an increase in facilities and other costs to continue the progression of our research and clinical programs.

General and administrative expenses

The following table summarizes our general and administrative expenses incurred during the years ended December 31, 2022 and 2021:

	Year Ended December 31,		
	2022	2021	Change
	(in thousands)		
Consulting and outside services	$ 10,807	$ 10,091	$ 716
Employee-related costs	12,084	10,448	1,636
Stock-based compensation expense	9,544	6,778	2,766
Facility and depreciation costs	977	2,449	(1,472)
Other	2,879	2,133	746
Total general and administrative expenses	$ 36,291	$ 31,899	$ 4,392

General and administrative expenses were $36.3 million for the year ended December 31, 2022, an increase of $4.4 million compared to $31.9 million for the year ended December 31, 2021. The increase in general and administrative expenses was primarily due to higher employee-related costs, including salaries, benefits and stock-based compensation expense, which resulted from increased headcount to support our operations, higher consulting and outside services costs to support our operations, and other costs. These increases were offset by a decrease in facilities costs, which are allocable from general and administrative to research and development expenses based on headcount. We expect our general and administrative expenses will continue to increase in the future as our operations grow to support further research and development.

Change in fair value of contingent consideration and contingent value rights liabilities

Change in fair value of contingent consideration and contingent value rights liabilities expense was $12.0 million for the year ended December 31, 2022, a decrease of $15.3 million compared to $27.3 million for the year ended December 31, 2021. The decrease primarily resulted from higher expenses in 2021 due to a change in estimate of the potential future proceeds derived from Aduro's license agreement with Merck for MK-5890 and a change in the fair value related to our non-renal assets in 2021. In 2021, Merck informed us that they intended to explore the potential benefits of the product candidate MK-5890 in a phase 2 clinical study for a new indication, which resulted in the CVR liability increasing. In 2021, we also sold certain of our non-renal assets in exchange for preferred shares in Sairopa, which resulted in a higher fair value. The decrease in expense was partially offset by a net increase in the CVR liability in 2022 primarily from remeasuring the value of our preferred shares in Sairopa at estimated fair value mainly as a result of Sairopa entering into a license agreement with Exelixis, Inc., or Exelixis, in November 2022 and due to a change in estimate of the potential future proceeds derived from Aduro's license agreement with Merck for MK-5890.

Amortization of intangible assets

Amortization of intangible assets expense was $1.7 million for both the years ended December 31, 2022 and 2021, and was related to normal amortization of finite-lived intangible assets acquired in the Merger.

Gain on sale of assets to equity method investment

Gain on sale of assets to equity method investment decreased $7.2 million for the year ended December 31, 2022, resulting from the agreement to sell certain non-renal assets of ours in exchange for stock in Sairopa in 2021. The gain is the difference between the fair value of the equity received and the carrying value of the non-renal assets.

Income tax expense

Income tax expense of $4.3 million for the year ended December 31, 2022, resulted from an increase in the valuation allowance to offset net operating losses that are not more likely than not to be fully utilized related to our wholly-owned subsidiaries in the Netherlands. Income tax expense of $2.1 million for the year ended December 31, 2021 resulted from the reduction of deferred tax liabilities related to our wholly-owned subsidiaries in the Netherlands.

Equity method investment loss

Equity method investment loss increased by $1.6 million for the year ended December 31, 2022 compared to the year ended December 31, 2021 due to our share of net loss in the Sairopa investment, net of any taxes. This increase was offset by a $1.1 million gain recorded in 2022, which resulted from changes in our ownership interest in Sairopa due to additional shares issued by Sairopa to other investors. Our equity method is adjusted each period for our share of the investee's income or loss, which is reported in our consolidated statements of operations and comprehensive loss on a one quarter lag. In November 2022, Sairopa executed a license agreement with Exelixis under which Exelixis made an upfront payment of $40.0 million to obtain an exclusive, worldwide license to develop and commercialize ADU-1805 and other anti-SIRPα antibodies, and for certain expenses to be incurred by Sairopa in conducting phase 1 clinical studies of ADU-1805. For additional information, refer to Note 10 "Equity Method Investment" within Part II, Item 8, "Financial Statements and Supplementary Data" in this Annual Report on Form 10-K.

Comparison of the Years Ended December 31, 2021 and 2020

For a discussion of our results of operations for the year ended December 31, 2021, as compared to the year ended December 31, 2020, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations—Comparison of the Years Ended December 31, 2021 and 2020 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 filed with the SEC on March 17, 2022.

Liquidity and Capital Resources

Overview

As of December 31, 2022, we had $385.3 million in cash, cash equivalents and marketable securities. We expect that our research and development and general and administrative expenses will increase, and, as a result, we anticipate that we will continue to incur increasing losses in the foreseeable future. We believe that our cash, cash equivalents and marketable securities as of December 31, 2022 will enable us to fund our operating expenses and capital expenditure requirements into 2025.

We have not generated any revenue from product sales, and we do not know when, or if, we will generate any revenue from product sales. We do not expect to generate any revenue from product sales unless and until we obtain regulatory approval of and commercialize any of our product candidates. Accordingly, we anticipate that we will need substantial additional funding in connection with our continuing operations. Our operations have been financed primarily through the issuance and sale of our common stock.

Sources of Liquidity

In May 2022, we completed an underwritten public offering of 7.6 million shares of our common stock at a price to the public of $14.00 per share, which included the exercise in full of the underwriters' option to purchase an additional 1.1 million shares of our common stock in June 2022. As part of this offering, we also sold to certain investors pre-funded warrants (the "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 in May 2022 resulted in gross proceeds to us of $120.7 million, before $7.7 million of underwriting discounts and commissions and estimated offering expenses.

In November 2021, we completed an underwritten public offering of 9.5 million shares of our common stock at a price to the public of $14.00 per share, which included the exercise in full of the underwriters' option to purchase an additional 1.7 million shares of our common stock. As part of this offering, we also sold to certain investors Pre-Funded Warrants to purchase up to an aggregate of 3.6 million shares of common stock at a purchase price of $13.9999 per pre-funded warrant. The underwritten public offering in November 2021 resulted in gross proceeds to us of $183.5 million, before $11.3 million of underwriting discounts and commissions and estimated offering expenses.

The Pre-Funded Warrants sold in May 2022 and November 2021 are exercisable at any time after the date of issuance and do not expire. A holder of Pre-Funded Warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than 4.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise. A holder of Pre-Funded Warrants may increase or decrease this percentage, but not in excess of 19.99%, by providing at least 61 days' prior notice to Chinook.

In April 2021, we entered into an "at-the-market" sales agreement (the "2021 Sales Agreement") with Cantor Fitzgerald & Co. and SVB Securities LLC, previously known as SVB Leerink LLC, through which we may offer and sell shares of our common stock having an aggregate offering of up to $75.0 million through our sales agents, Cantor Fitzgerald & Co. and SVB Securities LLC. In November 2022, we amended the 2021 Sales Agreement to provide for offerings of up to $150.0 million. We will pay the sales agents a commission of up to 3% of the gross proceeds of sales made through the 2021 Sales Agreement. During the years ended December 31, 2022 and 2021, we sold 1.5 million shares for $32.9 million and 2.2 million shares for $33.9 million, respectively, in net proceeds under the 2021 Sales Agreement. As of December 31, 2022, we have $135.6 million remaining under the 2021 Sales Agreement.

Funding Requirements

Our primary use of cash is to fund operating expenses, primarily research and development expenditures. Our future funding requirements will depend on many depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates;
- the clinical development plans we establish for these product candidates;
- the timelines of our clinical trials and the overall costs to conduct and complete the clinical trials;
- the number and characteristics of product candidates that we develop;
- the cost of manufacturing our product candidates for clinical development and any potential products we successfully commercialize;
- the timing of, and the costs involved in, obtaining regulatory approvals for any product candidates we develop;

- the cost of commercialization activities, if any, of any product candidates we develop independently that are approved for sale, including marketing, sales and distribution costs;
- the timing and amount of any sales of our product candidates, if any, or royalties thereon;
- our ability to establish new collaborations, licensing or other arrangements, if any, and the financial terms of such arrangements;
- opportunities to in-license or otherwise acquire new technologies and therapeutic candidates;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patents, including any litigation costs and the outcomes of any such litigation; and
- the effect of competing technological and market developments.

As of December 31, 2022, our short and long-term material cash requirements from known contractual and other obligations primarily relate to our contractual obligations related to our operating leases. For additional information on our operating lease commitments, refer to Note 12 “Commitments and Contingencies” within Part II, Item 8, “Financial Statements and Supplementary Data” in this Annual Report on Form 10-K.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, we expect to finance our future cash needs primarily through the issuance of additional equity, borrowings and strategic alliances with partner companies. To the extent that we raise additional capital through the issuance of additional equity, including through our at-the-market offering program or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market our product candidates to third parties that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Year Ended December 31,	
	2022	2021
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (117,481)	$ (102,744)
Investing activities	(99,993)	(112,639)
Financing activities	151,432	209,524
Effect of exchange rate changes	(244)	157
Net change in cash, cash equivalents, and restricted cash	$ (66,286)	$ (5,702)

Operating Activities

Net cash used in operating activities was $117.5 million for the year ended December 31, 2022, an increase of $14.7 million compared to $102.7 million for the year ended December 31, 2021. The increase was primarily due to an increased operating loss, primarily resulting from research and development and general and administrative spending, offset in part by changes in net working capital usage.

Investing Activities

Net cash used in investing activities was $100.0 million for the year ended December 31, 2022, an increase of $12.6 million compared to $112.6 million cash provided by investing activities for the year ended December 31, 2021. The increase in cash used was primarily due to purchases of marketable securities, net of proceeds from maturities of marketable securities.

Financing Activities

Net cash provided by financing activities was $151.4 million for the year ended December 31, 2022, a decrease of $58.1 million compared to $209.5 million for the year ended December 31, 2021. The decrease was primarily due to decreased aggregate net proceeds from the sale of common stock in an underwritten public offering and the at-the-market sales agreement, which decreased over the prior period by $60.5 million, and due to $7.5 million paid to the CVR holders in 2022, which resulted from a development milestone recognized in 2021 under the license agreement with Merck for MK-5890. The decrease was partially offset by increased proceeds from option exercises and the employee stock purchase plan in 2022.

Comparison of the Years Ended December 31, 2021 and 2020

For a discussion of cash flows for the year ended December 31, 2021, as compared to the year ended December 31, 2020, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Cash Flows included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 filed with the SEC on March 17, 2022.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Contingent Value Rights and Contingent Consideration Liabilities

The estimated fair value of the contingent value rights and contingent consideration liabilities, initially measured and recorded on the Merger date, are considered to be Level 3 instruments. The contingent value rights and contingent consideration liabilities are recorded at fair value at the end of each reporting period with changes in estimated fair values recorded in change in fair value of contingent consideration and contingent value rights liabilities in the consolidated statements of operations and comprehensive loss. In determining the fair value of the CVR and the contingent consideration liabilities, we used the income approach, primarily discounted cash flow models. The discounted cash flow models require the use of significant judgment, estimates and assumptions, including estimated revenues and costs, the probability of technical and regulatory success, and discount rates.

Intangible Assets

Our intangible assets include an acquired out-license agreement and indefinite-life in-process research and development assets ("IPR&D") acquired in the Merger with Aduro. The acquired out-license agreement represents the estimated fair value of an agreement with Merck and Co, Inc. ("Merck") related to a product candidate currently being studied in phase 2 clinical testing. The IPR&D represents the estimated fair value as of the acquisition date of two substantive in-process projects that have not reached technological feasibility: the BION-1301 product candidate currently being tested in a phase 1/2 clinical trial and the remaining non-renal assets intended for disposal. The primary basis for determining technological feasibility of these assets is, in the case of BION-1301 and the Merck agreement, obtaining regulatory approval. In the case of the non-renal assets, it is completing transactions for the out-license or sale of the assets. The fair value of the Merck out-license agreement and in-process BION-1301 research and development intangible assets were determined using probability-weighted discounted cash flow models, including a multi-period excess earnings method and use of a Monte Carlo simulation. Projecting discounted future cash flows requires management to make significant estimates regarding future revenue and expenses, probability of technological and regulatory success, revenue volatility and discount rates. The discount rate used was determined at the time of acquisition and includes a rate of return which accounts for the time value of money, as well as risk factors reflecting the economic risk that the projected cash flows may not be realized. The fair value of the non-renal IPR&D intangible assets were determined using a probability-weighted discounted cash flow model, including assumptions regarding probabilities, timing and prices for the sale or out-license of these assets.

We review our intangible assets at least annually, on October 1 of each year, for possible impairment. Intangible assets are reviewed for possible impairment between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of the assets below their carrying values. Our intangible assets totaled $60.8 million at December 31, 2022.

Research and Development Expenses

Research and development expenses represent costs incurred to conduct research, such as the discovery and development of our product candidates. Research and development costs include employee-related costs; licensing costs, materials and supplies, contracted research and manufacturing, consulting arrangements; allocated costs, such as facility costs; and other expenses incurred to advance our research and development activities. We recognize all research and development costs as they are incurred. In-licensing fees and other costs to acquire technologies that are utilized in research and development, and that are not expected to have alternative future use, are expensed when incurred. Clinical trial costs, contract manufacturing and other development costs incurred by third parties are expensed as the contracted work is performed. For service contracts that include a nonrefundable prepayment for future service, the upfront payment is deferred and recognized in the consolidated statements of operations and comprehensive loss as the services are rendered.

Stock-Based Compensation Expense

We measure and recognize compensation expense for all stock-based awards granted to employees and non-employees based on the estimated fair value of the award on the date of grant.

We use the Black-Scholes option pricing model to measure the fair value of stock option awards when they are granted. We make several estimates in determining stock-based compensation and these estimates generally require significant analysis and judgment to develop, including (i) the expected share price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) the expected dividend yield. Prior to the Merger, due to the lack of company-specific historical and implied volatility data, we based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded, which have characteristics similar to those of Private Chinook, including stage of product development and focus on the life science industry. For options granted after the Merger, we are using historical volatility of Aduro's and the Company's common stock, as it approximates the volatility of the formerly utilized peer group. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The expected term for options granted to employees represents the weighted-average period the awards are expected to remain outstanding and our estimates were determined using the simplified method. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. We use an assumed dividend yield of zero as we have never paid dividends and have no current plans to pay any dividends on our common stock.

Stock-based compensation expense for restricted stock and stock options is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective award. For performance-based stock units, we record stock-based compensation expense over the estimated service period once the achievement of the performance-based milestone is considered probable. At each reporting date, we assess whether the achievement of a milestone is considered probable, and if so, record stock-based compensation expense based on the portion of the service period elapsed to date with respect to the milestone, with a cumulative catch-up. We recognize remaining stock-based compensation expense with respect to a milestone, if any, over the remaining estimated service period. Forfeitures for equity awards are recorded as incurred.

For the years ended December 31, 2022, 2021 and 2020, stock-based compensation expense was $20.1 million, $12.8 million and $3.6 million, respectively. As of December 31, 2022, we had $66.6 million of total unrecognized stock-based compensation costs. Of the $66.6 million total unrecognized stock-based compensation costs, we had a total of $48.6 million that we expect to recognize over a weighted-average period of 2.3 years, and $18.0 million of total unrecognized stock-based compensation costs related to performance-based stock units with performance targets that are considered not probable of achievement.

Income Taxes

Income taxes are accounted for using an asset and liability approach that requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the consolidated financial statement and tax bases of assets and liabilities at the applicable enacted tax rates. We establish a valuation allowance for deferred tax assets if it is more likely than not that these items will expire before we are able to realize its benefits or that future deductibility is uncertain.

We recognize the tax benefit from uncertain tax positions only if it is more likely than not that the tax position will be sustained on examination by the tax authorities, based on the technical merits of the position. The tax position is measured based on the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement. We recognize interest and penalties related to income tax matters in income tax expense if incurred.

Recent Accounting Pronouncements

For information regarding recent accounting pronouncements, refer to Note 2 "Summary of Significant Accounting Policies" of the Notes to the Consolidated Financial Statements under Part II, Item 8 of this report.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. The primary objective of our investment portfolio is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. As of December 31, 2022 and 2021, we had total cash, cash equivalents and short- and long-term investments of $385.3 million and $355.1 million, respectively, which consisted of cash, money market funds, U.S. government and agency securities, corporate debt securities, and commercial paper.

Foreign Exchange Risk

Most of our operating expenses are denominated in U.S. dollars and, as a result, we have not experienced significant foreign currency transaction gains and losses to date. We have limited foreign currency exposure associated with certain of our operating expenses and gains or losses associated with our equity method investment in Sairopa. This is primarily limited to fluctuations in the Canadian Dollar and the Euro. Our operating expenses associated with our wholly-owned subsidiary in Canada are denominated in Canadian Dollars and converted to U.S. dollars. Gains and losses associated with our equity method investment in Sairopa are denominated in Euro and converted to U.S. dollars. We do not anticipate that foreign currency transaction gains or losses will be significant at our current level of operations. However, our operations may become subject to more significant fluctuations in foreign currency exchange rates in the future if we continue to contract with vendors outside of the U.S. and expand our operations internationally.

Item 8. Financial Statements and Supplementary Data.

CHINOOK THERAPEUTICS, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Chinook Therapeutics, Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Chinook Therapeutics, Inc. and its subsidiaries (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of operations and comprehensive loss, of redeemable convertible preferred stock and stockholders' equity (deficit) and of cash flows for each of the three years in the period ended December 31, 2022, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting

principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Valuation of Contingent Value Rights and Contingent Consideration Liabilities

As described in Notes 2, 3, and 5 to the consolidated financial statements, the Company completed its merger with Aduro Biotech, Inc. in 2020 and recorded liabilities for contingent value rights and contingent consideration liabilities. The contingent value rights and contingent consideration liabilities are recorded at fair value at the end of each reporting period, and determined by management using the income approach, primarily using discounted cash flow models. Management applied significant judgment in determining the fair value of the contingent value rights and contingent consideration liabilities, which involved the use of significant estimates and assumptions including estimated revenues and costs, the probability of technical and regulatory success and discount rates. The fair value of the contingent value rights and the contingent consideration liabilities as of December 31, 2022 is $39.8 million and $4.4 million, respectively.

The principal considerations for our determination that performing procedures relating to the valuation of the contingent value rights and contingent consideration liabilities is a critical audit matter are (i) the significant judgment by management when determining the fair value of the contingent value rights and contingent consideration liabilities and (ii) a high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating management's significant assumption relating to the probability of technical and regulatory success.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the valuation of the contingent value rights and contingent consideration liabilities. These procedures also included, among others, (i) reading and evaluating the agreements relating to the contingent value rights and contingent consideration liabilities; (ii) testing management's process for determining the fair value of the contingent value rights and contingent consideration liabilities; (iii) evaluating the appropriateness of the discounted cash flow models; and (iv) evaluating the reasonableness of the significant assumption used by management related to the probability of technical and regulatory success. The probability of technical and regulatory success was evaluated by considering external market and industry data.

/s/ PricewaterhouseCoopers LLP
Seattle, Washington
February 27, 2023

We have served as the Company's auditor since 2019.

Chinook Therapeutics, Inc.
Consolidated Balance Sheets
(in thousands, except per share amounts)

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 115,438	$ 181,724
Marketable securities	262,887	105,113
Accounts receivable	1,091	10,061
Prepaid expenses and other current assets	6,176	3,741
Total current assets	385,592	300,639
Marketable securities	6,989	68,215
Property and equipment, net	16,908	18,935
Restricted cash	2,074	2,074
Operating lease right-of-use assets	48,970	55,385
Investment in equity securities	41,200	41,200
Equity method investment	4,071	8,205
Intangible assets, net	24,287	26,009
In-process research & development	36,550	36,550
Goodwill	117	117
Other assets	7,326	6,474
Total assets	$ 574,084	$ 563,803
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 9,751	$ 8,580
Accrued and other current liabilities	33,636	17,104
Operating lease liabilities	4,948	4,401
Contingent value rights liability	2,500	10,000
Total current liabilities	50,835	40,085
Contingent value rights liability - non-current	37,318	24,591
Contingent consideration liability	4,420	5,160
Deferred tax liabilities	5,076	735
Operating lease liabilities, net of current maturities	34,494	39,589
Total liabilities	132,143	110,160
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000 shares authorized as of December 31, 2022 and 2021; no shares issued and outstanding as of December 31, 2022 and 2021	—	—
Common stock, $0.0001 par value; 300,000 shares authorized as of December 31, 2022 and 2021; 65,471 and 54,761 shares issued and outstanding as of December 31, 2022 and 2021, respectively	7	5
Additional paid-in capital	864,729	685,459
Accumulated deficit	(419,631)	(231,766)
Accumulated other comprehensive loss	(3,164)	(55)
Total stockholders' equity	441,941	453,643
Total liabilities and stockholders' equity	$ 574,084	$ 563,803

The accompanying notes are an integral part of these consolidated financial statements.

Chinook Therapeutics, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except per share amounts)

	Years ended December 31,		
	2022	2021	2020
Collaboration and license revenue	$ 6,128	$ 51,625	$ 827
Operating expenses:			
Research and development	141,211	96,987	36,051
General and administrative	36,291	31,899	19,071
Change in fair value of contingent consideration and contingent value rights liabilities	11,987	27,317	1,510
Amortization of intangible assets	1,722	1,687	422
Total operating expenses	191,211	157,890	57,054
Gain on sale of assets to equity method investment	—	7,227	—
Loss from operations	(185,083)	(99,038)	(56,227)
Investment and other income (expense):			
Investment and other income (expense), net	4,809	(170)	298
Change in fair value of redeemable convertible preferred stock tranche liability	—	—	(27,696)
Loss before income taxes and equity method investment loss	(180,274)	(99,208)	(83,625)
Income tax (expense) benefit	(4,341)	(2,093)	2,003
Equity method investment loss	(3,250)	(1,636)	—
Net loss	$ (187,865)	$ (102,937)	$ (81,622)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.92)	$ (2.26)	$ (6.20)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	64,370	45,607	13,168
Other comprehensive income (loss):			
Foreign currency translation adjustments, net of tax of $0	(1,191)	44	39
Unrealized loss on marketable securities, net of tax of $0	(1,918)	(110)	(21)
Total other comprehensive income (loss)	(3,109)	(66)	18
Comprehensive loss	$ (190,974)	$ (103,003)	$ (81,604)

The accompanying notes are an integral part of these consolidated financial statements.

Chinook Therapeutics, Inc.
Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	(Deficit)
Balances at December 31, 2019	7,597	$ 19,835	4,502	$ —	6,095	$ (47,207)	$ (7)	$ (41,119)
Issuance of common stock upon exercise of stock options, issuance of common stock under Employee Stock Purchase Plan, and vesting of restricted stock units	—	—	94	—	446	—	—	446
Repurchase of unvested restricted stock awards	—	—	(72)	—	—	—	—	—
Issuance of Series A redeemable convertible preferred stock, net of issuance costs	4,237	14,479	—	—	—	—	—	—
Reclassification of redeemable convertible preferred stock tranche liability upon exercise	—	9,723	—	—	—	—	—	—
Conversion of redeemable convertible preferred stock to common stock	(11,834)	(44,037)	11,834	1	44,036	—	—	44,037
Reclassification of redeemable preferred stock tranche liability to additional paid-in capital upon termination of rights	—	—		—	50,706	—	—	50,706
Issuance of common stock pursuant to subscription agreements prior to Merger	—	—	9,583	1	109,413	—	—	109,414
Aduro outstanding common stock assumed as a result of the Merger	—	—	16,307	2	248,629	—	—	248,631
Issuance of common stock for financial advisory services in connection with the Merger	—	—	34	—	500	—	—	500
Stock-based compensation expense	—	—	—	—	3,611	—	—	3,611
Other comprehensive gain	—	—	—	—	—	—	18	18
Net loss	—	—	—	—	—	(81,622)	—	(81,622)
Balances at December 31, 2020	—	$ —	42,282	$ 4	$ 463,436	$ (128,829)	$ 11	$ 334,622
Issuance of common stock upon exercise of stock options and warrants, issuance of common stock under Employee Stock Purchase Plan, and vesting of restricted stock units	—	—	724		3,106	—	—	3,106
Issuance of common stock under the at-the-market sales agreement, net of issuance costs	—	—	2,216	—	33,891	—	—	33,891
Issuance of common stock and accompanying pre-funded warrants in underwritten public offering, net of issuance costs	—	—	9,539	1	172,241	—	—	172,242
Stock-based compensation expense	—	—	—	—	12,785	—	—	12,785
Other comprehensive loss	—	—	—	—	—	—	(66)	(66)
Net loss	—	—	—	—	—	(102,937)	—	(102,937)
Balances at December 31, 2021	—	$ —	54,761	$ 5	$ 685,459	$ (231,766)	$ (55)	$ 453,643
Issuance of common stock upon exercise of stock options and warrants, issuance of common stock under Employee Stock Purchase Plan, and vesting of restricted stock units	—	—	1,676	1	13,250	—	—	13,251
Issuance of common stock under the at-the-market sales agreement, net of issuance costs	—	—	1,480	1	32,884	—	—	32,885
Issuance of common stock and accompanying pre-funded warrants in underwritten public offering, net of issuance costs	—	—	7,554	—	113,082	—	—	113,082
Stock-based compensation expense	—	—	—	—	20,054	—	—	20,054
Other comprehensive loss	—	—	—	—	—	—	(3,109)	(3,109)
Net loss	—	—	—	—	—	(187,865)	—	(187,865)
Balances at December 31, 2022	—	$ —	65,471	$ 7	$ 864,729	$ (419,631)	$ (3,164)	$ 441,941

The accompanying notes are an integral part of these consolidated financial statements.

Chinook Therapeutics, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Years ended December 31,		
	2022	**2021**	**2020**
Cash Flows from Operating Activities			
Net loss	$ (187,865)	$ (102,937)	$ (81,622)
Adjustments to reconcile net loss to net cash used in operating activities:			
Reversal of non-cash consideration related to revenue	—	(41,200)	—
Depreciation and amortization expense	3,377	3,065	992
Loss (gain) on disposal of property and equipment	256	—	(44)
Amortization of finance lease right-of-use asset	—	—	22
Amortization of intangible assets	1,722	1,687	422
Non-cash operating lease expense	6,279	5,688	1,486
Stock-based compensation expense	20,054	12,785	3,611
Change in fair value of redeemable convertible preferred stock tranche liability	—	—	27,696
Change in fair value of contingent consideration and contingent value rights liabilities	11,987	27,317	1,510
Accretion of discounts and amortization of premiums on marketable securities	(124)	211	4
Financial advisory expenses paid through issuance of common stock	—	—	500
Deferred income taxes	4,341	2,093	(2,003)
Gain on sale of assets to equity method investment	—	(7,227)	—
Equity method investment gain (loss)	3,250	1,636	—
Changes in operating assets and liabilities:			
Accounts receivable	8,970	(9,799)	818
Prepaid expenses and other assets	(3,323)	675	(7,980)
Accounts payable	1,380	4,547	553
Accrued and other liabilities	16,610	1,972	(825)
Operating lease liabilities	(4,395)	(3,162)	(423)
Deferred revenue	—	(95)	(565)
Net cash used in operating activities	(117,481)	(102,744)	(55,848)
Cash Flows from Investing Activities			
Cash, cash equivalents and restricted cash acquired in connection with the Merger	—	—	74,909
Purchases of marketable securities	(299,182)	(232,343)	(16,590)
Proceeds from marketable securities	200,842	121,315	52,000
Purchases of property and equipment	(1,653)	(1,878)	(797)
Proceeds from sale of property and equipment	—	267	150
Net cash provided by (used in) investing activities	(99,993)	(112,639)	109,672
Cash Flows from Financing Activities			
Proceeds from issuance of common stock pursuant to subscription agreements prior to Merger, net of issuance costs	—	—	109,414
Proceeds from issuance of common stock and accompanying pre-funded warrants in underwritten public offering, net of issuance costs	113,082	172,527	—
Proceeds from exercise of stock options and warrants and from Employee Stock Purchase Plan	13,251	3,106	446
Proceeds from at-the-market-sales agreement, net of issuance costs	32,885	33,891	—
Previously incurred issuance costs related to an underwritten public offering paid during period	(286)	—	—
Payment of contingent value rights liability	(7,500)	—	—
Proceeds from issuance of redeemable convertible preferred stock and related tranche rights, net of issuance costs	—	—	14,479
Repayment of finance lease liability	—	—	(47)
Net cash provided by financing activities	151,432	209,524	124,292
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(244)	157	27
Net increase (decrease) in cash, cash equivalents and restricted cash	(66,286)	(5,702)	178,143
Cash, cash equivalents and restricted cash at beginning of period	183,798	189,500	11,357
Cash, cash equivalents and restricted cash at end of period	$ 117,512	$ 183,798	$ 189,500
Reconciliation of Cash, Cash Equivalents and Restricted Cash			
Cash and cash equivalents	$ 115,438	$ 181,724	$ 187,750
Restricted cash	2,074	2,074	1,750
Total cash, cash equivalents and restricted cash	$ 117,512	$ 183,798	$ 189,500
Supplemental Cash Flow Information			
Cash paid for amounts included in the measurement of lease liabilities	$ 7,401	$ 6,270	$ 1,321
Supplemental Disclosure of Non-Cash Investing and Financing Activities			
Purchases of property and equipment included in accounts payable and in accrued and other current liabilities	$ 276	$ 174	$ 425
Right-of-use asset for office space acquired through leases	—	5,406	1,449
Issuance costs incurred but unpaid	—	286	—
Investment in equity securities acquired through non-cash consideration	—	41,200	—
Fair value of net assets acquired in Merger	—	—	185,992
Conversion of redeemable convertible stock to common stock upon closing of the Merger	—	—	44,037
Financial advisory expenses paid through issuance of common stock	—	—	500
Termination of redeemable convertible preferred stock tranche liability	—	—	9,723

The accompanying notes are an integral part of these consolidated financial statements.

1. Description of Business

Chinook Therapeutics, Inc. (the "Company", "Chinook", "we", "our", or "us") is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing precision medicines for kidney diseases. On October 5, 2020, Aduro Biotech, Inc. ("Aduro") completed its merger with Chinook Therapeutics U.S., Inc. ("Private Chinook"), pursuant to the terms of a merger agreement dated as of June 1, 2020, and amended on August 17, 2020, by which a wholly owned subsidiary of Aduro merged with and into Private Chinook, with Private Chinook continuing as a wholly owned subsidiary of Aduro (the "Merger"). Immediately following the Merger, Aduro changed its name to "Chinook Therapeutics, Inc." and the business conducted by Private Chinook became the primary business conducted by the Company. Refer to Note 3 "Reverse Merger and Contingent Value Rights" in the accompanying notes to the consolidated financial statements.

Our lead clinical program is atrasentan, a potent and selective endothelin A receptor antagonist. We are currently conducting the phase 3 ALIGN trial of atrasentan for IgA nephropathy ("IgAN") and the phase 2 AFFINITY basket trial for proteinuric glomerular diseases. Our second product candidate, BION-1301, is an anti-APRIL monoclonal antibody also in phase 2 development for patients with IgAN. Our third product candidate is CHK-336, an oral small molecule LDHA inhibitor for the treatment of primary and idiopathic hyperoxaluria that is currently in a phase 1 clinical trial in healthy volunteers. In addition, we are building our precision medicine pipeline through research and discovery programs for other rare, severe chronic kidney diseases. We were incorporated in Delaware and are headquartered in Seattle, Washington.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying consolidated financial statements and related disclosures have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") and follow the requirements of the Securities and Exchange Commission (the "SEC") for annual reporting. The consolidated financial statements include the accounts of Chinook Therapeutics, Inc. and our wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported amounts of expenses during the reporting periods. Such estimates include the valuation of intangible assets, acquired property and equipment, investments, contingent value rights ("CVR") liability, contingent consideration liability, redeemable convertible preferred stock tranche liability, lease right-of-use assets, and lease obligations, as well as accruals for research and development activities, stock-based compensation expense, and income taxes. Actual results could differ from those estimates.

Segments

We operate and manage our business as one reportable and operating segment, which is the business of discovering, developing and commercializing precision medicines for kidney diseases. Our President and Chief Executive Officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance.

Risks and Uncertainties

We are subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, reliance on single-source vendors and collaborators, availability of raw materials, patentability of our products and processes and clinical efficacy and safety of our products under development, compliance with government regulations and the need to obtain additional financing to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical studies, clinical trials and regulatory approval, prior to commercialization. These efforts will require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance and reporting.

Our product candidates are still in development and, to date, none of our product candidates have been approved for sale and, therefore, we have not generated any revenue from product sales.

There can be no assurance that our research and development will be successfully completed, that adequate protection for our intellectual property will be obtained or maintained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if our product development efforts are successful, it is uncertain when, if ever, we will generate revenue from product sales. We operate in an environment of rapid technological change and substantial competition from other pharmaceutical and biotechnology companies. In addition, we are dependent upon the services of our employees, consultants and other third parties.

Moreover, the current COVID-19 pandemic, which is impacting worldwide economic activity, poses risk that we or our employees, contractors, suppliers, and other partners may be prevented from conducting business activities for an indefinite period of time which may delay the start-up and conduct of our clinical trials, and negatively impact manufacturing and testing activities performed by third parties. Any significant delays may impact the use and sufficiency of our existing cash reserves, and we may be required to raise additional capital earlier than we had previously planned. We may be unable to raise additional capital if and when needed, which may result in further delays or suspension of our development plans. The extent to which the pandemic will impact our business will depend on future developments that are highly uncertain and cannot be predicted at this time.

Business Combination

Accounting for acquisitions requires extensive use of estimates and judgment to measure the fair value of the identifiable tangible and intangible assets acquired, including in-process research and development and liabilities assumed. Additionally, we must determine whether an acquired entity is considered a business or a set of net assets because the excess of the purchase price over the fair value of net assets acquired can only be recognized as goodwill in a business combination. We accounted for the Merger with Aduro as a business combination under the acquisition method of accounting pursuant to Accounting Standards Codification ("ASC") Topic 805, *Business Combinations*. Consideration paid to acquire Aduro was measured at fair value and included the exchange of Aduro's common stock, assumption of Aduro stock options and warrants, and assumption of CVR. Refer to Note 3 "Reverse Merger and Contingent Value Rights" for more information.

Cash and Cash Equivalents

We consider all highly liquid investments with maturities of three months or less at the time of acquisition to be cash equivalents. Cash and cash equivalents consist of cash held in bank accounts, money market funds, commercial paper, corporate debt securities, and U.S. government and agency securities.

Restricted Cash

We maintain a letter of credit as security for a facility lease that expires in 2029. The letter of credit is collateralized by a certificate of deposit in the amount of $1.8 million, which is classified as long-term restricted cash in our consolidated balance sheets. Additionally, we maintain a letter of credit as a security deposit for a facility lease that expires in 2026. The letter of credit is collateralized by a certificate of deposit in the amount of $0.3 million, which is classified as long-term restricted cash which is classified as long-term restricted cash in our consolidated balance sheets.

Marketable Securities

We classify our marketable securities as available-for-sale, which are reported at estimated fair value with unrealized gains and losses included in accumulated other comprehensive loss in stockholders' equity. Realized gains, realized losses and declines in the value of securities determined to be other-than-temporary, are included in investment and other income (expense), net. The cost of investments for purposes of computing realized and unrealized gains and losses is based on the specific identification method. Amortization of premiums and accretion of discounts are included in investment and other income (expense), net. Interest earned on all securities is included in investment and other income (expense), net. Accrued interest receivable is excluded from both the estimated fair value and the amortized cost basis of available-for-sale securities and included within prepaid expenses and other current assets in our consolidated balance sheets. Marketable securities with maturities of less than one year, where management's intent is to use the investments to fund current operations, or to make them available for current operations, are classified as current.

We regularly review our investments for declines in fair value below their amortized cost basis to determine whether the impairment is due to credit-related factors or noncredit-related factors. Our review includes the creditworthiness of the security issuers, the severity of the unrealized losses, whether we have the intent to sell the securities and whether it is more likely than not that we will be required to sell the securities before the recovery of their amortized cost bases. When we determine that a portion of the

unrealized loss is due to an expected credit loss, we recognize the loss amount in investment and other income (expense), net, with a corresponding allowance against the carrying value of the security we hold.

Concentration of Credit Risk

Financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash, cash equivalents, available-for-sale securities and accounts receivable. We are exposed to credit risk from our deposits of cash and cash equivalents in excess of amounts insured by the Federal Deposit Insurance Corporation. Substantially all of our cash, cash equivalents and available-for-sale securities are maintained at major financial institutions of high credit standing. We monitor the financial creditworthiness of the issuers of our investments and limit the concentration in individual securities and types of investments that exist within our investment portfolio. Generally, all of our investments carry high credit quality ratings, in accordance with our investment policy. At December 31, 2022, we do not believe there is a significant financial risk from non-performance by the issuers of our cash, cash equivalents, and marketable securities. We have no off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

Fair Value of Financial Instruments

We established the fair value of our assets and liabilities using the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date and established a fair value hierarchy based on the inputs used to measure fair value. Cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued and liabilities are carried at cost, which approximates fair value due to their short maturities. Additionally, we have CVR and contingent consideration liabilities, which are recorded at fair value at the end of each reporting period with changes in estimated fair values recorded in the consolidated statements of operations and comprehensive loss. The fair values of the CVR and contingent consideration liabilities are based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy. Refer to Note 5 “Fair Value Measurements” for more information.

There were no assets or liabilities measured at fair value on a nonrecurring basis during the years ended December 31, 2022, 2021 and 2020.

Redeemable Convertible Preferred Stock Tranche Liability

We determined that our obligations to issue additional shares of redeemable convertible preferred stock upon the achievement of certain milestones or at the option of the respective holders of such shares represented freestanding financial instruments. These instruments were initially measured at fair value and were subject to remeasurement with changes in fair value recognized in the consolidated statements of operations and comprehensive loss until they were exercised or settled. Upon closing of the Merger, the outstanding redeemable convertible preferred stock tranche rights terminated and all redeemable convertible preferred stock issued converted to common stock.

Refer to Note 12 “Commitments and Contingencies” for more information.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the assets. Upon retirement or sale of assets, the cost and the related accumulated depreciation or amortization of the respective assets are removed from the consolidated balance sheet and any resulting gain or loss is reflected in the consolidated statements of operations and comprehensive loss. Additions and improvements that increase the value or extend the life of an asset are capitalized. Repairs and maintenance costs are expensed as incurred.

The useful live of property and equipment are as follows:

Description	Estimated Useful Life (in years)
Research and lab equipment	5
Computer equipment and software	3
Furniture and fixtures	5
Leasehold improvements	Shorter of useful life or lease term

Goodwill and Intangible Assets

Goodwill represents the excess of the consideration transferred over the estimated fair value of assets acquired and liabilities assumed in a business combination. Intangible assets with indefinite useful lives are related to acquired in-process research and development ("IPR&D") projects and are measured at their respective fair values as of the acquisition date.

Our intangible assets include an acquired out-license agreement and indefinite-life IPR&D acquired in the Merger with Aduro. The acquired out-license agreement represents the estimated fair value of an agreement with Merck & Co., Inc. ("Merck"). The IPR&D represents the estimated fair value as of the acquisition date of two substantive in-process projects that have not reached technological feasibility. The fair value of an acquired out-licensed agreement and IPR&D acquired in a business combination is recorded on our consolidated balance sheets at the acquisition date fair value and is determined by estimating future revenue and expenses, probability of technological and regulatory success, revenue volatility and discount rates, and discounting the projected net cash flows to present value.

Goodwill and intangible assets with indefinite useful lives are not amortized but are tested for impairment annually on October 1 or more frequently if we become aware of any events or changes that would indicate the fair values of the assets are below their carrying amounts. Intangible assets related to IPR&D projects are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. If and when development is complete, which generally occurs if and when regulatory approval to market a product is obtained, the associated assets are deemed finite-lived and are amortized based on their respective estimated useful lives at that point in time.

Impairment of Long-Lived Assets

We assess the impairment of long-lived assets, primarily property and equipment, whenever events or changes in business circumstances indicate that the carrying amounts of the assets may not be fully recoverable. When such events occur, we determine whether there has been an impairment in value by comparing the asset's carrying value with its fair value, as measured by the anticipated undiscounted net cash flows of the asset. If an impairment in value exists, the asset is written down to its estimated fair value, as measured by anticipated discounted cash flows of the asset or market data. We have not recognized any impairment losses through December 31, 2022.

Leases

Leases related to our facilities are classified as operating leases.

We determine if an arrangement is a lease at inception. We have made a policy election to not separate lease and non-lease components for our real estate leases to the extent they are fixed. Non-lease components that are not fixed are expensed as incurred as variable lease expense. Our facility leases typically include variable non-lease components, such as common-area maintenance costs. Operating leases are included in operating lease right-of-use ("ROU") assets and operating lease liabilities on our consolidated balance sheets. Operating lease ROU assets represent our right to use an underlying asset for the lease term and operating lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease ROU assets and operating lease liabilities are recognized based on the present value of lease payments over the lease term. As our leases do not provide an implicit rate, we use our incremental borrowing rate, obtained from our bank and the financial statements of a known public company and adjusted for an appropriate level of risk based on the remaining term of the lease and our current financial condition, in determining the present value of lease payments. The operating lease ROU asset also includes any prepaid lease payments made and excludes lease incentives. Our leases may include options to extend or terminate the lease; lease terms are only adjusted for these options when it is reasonably certain that we will exercise such options to extend or terminate the lease. Lease expense is recognized on a straight-line basis over the lease term.

Assumptions made by us at the commencement date are re-evaluated upon occurrence of certain events, including a lease modification. A lease modification results in a separate contract when the modification grants the lessee an additional right of use not included in the original lease and when lease payments increase commensurate with the standalone price for the additional right of use. When a lease modification results in a separate contract, it is accounted for in the same manner as a new lease.

We have subleased a substantial portion of our leased facilities under agreements considered to be operating leases according to ASC Topic 842, *Leases*. We have not been legally released from our primary obligations under the original lease and, therefore, we continue to account for the original lease as we did before commencement of the subleases. We record both fixed and variable payments received from the sublessees in our consolidated statements of operations and comprehensive loss on a straight-line basis as an offset to rent expense and is recorded as a component of general and administrative expenses in the consolidated statement of operations and comprehensive loss.

Investment in Equity Securities

Our investment in equity securities represents an ownership interest held by us in an unconsolidated entity, SanReno Therapeutics ("SanReno"). Refer to Note 9 "Investment in Equity Securities" for additional information. Accounting Standard Update ("ASU") 2016-01 requires equity securities to be recorded at cost and adjusted to fair value at each reporting period. However, the guidance allows for a measurement alternative, which is to record investments at cost, less impairment, if any, and subsequently adjust for observable price changes of identical or similar investments of the same issuer. The measurement alternative is used when an investment does not qualify for the equity method of the practical expedient in ASC Topic 820, *Fair Value Measurement* ("ASC Topic 820"), which estimates fair value using the net asset value per share.

Due to the lack of readily determinable fair values for such investment, we account for this investment under the measurement alternative at cost, less impairment. We perform a qualitative impairment assessment on our investment recorded under the measurement alternative quarterly. The investment is re-measured on a non-recurring basis as the investment is re-measured upon future observable price changes(s) in an orderly transaction(s), or upon impairment, if any. If the investment is determined to be other-than-temporarily impaired, an impairment charge is recorded against such investment and reflected in the consolidated statements of operations and comprehensive loss. We have not recognized any impairment losses through December 31, 2022.

Dividends from our investment in equity securities, if declared, are reflected in the consolidated statements of operations and comprehensive loss. There were no dividends declared through December 31, 2022.

Equity Method Investment

We report our investments in unconsolidated entities, over whose operating and financial policies we have the ability to exercise significant influence but not control, under the equity method of accounting. Judgment regarding the level of influence over our equity method investment includes considering key factors such as ownership interest, representation on the board of directors, and participation in policy-making decisions. Our equity method investment is reported at cost and adjusted each period for our share of the investee's income or loss, which is reported in our consolidated statements of operations and comprehensive loss on a one quarter lag.

We evaluate our equity method investments for impairment whenever events or changes in circumstances indicate that the carrying value of our investment may not be recoverable. If it is determined that a decline in the fair value of our investment is not temporary, and if such reduced fair value is below its carrying value, an impairment is recorded. Determining fair value involves significant judgment. Our estimates consider available evidence including, but not limited, to general economic conditions and other relevant factors. We have not recognized any impairment losses through December 31, 2022.

Revenue Recognition

At inception, we determine whether contracts are within the scope of ASC Topic 606, *Revenue from Contracts with Customers* ("ASC Topic 606"). For contracts that are determined to be within the scope of ASC Topic 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which we expect to be entitled to receive in exchange for these goods and services, which is determined by applying the following five steps:

(i) identifying the contract with the customer;
(ii) identifying the performance obligations in the contract;
(iii) determining the transaction price;
(iv) allocating the transaction price to the performance obligations in the contract; and
(v) recognizing revenue when or as we satisfy a performance obligation.

We only apply the five-step model to contracts when we determine that collection of substantially all consideration for goods and services that are transferred is probable based on the customer's intent and ability to pay the promised consideration.

Performance obligations promised in a contract are identified based on the goods and services that will be transferred to the customer that are both capable of being distinct and are distinct in the context of the contract. To the extent a contract includes multiple promised goods and services, we apply judgment to determine whether promised goods and services are both capable of being distinct and distinct in the context of the contract. If these criteria are not met, the promised goods and services are accounted for as a combined performance obligation.

Determining the transaction price requires significant judgment. The transaction price in the contract is measured at fair value and reflects the consideration we expect to be entitled to in exchange for the goods and services. In the transaction price, variable consideration is only included to the extent that it is highly probable that a significant future reversal in the amount of cumulative revenue recognized under the contract will not occur. The transaction price is allocated to each performance obligation according to

their stand-alone selling prices ("SSP") and is recognized when control of the goods or services are transferred to the customer, either over time or at a point in time, depending on the specific terms and conditions in the contracts. Judgment is required to determine the SSP. In instances where the SSP is not directly observable, such as when a license or service is not sold separately, the SSP is determined using information that may include market conditions and other observable inputs.

In November 2021, we entered into a License Agreement with SanReno ("China License Agreement"). In addition, we assumed several existing collaboration agreements in conjunction with the Merger. These agreements may include the transfer of intellectual property rights in the form of licenses and obligations to provide research and development services, participate on certain development committees with the collaboration party and to provide manufacturing supply. The terms of such agreements generally include payment in the form of cash or equity securities to us for one or more of the following: development and commercialization licenses; research and development services; manufacturing supply; development, regulatory and commercial milestone fees; and royalties on net sales of licensed products. Judgment is required to determine whether the license to our intellectual property is distinct from the research and development services or participation on development committees.

As of the closing of the Merger, we considered all remaining performance obligations under the assumed agreements to determine appropriate revenue recognition. For agreements that include development, regulatory or commercial milestone payments, we evaluated whether the milestones are considered probable of being reached and concluded that all such milestones are not within the control of us or the licensee, such as regulatory approvals, and are not considered probable of being achieved until those approvals are received or the underlying activity has been completed. Accordingly, any future milestone payments received under the assumed agreements will be analogized to ASC Topic 606 and recorded as revenue upon or over a period following receipt, if such milestone payments are received.

We also assumed an existing out-license agreement with Merck under which all performance obligations of Aduro were completed prior to the Merger. We are eligible to receive future contingent payments pursuant to Merck's achievement of certain development, commercial and net sales milestones for a product candidate. In addition, we are eligible to receive royalties based on net sales of the product. Any such milestones and royalties earned will be payable by us to the CVR holders, net of deductions permitted under the agreement with the CVR holders, including taxes and certain other expenses.

Research and Development Expenses

Research and development expenses represent costs incurred to conduct research, such as the discovery and development of our product candidates. Research and development costs include employee-related costs; licensing costs, materials and supplies, contracted research and manufacturing, consulting arrangements; allocated costs, such as facility costs; and other expenses incurred to advance our research and development activities. We recognize all research and development costs as they are incurred. In-licensing fees and other costs to acquire technologies that are utilized in research and development, and that are not expected to have alternative future use, are expensed when incurred. Clinical trial costs, contract manufacturing and other development costs incurred by third parties are expensed as the contracted work is performed. For service contracts that include a nonrefundable prepayment for future service, the upfront payment is deferred and recognized in the consolidated statements of operations and comprehensive loss as the services are rendered.

Income Taxes

Income taxes are accounted for using an asset and liability approach that requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the consolidated financial statement and tax bases of assets and liabilities at the applicable enacted tax rates. We establish a valuation allowance for deferred tax assets if it is more likely than not that these items will expire before we are able to realize its benefits or that future deductibility is uncertain.

We recognize the tax benefit from uncertain tax positions only if it is more likely than not that the tax position will be sustained on examination by the tax authorities, based on the technical merits of the position. The tax position is measured based on the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement. We recognize interest and penalties related to income tax matters in income tax expense if incurred.

Fair value of Common Stock

Prior to the Merger, management estimated the fair value of our common stock consistent with the methods outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Determining the best estimated fair value of our common stock required significant judgment and management

considered several factors, including our stage of development, equity market conditions affecting comparable public companies, significant milestones and progress of research and development efforts.

Stock-Based Compensation Expense

We measure and recognize compensation expense for all equity awards granted to employees and non-employees based on the estimated fair value of the award on the date of grant.

The fair value of stock options is determined by using the Black-Scholes option pricing model. We make several estimates in determining stock-based compensation and these estimates generally require significant analysis and judgment to develop, including (i) the expected share price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) the expected dividend yield. Prior to the Merger, due to the lack of company-specific historical and implied volatility data, we based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded, which have characteristics similar to those of Private Chinook, including stage of product development and focus on the life science industry. For options granted after the Merger, we are using historical volatility of Aduro's and our common stock, as it approximates the volatility of the formerly utilized peer group. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The expected term for options granted to employees represents the weighted-average period the awards are expected to remain outstanding and our estimates were determined using the simplified method. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. We use an assumed dividend yield of zero as we have never paid cash dividends and do not currently intend to pay cash dividends.

The fair value of restricted stock units ("RSU") and performance-based stock units ("PSU") is determined on the date of grant based on the market price of our common stock on that date.

Stock-based compensation expense for equity award with time-based vesting is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective award. Stock-based compensation expense for equity awards with performance-based vesting is recognized over the estimated service period once the achievement of the performance-based target is considered probable. At each reporting date, we assess the likelihood of achievement of the performance targets for any PSUs that are outstanding to determine the probability of vesting. Stock-based compensation expense is recognized based on the probability of vesting for the portion of the service period elapsed to date with any cumulative catch-up. We recognize the remaining stock-based compensation expense, if any, over the remaining estimated service period. Forfeitures for equity awards are recorded as incurred.

Foreign Currency

Our functional currency is the U.S. dollar and the functional currency of our foreign subsidiaries is either the Canadian dollar or the U.S. dollar. For subsidiaries with the functional currency of the Canadian dollar, assets and liabilities are translated to U.S. dollars using the exchange rates at the balance sheet date and expenses are translated using the monthly average exchange rates in effect during the period in which the transactions occur. Foreign currency translation adjustments are recorded as a component of accumulated other comprehensive income (loss) within stockholders' equity. Remeasurement adjustments are recorded in investment and other income (expense), net. The effect of foreign currency exchange rates on cash and cash equivalents was not material for any of the periods presented.

Monetary assets and liabilities in the non-functional currency of our subsidiaries are remeasured using exchange rates in effect at the end of the period. Costs in the non-functional currency are remeasured using average exchange rates for the period, except for costs related to those balance sheet items that are remeasured using historical exchange rates. The resulting transaction gains and losses are included in the consolidated statements of operations and comprehensive loss as incurred and have not been material for all periods presented.

Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. This ASU replaces the existing incurred loss impairment model with an expected loss model. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. These changes will result in earlier recognition of credit losses. We adopted the standard on January 1, 2022 and concluded that adoption of the standard did not have a material impact on our consolidated financial statements.

In May 2021, the FASB issued ASU No. 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815- 40)*, which provides guidance on modifications or exchanges of a freestanding equity-classified written call option (such as a warrant) that is not within the scope of another Topic. This new standard provides clarification and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after modification or exchange. We adopted the standard on January 1, 2022 and concluded that adoption of the standard did not have a material impact on our consolidated financial statements.

3. Reverse Merger and Contingent Value Rights

We completed our Merger with Aduro on October 5, 2020 and we acquired 100 percent equity interest in Private Chinook by issuing 16.3 million shares of common stock. Based upon the terms of the merger agreement dated June 1, 2020 and amended August 17, 2020, Private Chinook was determined to be the acquiring company for accounting purposes, and the transaction was accounted for as a reverse acquisition under the acquisition method of accounting for business combinations in accordance with U.S. GAAP. Accordingly, the assets and liabilities of Aduro were recorded at estimated fair value as of the merger closing date.

At the effective time of the Merger, we issued shares of our common stock to Private Chinook stockholders, at an exchange rate of 0.292188 shares of Aduro common stock for each share of Private Chinook common stock outstanding immediately prior to the Merger, including shares sold in the Pre-Closing Financing and all shares of Series A redeemable convertible preferred stock which converted into Private Chinook's shares of common stock on a one-for-one basis prior to closing of the Merger (the "Exchange Ratio"). We also assumed all the stock options outstanding under the Private Chinook 2019 Equity Incentive Plan. Unless otherwise noted herein, references to our common share and per-share amounts give retroactive effect to the Exchange Ratio.

In August 2020, Private Chinook entered into subscription agreements (the "Pre-Closing Financing") with certain existing and new investors, pursuant to which we agreed to sell, and the investors agreed to purchase, an aggregate of $115.0 million of our common stock. On October 5, 2020, immediately prior to the closing of the Merger, investors purchased 9.6 million shares of common stock, at a price of $12.00 per share, in the Pre-Closing Financing.

At the effective time of the Merger, we also entered into an agreement pursuant to which Aduro's common stockholders of record as of the close of business on October 2, 2020 received one CVR for each outstanding share of Aduro common stock held by such stockholder on such date (the "CVR Agreement"). Each CVR represents the contractual right to receive payments from us upon the receipt of consideration resulting from certain events described in the CVR Agreement, such as milestones and royalties from certain pre-existing agreements and the disposition or licensing of any of Aduro's non-renal assets, net of deductions permitted under the CVR Agreement, including taxes and certain other expenses.

During the year ended December 31, 2021, we identified and recorded measurement period adjustments primarily for taxes, which impacted deferred tax liabilities, the fair value of the CVR liability, and other liabilities related to the Merger. The measurement period adjustments were the result of additional analyses performed and information identified during 2021 based on facts and circumstances that existed as of the Merger date.

Consideration Transferred

The fair value of the consideration transferred was based on the most reliable measure, which was determined to be the market price of Aduro shares of common stock as of the acquisition date. The fair value of the consideration transferred consisted of the following (in thousands):

	Fair Value at Acquisition Date	Measurement Period Adjustment	Adjusted Fair Value at Acquisition Date
Value of shares of the combined company owned by Aduro equity holders (1)	$ 238,003	$ —	$ 238,003
Fair value of Aduro stock options and warrants - pre-combination services (2)	10,628	—	10,628
Estimated fair value of CVR (3)	12,270	(2,696)	9,574
Total fair value of consideration	$ 260,901	$ (2,696)	$ 258,205

(1) Comprised of 16.3 million shares of common stock outstanding at the date of the Merger based on the closing price of $14.595 per share on October 5, 2020.

(2) Upon closing of the Merger, any Aduro stock option, warrant, or unvested restricted stock unit held by an Aduro employee who remained employed by Aduro as of immediately prior to the Merger, that is outstanding and unexercised as of immediately prior to the Merger, for accounting purposes was converted into a stock-based compensation award, or a Replacement Award, of the Company and is subject to the same terms and conditions after the Merger as the terms and conditions applicable to the corresponding Aduro stock-based compensation award. The amount included in Merger consideration represents the pre-combination service portion of the estimated fair value of the Replacement Awards issued to Aduro employees.

(3) Immediately prior to closing of the Merger, Aduro granted its stockholders one CVR for each share of Aduro common stock. This CVR gives the holder a right to receive certain cash proceeds from potential future proceeds derived from Aduro's license agreement with Merck and other non-renal assets for up to ten years.

Purchase Price Allocation

As Private Chinook was the accounting acquirer in the Merger, the purchase price was allocated to the acquired tangible and intangible assets and assumed liabilities of Aduro based on the estimated fair values as of the acquisition date. The excess of the acquisition consideration paid over the estimated fair values of net assets acquired was recorded as goodwill in our consolidated balance sheets. Our determination of the estimated fair values of the assets acquired and liabilities assumed included the consideration of third-party valuation estimates relating to the value of the acquired intangible assets, leasehold improvements, property and equipment, a favorable lease and the CVRs.

The following summarizes the estimated fair value of the assets acquired and the liabilities assumed at the acquisition date (in thousands):

	Fair Value at Acquisition Date	Measurement Period Adjustments	Adjusted Fair Value at Acquisition Date
Assets:			
Cash and cash equivalents	$ 73,159	$ —	$ 73,159
Marketable securities	98,057	—	98,057
Accounts receivable	1,122	—	1,122
Prepaids and other current assets	1,757	—	1,757
Property and equipment, net	19,039	—	19,039
Operating lease right-of-use assets	53,704	—	53,704
Intangible assets	28,118	—	28,118
IPR&D	39,295	—	39,295
Goodwill	22,441	(22,324)	117
Restricted cash	1,750	—	1,750
Other assets	295	—	295
Total assets acquired	338,737	(22,324)	316,413
Liabilities:			
Accounts payable	2,280	—	2,280
Accrued clinical trial and manufacturing expenses	1,632	—	1,632
Accrued compensation	6,854	—	6,854
Accrued and other current liabilities	6,092	(690)	5,402
Deferred revenue, current	660	—	660
Operating lease liability, current	2,230	—	2,230
Existing contingent consideration	1,800	(450)	1,350
Deferred tax liabilities	18,372	(17,735)	637
Operating lease liabilities, non-current	36,474	—	36,474
Other non-current liabilities	1,442	(753)	689
Total liabilities assumed	77,836	(19,628)	58,208
Net Fair Value	$ 260,901	$ (2,696)	$ 258,205

We determined that the historical values of Aduro's current assets and current liabilities approximate fair value at the date of the acquisition based on the short-term nature of such items, except for as noted below.

Acquired property and equipment anticipated to be used was valued using a cost approach, where fair value was estimated as replacement cost less depreciation factors that represented the condition of the assets. Acquired property and equipment intended to be disposed of was valued at their estimated liquidation value.

The fair value of the acquired renal ("BION-1301") IPR&D intangible asset of $32.4 million was determined using a probability-weighted discounted cash flow model prepared under the multi-period excess earnings method. The fair value of the acquired Merck license agreement intangible assets of $26.7 million and the related CVR liability of $8.1 million were valued under the income method using a probability-weighted discounted cash flow model and a Monte Carlo simulation model. We applied significant judgment in estimating the fair value of the acquired intangible assets and related contingent value rights, which involved the use of significant estimates and assumptions. Significant estimates and assumptions used in the valuation of the acquired BION-1301 IPR&D intangible asset related to future revenues and expenses, probabilities of technological and regulatory success and discount rate. Significant estimates and assumptions used in the valuation of the acquired Merck license agreement intangible assets and related contingent value rights related to future revenues and revenue volatility, probabilities of technological and regulatory success and discount rates. The fair value of the non-renal IPR&D intangible assets were determined using a probability-weighted discounted cash flow model, including assumptions regarding probabilities, timing and prices for the sale or out-license of these assets.

Favorable terms of an acquired lease were recorded as part of the operating lease ROU asset and was valued using a with-and-without income approach method.

Deferred revenue was valued based upon the estimated remaining costs to fulfill the legal performance obligation, plus a reasonable profit margin, which was expected to be satisfied within a year from the date of the Merger.

The existing contingent consideration liability related to the former shareholders of BioNovion Holdings BV was valued using a probability-weighted discounted cash flow assessment that considers probability and timing of future payments.

Goodwill is the excess of the consideration transferred over the fair values of assets acquired and liabilities assumed, which primarily reflects the future economic benefit arising from other assets acquired that could not be individually identified and separately recognized.

Our transaction costs were $4.5 million, which were expensed as incurred.

4. Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities consisted of the following (in thousands):

	December 31, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Cash and cash equivalents:				
Cash	$ 15,724	$ —	$ —	$ 15,724
Money market funds	45,443	—	—	45,443
Commercial paper	41,972	—	(15)	41,957
U.S. government and agency securities	12,311	3	—	12,314
Total cash and cash equivalents	$ 115,450	$ 3	$ (15)	$ 115,438
Marketable securities:				
Commercial paper	$ 69,630	$ 2	$ (58)	$ 69,574
U.S. government and agency securities	148,160	6	(1,461)	146,705
Corporate debt securities	54,123	—	(526)	53,597
Total marketable securities	$ 271,913	$ 8	$ (2,045)	$ 269,876

	December 31, 2021			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Cash and cash equivalents:				
Cash	$ 44,499	$ —	$ —	$ 44,499
Money market funds	117,023	—	—	117,023
Commercial paper	16,898	—	(1)	16,897
Corporate debt securities	3,306	—	(1)	3,305
Total cash and cash equivalents	$ 181,726	$ —	$ (2)	$ 181,724
Marketable securities:				
Commercial paper	$ 34,978	$ —	$ (10)	$ 34,968
U.S. government and agency securities	85,309	1	(88)	85,222
Corporate debt securities	53,172	4	(38)	53,138
Total marketable securities	$ 173,459	$ 5	$ (136)	$ 173,328

The amortized cost and estimated fair value of our available-for-sale marketable securities by contractual maturity are summarized below as of December 31, 2022 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Mature in one year or less	$ 264,866	$ 7	$ (1,986)	$ 262,887
Mature after one year through two years	7,047	1	(59)	6,989
Total available-for-sale marketable securities	$ 271,913	$ 8	$ (2,045)	$ 269,876

For all securities with a fair value less than its amortized cost basis, we determined the decline in fair value below amortized cost basis to be noncredit related. For the years ended December 31, 2022, 2021, and 2020, there was no impairment recognized.

5. Fair Value Measurements

We determine the fair value of certain financial assets and liabilities using the fair value of hierarchy, which establishes three levels of inputs that may be used to measure fair value, as follows:

Level 1: Unadjusted quoted prices in active, accessible markets for identical assets or liabilities.

Level 2: Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly.

Level 3: Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable activity.

The determination of a financial instrument's level within the fair value hierarchy is based on an assessment of the lowest level of any input that is significant to the fair value measurement. We consider observable data to be market data which is readily available, regularly distributed or updated, reliable and verifiable, not proprietary, and provided by independent sources that are actively involved in the relevant market.

The following tables present information about our financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets				
Cash and cash equivalents:				
Cash and money market funds	$ 61,167	$ —	$ —	$ 61,167
Commercial paper	—	41,957	—	41,957
U.S. government and agency securities	—	12,314	—	12,314
Total cash and cash equivalents	61,167	54,271	—	115,438
Marketable securities:				
Commercial paper	—	69,574	—	69,574
U.S. government and agency securities	—	146,705	—	146,705
Corporate debt securities	—	53,597	—	53,597
Total marketable securities	—	269,876	—	269,876
Total fair value of assets	$ 61,167	$ 324,147	$ —	$ 385,314
Liabilities				
Contingent value rights liability	$ —	$ —	$ 39,818	$ 39,818
Contingent consideration liability	—	—	4,420	4,420
Total fair value of liabilities	$ —	$ —	$ 44,238	$ 44,238

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
Assets				
Cash and cash equivalents:				
Cash and money market funds	$ 161,522	$ —	$ —	$ 161,522
Commercial paper	—	16,897	—	16,897
Corporate debt securities		3,305		3,305
Total cash and cash equivalents	161,522	20,202	—	181,724
Marketable securities:				
Commercial paper	—	34,968	—	34,968
U.S. government and agency securities	—	85,222	—	85,222
Corporate debt securities	—	53,138	—	53,138
Total marketable securities	—	173,328	—	173,328
Total fair value of assets	$ 161,522	$ 193,530	$ —	$ 355,052
Liabilities				
Contingent value rights liability	$ —	$ —	$ 34,591	$ 34,591
Contingent consideration liability	—	—	5,160	5,160
Total fair value of liabilities	$ —	$ —	$ 39,751	$ 39,751

Money market funds are included within Level 1 of the fair value hierarchy because they are valued using quoted market prices. Other cash equivalents and marketable securities, such as commercial paper, U.S. government and agency securities, and corporate debt securities are classified within Level 2 of the fair value hierarchy as the valuation is obtained from third-party pricing services, which utilize industry standard valuation models, including both income-based and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate the fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, estimated interest rates based on the issuer credit rating and term, and other observable inputs.

The following table presents a summary of the changes in the fair value of our Level 3 financial instruments (in thousands):

	Contingent Value Rights Liability	Contingent Consideration Liability
Fair Value as of December 31, 2019	$ —	$ —
Assumed in the Merger	12,270	1,800
Change in fair value upon remeasurement	1,510	—
Fair Value as of December 31, 2020	13,780	1,800
Change in fair value upon remeasurement	23,507	3,810
Measurement period adjustment	(2,696)	(450)
Fair Value as of December 31, 2021	$ 34,591	$ 5,160
Change in fair value upon remeasurement	12,727	(740)
Payment of contingent value rights liability	(7,500)	—
Fair Value as of December 31, 2022	$ 39,818	$ 4,420

The fair values of the CVR and contingent consideration liabilities are based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy. In determining the fair value of the CVR and the contingent consideration liabilities, we used the income approach, primarily discounted cash flow models. The discounted cash flow models require the use of significant judgment, estimates and assumptions, including estimated revenues and costs, the probability of technical and regulatory success, and discount rates.

The fair value of the CVR liability increased during the year ended December 31, 2022 by $5.2 million primarily due to remeasuring the value of our preferred shares in Sairopa at estimated fair value mainly as a result of Sairopa executing a license agreement for its SIRPa inhibitor ADU-1805 with Exelixis, Inc. in November 2022 and due to a change in estimate of the potential future proceeds derived from Aduro's license agreement with Merck for MK-5890. The increase was partially offset by a payment of $7.5 million to the CVR holders in 2022. The payment to the CVR holders resulted from a development milestone recognized in 2021 under the license agreement with Merck for MK-5890. The contingent consideration liability decreased during the year ended December 31, 2022 by $0.7 million primarily due to higher discount rates in 2022 driven by changes in market interest rates, which lowered the present value of future cash flows. We will hold the 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 under the CVR Agreement, including taxes and certain other expenses. Refer to Note 10 "Equity Method Investment" for more information.

6. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	December 31,	
	2022	2021
Research and lab equipment	$ 3,212	$ 3,366
Computer equipment and software	1,670	1,497
Furniture and fixtures	1,351	1,224
Leasehold improvements	16,957	16,976
Construction in progress	895	—
Total property and equipment	24,085	23,063
Total accumulated depreciation	(7,177)	(4,128)
Property and equipment, net	$ 16,908	$ 18,935

Depreciation and amortization expense for property and equipment for the years ended December 31, 2022, 2021, and 2020 was $3.4 million, $3.1 million, and $1.1 million, respectively. Approximately $2.5 million of our property and equipment as of December 31, 2022 is located in Canada.

7. Goodwill and Intangible Assets

Goodwill

The gross carrying amount and net book value of goodwill was $0.1 million at December 31, 2022, all of which resulted from the Merger. We test goodwill for impairment on an annual basis or more frequently if an impairment indicator exists. As part of the evaluation, we may elect to perform an assessment of qualitative factors. If this qualitative assessment indicates that it is more likely than not that the fair value of the reporting unit is less than its carrying value, then we would proceed with a quantitative impairment test to compare the fair value to the carrying value. If the carrying value of the reporting unit exceeds the fair value of the reporting unit, we record an impairment loss equal to that difference.

Intangible assets

The gross carrying amounts and net book value of intangible assets were as follows (in thousands):

	December 31, 2022		
	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Intangible assets with finite lives:			
Acquired license agreement	$ 26,685	$ 3,538	$ 23,147
In-place lease	1,433	293	1,140
Total intangible assets with finite lives	28,118	3,831	24,287
Acquired IPR&D assets	36,550	—	36,550
Total intangible and acquired IPR&D assets	$ 64,668	$ 3,831	$ 60,837

	December 31, 2021		
	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Intangible assets with finite lives:			
Acquired license agreement	$ 26,685	$ 1,968	$ 24,717
In-place lease	1,433	141	1,292
Total intangible assets with finite lives	28,118	2,109	26,009
Acquired IPR&D assets	36,550	—	36,550
Total intangible and acquired IPR&D assets	$ 64,668	$ 2,109	$ 62,559

Intangible assets are carried at cost less accumulated amortization and impairment. Amortization is over periods of 9 to 17 years, with an original weighted average period of 16.7 years, and the amortization expense is recorded in operating expenses. We test our Acquired IPR&D assets for impairment on an annual basis, or more frequently if an impairment indicator exists.

Amortization expense was $1.7 million for both the years ended December 31, 2022, and 2021, and was $0.4 million for the year ended December 31, 2020. Based on finite-lived intangible assets recorded as of December 31, 2022, the estimated future amortization expense for the next five years is as follows (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2023	$ 1,733
2024	1,733
2025	1,733
2026	1,733
2027	1,733
Thereafter	15,622

8. Accrued and Other Current Liabilities

Accrued and other current liabilities consisted of the following (in thousands):

	December 31,	
	2022	2021
Research and development costs	$ 21,970	$ 8,397
Compensation and benefits	11,085	6,455
Sublease rent and security deposit	157	1,067
Business taxes and licensing fees	—	421
Consulting and outside services	403	424
Other	21	340
Total accrued and other current liabilities	$ 33,636	$ 17,104

9. Investment in Equity Securities

In November 2021, we entered into agreements related to the formation of SanReno, a corporation established to develop, manufacture and commercialize kidney disease therapies in mainland China, Hong Kong, Macau, Taiwan and Singapore (collectively, the "Territory"). In connection with the formation of SanReno and pursuant to a license agreement entered into between Chinook and SanReno in November 2021 (the "China License Agreement"), Chinook granted SanReno exclusive licenses under certain intellectual property to develop and commercialize atrasentan and BION-1301 in the Territory for use in all human indications. In return, Chinook received 40.0 million Series A preferred shares in SanReno representing 50% ownership of the outstanding voting securities and a warrant to purchase a total of 5.0 million common shares of SanReno at an exercise price of $0.01 per share upon the attainment of regulatory exclusivity for atrasentan in the Territory. Such warrant will only be exercisable if and provided that SanReno obtains, before the 10-year anniversary of the closing of the formation of SanReno, the regulatory exclusivity for atrasentan in China for at least three years commencing from the New Drug Application approval by the National Medical Product Administration of China. The warrant will have a five-year exercise period after it becomes exercisable upon satisfaction of the exercise conditions and was valued at $1.2 million on the grant date based on the probability of exercise of the warrant and the market for such instruments. An investor syndicate led by Frazier Healthcare Partners and Pivotal bioVenture Partners China, along with existing Chinook investors Versant Ventures and Samsara BioCapital, invested $40.0 million in exchange for the remaining 50% of the outstanding voting securities of SanReno. Refer to Note 11 "Collaboration and License Agreements" for more information regarding the China License Agreement.

In connection with the formation of SanReno in November 2021, Chinook also entered into a Shareholders Agreement (the "Shareholders Agreement") providing for certain rights and obligations of SanReno and its shareholders. Pursuant to the Shareholders Agreement, Chinook has the right to designate an individual for election to the board of directors of SanReno and SanReno has agreed that certain specified events (including certain liquidation events) shall require the approval of shareholders of SanReno holding a supermajority of SanReno's Series A preferred shares. The Shareholders Agreement terminates by mutual consent of the parties, and automatically terminates upon the dissolution of SanReno or immediately prior to the consummation of a qualified initial public offering.

We account for the investment in SanReno in accordance with the provisions of ASC Topic 321, *Investments – Equity Securities*, and elect to use the measurement alternative therein. As such, the investment is valued at $41.2 million as of December 31, 2022, which was the total of the aggregate cost value of the 40.0 million preferred shares in SanReno received by us on the date of the closing of the formation of SanReno and the grant date value of the warrant. The investment will be re-measured upon future observable price changes(s) in orderly transaction(s) or upon impairment, if any. Refer to Note 2 "Summary of Significant Accounting Policies" for more information regarding our Investment in Equity Securities accounting policies. We have not recognized any impairment losses through December 31, 2022.

Pursuant to the terms of the Series A preferred stock, we are entitled to non-cumulative dividends at 8% of our initial investment, payable when and if declared by the board of directors of SanReno. Dividends from our investment in equity securities, if declared, are reflected in the consolidated statements of operations and comprehensive loss. There were no dividends declared through December 31, 2022.

10. Equity Method Investment

In April 2021, we entered into a definitive agreement with Sairopa B.V., a private company created by Van Herk Royalty B.V. and D.S. Chahal (the "Sairopa Investors") to acquire certain non-renal assets of Chinook in exchange for preferred stock in Sairopa. We will hold such shares until such time as there is a liquidation event, as defined in the shareholders agreement, in Sairopa. In accordance with the CVR Agreement, 50% of any net proceeds received from this transaction by way of a liquidation event of Sairopa by October 4, 2030, net of deductions permitted under the CVR Agreement, including taxes and certain other expenses, will accrue to the benefit of the CVR holders.

As of December 31, 2022, we own a 36% interest in Sairopa. We determined that we have the ability to exercise significant influence over Sairopa but do not have a controlling interest. Therefore, the investment in Sairopa was accounted for using the equity method. Judgment regarding the level of influence over each equity method investment includes considering key factors such as ownership interest, representation on the board of directors, and participation in policy-making decisions. The Sairopa Investors provided an initial capitalization of 12.5 million Euros. We recorded the equity method investment at $10.0 million, which is the fair value of the equity received by us in exchange for the non-renal assets. The sale of the non-renal assets to Sairopa resulted in a $7.2 million gain, which is the difference between the fair value of the equity received and the carrying value of the non-renal assets sold. The gain is reported in our consolidated statement of operations and comprehensive loss in the year ended December 31, 2021.

Our equity method investment was recorded at cost at inception and is adjusted each period for our share of the investee's income or loss, which is reported in our consolidated statements of operations and comprehensive loss on a one quarter lag. In November 2022, Sairopa executed a license agreement with Exelixis, Inc ("Exelixis"). Under the terms of the agreement, Exelixis made an upfront payment of $40.0 million to obtain an exclusive, worldwide license to develop and commercialize ADU-1805 and other anti-SIRPα antibodies, and for certain expenses to be incurred by Sairopa in conducting phase 1 clinical studies of ADU-1805. Additionally, in February 2023, Sairopa earned a $35.0 million milestone under the terms of the agreement. Sairopa is eligible to receive additional near-term development milestone payments totaling up to $62.5 million. Following the completion of certain clinical studies, Exelixis may exercise an option to continue the license agreement for $225.0 million based upon its evaluation of a pre-specified clinical data package to be delivered by Sairopa. Following the exercise of the option, Sairopa would be eligible to receive up to $465.0 million in additional development, commercial, and net sales milestone payments, as well as tiered royalties on future net sales of products.

Our equity method investment is also adjusted each period for gains or losses from changes in our ownership interest in Sairopa, if any. We recorded a gain of $1.1 million in our equity method investment in 2022 resulting from changes in our ownership interest in Sairopa due to additional shares issued by Sairopa to other investors.

We assess our equity method investment for impairment whenever events or changes in circumstances indicate that the carrying value of the investment may not be recoverable. We have not recognized any impairment losses through December 31, 2022. Refer to Note 2 "Summary of Significant Accounting Policies" for information regarding our Equity Method Investment accounting policies.

11. Collaboration and License Agreements

SanReno Therapeutics

In November 2021, we entered into the China License Agreement, pursuant to which we granted SanReno exclusive licenses under certain intellectual property to develop, manufacture and commercialize for atrasentan and BION-1301 in the Territory. Refer to Note 9 “Investment in Equity Securities” for further details on the agreements executed with SanReno. We evaluated the China License Agreement under ASC Topic 606 and determined that the China License Agreement represents a contract with a customer. We identified the following performance obligations: (i) the licenses to develop, manufacture and commercialize atrasentan and BION-1301; (ii) our obligation to transfer know-how for the licensed product candidates (“Technology Transfers”); (iii) manufacturing and supply services; and (iv) opt-in global studies.

We determined that the preferred shares we received in SanReno of $40.0 million plus the warrant granted to us of $1.2 million constituted the entire consideration to be included in the total transaction price at the outset of the arrangement. Further, in determination of the performance obligations under the license agreements, the stand-alone selling prices of the performance obligations and our responsibility in the development activities have also been considered. Accordingly, the licenses, Technology Transfers, manufacturing and supply services, and opt-in global studies are all considered distinct performance obligations.

Since both licensed product candidates are in the later stages of development, we determined that both licenses have significant stand-alone functionalities as of contract inception. SanReno can begin deriving benefit from the licenses prior to the Technology Transfers being completed. The Technology Transfers will be completed upon request of SanReno and are separate from the transfer of the licenses, which occurred at contract inception. We also considered that we are not contractually obligated to perform research and development activities that significantly affect SanReno’s ability to benefit from the licensed product candidates, and SanReno has full use of the licenses.

The estimated standalone selling price for the Technology Transfers was determined by estimating the costs of satisfying the performance obligation, plus an appropriate margin for such services. Pursuant to the China License Agreement, SanReno will reimburse the manufacturing and supply services at cost plus a mark-up and will reimburse the opt-in global studies at cost, which represent pass-through fees from third-party vendors, including clinical research organization. Revenue attributable to the manufacturing and supply services and opt-in global studies will be recognized as incurred. For the year ended December 31, 2022, we recognized revenue of $4.2 million under the China License Agreement for costs reimbursed related to opt-in global studies and manufacturing and supply services. For the year ended December 31, 2021, we recognized revenue of $41.2 million under the China License Agreement attributable to the licenses and Technology Transfers as the licenses were delivered upon contract inception and the amount of the total transaction price allocated to the Technology Transfers was not material.

We are also eligible to receive a progress-dependent milestone payment of up to approximately $25.0 million with respect to BION-1301. Under the China License Agreement, SanReno is also obligated to pay Chinook royalty payments at a percentage in the low teens based on net sales of atrasentan in the Territory on the portion of annual net sales in excess of a pre-determined amount, which royalty will be payable until the expiration of all licensed patents covering the sale of atrasentan in the Territory. The China License Agreement expires on a licensed product-by-licensed product basis on the latest of: (i) the expiration of the royalty term for atrasentan, (ii) the expiration of the last valid claim of a licensed patent for BION-1301 in the Territory. The parties may terminate the China License Agreement pursuant to terms specified in the agreement. Chinook and SanReno also have reciprocal rights of first negotiation in their respective territories for certain future kidney disease products developed or in-licensed by either company. Chinook retains full rights to atrasentan and BION-1301 outside of the Territory.

The potential progress-dependent cash milestone payment that we are eligible to receive was excluded from the total transaction price, as the milestone amount is fully constrained based on the probability of achievement. Accordingly, any future milestone payment received under the agreement will be recorded upon or over a period following receipt. Further, we will apply the exception under ASC Topic 606 for variable consideration related to sales-or-usage based royalties received in exchange for licensed intellectual property associated with atrasentan, therefore the royalties are not included in the transaction price until the licensee sells product. No progress-dependent milestone payments and royalties were received during the years ended December 31, 2022 and 2021.

AbbVie Ireland Unlimited Company

In December 2019, we entered into a license agreement (the "License Agreement") with AbbVie Ireland Unlimited Company ("AbbVie"), which granted us an exclusive license to develop and commercialize atrasentan, an endothelin receptor antagonist. Under the agreement, we assumed all global development and commercialization responsibilities for atrasentan. In consideration of the license and rights granted under the License Agreement, we made an upfront cash payment and issued 2.0 million shares of common stock for total consideration of $6.7 million to AbbVie. We concluded that this transaction should be accounted for as an asset purchase, and as such, recorded the associated expense within research and development expense in the consolidated statements of operations and comprehensive loss, as the product has not reached technological feasibility and does not have alternative future use. Under the License Agreement, we are obligated to make contingent development, regulatory and commercial milestone payments, of up to a maximum of $135.0 million in the aggregate, as well as pay royalties on the worldwide net sales of licensed products ranging from upper-single-digit to high-teen percentages.

We did not recognize any milestone payments for the year ended December 31, 2022, 2021 and 2020. As of December 31, 2022 and 2021, we did not have any payable or receivable balances associated with the License Agreement.

Merck

In connection with the Merger, we became party to an agreement with Merck. The agreement sets forth the parties' respective obligations for development, commercialization, regulatory and manufacturing and supply activities for antibody product candidates. All performance obligations of Aduro were completed prior to the Merger. We are eligible to receive future contingent payments, including up to $287.0 million in potential development milestone payments, and up to $135.0 million in commercial and net sales milestones for a product candidate. In addition, we are eligible to receive royalties at percentages in the mid-single digits to low teens based on net sales of the product. Future milestone payments and royalties will be recognized as revenue when earned as we have no performance obligations under this agreement. Any such milestones and royalties earned prior to October 4, 2030 will be payable by us to the CVR holders, net of deductions permitted under the CVR Agreement, including taxes and certain other expenses. A $10.0 million development milestone was earned in 2021 and received in 2022. We paid this milestone, net of taxes and expenses, to the CVR holders in 2022.

Eli Lilly and Company

In connection with the Merger, we assumed an ongoing research collaboration and exclusive license agreement with Eli Lilly and Company ("Lilly") for the research and development of novel immunotherapies for autoimmune and other inflammatory diseases. Our only remaining performance obligation under the agreement was to perform research services through 2021, for which we were reimbursed up to a specified amount. We are eligible to receive future contingent milestone payments of up to approximately $463.0 million per licensed product and tiered royalties on net sales at percentages in the single digits. We determined that the potential milestone payments are not considered probable of being achieved and, accordingly, such milestones will be recognized as revenue when earned. In 2022, we recognized revenue of $1.9 million upon notification of the achievement of a development milestone under the terms of the collaboration agreement with Lilly.

For the years ended December 31, 2022, 2021 and 2020, we recognized revenue of $1.9 million, $0.4 million and $0.8 million, respectively, under the Lilly agreement.

12. Commitments and Contingencies

Redeemable Convertible Preferred Stock Tranche Liability

In February 2019, as amended in July 2019, we entered into a Series A financing transaction, pursuant to which we were authorized to issue up to 19.0 million shares of Series A redeemable convertible preferred stock having a per share par value of $0.0001, at a purchase price of $3.4225 per share.

The terms of the Series A redeemable convertible preferred stock agreement include provisions requiring the investors to purchase, and obligating us to deliver, additional shares of redeemable convertible preferred stock at a specified price in the future based on the achievement of certain development-based milestones by us. The investors are also able to waive the milestone requirements, which provides the investors with an option to purchase additional Series A redeemable convertible preferred stock if the milestone is not met. The rights to purchase additional shares were recorded as a tranche liability at the estimated fair value of the obligation on the date of issuance with the carrying values adjusted at each reporting date for any changes in the estimated fair values. For the year ended December 31, 2020, we recorded $27.7 million, for the change in the fair value of the redeemable convertible preferred stock tranche liability.

Upon closing of the Merger, the outstanding redeemable convertible preferred stock tranche rights terminated and all redeemable convertible preferred stock that had been issued converted to common stock. The estimated fair value of the tranche rights at the time of termination was $50.7 million, which was recorded as an increase to additional paid-in capital as a deemed capital contribution from the Series A redeemable convertible preferred stockholders.

Leases

We have a total of four operating leases as of December 31, 2022 with remaining lease terms of approximately 4 to 7 years.

In June 2021, we entered into a sublease agreement for office space in Seattle, Washington ("Seattle Sublease"), which we expect to use as our corporate headquarters. The Seattle Sublease commenced on July 1, 2021 and continues for a period of 58 months. The aggregate estimated base rent payments due over the remaining term of the Seattle Sublease is approximately $4.2 million.

As of December 31, 2022, we are subleasing approximately 112,000 square feet in one of our facilities. Sublease income was $8.1 million, $6.2 million and $1.4 million for the years ended December 31, 2022, 2021 and 2020, respectively, which was netted against rent expense and is recorded as a component of general and administrative expenses in the consolidated statement of operations and comprehensive loss. Total sublease income to be earned, in aggregate, will be approximately $57.0 million over the remaining term of the sublease agreement.

The maturity of our operating lease liabilities at December 31, 2022 is as follows (in thousands):

Undiscounted Lease Payments	Amounts
2023	$ 7,662
2024	7,817
2025	7,976
2026	7,124
2027	6,475
Thereafter	12,422
Total undiscounted lease payments	49,476
Present value adjustment	(10,034)
Total net lease liability	39,442
Net lease liability - current	4,948
Net lease liability - non-current	34,494
Total net lease liability	$ 39,442

Rent expense recognized for operating leases was $9.4 million, $8.8 million and $2.9 million for the years ended December 31, 2022, 2021 and 2020, respectively. Variable lease payments, including non-lease components such as common area maintenance fees, recognized as rent expense for operating leases were $3.2 million, $2.4 million and $0.8 million for the years ended December 31, 2022, 2021 and 2020, respectively.

The following summarizes additional information related to our operating leases:

	December 31, 2022	December 31, 2021
Weighted-average remaining lease terms (in years)		
Operating leases	6.5	7.4
Weighted-average discount rate		
Operating leases	7.4%	7.5%

Indemnification Agreements

In the ordinary course of business, we enter into agreements that may include indemnification provisions. Pursuant to such agreements, we may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments we could be required to make under these provisions is not determinable. We have never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. We have also entered into indemnification agreements with our directors and officers that require us, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware corporate law. We currently maintain directors' and officers' liability insurance.

Legal Proceedings

From time to time, we may become involved in litigation relating to claims arising from the ordinary course of business. Management believes that there are no actions pending against us currently, the ultimate disposition of which would have a material adverse effect on our results of operations, financial condition or cash flows.

Other Commitments

We have various manufacturing, clinical, research and other contracts with vendors in the conduct of the normal course of our business. All contracts are terminable, with varying provisions regarding termination. If a contract with a specific vendor were to be terminated, we would only be obligated for the products or services that we had received at the time the termination became effective as well as non-cancelable and non-refundable obligations, including payment obligations for costs or expenses incurred by the vendor for products or services before the termination became effective. In the case of terminating a clinical trial agreement at a particular site, we would also be obligated to provide continued support for appropriate medical procedures at that site until completion or termination.

13. Common Stock

Issuance of Securities through an Underwritten Public Offering

In May 2022, we completed an underwritten public offering of 7.6 million shares of our common stock at a price to the public of $14.00 per share, which included the exercise in full of the underwriters' option to purchase an additional 1.1 million shares of our common stock in June 2022. In addition, in November 2021, we completed an underwritten public offering of 9.5 million shares of our common stock at a price to the public of $14.00 per share, which included the exercise in full of the underwriters' option to purchase an additional 1.7 million shares of our common stock. In both the May 2022 and November 2021 underwritten public offerings, we sold to certain investors pre-funded warrants (the "Pre-Funded Warrants") to purchase up to an aggregate of 1.1 million and 3.6 million shares, respectively, of common stock at a purchase price of $13.9999 per pre-funded warrant, which represents the per share public offering price for the common stock less the $0.0001 per share exercise price for each such warrant. The Pre-Funded Warrants are exercisable at any time after the date of issuance and do not expire. A holder of Pre-Funded Warrants may not exercise the warrant if the holder, together with its affiliates, would beneficially own more than 4.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise. A holder of Pre-Funded Warrants may increase or decrease this percentage, but not in excess of 19.99%, by providing at least 61 days' prior notice to Chinook. The May 2022 and November 2021 underwritten public offerings resulted in gross proceeds to us of $120.7 million and $183.5 million, respectively, before $7.7 million and $11.3 million, respectively, of underwriting discounts and commissions and estimated offering expenses.

We evaluated the Pre-Funded Warrants for liability or equity classification in accordance with the provisions of ASC Topic 480, *Distinguishing Liabilities from Equity*, and determined that equity treatment was appropriate because the Pre-Funded Warrants did not meet the definition of liability instruments. The Pre-Funded Warrants are classified as a component of permanent equity because they are freestanding financial instruments that are legally detachable and separately exercisable from the share of common stock with which they were issued, are immediately exercisable, do not include repurchase rights, cash settlement, or other put provisions, and permit the holders to receive a fixed number of shares of common stock upon exercise. In addition, the Pre-funded Warrants do not provide any guarantee of value or return. We valued the May 2022 Pre-Funded Warrants to purchase 1.1 million shares of common stock at an aggregate value of $15.0 million and we valued the November 2021 Pre-Funded Warrants to purchase 3.6 million shares of common stock at an aggregate value of $50.0 million. The value of $13.9999 per pre-funded warrant was measured on the grant date based on the common stock price in the underwritten public offering of $14.00 per share, less the $0.0001 per share exercise price of the warrant. As of December 31, 2022, none of the Pre-Funded Warrants have been exercised.

At-the-Market Sales Agreement

In April 2021, we entered into an "at-the-market" sales agreement (the "2021 Sales Agreement"), with Cantor Fitzgerald & Co. and SVB Securities LLC, previously known as SVB Leerink LLC, through which we may offer and sell shares of our common stock having an aggregate offering of up to $75.0 million through our sales agents, Cantor Fitzgerald & Co. and SVB Securities LLC. In November 2022, we amended the 2021 Sales Agreement to provide for offerings of up to $150.0 million. We will pay the sales agents a commission of up to 3% of the gross proceeds of sales made through the 2021 Sales Agreement. During the years ended December 31, 2022 and 2021, we sold 1.5 million shares for $32.9 million and 2.2 million shares for $33.9 million, respectively, in net proceeds under the 2021 Sales Agreement. As of December 31, 2022, we have $135.6 million remaining under the 2021 Sales Agreement, which is subject to the continued effectiveness of our automatic shelf registration statement on Form S-3 ASR (Registration No. 333-265168), or upon an effective replacement shelf registration statement.

Warrants

We assumed certain common stock warrants in the Merger. At December 31, 2022, warrants outstanding were not material.

Restricted Stock Awards ("RSAs")

We sold 0.6 million shares of restricted common stock to founding employees, directors and investors for $0.00034 per share. In the event continuous service terminates, the restricted shares sold to employees and directors include a provision whereby we have the option to repurchase unvested shares at the lower of the amount paid at grant or the fair market value as of repurchase date.

The following table summarizes RSA activity:

	RSAs Outstanding	
	Number of RSAs (in thousands)	Weighted Average Grant Date Fair Value Per Share
Balance, December 31, 2021	99	$ 0.00034
Vested	(89)	0.00034
Canceled or forfeited	(6)	0.00034
Balance, December 31, 2022	4	$ 0.00034

The fair value of restricted stock vested during the years ended December 31, 2022, 2021 and 2020 was $1.5 million, $1.4 million and less than $0.1 million, respectively.

14. Stock-Based Compensation

Equity Incentive Plans

In February 2019, Private Chinook adopted the 2019 Equity Incentive Plan (the "2019 Plan").

In connection with the Merger, we assumed Aduro's two equity incentive plans, the 2015 Equity Incentive Plan (the "2015 Plan") and the 2009 Stock Incentive Plan (the "2009 Plan" and collectively the "Aduro Plans"). No additional grants may be made from the 2009 Plan; however, shares subject to awards granted under the 2009 Plan remain subject to the terms of the 2009 Plan. The number of shares subject to and the exercise prices applicable to these outstanding options were adjusted to reflect the one-for-five reverse stock split completed in connection with the Merger.

The 2019 Plan, the 2015 Plan, and the 2009 Plan (collectively, "The Plans") are administered by our Board of Directors, or a committee of our Board of Directors, which determines the types of awards to be granted, including the number of shares subject to the awards, the exercise price and the vesting schedule. The exercise price of incentive stock options and nonqualified stock options will be no less than 100 percent of the fair value per share of our common stock on the date of grant. Options generally vest with respect to 25 percent of the shares one year after the options' vesting commencement date and the remainder ratably on a monthly basis over the following three years. Options granted under the Plans have a maximum term of 10 years. Restricted stock units ("RSU") generally vest with respect to one-third of the shares one year after the RSUs' vesting commencement date and the remainder ratably on an annual basis over the following two years. Performance stock units ("PSU") vest based on the achievement of specified performance targets.

As of December 31, 2022, there were 0.6 million shares available for future grant under the Plans. On January 1 of each year through 2025, the number of shares authorized for issuance under the 2015 Plan automatically increases by an amount equal to the lower of (i) 4 percent of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or (ii) a lower number determined by the Board of Directors.

In 2022, our Board of Directors approved the 2022 Employment Inducement Incentive Award Plan (the "2022 Inducement Plan"). We reserved 1.5 million shares of our common stock for issuance pursuant to awards to be granted under the 2022 Inducement Plan. The terms of the 2022 Inducement Plan are substantially similar to the terms of the Plans with the exception that awards may only be made to an employee who has not previously been an employee or member of our Board of Directors if the award is in connection with commencement of employment. As of December 31, 2022, 1.5 million shares are available for future issuance under the 2022 Inducement Plan.

In connection with the Merger, we assumed Aduro's 2015 employee stock purchase plan ("2015 ESPP"). Under the 2015 ESPP, our employees may purchase common stock through payroll deductions at a price equal to 85% of the lower of the fair market value of the stock at the beginning of the offering period or at the end of each applicable purchase period. The 2015 ESPP generally provides for offering periods of six months in duration with purchase periods ending on either May 15 or November 15. ESPP purchases are settled with common stock from the 2015 ESPP previously authorized and available pool of shares. As of December 31, 2022, there were 1.1 million shares available for future issuance under the ESPP. As of December 31, 2022, there is $0.3 million of total unrecognized compensation expense related to ESPP that is expected to be recognized over a weighted-average period of 0.4 years. On January 1 of each year through 2025, the number of shares authorized for issuance under the ESPP, automatically increases by an amount equal to the lower of (i) 1 percent of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or (ii) a lower number determined by the Board of Directors.

Stock option activity under the Plans is set forth below:

	Outstanding Awards			
	Number of Shares Underlying Outstanding Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance—December 31, 2021	5,842	$ 12.73	7.00	$ 34,928
Granted	2,405	14.70		
Exercised	(1,274)	9.38		
Canceled or forfeited	(846)	25.08		
Balance—December 31, 2022	6,127	$ 12.49	8.21	$ 85,766
Options exercisable December 31, 2022	2,226	$ 10.57	7.39	$ 36,573
Options vested and expected to vest, December 31, 2022	6,127	$ 12.49	8.21	$ 85,766

The aggregate intrinsic values of stock options outstanding, exercisable, and vested and expected to vest were calculated as the difference between the exercise price of the options and the market price for shares of our common stock as of December 31, 2022. During the years ended December 31 2022, 2021 and 2020, 1.3 million, 0.5 million and less than 0.1 million stock options, respectively, were exercised, with an intrinsic value of $12.7 million, $5.4 million and $0.8 million, respectively. As of December 31, 2022, there is $32.4 million of total unrecognized compensation expense related to stock options that is expected to be recognized over a weighted-average period of 2.5 years.

RSU activity under the Plans is set forth below:

	RSUs Outstanding	
	Number of RSUs (in thousands)	Weighted-Average Grant Date Fair Value Per Share
Balance, December 31, 2021	823	$ 14.76
Granted	976	15.55
Vested	(300)	14.72
Canceled or forfeited	(135)	14.79
Balance, December 31, 2022	1,364	$ 15.33

The total fair value of RSUs that vested under the Plans, in the years ended December 31, 2022, 2021 and 2020 was $5.2 million, $1.9 million and $0.1 million, respectively. As of December 31, 2022, there is $15.9 million of total unrecognized compensation expense related to RSUs that is expected to be recognized over a weighted-average period of 1.9 years.

PSU activity under the Plans is set forth below:

	PSUs Outstanding	
	Number of PSUs (in thousands)	Weighted-Average Grant Date Fair Value Per Share
Balance, December 31, 2021	—	$ —
Granted	816	21.99
Vested	—	—
Canceled or forfeited	(4)	21.75
Balance, December 31, 2022	812	$ 22.00

In 2022, we granted PSUs to our employees under the Plans. The vesting of these awards is subject to the achievement of specified regulatory performance targets. As of December 31, 2022, there is $18.0 million of total unrecognized compensation expense related to these PSUs with performance targets that are considered not probable of achievement.

Valuation Assumptions

The weighted-average assumptions used to estimate the fair value of stock options using the Black-Scholes option-pricing model and the resulting weighted-average grant date fair value were as follows:

	Years Ended December 31,		
	2022	2021	2020
Assumptions:			
Expected term (in years)	6.3	6.1	6.1
Volatility	77.4%	78.8%	77.6% – 90.0%
Risk-free interest rate	2.2%	0.9%	0.1% – 0.9%
Dividend yield	0%	0%	0%
Fair Value:			
Weighted-average grant date fair value per share	$ 10.13	$ 10.34	$ 9.99

The weighted-average assumptions used to estimate the fair value of our common stock to be issued under the 2015 ESPP using a Black-Scholes option-pricing model and the resulting weighted-average grant date fair value were as follows:

	Years Ended December 31,		
	2022	2021	2020
Assumptions:			
Expected term (in years)	0.5	0.5	0.5
Volatility	58.0%	63.3%	81.5% – 127.5%
Risk-free interest rate	3.0%	0.1%	0.1% – 0.2%
Dividend yield	—	—	—
Fair Value:			
Weighted-average grant date fair value per share	$ 5.61	$ 5.16	$ 5.42

Stock-Based Compensation Expense

Total stock-based compensation expense recognized was as follows (in thousands):

	Years Ended December 31,		
	2022	2021	2020
Research and development	$ 10,510	$ 6,007	$ 1,759
General and administrative	9,544	6,778	1,852
Total stock-based compensation expense	$ 20,054	$ 12,785	$ 3,611

15. Defined Contribution Plans

We have a defined contribution plan (the "401(k) Plan") for our full-time, U.S. based employees, with eligibility commencing in the month following an employee's hire date. Employee contributions to the 401(k) Plan are based on a percentage of the employee's gross compensation, limited by IRS guidelines for such plans. The 401(k) Plan provides for matching and discretionary contributions by us within a prescribed limit for each calendar year. Matching contributions were $0.4 million, $0.3 million and less than $0.1 million, for the years ended December 31, 2022, 2021 and 2020, respectively.

We also have a defined contribution plan (the "RRSP Program") for our full-time, Canadian employees, with eligibility commencing on the employee's hire date. Employee contributions to the RRSP Program are processed according to the instructions of each employee, with no cap on the amount each employee may contribute. Employees are individually responsible for ensuring their contributions from all sources do not exceed their individual RRSP contribution limit for the year, as defined by the Canada Revenue Agency. The RRSP Program provides for matching contributions by us within a prescribed limit for each calendar year. Matching contributions were $0.1 million, $0.1 million and less than $0.1 million for the years ended December 31, 2022, 2021 and 2020, respectively.

In 2020, in connection with the Merger, we assumed a defined contribution plan (the "Aduro 401(k) Plan") for Aduro's full-time, U.S. based employees, continuing employment with the Company. Employee contributions to the Aduro 401(k) Plan were based on a percentage of the employee's gross compensation, limited by IRS guidelines for such plans. The Aduro 401(k) Plan provided for matching and discretionary contributions, which were made in the subsequent year. Matching contributions were $0.2 million for the period beginning at the time of the Merger through December 31, 2020.

16. Income Taxes

Loss before income taxes was as follows (in thousands):

	Years ended December 31,		
	2022	2021	2020
Domestic	$ (152,508)	$ (59,702)	$ (68,636)
Foreign	(31,016)	(41,142)	(14,989)
Loss before income tax (expense) benefit	$ (183,524)	$ (100,844)	$ (83,625)

The federal, state, and foreign income tax (expense) benefit consists of the following:

	Years ended December 31,		
	2022	2021	2020
Current:			
U.S. – Federal	$ —	$ —	$ —
U.S. – State	—	—	—
Foreign	—	—	—
Total current	—	—	—
Deferred:			
U.S. – Federal	—	(1,690)	1,607
U.S. – State	—	98	234
Foreign	(4,341)	(501)	162
Total deferred	(4,341)	(2,093)	2,003
Total income tax (expense) benefit	$ (4,341)	$ (2,093)	$ 2,003

The effective tax rate of the provision for income taxes differed from the federal statutory rate as follows:

	Years ended December 31,		
	2022	2021	2020
Federal tax benefit at statutory rate	21.0%	21.0%	21.0%
State taxes, net of federal benefit	3.5%	1.1%	0.2%
Change in valuation allowance	(21.5%)	(13.8%)	(12.0%)
Foreign rate differential	(2.8%)	(4.4%)	1.0%
Redeemable convertible preferred stock tranche liability	0.0%	0.0%	(7.0%)
U.S. impact of foreign operations	(1.5%)	(4.5%)	0.0%
Other	(1.1%)	(1.5%)	(0.9%)
Effective income tax rate	(2.4%)	(2.1%)	2.3%

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The significant components of deferred tax assets and liabilities consisted of the following (in thousands):

	Years ended December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 75,573	$ 53,923
Accruals and reserves	3,269	1,350
Contingent payments	3,973	3,350
Stock-based compensation expense	4,183	2,821
Business tax credits	3,209	2,450
Capitalized R&D	26,090	—
Other	—	2,523
Lease liabilities	10,390	9,824
Gross deferred tax assets	126,687	76,241
Valuation allowance	(98,718)	(59,762)
Total deferred tax assets, net of valuation allowance	27,969	16,479
Deferred tax liabilities:		
Fixed asset basis	(2,765)	(2,142)
Right of use asset	(12,895)	(12,299)
Intangible asset basis	(17,385)	(2,773)
Total deferred tax liabilities	(33,045)	(17,214)
Net deferred tax liabilities	$ (5,076)	$ (735)

We are required to reduce our deferred tax assets by a valuation allowance if it is more likely than not that some or all of our deferred tax assets will not be realized. We must use judgment in assessing the potential need for a valuation allowance, which requires an evaluation of both negative and positive evidence. The weight given to the potential effect of negative and positive evidence should be commensurate with the extent to which it can be objectively verified. In determining the need for and amount of the valuation allowance, if any, we assess the likelihood that we will be able to recover our deferred tax assets using historical levels of income, estimates of future income and tax planning strategies. As a result of historical consolidated cumulative losses, we determined that, based on all available evidence, there was substantial uncertainty as to whether we would recover a majority of our recorded net deferred taxes in future periods. As a result, we recorded a valuation allowance against the worldwide net deferred tax assets at December 31, 2022, 2021 and 2020. The valuation allowance increased by $39.0 million, $44.7 million and $10.0 million during the years ended December 31, 2022, 2021 and 2020, respectively.

At December 31, 2022, we have generated net operating loss (“NOL”) carryforwards (before tax effects) for federal, state and foreign income tax purposes of $199.9 million, $162.7 million and $73.8 million, respectively. The federal, state and foreign NOL carryforwards will begin to expire in 2029, 2039 and 2039, respectively, if not utilized. In addition, we have foreign business tax credits of $3.2 million to offset future income tax liabilities, which will start to expire in 2039, if not utilized.

Our ability to utilize NOL carryforwards or other tax attributes, such as research tax credits, in any taxable year may be limited if we have experienced an ownership change under Section 382 of the Internal Revenue Code (the Code) of 1986, as amended. The Merger resulted in such an ownership change and, accordingly, our NOL carryforwards and certain other tax attributes will be subject to further limitations on their use. We assessed whether we had an ownership change, as defined by Section 382 of the Code from our formation through December 31, 2021. Based upon this assessment, we experienced an ownership change on October 5, 2020. Due to these ownership changes, reductions were made to our NOL and tax credit carryforwards under these rules. Additional ownership changes in the future could result in additional limitations on our NOL and tax credit carryforwards.

Uncertain Tax Positions

We account for uncertainty in income taxes in accordance with ASC Topic 740. Tax positions are evaluated in a two-step process, whereby we first determine whether it is more likely than not that a tax position will be sustained upon examination by the tax authority, including resolutions of any related appeals or litigation processes, based on technical merit. If a tax position meets the more-likely-than-not recognition threshold, it is then measured to determine the amount of benefit to recognize in the financial statements. The tax position is measured as the largest amount of benefit that is greater than 50 percent likely of being realized upon ultimate settlement.

The following table summarizes the activity related to our unrecognized benefits (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Balance at beginning of year	$ —	$ 753	$ 753
Additions based on tax positions related to prior year	—	—	—
Reductions based on tax positions related to prior year	—	(753)	—
Additions based on tax positions related to current year	—	—	—
Reductions based on tax positions related to current year	—	—	—
Balance at end of year	$ —	$ —	$ 753

Our policy is to classify interest and penalties associated with unrecognized tax benefits as income tax expense. We had no interest or penalty accruals associated with uncertain tax benefits in our consolidated balance sheets and consolidated statement of operations and comprehensive loss for the year ended December 31, 2022. We do not have any tax positions for which it is reasonably possible that the total amount of gross unrecognized tax benefits will significantly change within 12 months of December 31, 2022.

We file federal, state and foreign income tax returns in jurisdictions with varying statutes of limitations. Due to our net operating loss carryforwards, our income tax returns remain subject to examination by federal, state and foreign tax authorities for all tax years. We received a notice from taxing authorities in the Netherlands of their intent to examine our 2020 income tax return.

17. Net Loss Per Common Share

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and pre-funded warrants outstanding during the period, without consideration of potentially dilutive securities.

The following table sets forth the calculation of basic and diluted net loss per share attributable to common stockholders, which excludes legally outstanding but unvested restricted shares that are subject to repurchase by us (in thousands, except per share amounts):

	Years Ended December 31,		
	2022	2021	2020
Numerator:			
Net loss attributable to common stockholders	$ (187,865)	$ (102,937)	$ (81,622)
Denominator:			
Weighted-average shares outstanding	64,416	45,755	13,463
Less: weighted-average unvested restricted shares and shares subject to repurchase	(47)	(148)	(295)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	64,370	45,607	13,168
Net loss per share attributable to common stockholders, basic and diluted	$ (2.92)	$ (2.26)	$ (6.20)

As of December 31, 2022 and 2021, 4.6 million and 3.6 million Pre-Funded Warrants to purchase common stock, respectively, issued in connection with the November 2021 and May 2022 public offerings, were included in the weighted-average shares outstanding used in the calculation of basic and diluted net loss per share as the exercise price of the Pre-Funded Warrants is negligible and the Pre-Funded Warrants are fully vested and exercisable. Refer to Note 13 “Common Stock” for more information.

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the period presented because including them would have been antidilutive (in thousands):

	December 31,		
	2022	2021	2020
Unvested RSUs	1,364	823	441
Unvested RSAs	4	99	196
Unvested PSUs	812	—	—
Common stock warrants	—	—	9
Options to purchase common stock	6,127	5,842	5,514
Total	8,307	6,764	6,160

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures.

Our management, with the participation of our President and Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) prior to the filing of this Annual Report on Form 10-K. Based on that evaluation, our President and Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2022.

Management's Annual Report on Internal Control over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended. Our internal control over financial reporting is a process to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Our management, with the participation of our President and Chief Executive Officer and our Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2022. In making this assessment, our management used the criteria set forth by the *Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013)*. Based on our evaluation, we concluded that our internal control over financial reporting was effective as of December 31, 2022.

The effectiveness of our internal control over financial reporting as of December 31, 2022 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included in Item 8 in this Annual Report on Form 10-K.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in internal control over financial reporting.

There were no changes in our internal control financial reporting during the quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is incorporated herein by reference to the Company's definitive proxy statement relating to the 2023 annual meeting of stockholders, or 2023 Proxy Statement, to be filed with the Securities and Exchange Commission, or SEC, within 120 days of the Company's fiscal year ended December 31, 2022.

Item 11. Executive Compensation.

The information required by this item is incorporated herein by reference to the 2023 Proxy Statement, to be filed with the SEC within 120 days of the Company's fiscal year ended December 31, 2022.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item is incorporated herein by reference to the 2023 Proxy Statement, to be filed with the SEC within 120 days of the Company's fiscal year ended December 31, 2022.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item is incorporated herein by reference to the 2023 Proxy Statement, to be filed with the SEC within 120 days of the Company's fiscal year ended December 31, 2022.

Item 14. Principal Accounting Fees and Services.

The information required by this item is incorporated herein by reference to the 2023 Proxy Statement, to be filed with the SEC within 120 days of the Company's fiscal year ended December 31, 2022.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this report:

1. Financial Statements

Information in response to this Item is included in Part II, Item 8 of this Annual Report on Form 10-K.

2. Financial Statement Schedules

All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. Exhibits

See Index to Exhibits below.

INDEX TO EXHIBITS

		Incorporated by Reference				Filed Herewith
Exhibit No.	Description of Exhibit	Form	File No.	Exhibit	Filing Date	
2.1^	Agreement and Plan of Merger and Reorganization, dated June 1, 2020, by and among Aduro Biotech, Inc., Aspire Merger Sub, Inc., and Chinook Therapeutics U.S., Inc.	8-K	001-37345	2.1	06/02/2020	
2.2	Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated August 17, 2020, by and among Aduro Biotech, Inc., Aspire Merger Sub, Inc., and Chinook Therapeutics U.S., Inc.	8-K	001-37345	2.1	08/18/2020	
3.1	Restated Certificate of Incorporation of the Registrant.	8-K	001-37345	3.1	04/20/2015	
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant, dated October 1, 2020.	8-K	001-37345	3.1	10/01/2020	
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant, dated October 5, 2020.	S-8	333-249351	4.6	10/06/2020	
3.4	Amended and Restated Bylaws of the Registrant.	8-K	001-37345	3.1	02/24/2023	
4.1	Form of Registrant's Common Stock certificate.	S-1/A	333-202667	4.1	04/06/2015	
4.2	Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.	10-K	001-37345	4.2	04/07/2021	
4.3	2022 Form of Warrant to Purchase Common Stock	8-K	001-37345	4.1	05/25/2022	
10.1+	Aduro Biotech 2009 Stock Incentive Plan.	S-1	333-202667	10.5	03/11/2015	
10.2+	Forms of Stock Option Agreement and Notice of Grant of Stock Option under the 2009 Stock Plan.	S-1	333-202667	10.6	03/11/2015	
10.3+	2015 Equity Incentive Plan.	S-1/A	333-202667	10.7	04/06/2015	

Exhibit No.	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.4+	Forms of Stock Option Agreement and Notice of Grant of Stock Option under the 2015 Equity Incentive Plan.	S-1/A	333-202667	10.8	04/06/2015	
10.5+	2015 Employee Stock Purchase Plan.	S-1/A	333-202667	10.9	04/06/2015	
10.6+	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement.	8-K	001-37345	10.1	09/14/2016	
10.7+	Chinook 2019 Equity Incentive Plan and forms of award agreements thereunder	S-8	333-249351	99.1	10/06/2020	
10.8	Form of Indemnification Agreement.	8-K	001-35890	10.5	10/7/2020	
10.9+	Form of Employment Agreement (US).	8-K	001-35890	10.6	10/7/2020	
10.10+	Form of Employment Agreement (Canada).	8-K	001-35890	10.7	10/7/2020	
10.11#^	License Agreement, dated December 16, 2019, by and between Chinook Therapeutics U.S., Inc. and AbbVie Ireland Unlimited Company.	S-4	333-239989	10.1	7/22/2020	
10.12	Contingent Value Rights Agreement, dated October 2, 2020, by and between Aduro Biotech, Inc. and Computershare Trust Company, N.A.	10-Q	001-37345	10.8	11/5/2020	
10.13#	Office/Laboratory Lease between Seventh Street Properties VII, LLC and Aduro Biotech, Inc., dated September 11, 2015.	10-Q	001-37345	10.1	11/23/2015	
10.14#	Sublease between the Registrant and Perfect Day, Inc., dated August 25, 2020	10-Q	001-37345	10.9	11/5/2020	
10.15+	Form of Inducement Stock Option Agreement.	10-K	001-37345	10.23	04/07/2021	
10.16	Sublease between the Registrant and Wireless Advocates LLC dated May 24, 2021.	10-Q	001-37345	10.24	08/12/2021	
10.17#^	SanReno Shareholder's Agreement between the Registrant and SanReno Therapeutics Holdings Limited and SanReno Therapeutics (Hong Kong) Limited, a wholly owned subsidiary of SanReno Therapeutics Holdings Limited, dated November 24, 2021.	10-K	001-37345	10.25	03/17/2022	
10.18#^	SanReno License Agreement between the Registrant and SanReno Therapeutics Holdings Limited and SanReno Therapeutics (Hong Kong) Limited, a wholly owned subsidiary of SanReno Therapeutics Holdings Limited, dated November 24, 2021.	10-K	001-37345	10.26	03/17/2022	
10.19+	2022 Equity Inducement Plan and forms of award agreements thereunder	S-8	333-268295	99.1	11/10/2022	
21.1	Subsidiaries of the Registrant.					X
23.1	Consent of PricewaterhouseCoopers, LLP, independent registered public accounting firm.					X

Exhibit No.	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
24.1	Power of Attorney (included in the signature page hereto).					X
31.1	Certification of Principal Executive Officer pursuant to rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended.					X
31.2	Certification of Principal Financial Officer pursuant to rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended.					X
32.1*	Certification of Principal Executive Officer and Principal Financial Officer, as required by rules 13a-14(a) and 15d-14(a) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).					X
101.INS	Inline XBRL Instance Document					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)					

+ **Indicates management contract or compensatory plan, contract or agreement.**

Registrant has omitted portions of the exhibit as permitted under Item 601(b)(10) of Regulation S-K.

^ **Registrant has omitted schedules and exhibits pursuant to Item 601(b)(2) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of the omitted schedules and exhibits to the SEC upon request.**

***** **The certifications attached as Exhibit 32.1 accompany this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.**

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Seattle, State of Washington, on the 27th day of February 2023.

CHINOOK THERAPEUTICS, INC.

By: /s/ Eric L. Dobmeier
Eric L. Dobmeier
President and Chief Executive Officer
(principal executive officer)

By: /s/ Eric H. Bjerkholt
Eric H. Bjerkholt
Chief Financial Officer
(principal financial and accounting officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Eric L. Dobmeier and Eric H. Bjerkholt, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their, his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Eric L. Dobmeier Eric L. Dobmeier	President and Chief Executive Officer (principal executive officer)	February 27, 2023
/s/ Eric H. Bjerkholt Eric H. Bjerkholt	Chief Financial Officer (principal financial and accounting officer)	February 27, 2023
/s/ Srinivas Akkaraju Srinivas Akkaraju	Director	February 27, 2023
/s/ Jerel Davis Jerel Davis	Director	February 27, 2023
/s/ William M. Greenman William M. Greenman	Director	February 27, 2023
/s/ Michelle Griffin Michelle Griffin	Director	February 27, 2023
/s/ Ross Haghighat Ross Haghighat	Director	February 27, 2023
/s/ Dolca Thomas Dolca Thomas	Director	February 27, 2023
/s/Mahesh Krishnan Mahesh Krishnan	Director	February 27, 2023

Exhibit 21.1

The following table presents the name of significant subsidiaries of Chinook Therapeutics, Inc. and the location of jurisdiction or organization for such subsidiaries.

Name:	**Jurisdiction/Organization**
Chinook Therapeutics U.S, Inc.	Delaware
Chinook Therapeutics Canada, Inc.	British Columbia, CA
Aduro Biotech Holdings, Europe B.V.	Netherlands
Aduro Biotech Europe B.V.	Netherlands
Aduro Netherlands Cooperatief UA	Netherlands

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-203508, 333-210016, 333-216373, 333-223382, 333-229915, 333-237034, 333-249351, 333-255109, 333-263649 and 333-268295), the Registration Statement on Form S-3 (No. 333-255099), and the Registration Statement on Form S-3ASR (No. 333-265168) of Chinook Therapeutics, Inc. of our report dated February 27, 2023 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Seattle, Washington
February 27, 2023

Exhibit 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Eric L. Dobmeier, certify that:

1. I have reviewed this annual report on Form 10-K of Chinook Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2023

/s/ Eric L. Dobmeier
Eric L. Dobmeier
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Eric H. Bjerkholt, certify that:

1. I have reviewed this annual report on Form 10-K of Chinook Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2023

/s/ Eric H. Bjerkholt
Eric H. Bjerkholt, M.B.A.
Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Eric L. Dobmeier, President and Chief Executive Officer of Chinook Therapeutics Inc. (the "Company"), and Eric H. Bjerkholt, Chief Financial Officer of the Company, each hereby certifies, that to the best of his knowledge:

1. the Annual Report on Form 10-K of the Company for the fiscal year ended December 31, 2022 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 27, 2023

/s/ Eric L. Dobmeier
Eric L. Dobmeier
President, Chief Executive Officer and Director
(Principal Executive Officer)

Dated: February 27, 2023

/s/ Eric H. Bjerkholt
Eric H. Bjerkholt
Chief Financial Officer
(Principal Accounting and Financial Officer)