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, 2020

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.)**

1600 Fairview Avenue East, Suite 100
Seattle, WA 98102
(Address of principal executive offices including zip code)

Registrant's telephone number, including area code: (206) 485-7051

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. ☐

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, 2020, based on the closing price of the shares of common stock on the Nasdaq Stock Market for such date, was $152,198,513.

The number of shares of Registrant's Common Stock outstanding as of April 5, 2021 was 42,377,432.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Corporate Information

Chinook Therapeutics, Inc., or Chinook or the Company, is a clinical-stage biopharmaceutical company. On October 5, 2020, Aduro Biotech, Inc., or Aduro, completed its acquisition of Chinook Therapeutics U.S., Inc., or Private Chinook, pursuant to the terms of a merger agreement dated as of June 1, 2020, as 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; 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

We are 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 program is atrasentan, an endothelin A receptor antagonist that was in-licensed from AbbVie in late 2019. In March 2021 we initiated a phase 3 trial of atrasentan called ALIGN for IgA nephropathy, or IgAN, and in April 2021 we initiated a phase 2 basket trial called AFFINITY for proteinuric glomerular diseases. Our second product candidate, BION-1301, is an anti-APRIL monoclonal antibody also in development for patients with IgAN, and we anticipate presenting interim results from the ongoing phase 1b trial at multiple nephrology conferences in 2021. We are also advancing our third program, CHK-336, which is currently in IND enabling studies, towards an expected IND submission in late 2021 or early 2022, for the treatment of primary hyperoxaluria. In addition, we are conducting research programs in several other rare, severe chronic kidney diseases. We seek to build our pipeline by utilizing precision medicine approaches, including leveraging insights from kidney single cell RNA sequencing, human-derived organoids and new translational models, to discover and develop therapeutic candidates with mechanisms of action targeted against key kidney disease pathways. To support these efforts, we recently entered into a strategic collaboration with Evotec SE (Evotec) to utilize proprietary comprehensive molecular datasets from thousands of patients across chronic kidney diseases of multiple underlying etiologies.

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, $120 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 indicated biomarkers, such as proteinuria and eGFR, may be accepted 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 systems biology to 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.

Our experienced research and development 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. Additionally, under our collaboration with Evotec, we are utilizing Evotec's proprietary comprehensive molecular datasets from thousands of patients across chronic kidney diseases of multiple underlying etiologies to identify, characterize and validate novel mechanisms and discover precision medicines for PKD, lupus nephritis, IgA nephropathy and other primary glomerular diseases. The collaboration will also involve further characterization of pathways and patient stratification strategies for programs currently in our clinical and preclinical pipeline.

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 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 a serious progressive autoimmune disease of the kidney with no approved therapies. Up to 45 percent of IgAN patients progress to end-stage kidney disease, or ESKD. Although IgAN is an orphan disease, we estimate that it affects approximately 140,000 people in the United States, approximately 200,000 people in Europe and several million people in Asia. 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 protein and blood leaking into the urine, called proteinuria or hematuria, respectively. 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 endothelin A receptor, or 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 through multiple clinical trials, including the phase 3 SONAR trial, which evaluated atrasentan in over 5,000 patients.

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 World Congress of Nephrology 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 end-stage kidney disease 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 diabetic kidney disease 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, in March 2021 we initiated the phase 3 ALIGN trial of atrasentan in patients with IgAN at high risk of kidney function decline. 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 an NDA seeking accelerated approval based on surrogate endpoints, including proteinuria. In April 2021, we initiated the phase 2 AFFINITY trial in other proteinuric glomerular diseases, including cohorts of patients with lower proteinuria IgAN, focal segmental glomerosclerosis, or FSGS, and Alport Syndrome, as well as diabetic kidney disease combined with sodium/glucose cotransporter-2, or SGLT2 inhibitors such as canagliflozin or dapagliflozin, which have recently been shown to provide clinical benefit in patients with diabetic kidney disease. If our trials proceed as planned, we anticipate reporting data from initial cohorts of the AFFINITY trial during 2022 and data for the primary proteinuria endpoint in the ALIGN trial in 2023 to support accelerated approval.

BION-1301

We are also developing BION-1301, an investigational humanized IgG4 monoclonal antibody that blocks APRIL binding to both the B-cell maturation antigen, or BCMA, and transmembrane activator and CAML interactor, or TACI, receptors, as a novel disease-modifying therapy for IgAN. APRIL is a soluble factor that binds to BCMA and TACI receptors thereby inducing signaling and is believed to be implicated in IgAN and other indications.

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 is a soluble factor that functions via binding to the BCMA and TACI receptors, and that APRIL critically drives IgA class switching through TACI and survival of IgA-producing plasma cells through BCMA. Our experiments demonstrate that blocking APRIL inhibits the survival and immunoglobulin production of human plasma cells. We have also demonstrated that IgA-producing plasma cells are more sensitive to immunomodulation by BION-1301, possibly due to their enhanced expression of TACI and BCMA. BION-1301 also downregulates IgG- and IgM-producing plasma cells, which is critical because autoantibodies targeting Gd-IgA can be of all Ig classes. Blocking APRIL is a distinct approach to potentially downmodulate two key processes in the pathogenesis of IgAN: reducing circulating levels of IgA, Gd-IgA1 and anti-Gd-IgA1 autoantibodies as well as immune complex formation. 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 the potential to neutralize APRIL, inhibit secretion of Gd-IgA and thereby reduce immune complex formation and kidney deposition.

A phase 1b clinical trial of BION-1301 in healthy volunteers and patients with IgA nephropathy is currently ongoing. Parts 1 and 2 of this trial evaluating the safety and tolerability of BION-1301 in healthy volunteers have been completed. In healthy volunteers, BION-1301 was well-tolerated, demonstrated dose-dependent increases in target engagement as measured by free APRIL levels, dose-dependently and durably reduced IgA, IgM and IgG levels (to a lesser extent) and had a half-life of approximately 33 days, suggesting the potential for an extended dosing interval. We anticipate presenting Gd-IgA1 biomarker data from Parts 1 and 2 of the study in healthy volunteers at the ISN World Congress of Nephrology in April 2021, or WCN ’21. We are currently enrolling patients with IgAN in Part 3 of this trial, and we anticipate presenting interim results from this trial at the 58th ERA-EDTA conference in June 2021. Patients completing Part 3 may be eligible for a long-term extension study. In addition, we have completed a phase 1 intravenous (IV) to subcutaneous (SC) bioavailability study in healthy volunteers, with potential for SC administration of BION-1301 in the ongoing phase 1b trial and future studies. Results from the IV to SC bioavailability study will be presented at WCN ’21.

CHK-336

Our third clinical development candidate is CHK-336, a liver-targeted oral small molecule lactate dehydrogenase, or LDHA, inhibitor, which we are developing for the treatment of primary hyperoxaluria, or PH. 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 end-stage kidney disease at a young age. We also believe CHK-336 may have potential in the treatment of patients with secondary hyperoxaluria and idiopathic stone formation.

In preclinical studies, CHK-336 produced dose-dependent urinary oxalate reductions in PH1 mouse models into the range observed in normal wildtype mice. The non-clinical safety assessment of CHK-336 supports continued advancement into IND-enabling studies, with an excellent in vitro safety profile, low drug-drug interaction potential and a promising non-GLP in vivo safety profile. CHK-336 is currently progressing through IND-enabling studies, with IND submission expected in late 2021 or early 2022. We believe clinical proof of concept 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 traditional approval of this program in PH.

In 2021, we were granted rare pediatric disease designation by the FDA for CHK-336 for PH. Through the FDA’s rare pediatric disease designation and voucher programs, the FDA may grant a priority review voucher at the time of product approval for a rare pediatric disease. Subject to FDA approval of CHK-336 for the treatment of PH, we believe we may be eligible to receive a voucher that may be redeemed to receive priority review for a subsequent marketing application for a different product candidate or which could be sold or transferred.

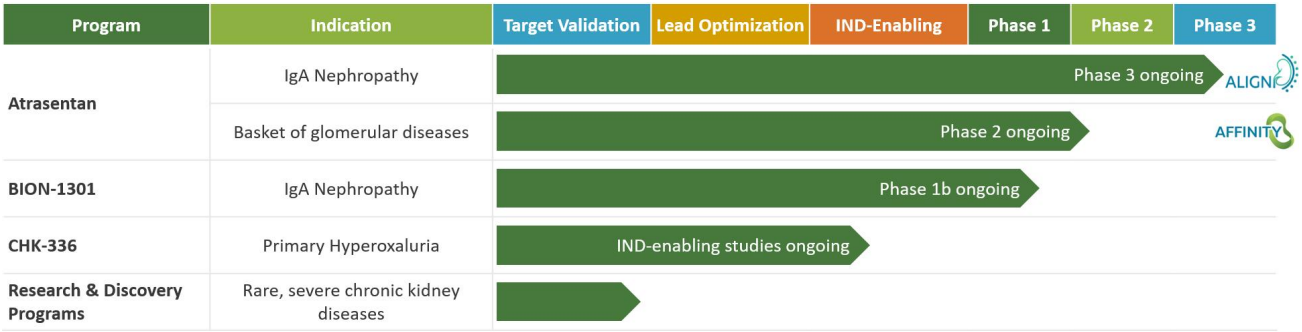
Research and Discovery Programs

Beyond CHK-336, we have active research and discovery efforts focused on other rare, severe kidney diseases. Our overall 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 scientific guidance on target selection, target prioritization and target validation strategies, as well as access to technology platforms that support target validation efforts, by providing deep biological insights into human disease mechanisms as well as 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 PKD, lupus nephritis, IgA nephropathy and other primary glomerular diseases. The collaboration will leverage access to the National Unified Renal Translational Research Enterprise (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. Through our collaboration with Evotec, we intend to characterize molecular drivers, identify and validate novel targets and drive patient stratification strategies in kidney disease.

Our Pipeline

We have assembled a portfolio of precision medicines 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:

Rapidly advance the phase 3 ALIGN trial of atrasentan for IgAN and the phase 2 AFFINITY trial for proteinuric glomerular diseases. We initiated the phase 3 ALIGN trial of our lead product candidate, atrasentan, for IgAN in March 2021. We have received feedback from the FDA and EMA on our phase 3 trial design, which utilizes reduction in proteinuria after six months of treatment as the primary endpoint to support an NDA using the accelerated approval pathway 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. In April 2021 we initiated the phase 2 AFFINITY trial in proteinuric glomerular diseases.

Rapidly advance the ongoing phase 1b clinical trial of BION-1301 in IgAN. We plan to advance the ongoing phase 1b clinical trial of BION-1301 to assess the safety profile, determine the PK/PD profile and establish the proof-of-mechanism, characterized by the reduction of IgA, Gd-IgA and proteinuria, in IgAN patients. Data from this trial will inform our future clinical development strategy for BION-1301.

Complete IND-enabling studies of CHK-336 to enable submission of an IND. We are advancing our CHK-336 development candidate through manufacturing, toxicology and other preclinical studies to enable IND submission in late 2021 or early 2022 for PH. We believe CHK-336 could represent an important new treatment option for patients with diseases caused by excess oxalate production.

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 connection to 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 own global commercial rights to all of our pipeline programs, including our lead product candidate, atrasentan. We intend to build a fully integrated biopharmaceutical company and pursue the development and commercialization of our product candidates. As we continue to advance our programs, we may pursue 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 also plan to seek orphan drug exclusivity for atrasentan and BION-1301 in IgAN, and for CHK-336 in PH. We continually assess and refine our intellectual property strategy and will file additional patent applications as appropriate.

Chronic Kidney Disease Background

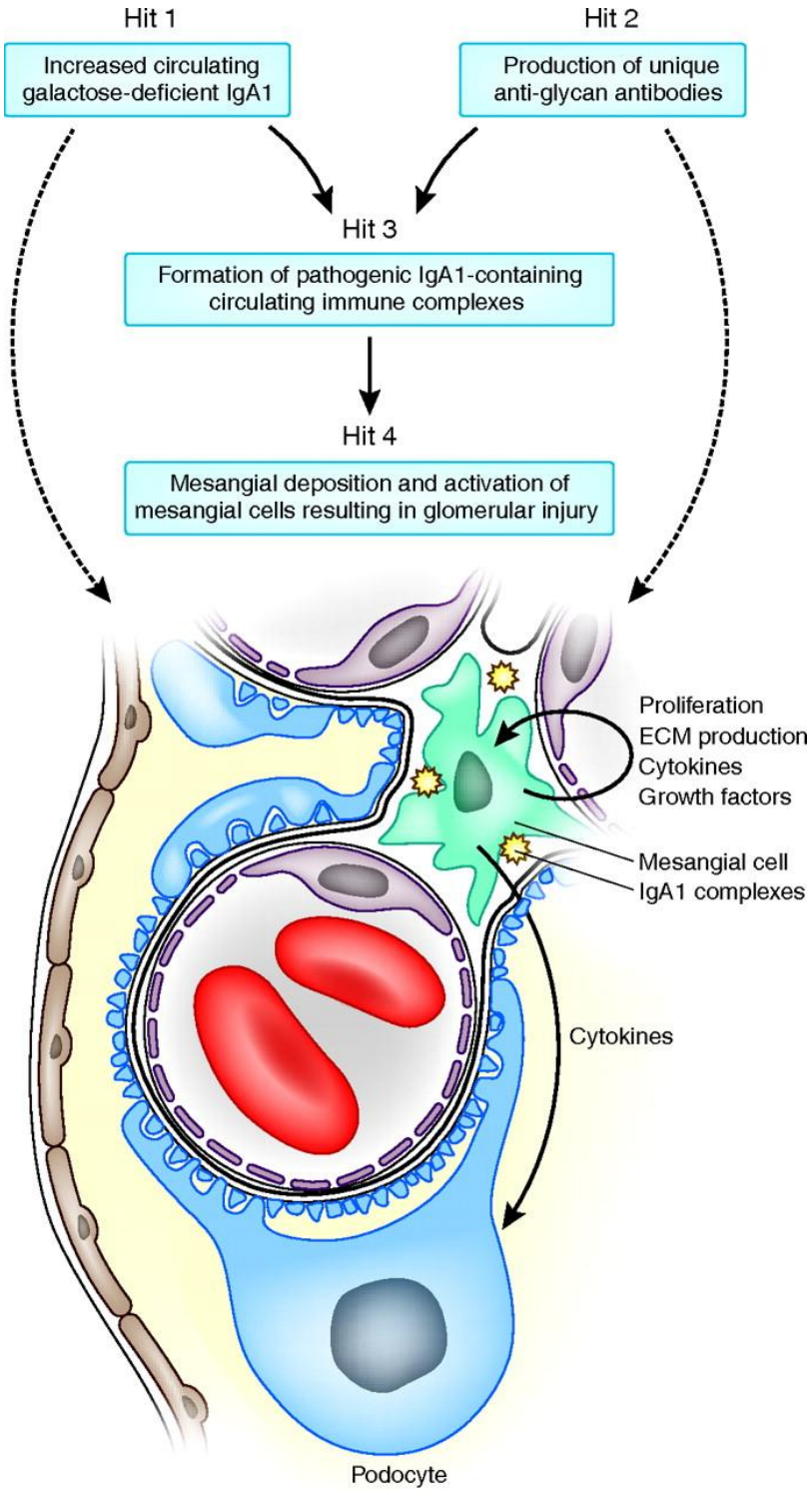
Chronic kidney disease, or CKD, is a large and growing problem globally. In 2017, the global prevalence of CKD was 9.1 percent (697.5 million cases) and the all-age global prevalence of CKD increased by 29.3 percent between 1990 and 2017. Overall, nearly one in ten people around the world have CKD. In the United States alone, the health care system spends over $120 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. Our initial focus with atrasentan and BION-1301 is on 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. Limited data from population-based studies in the United States indicate that the annual incidence of biopsy-proven disease is approximately one 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, which is recognized as an autoantigen by circulating autoantibodies, may be the initiating event causing IgAN. As demonstrated in the figure below, immune recognition results in the formation of toxic immune complexes that deposit in the kidney and activate mesangial cells, 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.

There are no approved treatments for IgAN and 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 do not have established safe and effective treatment options. While current standards of care suggest considering a six-month course of glucocorticoids for such patients, the evidence in support of this recommendation is of low quality, and any benefit in renal protection may be offset by important systemic acute and chronic toxicities. The evidence to support use of corticosteroids as well as other immunosuppressants such as rituximab, cyclophosphamide and mycophenylate mofetil remains unclear and practice patterns vary widely. Therefore, there is an important unmet medical need to develop therapies for patients with IgAN who remain at risk for progressive renal function loss despite optimal conservative management.

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 8 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. Alport Syndrome patients 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, atrasentan, is a potent and selective small molecule ET_A receptor antagonist, or ERA. Atrasentan is designed to reduce proteinuria and slow the progression of IgAN. We have initiated a global pivotal phase 3 clinical trial of atrasentan called ALIGN in IgAN patients, and a phase 2 basket trial of atrasentan called AFFINITY in proteinuric glomerular diseases.

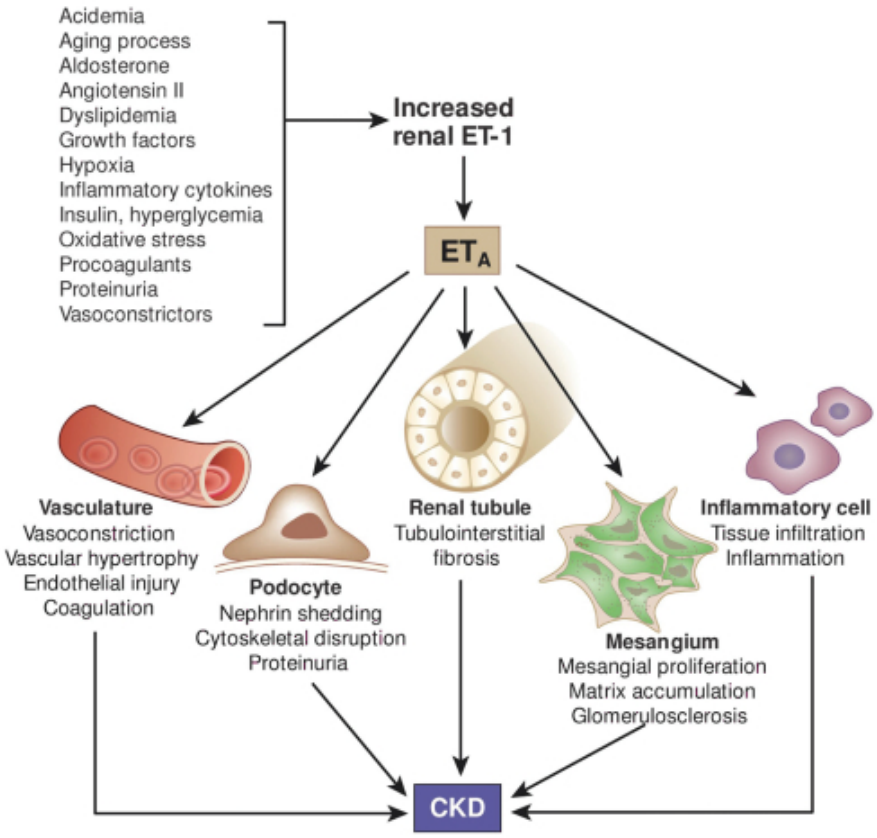
Endothelin System in Chronic Kidney Disease

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 the most potent and long-lasting vasoconstrictor that has been identified. This effect of ET-1 contributes 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 human IgAN patients. High kidney levels of ET-1 are often seen in IgAN patients with high levels of proteinuria and predict rapid progression of IgAN. Selective inhibition of ET_A was studied in a clinical trial of proteinuric CKD patients without diabetes, with the selective ET_A inhibitor sitaxsentan. In this study, sitaxsentan was shown to reduce proteinuria by approximately 30 percent in this proteinuric CKD population including individuals with IgAN. In addition, ET_A blockade with sitaxsentan reduced arterial stiffness and appeared to be well tolerated with no clinically significant adverse effects

reported. However, sitaxsentan was subsequently removed from the market due to liver toxicity believed to be specifically associated with the chemical structure of sitaxsentan and unrelated to ET_A inhibition.

Mechanism of Action of Atrasentan

Atrasentan is designed to be a potent, selective blocker of the ET_A receptor, and 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

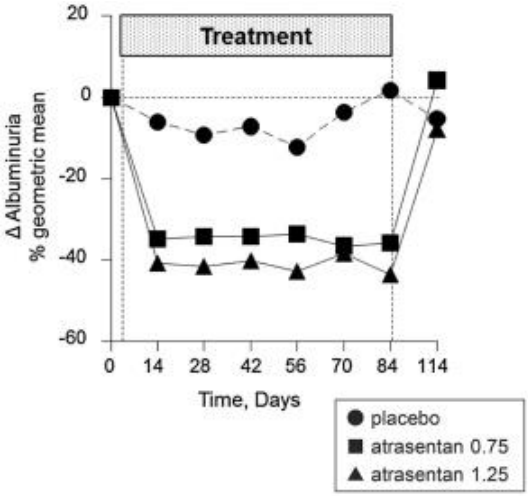
We in-licensed atrasentan from Abbvie in late 2019. Before AbbVie made the strategic decision to terminate development of atrasentan, it had been investigated in multiple phase 1, 2 and 3 clinical trials involving approximately 622 healthy volunteers, and more than 5,000 patients with diabetic nephropathy. 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 diabetic nephropathy 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 the urine albumin to creatinine ratio, or UACR, in multiple phase 2 and phase 3 trials in diabetic nephropathy patients. 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.

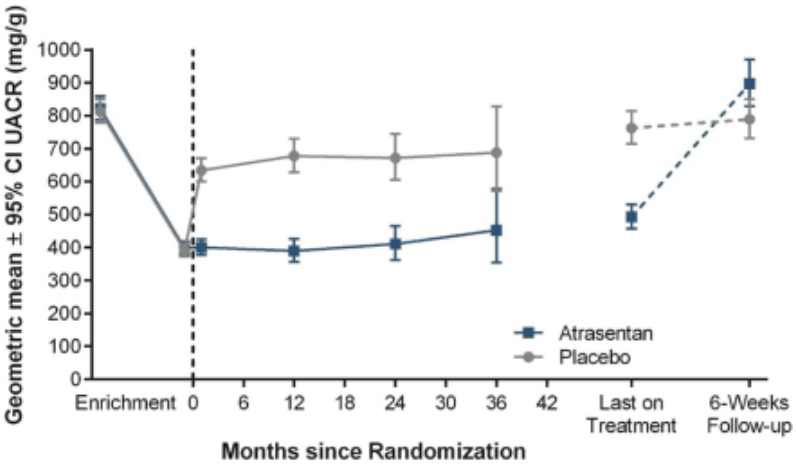
From 2013 to 2017, AbbVie conducted the global phase 3 SONAR trial, which was a randomized, double-blind, parallel, placebo-controlled, multicenter study designed to assess the effects of atrasentan on renal outcomes in patients with type 2 diabetes and CKD while they continued to be treated with the 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, provides 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 diabetic nephropathy 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 diabetic kidney disease, 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.

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. We expect the Food and Drug Administration, or 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.

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. While patients in each clinical trial have a unique set of baseline characteristics, the mean ages of patients in two previous clinical trials in IgAN conducted by competitors were both 39 years old, while the mean age of patients in the SONAR trial was 65 years old. Additionally, patients with diabetic kidney disease are at greater risk of myocardial infarction, congestive heart failure and stroke than the non-diabetic population.

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 drives 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.

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 typically 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 end points 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 need to be verified in a post-marketing confirmatory trial.

Ongoing Phase 3 ALIGN Trial of Atrasentan in 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 six months post 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 expected to be conducted in approximately 15-20 countries on four continents at approximately 120-140 investigative sites. We initiated the trial in March 2021 and anticipate top-line data for the primary proteinuria endpoint in 2023.

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 accelerated approval pathway in the United States. Additionally, we have also received feedback on the study design from the European Medicines Agency, or 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.

Ongoing Phase 2 AFFINITY Trial in 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 diabetic kidney disease combined with an SGLT2 inhibitor. Approximately 20 patients are planned to be treated with open-label atrasentan in each cohort. The primary endpoint for each cohort will be the change from baseline in proteinuria at 12 weeks. Other proteinuric glomerular diseases may be added to the basket study. We expect to be able to report data from initial cohorts of the phase 2 basket trial in 2022 and believe the study will provide signal-seeking data to inform our life cycle management strategy for atrasentan.

BION-1301

Our second product candidate, BION-1301, is a humanized IgG4 monoclonal antibody that fully blocks APRIL binding to both the BCMA and TACI receptors and is being developed as a novel and potentially disease-modifying therapy that targets the underlying causes of IgAN.

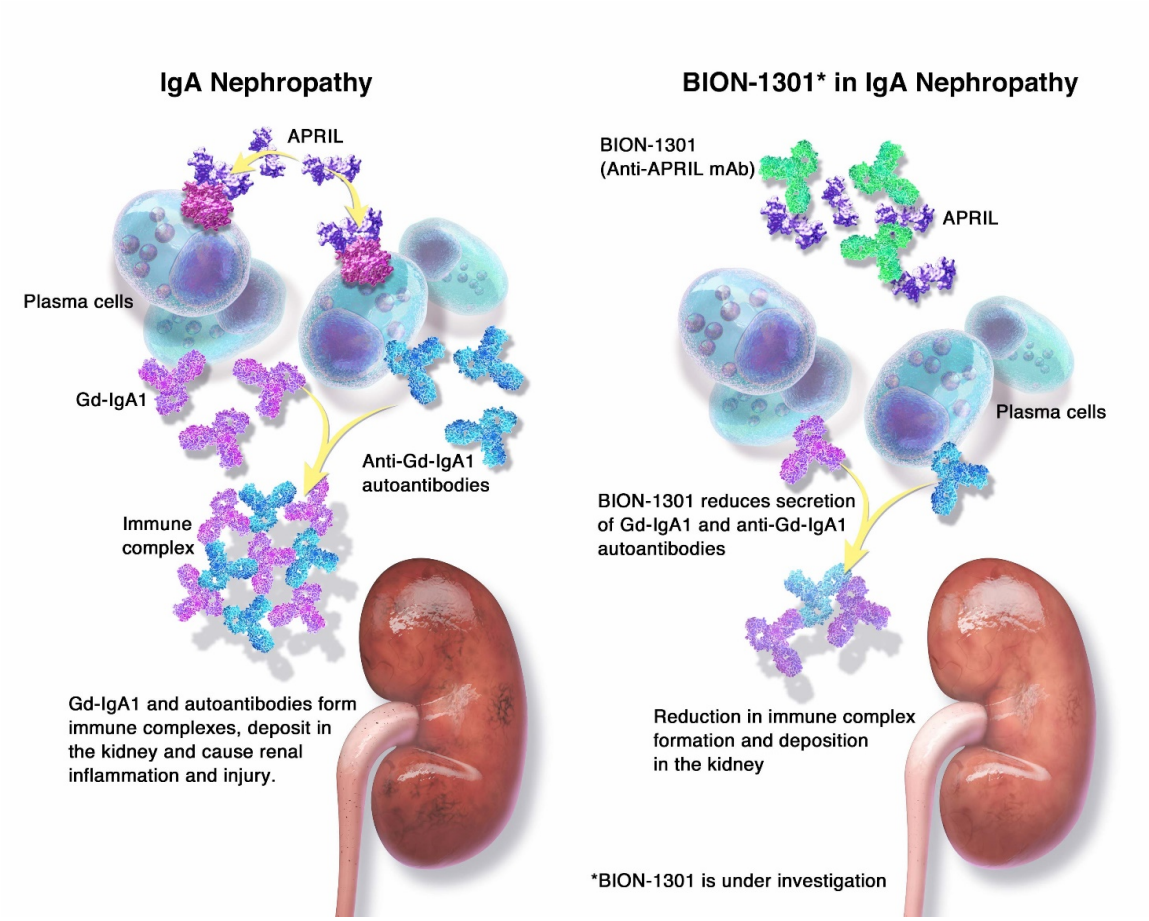
BION-1301 is currently in a phase 1b trial for patients with IgAN, and we anticipate presenting interim results from the ongoing phase 1b trial at multiple nephrology conferences in 2021.

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 (BCMA and TACI), has been shown in preclinical studies to reduce serum IgA levels in mice and monkeys, demonstrating compelling rationale for its use in IgAN.
- *Novel Mechanism.* Blocking APRIL is a distinct approach to reduce circulating levels of IgA, Gd-IgA, anti-Gd-IgA autoantibodies and immune complex formation, with disease-modifying potential in 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 controls, and higher APRIL levels in these patients correlate with poor prognosis in the form of increased galactose-deficient immunoglobulin A (Gd-IgA), increased proteinuria and decreased eGFR. Gd-IgA is recognized as a critical autoantigen to which IgAN patients develop autoantibodies, resulting in the formation and deposition of immune complexes in the kidneys, which ultimately causes local inflammation and functional damage. We know from published literature that APRIL is a soluble factor that functions via binding to the BCMA and TACI receptors, and that APRIL critically drives IgA class switching through TACI and survival of IgA-producing plasma cells through BCMA. Our experiments demonstrate that blocking APRIL inhibits the survival and immunoglobulin production of human plasma cells. We have also demonstrated that IgA-producing plasma cells are more sensitive to immunomodulation by BION-1301, possibly due to their enhanced expression of TACI and BCMA. BION-1301 also downregulates IgG- and IgM-producing plasma cells, which is critical because autoantibodies targeting gd-IgA can be of all Ig classes. Blocking APRIL is a distinct approach to potentially downmodulate two key processes in the pathogenesis of IgAN: reducing circulating levels of IgA, gd-IgA and anti-gd-IgA autoantibodies as well as immune complex formation.

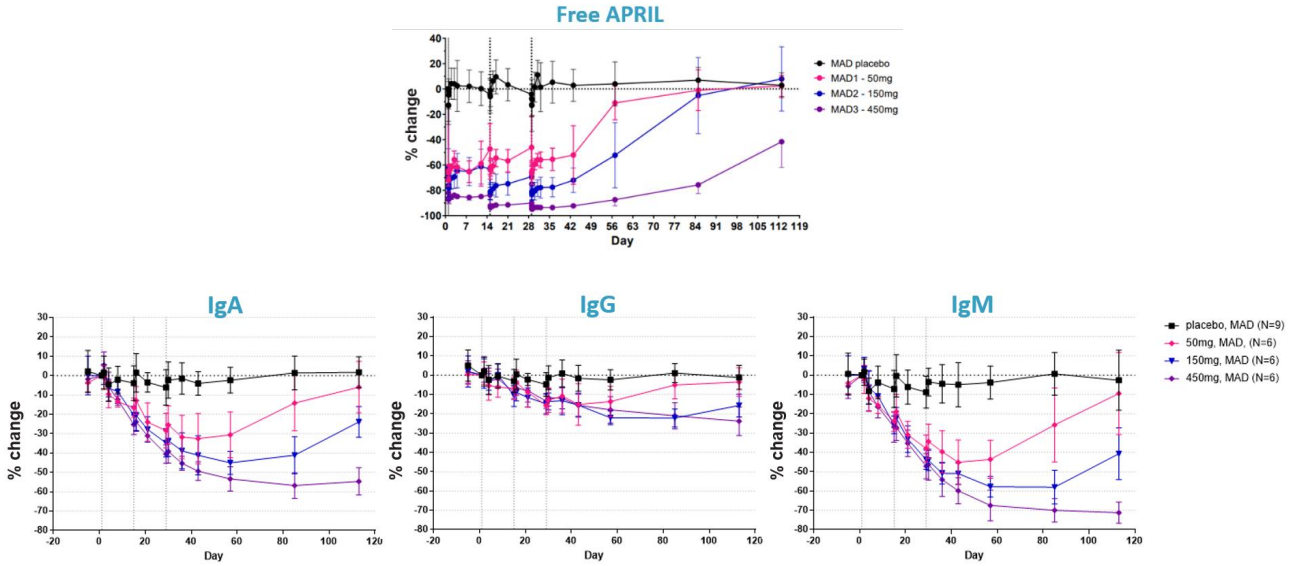
In preclinical studies, BION-1301 has demonstrated binding to a specifically defined epitope on APRIL, resulting in complete blockade of APRIL-induced receptor activation. Dosing of BION-1301 in a preclinical study of non-human primates led to a significant reduction of blood IgA levels and a favorable safety profile. Additional preclinical studies demonstrated that hAPRIL 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. No adverse effects were reported in non-human primate toxicology studies of BION-1301 evaluating IV administration for up to six months and SC administration of BION-1301 for up to one month. In patients with IgAN, BION-1301 has the potential to neutralize APRIL, inhibit secretion of gd-IgA, and thereby reduce immune complex formation and kidney deposition. The illustration below shows the potential reduction of immune complex formation in the kidneys by BION-1301 and its effect in IgAN.



In May 2019, we initiated a phase 1 clinical trial evaluating BION-1301 in healthy volunteers and patients with IgAN. The phase 1 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. 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).

We presented data from Parts 1 and 2 of the study in healthy volunteers at the 57th ERA-EDTA Virtual Congress in June 2020 and ASN Kidney Week 2020 Reimagined. 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. As depicted in the figures below, 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. The below figures summarize these data findings.

We anticipate presenting Gd-IgA1 biomarker data from Parts 1 and 2 of the study in healthy volunteers at WCN ‘21.



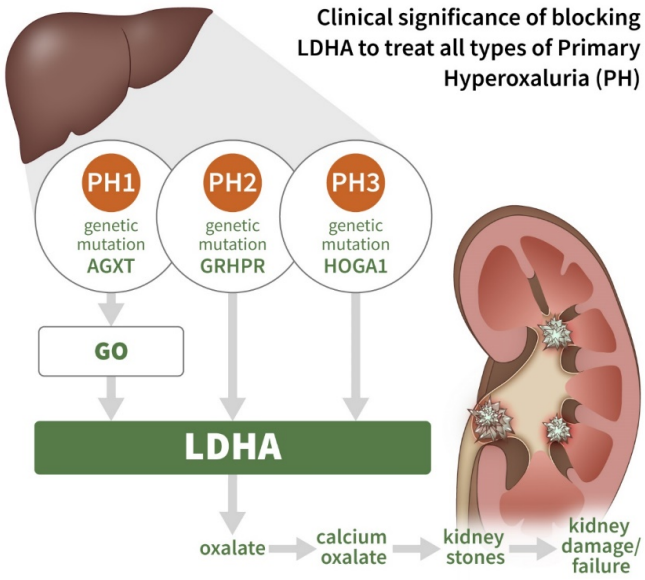
We are currently enrolling IgAN patients in Part 3 of the ongoing phase 1b trial, and we anticipate presenting interim results from this trial at the 58th ERA-EDTA conference in June 2021. Patients completing Part 3 may be eligible for our long-term extension study.

In addition, a phase 1 IV to SC bioavailability study in healthy volunteers is ongoing with potential for SC administration of BION-1301 in the long-term extension and planned phase 2 studies. Results from this study will be presented at WCN ‘21.

CHK-336

CHK-336 is a liver-targeted oral small molecule lactate dehydrogenase, or LDHA, inhibitor that we are developing for the treatment of primary hyperoxaluria, or PH. 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, severe pain, blood in the urine and urinary tract infections, 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 end-stage kidney disease at a young age. We also believe CHK-336 may have potential in the treatment of patients with secondary hyperoxaluria and idiopathic stone formation.

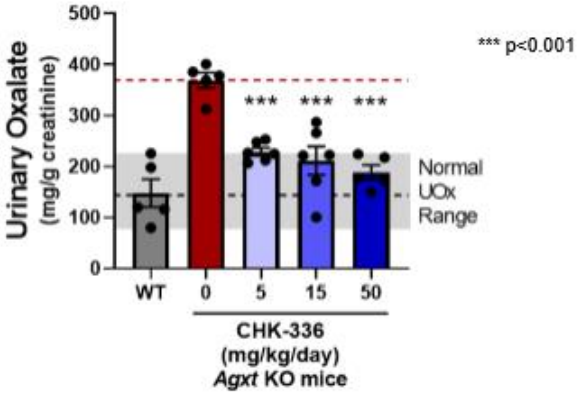
As seen in the illustration below, LDHA catalyzes the terminal step in the production of oxalate from glyoxalate in the liver, therefore LDHA inhibition has the potential to treat all forms of PH – PH1, PH2 and PH3 – as well as other disorders arising from excess oxalate. This is a point of differentiation 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.



The non-clinical safety assessment of CHK-336 conducted to date supports continued advancement into IND-enabling studies, with an excellent in vitro safety profile, low drug-drug interaction potential and a promising non-GLP in vivo safety profile. CHK-336 is currently progressing through IND-enabling studies with IND submission expected in late 2021 or early 2022. We believe clinical proof of concept 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.

Preclinical Product Candidates

In addition to our lead product candidates, we are also conducting discovery and research 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.

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 PKD, lupus nephritis, IgA nephropathy 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, will enable us 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. 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.

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 currently establishing the stability of this drug product and drug substance received from AbbVie and plan to resupply our clinical trials and prepare for future commercial launch with additional manufacturing campaigns. In addition, 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 a CMO to develop, produce and release drug substance and drug product for use in the ongoing phase 1 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. We recently initiated scale-up manufacturing activities for CHK-336, an orally-administered small molecule drug, to support IND enabling studies and an expected IND submission in late 2021 or early 2022.

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. 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. There are no approved drugs for IgAN, but there are a variety of treatments utilized that include renin angiotensin inhibitors, steroids, chemotherapy drugs and immunomodulatory approaches. In addition, there are several competitors in clinical development for the treatment of IgAN, at a similar stage of development or more advanced than us, including companies such as Travere, Calliditas, Omeros, Visterra/Otsuka and Vera Therapeutics.

Many of our competitors, either alone or with strategic partners, have substantially greater financial, technical and human resources than we do. 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. Merger and acquisition activity 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 substantially limited if our competitors develop and commercialize products that are more effective, safer, less toxic, more convenient or less expensive than our comparable products. In geographies that are critical to our commercial success, competitors may also obtain regulatory approvals before us, resulting in our competitors building a strong market position in advance of the entry of our products. 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 all active patent portfolios directed to compositions of matter, formulations, and methods of use related directly to atrasentan from AbbVie, which includes issued U.S. patents and pending U.S. and foreign patent applications. These exclusively licensed patents included eight issued U.S. patents and three 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. patent applications with claims that are intended to cover additional methods of treatment and combinations of atrasentan with other therapies in kidney disease. Any patents that may issue from these currently pending patent applications, including PCT international applications, U.S. patent applications, and foreign patent applications, are expected to expire in 2040-2041, absent any patent term adjustments or extensions.

With respect to BION-1301, we have four issued U.S. patents, eight issued foreign patents, one pending U.S. patent and 13 pending foreign patents, 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 2036, absent any patent term adjustments or extensions.

With respect to CHK-336, we have in-licensed U.S. and foreign issued patents and have filed U.S. and foreign patent applications with claims that cover the composition of matter of CHK-336 and other class compounds, as well as methods of use. As of December 31, 2020, any patents that may issue from these currently pending patent applications, including PCT international applications, U.S. patent applications, and foreign patent applications, are expected to expire in 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 2036, 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. 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 United States Patent and Trademark Office and foreign trademark organizations. We intend to register and maintain the trademark "Chinook Therapeutics" in the United States Patent and Trademark Office and in numerous other jurisdictions, including but not limited to the European Union, China, India 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 Food and Drug Administration, or 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. 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, 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 U.S. typically involves preclinical laboratory and animal tests, the submission to the FDA of an investigational new drug application, or 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. 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 practice, 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 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 and to provide adequate information for the labeling of the drug. In most cases the FDA requires two adequate and well-controlled phase 3 clinical trials to demonstrate the efficacy of the drug. 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 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.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA 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 is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, currently exceeding $2,875,000 for Fiscal Year 2021 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 for products designated as orphan drugs, unless the product also includes a non-orphan indication. The applicant under an approved NDA are also subject to annual program fees, currently exceeding $336,000 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 before it determines whether to file it and may request additional information. The FDA must make a decision on whether to file an NDA 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. The FDA has agreed to certain performance goals in the review of NDAs. Most applications for standard review drug products are reviewed within ten to twelve months; most applications for priority review drugs are reviewed in six to eight months. Priority review can be applied to drugs 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, and the review process can be extended by FDA requests for additional information or clarification.

The FDA may also refer applications for novel drug products, or drug 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, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with 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 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 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 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, the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug 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. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. 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 supplement or, in some case, a new NDA, before the change can be implemented. An NDA 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 supplements as it does in reviewing NDAs.

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

FDA is required to facilitate the development, and expedite the review, of drugs 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 drug candidate. The FDA must determine if the drug 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 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 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.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs 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. After the FDA grants orphan drug designation, the identity of the drug 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 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 U.S. 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 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 for the same disease or condition, or the same drug 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 supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug 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 for an indication for which orphan designation has been granted, with certain exceptions.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity—patent or nonpatent—for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug 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.

Section 529 of the FD&C Act 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 for rare diseases, pediatric populations, and unmet medical needs, section 529 provides an additional incentive for rare pediatric diseases, which may be used alone or in combination with other incentive programs. "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 U.S. 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 drug in the U.S. can be recovered from sales of the drug in the U.S.

Under section 529, the sponsor of a human drug 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 human drug application submitted under section 505(b)(1) of the FD&C Act or section 351 of the Public Health Service Act after the date of approval of the rare pediatric disease drug product. The rare pediatric disease priority review vouchers 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.

Post-Approval Requirements

Once an NDA 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, 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 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. The FDA also may require post-marketing testing, known as phase 4 testing, risk evaluation and mitigation strategies, or 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, drug manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug 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.

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 United States Patent and Trademark Office, or 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 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.

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, knowingly and willfully offering, paying, soliciting or receiving remuneration 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 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 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 to collect and report information on certain payments or transfers of value to physicians and teaching hospitals, as well as investment interests held by physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and their immediate family members. The first reports were due in 2014 and must be submitted on an annual basis. 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. Effective January 1, 2022, reporting on transfers of value to physician assistants, nurse practitioners or clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives will also be required.

In addition, several states now require prescription drug companies to report certain expenses relating to the marketing and promotion of drug 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 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

In the United States there have been, and continue to be, proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of health care and, more generally, to reform the U.S. healthcare system. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the ACA was enacted, which was intended 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 the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, (i) subjected therapeutic biologics to potential competition by lower-cost biosimilars by creating a licensure framework for follow-on biologic products, (ii) proscribed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and therapeutic biologics that are inhaled, infused, instilled, implanted or injected, (iii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, (iv) established annual nondeductible fees and taxes on manufacturers of certain branded prescription drugs and therapeutic biologics, apportioned among these entities according to their market share in certain government healthcare programs, (v) established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50 percent (now 70 percent) point of-sale discounts off negotiated prices of applicable brand drugs and therapeutic biologics to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs and therapeutic biologics to be covered under Medicare Part D, (vi) expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133 percent of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability, (vii) expanded the entities eligible for discounts under the Public Health program, (viii) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research, and (ix) established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There have been legislative and judicial efforts to modify, repeal, or otherwise invalidate all, or certain provisions of the ACA, including measures taken during the Trump administration. By way of example, the Tax Cuts and Jobs Act of 2017, or the TCJA, was enacted and included, among other things, a provision that repealed, effective January 1, 2019, 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 November 2020, the U.S. Supreme Court held oral arguments on the Fifth Circuit U.S. Court of Appeals decision that held that the individual mandate is unconstitutional. It is unclear when a decision will be made or how the Supreme Court will rule. It is also unclear how other efforts to repeal, replace, modify or challenge the ACA will impact the ACA. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on its business.

The 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on certain high cost employer-sponsored insurance plans and the medical device excise tax on non-exempt medical devices, and effective January 1, 2021, also eliminates the health insurer tax. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In addition, CMS published a final rule that would give states greater marketplaces, which may have the effect of relaxing essential health benefits required under the ACA for plans sold through such marketplaces.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted to reduce healthcare expenditures. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This included aggregate reductions of Medicare payments to providers of 2 percent per

fiscal year, which went into effect on April 1, 2013 and will remain in effect through 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2 percent Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. The Consolidated Appropriations Act, 2021 extended the suspension of the 2 percent Medicare sequester through March 31, 2021. Moreover, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If federal spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve research and development, manufacturing, and marketing activities, which may delay Chinook's ability to develop, market and sell any products Chinook may develop.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several 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. At the federal level, the Trump administration's budget proposal for fiscal year 2021 included a 135 billion allowance to support legislative proposals seeking to reduce drug process, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower cost generic and biosimilar drugs. In particular, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. FDA also released a final rule in September 2020 providing guidance for states to build and submit importation plans for drugs from Canada. Further, in November 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The CMS also issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. In December 2020, CMS issued a final rule implementing significant manufacturer price reporting changes under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. It is unclear to what extent these new regulations will be implemented and to what extent these regulations or any future legislation or regulations by the Biden administration will have on our business, including our ability to generate revenue and achieve profitability. 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.

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 1 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.

Data Privacy & Security Laws

Numerous 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 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 (e.g., Section 5 of the FTC Act), 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. Entities that are found to be in violation of HIPAA 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.

Even when HIPAA does not apply, according to the 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, such as the GDPR and 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, California recently enacted legislation, the California Consumer Privacy Act, or CCPA, which went into effect January 1, 2020. The CCPA, 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 certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. In Europe, the GDPR went into effect in May 2018 and introduces strict requirements for processing the personal data of individuals within the 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. Further, recent legal developments in Europe have created complexity and compliance uncertainty regarding certain transfers of information from the EEA to the United States. For example, on June 16, 2020, the Court of Justice of the European Union, or the CJEU, declared the EU-U.S. Privacy Shield framework, or the Privacy Shield, to be invalid. As a result, Privacy Shield is no longer a valid mechanism for transferring personal data from the EEA to the United States. Moreover, it is uncertain whether the standard contractual clauses will also be invalidated by the European courts or legislature, which seems possible given the rationale behind the CJEU's concerns about U.S. law and practice on government surveillance. 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 United Kingdom's withdrawal from the European Union and the EEA, companies have to comply with the GDPR and the GDPR as incorporated into United Kingdom 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. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk. In Canada, PIPEDA and similar provincial laws impose obligations on companies with respect to processing personal information, including health-related information, and provides individuals certain rights with respect to such information, including the right to access and challenge the accuracy of their personal information held by an organization. Failure to comply with PIPEDA could result in significant fines and penalties.

Employees and Human Capital Resources

As of December 31, 2020, we had 105 employees, of which 30 held a Ph.D. or M.D. Of this total, 13 are former Aduro employees whose employment terminated on December 31, 2020 and an additional 13 are transitional employees who are former Aduro employees expected to terminate their employment by May 2021. 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 equity 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, see Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations — Overview — Business Combination with Aduro" 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 1600 Fairview Avenue East, Suite 100, Seattle, WA 98102 and our telephone number is (206) 485-7051. 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. 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.

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.

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.
- The outbreak of COVID-19, or 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.
- 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.
- We have identified material weaknesses in our internal control over financial reporting. Failure to achieve and maintain effective internal control over financial reporting could harm our business and negatively impact the value of our common stock.
- 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.
- 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.
- 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.

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 and the merger between Aduro and Private Chinook.

We have incurred net losses in each year since our inception. We incurred net losses of $81.6 million for the year ended December 31, 2020. As of December 31, 2020, we had an accumulated deficit of $128.8 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 and cash equivalents held as of December 31, 2020 will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months. 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.

We have identified material weaknesses in our internal control over financial reporting. Failure to achieve and maintain effective internal control over financial reporting could harm our business and negatively impact the value of our common stock.

We have identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. In preparing our consolidated financial statements as of and for the years ended December 31, 2020 and December 31, 2019, our management identified the following material weaknesses in its internal control over financial reporting: (i) we did not design or maintain an effective control environment commensurate with its financial reporting requirements due to lack of sufficient accounting professionals with the appropriate level of skill, experience and training commensurate with its financial reporting requirements. Additionally, the limited personnel resulted in our inability to consistently establish appropriate authorities and responsibilities in pursuit of its financial reporting objectives, as demonstrated by, among other things, insufficient segregation of duties in its finance and accounting functions. This contributed to additional material weaknesses as: (ii) we did not design and maintain formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting reporting and disclosures, including controls over the preparation and review of account reconciliations, journal entries and period end financial reporting; and (iii) we did not design and maintain controls over the operating effectiveness of information technology general controls for information systems that are relevant to the preparation of its financial statements. Specifically, we did not design and maintain effective controls over program change management; user access, including segregation of duties; or computer operations.

These material weaknesses could result in adjustments to our consolidated financial statements. Additionally, these material weaknesses could result in a misstatement of our accounts or disclosures that would result in a material misstatement of our future annual or interim financial statements that would not be prevented or detected, and accordingly, we determined that these control deficiencies constitute material weaknesses.

We have recently hired and are actively recruiting additional accounting personnel with appropriate experience, certification, education and training as a component of our plans to remediate the material weaknesses. To the extent that we are not able to hire and retain such individuals, the material weaknesses identified may not be remediated and management may be required to record additional adjustments to our financial statements in the future.

Our internal control over financial reporting may not meet the standards required by Section 404 of the Sarbanes-Oxley Act, and failure to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act, could have a material adverse effect on the combined company's business and share price.

As a privately held company, Private Chinook was not required to evaluate its internal control over financial reporting in a manner that meets the standards of publicly traded companies required by Section 404 of the Sarbanes-Oxley Act, or Section 404. Following the merger, our management is required to report on the effectiveness of the combined company's internal control over financial reporting. The rules governing the standards that must be met for the combined company's management to assess the combined company's internal control over financial reporting are complex and require significant documentation, testing and possible remediation.

In preparing Private Chinook's consolidated financial statements as of and for the years ended December 31, 2019 and 2020, , we identified material weaknesses in our internal control over financial reporting. We cannot assure you that the material weaknesses identified will be remediated on the timelines currently anticipated by the company, or at all, and/or that there will not be additional material weaknesses or significant deficiencies in the company's internal control over financial reporting in the future. Any failure to maintain effective internal control over financial reporting could severely inhibit our ability to accurately report on the combined company's financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its reporting on internal control over financial reporting, investors may lose confidence in the accuracy and completeness of the combined company's financial reports, the market price of the combined company's common stock could decline, and the combined company could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. 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.

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.

In addition, as a newly integrated business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will also need to transition from a company with a focus predominantly on licensing and research to a company that is also capable of supporting multiple clinical trials and commercial activities. We may not be successful in such a transition.

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 candidate, atrasentan, an endothelin receptor antagonist, for the treatment of proteinuric glomerular diseases. We initiated the ALIGN phase 3 clinical trial of atrasentan, for the treatment of IgAN in March 2021, and in April 2021 we initiated the phase 2 AFFINITY clinical trial for certain proteinuric glomerular diseases. In addition, we are conducting a phase 1 clinical trial of BION-1301 for the treatment of IgAN and expect to present interim results in 2021. We also plan to advance our CHK-336 program in primary hyperoxaluria towards IND submission expected in late 2021 or early 2022, and are advancing multiple research programs for 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 U.S. Food and Drug Administration, or FDA, the Health Products and Food Branch of Health Canada, or HPFB, the European Medicines Agency, or 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 Good Laboratory Practices, or 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 Good Clinical Practices, or GCPs;
- effective 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, political instability or global pandemics such as the outbreak of the novel strain of coronavirus, COVID-19; 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 diabetic kidney disease, 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 3 and planned phase 2 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 or have yet to enter 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, 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 of 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 such 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.

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 Risk Evaluation and Mitigation Strategies, 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.

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

Public health crises such as pandemics or similar outbreaks could adversely impact our business. In December 2019, a novel strain of the coronavirus SARS-CoV-2, was identified in Wuhan, China. This virus spread globally, including within the United States and in March 2020 the World Health Organization declared the disease caused by SARS-CoV-2, COVID-19, a pandemic. The pandemic and government measures taken in response have also 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 1b clinical trial of BION-1301 and our phase 3 and planned phase 2 clinical trials of atrasentan 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. If the global effort to control the spread of COVID-19 and treat COVID-19 patients continues on the current trajectory for an extended period of time, we risk a delay in activating sites and enrolling subjects as previously projected. Any such 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 are disrupting 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 limited access to our offices and have undertaken safety precautions to reduce the risk of transmission in our workforce. Due to shelter-in-place orders or other mandated local travel restrictions, 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.

The spread of COVID-19, which has caused a broad impact globally, including restrictions on travel and quarantine policies put into place by businesses and governments, may have a material adverse effect on our business. 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 is likely to result in further, 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.

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 ERAs have been required to include a REMS for women of child-bearing age regarding the risk of embryo-fetal toxicity. 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 140,000 patients in the United States, approximately 200,000 people in Europe and several million people in Asia. 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. 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 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 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 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 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 end-stage kidney disease. 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 product, however, does not assure that other payors will also provide coverage for the drug product. Further, a payor's decision to provide coverage for a drug 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 it 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 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 no approved drugs for IgAN, but there are a variety of treatments utilized that include renin angiotensin inhibitors, 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 AstraZeneca PLC, Calliditas Therapeutics AB, Novartis AG, Omeros Corporation, Reata Pharmaceuticals, Inc., Travere Therapeutics, 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 drugs 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 intend 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 manufacturing agreement for atrasentan with AbbVie or any other CMO. We will need to establish manufacturing relationships for the production of sufficient atrasentan in order to complete our existing and planned clinical trials and 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 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 drugs is complex, highly-regulated and subject to multiple risks. Manufacturing drugs 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, it is 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 on 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. 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 in 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 is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug 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 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 may decide 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 drug 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'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'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 on an expedited basis.

We intend to use reduction in proteinuria as a surrogate endpoint in our phase 3 ALIGN trial of atrasentan. However, there is no guarantee that atrasentan will 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 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 be more difficult or may not occur.

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.

As part of our business strategy, we may seek Orphan Drug Designation for atrasentan in the United States, Europe 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 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.

Section 529 of the FD&C Act 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 for rare diseases, pediatric populations, and unmet medical needs, section 529 provides an additional incentive for rare pediatric diseases, which may be used alone or in combination with other incentive programs. 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 U.S. 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 drug in the U.S. can be recovered from sales of the drug in the U.S.

Under section 529, the sponsor of a drug 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 drug application submitted under section 505(b)(1) of the FD&C Act or section 351 of the Public Health Service Act after the date of approval of the rare pediatric disease drug product. The rare pediatric disease priority review vouchers 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. Although we have obtained designation of CHK-336 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.

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.

For example, 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. As implementation of the ACA is ongoing, 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 legislative and judicial efforts to modify, repeal or otherwise invalidate all or certain aspects of the ACA, including measures taken during the Trump administration. By way of example, the Tax Cuts and Jobs Act, or the TCJA, was enacted, effective January 1, 2019, and included, among other things, 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 November 2020, the U.S. Supreme Court held oral arguments on the Fifth Circuit U.S. Court of Appeals decision that held that the individual mandate is unconstitutional. It is unclear when a decision will be made or how the Supreme Court will rule. In addition, there may be other 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. These changes included aggregate reductions to Medicare payments to providers of 2 percent per fiscal year, which went into effect April 1, 2013 and will stay in effect through 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relieve, and Economic Security Act, or the CARES Act, which was signed into law in March 2020, suspended the 2 percent Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. The Consolidated Appropriations Act, 2021 extended the suspension of the 2 percent Medicare sequester through March 31, 2021. 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 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. At the federal level, the Trump administration's budget proposal for fiscal year 2021 included a 135 billion allowance to support legislative proposals seeking to reduce drug process, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower cost generic and biosimilar drugs. In particular, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. FDA also released a final rule in September 2020 providing guidance for states to build and submit importation plans for drugs from Canada. Further, in November 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The CMS also issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. In December 2020, CMS issued a final rule implementing significant manufacturer price reporting changes under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. It is unclear to what extent these new regulations will be implemented and to what extent these regulations or any future legislation or regulations by the Biden administration will have on our business, including our ability to generate revenue and achieve profitability. 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.

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.

We expect that the ACA, 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.

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.

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.

Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and, subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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, certain other healthcare providers starting in 2022 (for payments made in 2021), 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 licenses 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 owns 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 fail to comply with these obligations, our licensor 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 in 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. We have applied for patent applications intended to specifically cover additional methods of treatment 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 our other product candidates, as well as methods-of-use directed to the use of an API 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-licenses 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 pending 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 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 patents;
- 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 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 drug 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 drug 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 drug 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 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 in our trade secrets or proprietary technology and processes. We have also adopted policies and conducts 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 secret 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 in 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 has 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 cost 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 of 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 to 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 of 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 in 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 US 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 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 itself 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. Each of Private Chinook and Aduro likely experienced 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 the milestones described in the CVR agreement and the consideration received being greater than the amounts permitted to be withheld or deducted under the CVR Agreement. There is no guarantee that we will be able to successfully partner, license or sell any of the non-renal assets related to the CVR. In the event that no CVR milestones occur within the time periods specified in the CVR Agreement or the consideration received is not greater than the amounts permitted to be withheld or deducted by us, no payments will be made under the CVR Agreement, and the CVRs will expire valueless.

Subject to ongoing clinical trial obligations and obligations to use commercially reasonable efforts to complete dispositions for which a sale agreement has been entered into, we will 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.

If the assets subject to the CVR Agreement are not disposed of in a timely manner, we may have to incur time and resources to wind down or dispose of such assets.

Pursuant to the terms of the CVR Agreement, if the committee appointed by the board of directors is unable to partner, license or sell the assets subject to the CVR Agreement, we will be responsible for any wind-down costs associated with the termination of such assets. Further, pursuant to the terms of the CVR Agreement, the CVR holders, rather than our stockholders, are the primary recipients of any net proceeds of the disposition of the assets subject to the CVR Agreement. Absent such CVR Agreement, we could have allocated such funds, time and resources to our core programs and the foregoing could be a distraction to our management and employees. As a result, our operations and financial condition may be adversely affected.

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 and preclinical studies of our product candidates, or those of our competitors or the combined company's 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;
- if we do not achieve the perceived benefits of the merger as rapidly or to the extent anticipated by financial or industry analysts;
- 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;
- 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 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 it 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.

Once we are no longer a smaller reporting company or otherwise no longer qualify for applicable exemptions, we 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. While we ceased being an emerging growth company on December 31, 2020, we continue to qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Exchange Act, in at least the near term, which will allow us to take advantage of many exemptions from disclosure requirements applicable to smaller reporting companies and non-accelerated filers, including not being required to have our independent auditors attest to its internal control over financial reporting under Section 404(a) of the Sarbanes-Oxley Act of 2002 and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. Once we are no longer, a smaller reporting company or otherwise qualify for these exemptions, we will be required to comply with these 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, the combined company 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 the combined company's 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 the combined company's assets. This concentration of voting power could delay or prevent an acquisition of the combined company 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 that could result from the COVID-19 pandemic could cause extreme volatility and disruptions in the capital and credit markets. 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, 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. In addition, the impact of COVID-19 is likely to cause substantial changes in consumer behavior and has caused restrictions on business and individual activities, which are likely to lead to reduced economic activity. Extraordinary actions taken by international, federal, state and local public health and governmental authorities to contain and combat the outbreak and spread of COVID-19 in regions throughout the world, including travel bans, quarantines, "stay-at-home" orders and similar mandates for many individuals and businesses to substantially restrict daily activities could have an adverse effect on our financial condition and ability to raise financing.

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. 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 is unable at this time to estimate the extent of the effect of COVID-19 on our business. The extent and duration of the economic slowdown attributable to COVID-19 remains 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.

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 the 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 breaches, which could result in a material disruption of our development programs.

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 computer viruses, 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. Our internal information technology systems and infrastructure are also vulnerable to damage from natural disasters, terrorism, war, telecommunication and electrical failures. 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.

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 studies, and are subject to laws and regulations governing the privacy and security of such information. 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. Each of these laws is subject to varying interpretations and constantly evolving. In addition, 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. Depending on the facts and circumstances, the Company could be subject to criminal penalties if it knowingly obtains, uses or discloses individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA.

Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. For example, California enacted the California Consumer Privacy Act, or the CCPA, which took effect on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business.

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. 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 (up to the greater of €20 million or 4 percent of our consolidated annual worldwide gross revenue). Further, recent legal developments in Europe have created complexity and compliance uncertainty regarding certain transfers of information from the EEA to the United States. For example, on June 16, 2020, the Court of Justice of the European Union, or the CJEU, declared the EU-U.S. Privacy Shield framework, or the Privacy Shield, to be invalid. As a result, Privacy Shield is no longer a valid mechanism for transferring personal data from the EEA to the United States. Moreover, it is uncertain whether the standard contractual clauses will also be invalidated by the European courts or legislature, which seems possible given the rationale behind the CJEU's concerns about U.S. law and practice on government surveillance. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR.

Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition and results of operations.

We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential information, damage our reputation, and subject us to significant financial and legal exposure.

Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud or other means to threaten data confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including 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. For example, there has been an increase in phishing and spam emails as well as social engineering attempts from "hackers" hoping to use the recent COVID-19 pandemic to their advantage.

Although we devote resources to protect our information systems, we realize that cyberattacks 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.

In addition, the computer systems of various third parties on which we rely, including our CROs, CMOs and other contractors, consultants and law and accounting firms, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches.

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

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.

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.

In December 2018, we entered into a services agreement with a related party under which office space of approximately 12,265 square feet is leased in Vancouver, Canada. We assumed the underlying lease in April 2020, which has an expiration date of August 31, 2027.

In December 2019, we entered into a non-cancelable lease agreement for approximately 3,000 square feet of office space located in Seattle, Washington. The term of the lease is 2 years commencing on January 1, 2020. We have an option to extend the lease term for 24 months after expiration of the initial lease term.

In connection with the Aduro merger, we assumed two facility leases. One is for an office and laboratory facility in Berkeley, California totaling approximately 110,853 square feet 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. The other is for a facility in Oss, the Netherlands, that expired in December 2020 and was not renewed. We are subleasing approximately 83,883 square feet of the Berkeley facility at December 31, 2020 under a sublease agreement, which ultimately will cover the entire leased premises, and which 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." Prior to that date, there was no public trading market for our common stock. On October 2, 2020, in connection with the business combination of Aduro Biotech, Inc. and Chinook Therapeutics U.S., Inc., Aduro completed a 1-for-5 reverse stock split. Commencing on October 5, 2020, our common stock began trading on the Nasdaq Global Select Market under the symbol "KDNY." All share-related information presented in this Annual Report on Form 10-K has been adjusted to reflect the reverse stock split.

On March 26, 2021, the last reported sale price of our common stock on the Nasdaq Global Select Market was $16.73 per share.

Holders of Record

As of March 26, 2021, we had 99 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. 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.

Item 6. Selected Financial Data

A smaller reporting company is not required to provide the information required by this Item.

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. For discussion related to changes in financial condition and the results of operations for fiscal year 2018, refer to Chinook Management's Discussion and Analysis of Financial Condition and Results of Operations in our Prospectus filed pursuant to Rule 424(b)(3) with the Securities and Exchange Commission on August 26, 2020. 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

We are 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, an endothelin A receptor antagonist that we in-licensed from AbbVie in late 2019. In March 2021 we initiated the phase 3 ALIGN trial of atrasentan for IgAN, and in April 2021 we initiated the phase 2 AFFINITY basket trial for proteinuric glomerular diseases. Our second product candidate, BION-1301, is an anti-APRIL monoclonal antibody also in development for patients with IgAN and we anticipate presenting interim results from the ongoing phase 1b trial at multiple nephrology conferences in 2021. We are also advancing our third program, CHK-336, which is currently in IND-enabling studies, towards an expected IND submission in late 2021 or early 2022 for the treatment of PH. 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, human-derived organoids and new translational models, to discover and develop therapeutic candidates with mechanisms of action targeted against key kidney disease pathways. To support these efforts, we have entered into a strategic collaboration with Evotec. 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 PKD, lupus nephritis, IgA nephropathy 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.

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 systems biology to 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.

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. 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 a serious progressive autoimmune disease of the kidney with no approved therapies. Up to 45 percent of IgAN patients progress to end-stage kidney disease, or ESKD. Although IgAN is an orphan disease, we estimate that it affects approximately 140,000 people in the United States, approximately 200,000 people in Europe and several million people in Asia. 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 protein and blood leaking into the urine, called proteinuria or hematuria, respectively. 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 endothelin A receptor, or 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 through multiple clinical trials, including the phase 3 SONAR trial, which evaluated atrasentan in over 5,000 patients.

Based on the encouraging data from SONAR and strong mechanistic rationale, in March 2021 we initiated the phase 3 ALIGN trial of atrasentan in patients with IgAN at high risk of kidney function decline. 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 an NDA seeking accelerated approval based on surrogate endpoints, including proteinuria. In April 2021, we initiated the phase 2 AFFINITY trial in other proteinuric glomerular diseases, including cohorts of patients with lower proteinuria IgAN, FSGS and Alport Syndrome, as well as diabetic kidney disease combined with SGLT2 inhibitors, such as canagliflozin or dapagliflozin, which have recently been shown to provide clinical benefit in patients with diabetic kidney disease. If our trials proceed as planned, we anticipate reporting data from initial cohorts of the AFFINITY trial during 2022, and data for the primary proteinuria endpoint in the ALIGN trial in 2023 to support accelerated approval.

BION-1301

We are also developing BION-1301, an investigational humanized IgG4 monoclonal antibody that blocks APRIL binding to both the B-cell maturation antigen, or BCMA, and transmembrane activator and CAML interactor, or TACI, receptors, as a novel disease-modifying therapy for IgAN. APRIL is a soluble factor that binds to BCMA and TACI receptors thereby inducing signaling and is believed to be implicated in IgAN and other indications.

A phase 1b clinical trial of BION-1301 in healthy volunteers and patients with IgA nephropathy is currently ongoing. Parts 1 and 2 of this trial evaluating the safety and tolerability of BION-1301 in healthy volunteers have been completed. In healthy volunteers, BION-1301 was well-tolerated, demonstrated dose-dependent increases in target engagement as measured by free APRIL levels, dose-dependently and durably reduced IgA, IgM and IgG levels (to a lesser extent) and had a half-life of approximately 33 days, suggesting the potential for an extended dosing interval. We anticipate presenting Gd-IgA1 biomarker data from Parts 1 and 2 of the study in healthy volunteers at the World Congress of Nephrology in April 2021, or WCN ’21. We are currently enrolling patients with IgAN in Part 3 of this trial, and we anticipate presenting interim results from this trial at the 58th ERA-EDTA conference in June 2021. Patients completing Part 3 may be eligible for a long-term extension study. In addition, we have completed a phase 1 intravenous (IV) to subcutaneous (SC) bioavailability study in healthy volunteers, with potential for SC administration of BION-1301 in the ongoing phase 1b trial and future studies. Results from the bioavailability study will be presented at WCN ’21.

CHK-336

Our third clinical development candidate is CHK-336, a liver-targeted oral small molecule lactate dehydrogenase, or LDHA, inhibitor, which we are developing for the treatment of primary hyperoxaluria, or PH. 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 end-stage kidney disease at a young age. We also believe CHK-336 may have potential in the treatment of patients with secondary hyperoxaluria and idiopathic stone formation.

Research and Discovery Programs

Beyond CHK-336, we have active research and discovery efforts focused on other rare, severe kidney diseases. Our overall 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 scientific guidance on target selection, target prioritization and target validation strategies, as well as access to technology platforms that support target validation efforts, by providing deep biological insights into human disease mechanisms as well as 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 PKD, lupus nephritis, IgA nephropathy and other primary glomerular diseases. The collaboration will leverage access to the National Unified Renal Translational Research Enterprise (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. Through our collaboration with Evotec, we intend to characterize molecular drivers, identify and validate novel targets and drive patient stratification strategies in kidney disease.

Components of Operating Results

Change in Fair Value of Redeemable Convertible Preferred Stock Tranche Liability

As a private company, we issued Series A redeemable convertible preferred stock (Series A stock). The terms of the Series A stock agreement included provisions requiring the investors to purchase, and obligating the Company 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.

The Company estimated the fair value of the redeemable convertible preferred stock tranche liability related to each milestone utilizing the income approach using unobservable inputs including (a) future per share value of Series A stock upon achievement of the milestone, (b) estimated term until date of milestone achievement, and (c) probability of milestone achievement. The future per share value of Series A stock upon achievement of the milestone and the probability of milestone achievement for each tranche were calculated on a probability-weighted basis giving equal weighting to public offering and private exit scenarios. The future cash flows were discounted to their fair values as of the valuation date using one or more discount rates, depending on the number of probability-weighted scenarios employed.

Upon issuance, the fair value of the redeemable convertible preferred stock tranche liability was recorded as a reduction in the amounts paid by investors for the purchase of Series A stock.

Upon closing of the Merger, the outstanding redeemable convertible preferred stock tranche rights terminated pursuant to the terms of the merger agreement.

Collaboration and License Revenue

We have not generated any revenue from product sales. Prior to 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.

We have evaluated the remaining performance obligations under these pre-existing agreements and concluded that the only revenue we expect to recognize in the near term is under the agreement with Lilly related to research and development services expected to be performed by us in 2020 and 2021. Potential milestone payments related to development, regulatory or commercial milestone payments may be earned in the future, 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 expect that any revenue we generate from the pre-existing collaboration agreements will be nominal, as such agreements relate to non-renal development programs, all of which are outside our ongoing focus in renal disease.

Research and Development Expenses

The largest component of our total operating expenses has historically been 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 personnel 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. 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 personnel costs, expenses for outside professional services, and other allocated expenses. Personnel costs consist of salaries, bonuses, benefits and stock-based compensation. Outside professional services consist of legal, accounting and audit services, insurance expenses, investor relations activities, administrative services and other consulting fees. Allocated expenses consist of rent expense related to our offices and research and development facility.

Other Income (Expense), Net

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

Income Tax 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.

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

	Year Ended December 31,		Change
	2020	2019	$
	(in thousands)		
Collaboration and license revenue	$ 827	$ —	$ 827
Operating expenses:			
Research and development	36,051	17,010	19,041
General and administrative	19,071	2,956	16,115
Change in fair value of contingent consideration	1,510	—	1,510
Amortization of intangible assets	422	—	422
Total operating expenses	57,054	19,966	37,088
Loss from operations	(56,227)	(19,966)	(36,261)
Interest expense – related party	(15)	(33)	18
Other income (expense), net	313	299	14
Change in fair value of redeemable convertible preferred stock tranche liability.	(27,696)	(26,819)	(877)
Loss before income tax benefit	(83,625)	(46,519)	(37,106)
Income tax benefit	2,003	—	2,003
Net loss	$ (81,622)	$ (46,519)	$ (35,103)

Revenue

Total revenue was $0.8 million for the year ended December 31, 2020, an increase of $0.8 million compared to zero for the year ended December 31, 2019. The increase was due to revenue recognized related to research and development services provided under our collaboration agreement with Lilly.

Research and Development

The following tables summarize our research and development expenses by program and by category incurred during the years ended December 31, 2020 and 2019.

	Year Ended December 31,		
	2020	2019	Change
	(in thousands)		
Product candidates:			
Atrasentan	$ 16,255	$ 7,188	$ 9,067
BION-1301	1,405	—	1,405
CHK-336	4,267	4,420	(153)
Other	4,999	1,408	3,591
Discovery research and other development costs	6,084	3,130	2,954
Subtotal	33,010	16,146	16,864
Stock-based compensation expense	1,759	44	1,715
Facility costs and depreciation	1,282	820	462
Total research and development	$ 36,051	$ 17,010	$ 19,041

	Year Ended December 31,		
	2020	2019	Change
	(in thousands)		
Contract research and manufacturing	$ 18,367	$ 2,641	$ 15,726
Personnel costs	9,450	2,180	7,270
Supplies used in research and development	1,863	845	1,018
Stock-based compensation expense	1,759	44	1,715
Facility costs and depreciation	1,282	820	462
Costs associated with license agreements	1,121	6,937	(5,816)
Consulting and outside services	1,037	1,011	26
Purchase of intellectual property and know-how	—	2,000	(2,000)
Other	1,172	532	640
Total research and development	$ 36,051	$ 17,010	$ 19,041

Research and development expense was $36.1 million for the year ended December 31, 2020, an increase of $19.0 million compared to $17.0 million for the year ended December 31, 2019. The increase was primarily due to external clinical and manufacturing expenses related to the atrasentan and BION-1301 clinical programs, higher personnel expenses, including salaries, benefits and stock-based compensation expense, associated with hiring staff to build out our clinical and development capabilities, and increased spending for consulting and outside services. The increase was partially offset by expenses in the prior year period for the in-license of atrasentan, and the purchase of intellectual property and know-how from a related party to support the CHK-336 program, and discovery research activities.

General and Administrative

The following table summarizes our general and administrative expenses incurred during the years ended December 31, 2020 and 2019:

	Year Ended December 31,		
	2020	2019	Change
	(in thousands)		
Consulting and outside services	$ 9,170	$ 1,157	$ 8,013
Personnel costs	4,984	1,313	3,671
Stock-based compensation expense	1,852	52	1,800
Facility costs and depreciation	1,170	2	1,168
Other	1,895	432	1,463
Total general and administrative	$ 19,071	$ 2,956	$ 16,115

General and administrative expense was $19.1 million for the year ended December 31, 2020, an increase of $16.1 million compared to $3.0 million for the year ended December 31, 2019. The increase was primarily due to legal, consulting and accounting costs related to the merger, an increase in personnel costs, including salaries, benefits and stock-based compensation expense, due to the addition of administrative staff to buildout our public-company infrastructure, and an increase in facilities and other costs.

Change in fair value of redeemable convertible preferred stock tranche liability

Change in fair value of redeemable convertible preferred stock tranche liability decreased by $0.9 million for the year ended December 31, 2020 compared to the year ended December 31, 2019, primarily due to changes in the fair value of the Company's Series A redeemable preferred stock underlying the tranche rights.

Income tax benefit

Income tax benefit of $2.0 million for the year ended December 31, 2020 was due to a deferred tax liability generated in connection with the Merger that was used to realize certain deferred tax assets, which previously had a full valuation allowance

Liquidity and Capital Resources

As of December 31, 2020, we had $250.4 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, 2020 will enable us to fund our operating expenses and capital expenditure requirements to the middle of 2023.

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. At the same time, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our product candidates. Accordingly, we anticipate that we will need substantial additional funding in connection with our continuing operations.

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 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,	
	2020	2019
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (55,848)	$ (13,588)
Investing activities	109,672	(758)
Financing activities	124,292	25,686
Effect of exchange rate changes	27	17
Net change in cash, cash equivalents, and restricted cash	$ 178,143	$ 11,357

Operating Activities

Net cash used in operating activities was $55.8 million for the year ended December 31, 2020, an increase of $42.3 million compared to $13.6 million for the year ended December 31, 2019. The increase was primarily due to an increased operating loss resulting from increased research and development spending on the atrasentan and BION-1301 clinical programs, including hiring additional staff, and outside spending for clinical and manufacturing activities, and an increase in general and administrative spending for merger-related costs, and the hiring of additional personnel to support our needs as a public company.

Investing Activities

Net cash provided by investing activities was $109.7 million for the year ended December 31, 2020, an increase of $110.4 million compared to $0.8 million cash used for the year ended December 31, 2019. The increase was primarily due to the receipt of cash and cash equivalents acquired in connection with the Merger, and proceeds from maturities of marketable securities, net of purchases of marketable securities.

Financing Activities

Net cash provided by financing activities was $124.3 million for the year ended December 31, 2020, an increase of $98.6 million compared to $25.7 million for the year ended December 31, 2019. The increase was primarily due to net proceeds received from the sale of common stock and the issuance of redeemable convertible preferred stock.

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.

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. 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 contingent value rights.

We allocated the purchase price to the acquired tangible and intangible assets and assumed liabilities of Aduro based on their estimated fair values as of the acquisition date. The allocation of the purchase price resulted in recognition of intangible assets related to an acquired license agreement, an in-place sublease broker commission, in-process research and development and goodwill. The fair value of the identifiable intangible assets is based on detailed valuations using information and assumptions such as the timing and estimated costs to complete the in-process projects, projecting regulatory approvals, developing an appropriate discount rate and estimating future cash flows.

Contingent Value Rights Liability

The estimated fair value of the contingent value rights liability, initially measured and recorded on the Merger date, is considered to be a Level 3 instrument. The contingent value rights liability is 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 in the consolidated statements of operations and comprehensive loss.

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 clinical trial and the non-renal assets intended to be disposed of. 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 is 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 in-process research and development 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 $66.9 million at December 31, 2020.

Accrued Research and Development Expenses

We record accrued expenses for estimated costs of its research and development activities conducted by third-party service providers, which include the conduct of preclinical studies and clinical trials and contract manufacturing activities. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced, and we include these costs in accrued liabilities in the consolidated balance sheets and within research and development expense in the consolidated statement of operations and comprehensive loss. These costs are a significant component of our research and development expense. We record accrued expenses for these costs based on the estimated amount of work completed and in accordance with agreements established with these third parties.

We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed, the number of patients enrolled, and the rate of patient enrollment may vary from its estimates and could result in our reporting amounts that are too high or too low in any particular period. Our accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from clinical research organizations and other third-party service providers. To date, there have been no material differences from our accrued expenses to actual expenses.

Estimated Fair Value of Redeemable Convertible Preferred Stock Tranche Liability

We had a liability related to future tranche options for purchase of our Series A redeemable convertible preferred stock. Such redeemable convertible preferred stock tranche rights terminated upon the closing of the merger. The tranche options were accounted for as a liability at its estimated fair value at the inception of the obligation and was remeasured to fair value as of each balance sheet

date, with the related re-measurement adjustment recognized as a component of other income (expense) in the consolidated statement of operations and comprehensive loss. The estimated fair value of the tranche options was determined using an option pricing model that considered the redeemable convertible preferred stock price, the exercise price of the option, the estimated time period the option would have been outstanding, the volatility of the underlying stock, the risk-free interest rate associated with the life of the option, and the dividend yield of the underlying Series A redeemable convertible preferred stock. The value derived from the option pricing model was adjusted for the probability of the related milestones not being met. Our management used its judgment to estimate many of these variables. We have recorded adjustments to the estimated fair value of the redeemable convertible preferred stock tranche liability until which time the tranche options expired upon closing of the merger.

Stock-based Compensation

We recognize noncash stock-based compensation expense related to stock-based awards to employees, non-employees and directors, including stock options, based on the fair value on the grant date using the Black-Scholes option pricing model. The related stock-based compensation is recognized as expense on a straight line-basis over the employee's, non-employee's or director's requisite service period (generally the vesting period). Noncash stock compensation expense is based on awards ultimately expected to vest. However, the Company has elected to account for forfeitures as incurred.

In determining the fair value of stock options, we use the Black-Scholes option-pricing model and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment to determine.

Fair Value of Common Stock—The fair value of the shares of common stock underlying stock options has historically been determined by our board of directors. Because until recently there has been no public market for our common stock, the board of directors has exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including important developments in its operations, sales of redeemable convertible preferred stock, actual operating results and financial performance, the conditions in the life sciences industry and the economy in general, the stock price performance and volatility of comparable public companies, and the lack of liquidity of our common stock, among other factors.

Expected Term—Our expected term represents the period that the stock-based awards are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term

Expected Volatility—Prior to the Merger, due to the lack of company-specific historical and implied volatility data, the Company based its 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, the Company is 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.

Risk-Free Interest Rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of option.

Expected Dividend—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we use an expected dividend yield of zero.

For the years ended December 31, 2020 and 2019, stock-based compensation expense was $3.6 million and $0.1 million, respectively. As of December 31, 2020, we had $20.1 million of total unrecognized stock-based compensation costs, which we expect to recognize over a weighted-average period of 3.2 years.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Recent Accounting Pronouncements

For information regarding recent accounting pronouncements, see Note 2 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.

A smaller reporting company is not required to provide the information required by this Item.

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.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Chinook Therapeutics, Inc. and its subsidiaries (the "Company") as of December 31, 2020 and 2019, and the related consolidated statements of operations and comprehensive loss, of redeemable convertible preferred stock and stockholders' equity (deficit) and of cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements 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 of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits 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. We believe that our audits provide a reasonable basis for our opinion.

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.

Acquisition of Aduro Biotech, Inc. - Valuation of certain intangible assets and related contingent value rights

As described in Notes 1 and 3 to the consolidated financial statements, in 2020, the Company completed its acquisition of Aduro Biotech, Inc. for a total purchase price of $260.9 million. Identified intangible assets acquired as part of the acquisition included $32.4 million of an acquired renal in-process research and development intangible asset and $26.7 million of license agreement intangible assets. Additionally, the Company recorded $10.8 million of contingent consideration liabilities for contingent value rights related to the license agreement intangible assets. The fair value of the acquired renal in-process research and development intangible asset was determined using a probability-weighted discounted cash flow model prepared under the multi-period excess earnings method and the fair value of the acquired license agreement intangible assets and related contingent value rights were valued under the income method using a probability-weighted discounted cash flow model and a Monte Carlo simulation model. Management applied significant judgment in estimating the fair value of certain 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 renal in-process research and development 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 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 principal considerations for our determination that performing procedures relating to the valuation of certain acquired intangible assets and related contingent value rights from the Aduro Biotech, Inc. acquisition is a critical audit matter are (i) the significant judgment by management when determining the fair values of certain acquired intangible assets and related contingent value rights; (ii) the high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating management’s significant assumptions related to future revenues, revenue volatility and expenses, probabilities of technological and regulatory success, and discount rates; and (iii) the audit effort involved the use of professionals with specialized skill and knowledge.

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, among others, (i) reading and evaluating the merger, license and contingent value rights agreements; (ii) testing management’s process for determining the fair value of certain acquired intangible assets and related contingent value rights; (iii) evaluating the appropriateness of the multi-period excess earnings method and the probability-weighted discounted cash flow and Monte Carlo simulation models; (iv) testing the completeness and accuracy of the underlying data used in the probability-weighted discounted cash flow models; and (v) evaluating the reasonableness of the significant assumptions used by management related to future revenues, revenue volatility and expenses, probabilities of technological and regulatory success, and discount rates. Evaluating the reasonableness of the significant assumptions related to future revenues involved considering the consistency with external market and industry data and industry forecasts. Evaluating the reasonableness of future expenses involved considering (i) the actual performance and activities of the Company; (ii) the consistency with external market and industry data; and (iii) whether these assumptions were consistent with evidence obtained in other areas of the audit. In addition, the probabilities of technological and regulatory success, revenue volatility and discount rates were evaluated by considering external market and industry data. Professionals with specialized skill and knowledge were used to assist in evaluating (i) the appropriateness of the multi-period excess earnings method and probability-weighted discounted cash flow and Monte Carlo simulation models and (ii) the reasonableness of the significant assumptions related to revenue volatility and discount rates.

/s/ PricewaterhouseCoopers LLP
Seattle, Washington
April 7, 2021

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

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

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 187,750	$ 11,203
Restricted cash	—	154
Marketable securities	59,622	—
Accounts receivable	262	—
Prepaid expenses and other current assets	6,447	1,174
Total current assets	254,081	12,531
Marketable securities	3,000	—
Property and equipment, net and finance right-of-use asset	20,626	1,311
Restricted cash	1,750	—
Operating lease right-of-use assets	55,673	1,880
Intangible assets, net	27,696	—
IPR&D	39,295	—
Goodwill	22,441	—
Other assets	4,440	—
Total assets	$ 429,002	$ 15,722
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable (including amounts due to related party of $9 and $250 at December 31, 2020 and 2019, respectively)	$ 3,995	$ 939
Accrued and other current liabilities (including amounts due to related party of $192 and $489 at December 31, 2020 and 2019, respectively)	15,674	1,250
Operating lease liabilities (including amounts due to related party of $0 and $163 at December 31, 2020 and 2019, respectively)	3,045	163
Finance lease liabilities – related party	—	75
Deferred revenue	95	—
Total current liabilities	22,809	2,427
Redeemable convertible preferred stock tranche liability	—	32,733
Contingent value right liability	13,780	—
Contingent consideration related to acquisition	1,800	—
Deferred tax liabilities	16,377	—
Operating lease liabilities, net of current maturities (including amounts due to related party of $0 and $1,732 at December 31, 2020 and 2019, respectively)	38,709	1,732
Finance lease liabilities, net of current maturities – related party	—	114
Other long-term liabilities	905	—
Total liabilities	94,380	37,006
Commitments and contingencies (Note 15)		
Redeemable convertible preferred stock, $0.0001 par value; none and 65,000,000 shares authorized as of December 31, 2020 and 2019, respectively; none and 7,596,886 shares issued and outstanding as of December 31, 2020 and 2019, respectively; liquidation preference $0 and $26,000 as of December 31, 2020 and 2019, respectively	—	19,835
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 and no shares authorized as of December 31, 2020 and 2019, respectively; no shares issued and outstanding as of December 31, 2020 and 2019	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized as of December 31, 2020 and 2019; 42,282,381 and 4,501,885 shares issued and outstanding as of December 31, 2020 and 2019, respectively	4	—
Additional paid-in capital	463,436	6,095
Accumulated deficit	(128,829)	(47,207)
Accumulated other comprehensive income (loss)	11	(7)
Total stockholders' equity (deficit)	334,622	(41,119)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 429,002	$ 15,722

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 share and per share amounts)

	Years ended December 31,	
	2020	2019
Collaboration and license revenue	$ 827	$ —
Operating expenses:		
Research and development (including related party expenses of $362 and $3,864 for the years ended December 31, 2020 and 2019, respectively)	36,051	17,010
General and administrative (including related party expenses of $224 and $1,032 for the years ended December 31, 2020 and 2019, respectively)	19,071	2,956
Change in fair value of contingent consideration	1,510	—
Amortization of intangible assets	422	—
Total operating expenses	57,054	19,966
Loss from operations	(56,227)	(19,966)
Other income (expense):		
Interest expense – related party	(15)	(33)
Other income (expense), net	313	299
Change in fair value of redeemable convertible preferred stock tranche liability	(27,696)	(26,819)
Loss before income tax	(83,625)	(46,519)
Income tax benefit	2,003	—
Net loss	$ (81,622)	$ (46,519)
Net loss per share attributable to common stockholders, basic and diluted	$ (6.20)	$ (25.48)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	13,168,143	1,825,716
Other comprehensive income (loss):		
Foreign currency translation adjustments, net of tax of $0	39	(13)
Unrealized (loss) gain on marketable debt securities, net of tax of $0	(21)	—
Total other comprehensive income (loss)	18	(13)
Comprehensive loss	$ (81,604)	$ (46,532)

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, except share amounts)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances at January 1, 2019	—	—	1,971,101	—	1	(688)	6	(681)
Net loss	—	—	—	—	—	(46,519)	—	(46,519)
Other comprehensive loss	—	—	—	—	—	—	(13)	(13)
Stock-based compensation expense	—	—	—	—	95	—	—	95
Issuance of common stock for acquisition or license of intellectual property	—	—	2,484,447	—	5,997	—	—	5,997
Issuance of restricted common stock	—	—	46,337	—	2	—	—	2
Issuance of Series A redeemable convertible preferred stock, net of issuance cost of $168, adjusted for $5,960 redeemable convertible preferred stock tranche liability	7,596,886	19,835	—	—	—	—	—	—
Balances at December 31, 2019	7,596,886	19,835	4,501,885	—	6,095	(47,207)	(7)	(41,119)
Net loss	—	—	—	—	—	(81,622)	—	(81,622)
Other comprehensive loss	—	—	—	—	—	—	18	18
Stock-based compensation expense	—	—	—	—	3,611	—	—	3,611
Issuance of common stock upon exercise of stock options	—	—	82,287	—	362	—	—	362
Vesting of restricted stock units	—	—	4,989	—	—	—	—	—
Issuance of common stock under Employee Stock Purchase Plan			6,811	—	84	—	—	84
Repurchase of unvested restricted stock awards	—	—	(71,951)	—	—	—	—	—
Issuance of Series A redeemable convertible preferred stock, net of issuance cost of $21	4,236,725	14,479	—	—	—	—	—	—
Reclassification of redeemable convertible preferred stock tranche liability upon exercise	—	9,723	—	—	—	—	—	—
Conversion of redeemable convertible preferred stock to common stock	(11,833,611)	(44,037)	11,833,611	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	—	—	9,583,326	1	109,413	—	—	109,414
Aduro outstanding common stock assumed as a result of the Merger	—	—	16,307,177	2	248,629	—	—	248,631
Issuance of common stock for financial advisory services in connection with the Merger	—	—	34,246	—	500	—	—	500
Balances at December 31, 2020	—	$ —	42,282,381	$ 4	$ 463,436	$ (128,829)	$ 11	$ 334,622

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,	
	2020	**2019**
Cash flows from operating activities		
Net loss	$ (81,622)	$ (46,519)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization expense	992	136
Amortization of finance lease right-of-use asset	22	85
Amortization of intangible assets	422	—
Gain on disposal of property and equipment	(44)	—
Non-cash operating lease expense	1,486	159
Stock-based compensation expense	3,611	95
Accretion of discounts and amortization of premiums on marketable securities	4	—
Change in fair value of redeemable convertible preferred stock tranche liability	27,696	26,819
Change in fair value of contingent consideration	1,510	—
Research and development expenses paid through issuance of common stock (including $150 to related party for the year ended December 31, 2019)	—	5,982
Financial advisory expenses paid through issuance of common stock	500	—
Deferred income tax	(2,003)	—
Changes in operating assets and liabilities:		
Accounts receivable	818	—
Prepaid expenses and other current assets	(3,586)	(1,150)
Non-current assets	(4,394)	—
Accounts payable (including related party amounts of $(241) and $(231) for the years ended December 31, 2020 and 2019, respectively)	553	283
Accrued and other current liabilities (including related party amounts of $(297) and $409 for the years ended December 31, 2020 and 2019, respectively)	(213)	667
Long-term liabilities	(612)	—
Operating lease liabilities (including related party amounts of $(52) and $(145) for the years ended December 31, 2020 and 2019, respectively)	(423)	(145)
Deferred revenue	(565)	—
Net cash used in operating activities	(55,848)	(13,588)
Cash flows from investing activities		
Cash, cash equivalents and restricted cash acquired in connection with the Merger	74,909	—
Purchases of marketable securities	(16,590)	—
Proceeds from marketable securities	52,000	—
Purchases of property and equipment (including related party amounts of $(270) and $(372) for the years ended December 31, 2020 and 2019, respectively)	(797)	(758)
Proceeds from sale of property and equipment	150	—
Net cash provided by (used in) investing activities	109,672	(758)
Cash flows from financing activities		
Proceeds from issuance of common stock, net of offering costs	109,414	17
Proceeds from issuance of redeemable convertible preferred stock and related tranche rights, net of issuance costs	14,479	25,748
Proceeds from exercise of stock options	362	—
Proceeds from employee stock purchase plan	84	—
Repayment of finance lease liability-related party	(47)	(79)
Net cash provided by financing activities	124,292	25,686
Effect of exchange rate changes on cash, cash equivalents and restricted cash	27	17
Net change in cash, cash equivalents and restricted	178,143	11,357
Cash, cash equivalents and restricted cash, at the beginning of the year	11,357	—
		—
Cash, cash equivalents and restricted cash, at the end of the year	$ 189,500	$ 11,357
Reconciliation of cash, cash equivalents and restricted cash to consolidated balance sheets amounts		
Cash and cash equivalents	$ 187,750	$ 11,203
Restricted cash	1,750	154
Cash, cash equivalents and restricted cash in consolidated balance sheets	$ 189,500	$ 11,357
Supplemental cash flow information		
Cash paid for amounts included in the measurement of lease liabilities included in cash flows used in operating activities (related party)	$ —	$ 323
Supplemental disclosures of noncash investing and financing activities		
Purchases of property and equipment included in accounts payable and in accrued and other current liabilities (including related party amounts of $0 and $506 at December 31, 2020 and 2019, respectively)	$ 425	$ 514
Operating lease right-of-use asset recorded on the adoption of ASC 842-related party	$ —	$ 1,995
Right-of-use asset for office space acquired through leases	$ 1,449	$ —
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	$ 47
Research and development expenses paid through issuance of common stock	$ —	$ 5,982

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

1. Description of Business

Chinook Therapeutics, Inc. (the "Company" or "Chinook") is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing precision medicines for kidney diseases. The Company's lead clinical program is atrasentan, an endothelin receptor antagonist that we in-licensed from AbbVie in late 2019. In March 2021, we initiated the phase 3 ALIGN trial of atrasentan for IgA nephropathy ("IgAN"), in early 2021. The Company's pipeline also includes BION-1301, which is being tested in a phase 1b study in IgAN, and CHK-336 a preclinical candidate for the treatment of primary hyperoxaluria. In addition, the Company is conducting research programs other rare, severe chronic kidney diseases. The Company was incorporated in Delaware and is headquartered in Seattle, Washington.

Reverse Merger, Subscription Agreements and Contingent Value Rights

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, as 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.

In August 2020, Private Chinook entered into subscription agreements (the "Pre-Closing Financing") with certain existing and new investors, pursuant to which the Company agreed to sell, and the investors agreed to purchase, an aggregate of $115.0 million of the Company's common stock. On October 5, 2020, immediately prior to the closing of the Merger, investors purchased 9,583,326 shares of common stock, at a price of $12.00 per share, in the Pre-Closing Financing.

At the effective time of the Merger, the Company issued shares of its 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"). The Company also assumed all of the stock options outstanding under the Private Chinook 2019 Equity Incentive Plan. Unless otherwise noted herein, references to the Company's common share and per-share amounts give retroactive effect to the Exchange Ratio.

At the effective time of the Merger, Aduro 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 contingent value right ("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 the Company upon the receipt of consideration resulting from the disposition or licensing of any of Aduro's non-renal assets, net of any tax, transaction costs and certain other expenses.

The Merger has been accounted for as a business combination pursuant to Accounting Standards Codification ("ASC") Topic 805, Business Combinations. Further, for financial reporting purposes, the transaction has been determined to be a reverse merger, with Private Chinook the accounting acquirer and Aduro the acquired company. As Private Chinook was determined to be the predecessor to Aduro, the accompanying consolidated financial statements reflect the accounts of Private Chinook prior to the Merger (as adjusted to reflect the functional recapitalization that resulted from the Merger) and those of the combined companies after the Merger. Refer to Note 3 for more information.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The consolidated financial statements and related disclosures have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The consolidated financial statements include the Company's accounts and the accounts of Chinook Therapeutics Canada, Inc., the Company's wholly owned Canadian subsidiary ("Chinook Canada"), and Aduro Biotech Holdings, Europe B.V., a wholly owned subsidiary based in the Netherlands ("Aduro Europe"). 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, contingent consideration, 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

The Company operates and manages its business as one reportable and operating segment, which is the business of developing precision medicines for kidney diseases. The Company's 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

The Company is 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 the Company's products and processes and clinical efficacy and safety of the Company's 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.

The Company's product candidates are still in development and, to date, none of the Company's product candidates have been approved for sale and, therefore, the Company has not generated any revenue from product sales.

There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's 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 the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate revenue from product sales. The Company operates in an environment of rapid technological change and substantial competition from other pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees, consultants and other third parties.

Moreover, the current COVID-19 (coronavirus) pandemic, which is impacting worldwide economic activity, poses risk that the Company or its 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 the Company's clinical trials, and negatively impact manufacturing and testing activities performed by third parties. Any significant delays may impact the use and sufficiency of the Company's existing cash reserves, and the Company may be required to raise additional capital earlier than it had previously planned. The Company may be unable to raise additional capital if and when needed, which may result in further delays or suspension of its development plans. The extent to which the pandemic will impact the Company's business will depend on future developments that are highly uncertain and cannot be predicted at this time.

Cash and Cash Equivalents

The Company considers 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 and U.S. government and agency securities. The recorded carrying amount of cash equivalents approximates their fair value.

Restricted Cash

The Company maintains 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 2019, the Company purchased a $0.2 million certificate of deposit to collateralize a credit card account with a commercial bank that was classified as short-term as of December 31, 2019. The certificate of deposit was released as collateral in September 2020 and was no longer restricted.

Marketable Securities

The Company classifies its marketable debt 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 judged to be other-than-temporary, are included in 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 other income (expense), net. Interest earned on all securities are included in other income (expense), net. Investments in securities with maturities of less than one year, or 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.

If the estimated fair value of a debt security is below its carrying value, the Company evaluates whether it is more likely than not that it will sell the security before its anticipated recovery in market value and whether evidence indicating that the cost of the investment is recoverable within a reasonable period of time outweighs evidence to the contrary. The Company also evaluates whether or not it intends to sell the investment. If the impairment is considered to be other-than-temporary, the security is written down to its estimated fair value (with a corresponding charge to the statement of operations). In addition, the Company considers whether credit losses exist for any securities. A credit loss exists if the present value of cash flows expected to be collected is less than the amortized cost basis of the security. Other-than-temporary declines in estimated fair value and credit losses are charged against other income (expense).

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalent, available-for-sale securities and accounts receivable. The Company is exposed to credit risk from its deposits of cash and cash equivalents in excess of amounts insured by the Federal Deposit Insurance Corporation. Substantially all of the Company's cash, cash equivalents and available-for-sale securities are maintained at major financial institutions of high credit standing. The Company monitors the financial credit worthiness of the issuers of its investments and limits the concentration in individual securities and types of investments that exist within its investment portfolio. Generally, all of the Company's investments carry high credit quality ratings, which is in accordance with its investment policy. At December 31, 2020, the Company does not believe there is a significant financial risk from non-performance by the issuers of the Company's cash, cash equivalents, and marketable securities. The Company has 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

The Company established the fair value of its 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, accounts payable and accrued liabilities are carried at cost, which approximates fair value. Refer to Note 5 for more information.

Redeemable Convertible Preferred Stock

The Company records all shares of redeemable convertible preferred stock at their respective fair values on the dates of issuance, net of issuance costs, if applicable. The redeemable convertible preferred stock is recorded outside of permanent stockholders' equity because while it is not mandatorily redeemable, in certain events considered not solely within the Company's control, such as a merger, acquisition, or sale of all or substantially all of the Company's assets (each, a "deemed liquidation event"), the redeemable convertible preferred stock becomes redeemable at the option of the holders of at least a majority of the then outstanding shares.

Redeemable Convertible Preferred Stock Tranche Liability

The Company determined that its 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 represent freestanding financial instruments. These instruments were initially measured at fair value and are subject to remeasurement with changes in fair value recognized in the consolidated statements of operations and comprehensive loss until they are exercised or settled. Refer to Note 10 for more information.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the depreciable assets. Research equipment as well as furniture and fixtures are depreciated over 5 years. Computer equipment and software are depreciated over 3 years. Leasehold improvements are amortized over the shorter of the applicable remaining lease term or the estimated useful life of the related assets. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is reflected in the consolidated statements of comprehensive loss in the year of disposition. Additions and improvements that increase the value or extend the life of an asset are capitalized. Repairs and maintenance costs are expensed as incurred.

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, the Company 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. The Company accounted for the Merger with Aduro as a business combination under the acquisition method of accounting. 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 contingent value rights.

Contingent Value Rights Liability

The estimated fair value of the contingent value rights liability, initially measured and recorded on the Merger date, is considered to be a Level 3 instrument. The contingent value rights liability is recorded at fair value at the end of each reporting period with changes in estimated fair values recorded in research and development expenses in the consolidated statements of operations and comprehensive loss.

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.

The Company's 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 the Company's 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 the Company becomes 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

The Company assesses 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, the Company determines 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. The Company has not recognized any impairment losses through December 31, 2020.

Revenue Recognition

The Company 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, obligations to provide research and development services and obligations to participate on certain development committees with the collaboration party. The terms of such agreements generally include payment to the Company 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. The Company assesses whether the counterparty to the agreement is a customer, as defined by ASC Topic 606, *Revenue from Contracts with Customers*, and whether the promises in these agreements are considered distinct performance obligations that should be accounted for separately. Judgment is required to determine whether the license to the Company's intellectual property is distinct from the research and development services or participation on development committees.

The transaction price in each agreement is allocated to the identified performance obligations based on the standalone selling price, ("SSP"), of each distinct performance obligation. Judgment is required to determine SSP. In instances where SSP is not directly observable, such as when a license or service is not sold separately, SSP is determined using information that may include market conditions and other observable inputs.

Revenue associated with nonrefundable upfront license fees where the license fees and research and development services cannot be accounted for as separate performance obligations is deferred and recognized as revenue over the expected period of performance. The Company utilizes judgment to assess the pattern of delivery of the performance obligation and the appropriate methodology for determining proportional performance. For any payments under contracts not with a customer, the Company applies judgment to determine the appropriate recognition method.

As of the closing of the Merger, the Company considered all remaining performance obligations under the assumed agreements to determine appropriate revenue recognition. For agreements that include development, regulatory or commercial milestone payments, the Company evaluated whether the milestones are considered probable of being reached and concluded that all such milestones are not within the control of the Company 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.

The Company also assumed an existing out-license agreement with Merck under which all performance obligations of Aduro were completed prior to the Merger. The Company is 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, the Company is eligible to receive royalties based on net sales of the product. Any such milestones and royalties earned will be payable by the Company to the holders of the CVRs, after deduction for any associated expenses.

Research and Development Expense

Research and development expenses consist primarily of salaries, benefits and stock-based compensation for the Company's personnel in research or development functions, licensing costs, occupancy, materials and supplies, contracted research and manufacturing, consulting arrangements and other expenses incurred to advance the Company's research and development programs. Research and development costs are expensed as 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. 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.

Accrued Research and Development

The Company has entered into various contract research agreements. Accruals for the related research and development expense are estimated based on the level of services performed, progress of the research, including the phase or completion of events, and contracted costs. The estimated costs of research and development provided, but not yet invoiced, are included in accrued and other current liabilities on the consolidated balance sheets. If the actual timing of the performance of services or the level of effort varies from the original estimates, the Company will adjust the accrual accordingly. Payments made under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets until the services are rendered.

Patent Costs

Costs related to filing and pursuing patent applications are expensed as incurred, as recoverability of such expenditures is uncertain. These patent-related legal costs are reported as a component of general and administrative expense.

General and Administrative Expense

General and administrative costs are expensed as incurred and include employee-related expenses including salaries, benefits, travel and stock-based compensation for the Company's personnel in executive, finance and accounting, and other administrative functions, as well as fees paid for legal, accounting and tax services, consulting fees and facilities costs not otherwise included in research and development expense. Legal costs include general corporate legal fees and patent costs.

Leases

The Company leases its facilities and meets the requirements to account for these leases as operating leases. Until April 2020, the Company was leasing all of its equipment under a lease arrangement that was required to be accounted for as a finance lease. Accordingly, at December 31, 2019 finance lease assets were included in property and equipment, net, and finance lease liabilities were reported as finance lease liabilities and finance lease liabilities, net of current maturities on the Company's consolidated balance sheets.

The Company determines if an arrangement is a lease at inception. The Company has made a policy election to not separate lease and non-lease components for its real estate leases to the extent they are fixed. Non-lease components that are not fixed are expensed as incurred as variable lease expense. The Company's 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 the Company's consolidated balance sheets. Operating lease ROU assets represent the Company's right to use an underlying asset for the lease term and operating lease liabilities represent the Company's 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 the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate, obtained from the Company's 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 the Company's 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. The Company's leases may include options to extend or terminate the lease; lease terms are only adjusted for these options when it is reasonably certain that the Company 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 the Company 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.

The Company has subleased a substantial portion of its leased facilities under agreements considered to be operating leases according to ASC 842. The Company has not been legally released from its primary obligations under the original lease and therefore it continues to account for the original lease as it did before commencement of the subleases. The Company records both fixed and variable payments received from the sublessees in its statements of operations on a straight-line basis as an offset to rent expense.

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. The Company establishes a valuation allowance for deferred tax assets if it is more likely than not that these items will expire before the Company is able to realize its benefits or that future deductibility is uncertain.

The Company recognizes 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. The Company recognizes 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 the Company's 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 the Company's common stock requires significant judgment and management considered several factors, including the Company's stage of development, equity market conditions affecting comparable public companies, significant milestones and progress of research and development efforts.

Stock-Based Compensation

The Company measures and recognizes 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.

The Company uses the Black-Scholes option pricing model to measure the fair value of stock option awards when they are granted. The Company makes 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, the Company based its 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, the Company is 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 Company uses the simplified method to calculate the expected term for options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting-tranche for awards with graded vesting. The mid-point between the vesting date and the maximum contractual expiration date is used as the expected term under this method. For awards with multiple vesting-tranches, the times from grant until the mid-points for each of the tranches may be averaged to provide an overall expected term. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. The Company uses an assumed dividend yield of zero as the Company has never paid dividends and has no current plans to pay any dividends on its 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. The Company records forfeitures as incurred.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as a change in equity of a business enterprise during a period, resulting from transactions from non-owner sources. The other comprehensive loss disclosed in the Company's consolidated statements of operations and comprehensive loss for the years ended December 31, 2020 and 2019 consists of foreign currency translation adjustments and unrealized gains (losses) on marketable debt securities.

Net Loss per Share Attributable to Common Stockholders

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 outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, the redeemable convertible preferred stock, redeemable convertible preferred stock tranche liability, common stock subject to repurchase, warrants, and stock options are considered to be potentially dilutive securities. Basic and diluted net loss per share attributable to common stockholders is presented in conformity with the two-class method required for participating securities as the redeemable convertible preferred stock and early exercised stock options are considered to be participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income (loss) available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to share in undistributed earnings as if all income (loss) for the period had been distributed. The Company's participating securities do not have a contractual obligation to share in the Company's losses. Accordingly, the Company's net loss is attributed entirely to common stockholders. Since the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods.

Foreign Currency

The Company's functional currency, which is determined by the currency of the economic environment in which the majority of its cash is generated and expended, is the U.S. dollar.

The functional currency of our foreign subsidiaries is either the Canadian dollar or the U.S. dollar. For Chinook Canada 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 within stockholders' equity. Remeasurement adjustments are recorded in 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

Accounting Pronouncements Not Yet Adopted

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. The standard is effective for smaller reporting companies in fiscal years beginning after December 15, 2022 with early adoption permitted for all periods beginning after December 15, 2018. The Company does not plan to early adopt ASU No. 2016-13 and is currently evaluating the impact the adoption of this ASU will have on its consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12 – *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. The standard update simplifies the accounting for income taxes by removing certain exceptions to the general principles in ASC 740 and also improves consistent application by clarifying and amending existing guidance. The standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The Company is assessing the impact of ASU No. 2019-12 and is continuing to evaluate its impact on the consolidated financial statements.

Recently Adopted Accounting Pronouncements

In August 2018, the FASB issued ASU No. 2018-13 – *Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*. The standard eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information, and modifies some disclosure requirements. The new standard is effective for fiscal years and interim periods beginning after December 15, 2019. Early adoption is permitted upon issuance of this ASU. Entities making this election to early adopt are permitted to early adopt the eliminated or modified disclosure requirements and delay the adoption of the new disclosure requirements until their effective date. The Company adopted the new standard on January 1, 2020, which resulted in the Company no longer being required to disclose (1) the amount of and the reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, (2) the policy for timing of transfers between levels, and (3) the valuation process for Level 3 fair value measurements. Additionally, the Company is required to disclose (1) the changes in unrealized gains and losses for the period included in other comprehensive income (loss) for recurring Level 3 fair value measurements held at the end of the reporting period and (2) the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements.

3. Reverse Merger

On October 5, 2020, the Merger closed on the terms described in more detail in Note 1 and the Company acquired 100 percent equity interest in Private Chinook by issuing 16,307,177 shares of common stock. Immediately after the Merger, there were 42,158,435 shares of common stock outstanding, and Private Chinook's former stockholders and option holders owned, or held rights to acquire, approximately 61 percent of the fully-diluted common stock of the Company.

For accounting purposes, no adjustments were made to Private Chinook's historical financial statements to reflect the Merger, other than adjustments to reflect Aduro's historical legal capital structure and to adjust Private Chinook's historical share and per share amounts to reflect the Exchange Ratio.

In addition to the operating assets and liabilities of Aduro, the Company also acquired Aduro's tax attributes, which primarily consisted of net operating loss carryforwards which begin to expire in 2025. The Company's ability to utilize the tax attributes of Aduro may be limited under Section 382 of the U.S. Internal Revenue Service and as such, have been reserved. A deferred tax liability was recorded related to future tax benefits arising from in-process research and development ("IPR&D") and other intangible assets held by Aduro.

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):

Value of shares of the combined company owned by Aduro equity holders (1)	$	238,003
Fair value of Aduro stock options and warrants -pre-combination services (2)		10,628
Estimated fair value of CVR (3)		12,270
Total fair value of consideration	$	260,901

(1) Comprised of 16,307,177 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 contingent value right (“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 the Company’s balance sheets. Management’s determination of the estimated fair values of the assets acquired and liabilities assumed required significant judgment, which 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 final allocation of the purchase price was as follows (in thousands):

	Fair Value
Assets:	
Cash and cash equivalents	$ 73,159
Marketable securities	98,057
Accounts receivable	1,122
Prepaids and other current assets	1,757
Property and equipment, net	19,039
Operating lease right-of-use assets	53,704
Intangible assets	28,118
IPR&D	39,295
Goodwill	22,441
Restricted cash	1,750
Other assets	295
Total assets acquired	338,737
Liabilities:	
Accounts payable	2,280
Accrued clinical trial and manufacturing expenses	1,632
Accrued compensation	6,854
Accrued and other current liabilities	6,092
Deferred revenue, current	660
Operating lease liability, current	2,230
Existing contingent consideration	1,800
Deferred tax liabilities	18,372
Operating lease liabilities, non-current	36,474
Other non-current liabilities	1,442
Total liabilities assumed	77,836
Net Fair Value	$ 260,901

The Company 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") in-process research and development intangible asset of $32.4 million was determined using a probability-weighted discounted cash flow model prepared under the multi-period excess earnings method and the fair value of the acquired Merck license agreement intangible assets of $26.7 million and contingent consideration liabilities for related contingent value rights of $10.8 million were valued under the income method using a probability-weighted discounted cash flow model and a Monte Carlo simulation model. The Company 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 in-process research and development 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 right-of-use asset and were 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 is expected to be satisfied within the next 12 months.

The existing contingent consideration 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.

The transaction costs of the Company were $4.5 million, which were expensed as incurred.

Pro Forma Financial Information

The Company's operating results for the period October 5, 2020 through December 31, 2020 include $0.8 million of revenue and $13.5 million of operating expenses attributable to the former Aduro business activities.

The following pro forma consolidated results of operations for the year ended December 31, 2020 assume the business combination was completed as of January 1, 2019 (in thousands, except per share amounts):

	Year Ended December 31, 2020	Year Ended December 31, 2019
Pro forma revenues	$ 14,904	$ 4,213
Pro forma net loss	$ (92,666)	$ (134,481)

For purposes of the pro forma disclosures above, pro forma adjustments primarily relate to the following non-recurring items directly attributable to the business combination:

- Elimination of revenue of $9.2 million and $13.0 million for the years ended December 31, 2020 and 2019, respectively, due to the deferred revenue fair value adjustment;
- Elimination of transaction costs of $11.0 million for the year ended December 31, 2020. The year ended December 31, 2019 pro forma earnings were adjusted to include these charges;
- Elimination of severance bonuses and other expenses contingent upon the change in control of approximately $6.6 million for the year ended December 31, 2020. The year ended December 31,2019 pro forma earnings were adjusted to include these charges.
- Elimination of the impact of the change in fair value of Private Chinook's redeemable convertible preferred stock tranche liability of $27.7 million and $26.8 million for the years ended December 31, 2020 and 2019, respectively, which tranche rights were terminated in connection with the closing of the Merger;
- Addition of rent expense of $1.0 million and $1.3 million for the years ended December 31, 2020 and 2019, respectively, due to the favorable terms of the lease fair value adjustment to the operating lease right-of-use asset.
- Addition of amortization expense of $0.7 million and $0.9 million for the years ended December 31, 2020 and 2019, respectively, due to the fair value adjustment of Aduro's anti-CD27 antibody intangible asset.

4. Cash, Cash Equivalents and Marketable Securities

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

	December 31, 2020			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated Fair Value
Cash and cash equivalents:				
Cash	$ 5,659	$ —	$ —	$ 5,659
Money market funds	113,592	—	—	113,592
Certificate of deposit	157	—	—	157
Commercial paper	40,844	—	—	40,844
U.S. government and agency securities	27,498	—	—	27,498
Total cash and cash equivalents	$ 187,750	$ —	$ —	$ 187,750
Marketable securities:				
Commercial paper	$ 35,089	$ —	$ —	$ 35,089
U.S. government and agency securities	26,026	6	(3)	26,029
Corporate debt securities	1,504	—	—	1,504
Total marketable securities	$ 62,619	$ 6	$ (3)	$ 62,622

	December 31, 2019			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated Fair Value
Cash and cash equivalents:				
Cash	$ 1,865	$ —	$ —	$ 1,865
Money market funds	9,338	—	—	9,338
Total cash and cash equivalents	$ 11,203	$ —	$ —	$ 11,203

Marketable securities that were in a continuous unrealized loss position are summarized below as of December 31, 2020 (in thousands):

	Amortized cost	Unrealized gains	Unrealized losses	Estimated Fair Value
Mature in one year or less	$ 59,620	$ 5	$ (3)	$ 59,622
Mature after one year through two years	2,999	1		3,000
Total available-for-sale marketable securities	$ 62,619	$ 6	$ (3)	$ 62,622

None of the Company's marketable securities were in a continuous unrealized loss position as of December 31, 2020.

The Company reviews the individual securities in its portfolio to determine whether a decline in a security's fair value below the amortized cost basis is other-than-temporary. The Company determined that as of December 31, 2020, there were no investments in its portfolio that were other-than-temporarily impaired.

5. Fair Value Measurements

The Company records certain financial assets and liabilities at fair value in accordance with the provisions of ASC Topic 820 on fair value measurements. As defined in the guidance, fair value, defined as an exit price, represents the amount that would be received to sell an asset or pay to transfer a liability in an orderly transaction between market participants. As a result, fair value is a market-based approach that should be determined based on assumptions that market participants would use in pricing an asset or a liability. As a basis for considering these assumptions, the guidance defines a three-tier valuation hierarchy that prioritizes the inputs used in the valuation methodologies in measuring fair value.

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 fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. 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. The Company considers 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 the Company's 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, 2020			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents (1):				
Money market funds	$ 113,592	$ —	$ —	$ 113,592
Certificate of deposit	—	157	—	157
Commercial paper	—	40,844	—	40,844
U.S. government and agency securities	—	27,498	—	27,498
Total cash equivalents	113,592	68,499	—	182,091
Marketable securities:				
Commercial paper	—	35,089	—	35,089
U.S. government and agency securities	—	26,029	—	26,029
Corporate debt securities	—	1,504	—	1,504
Total marketable securities	—	62,622	—	62,622
Total fair value of assets	$ 113,592	$ 131,121	$ —	$ 244,713
Liabilities				
Contingent value rights liability	$ —	$ —	$ 13,780	$ 13,780
Contingent consideration related to acquisition	—	—	1,800	1,800
Total fair value of liabilities	$ —	$ —	$ 15,580	$ 15,580

(1) Included in cash and cash equivalents in the consolidated balance sheets

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents (1):				
Money market funds	$ 9,338	$ —	$ —	$ 9,338
Total cash equivalents	9,338	—	—	9,338
Restricted cash:				
Certificate of deposit	—	154	—	154
Total restricted cash	—	154	—	154
Total fair value of assets	$ 9,338	$ 154	$ —	$ 9,492
Liabilities				
Redeemable convertible preferred stock tranche liability	$ —	$ —	$ 32,733	$ 32,733
Total fair value of liabilities	$ —	$ —	$ 32,733	$ 32,733

(1) Included in cash and cash equivalents in the consolidated balance sheets

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, as well as certificate of deposit, 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 the Company's Level 3 financial instruments (in thousands):

	Redeemable Convertible Preferred Stock Tranche Liability	Contingent Value Rights Liability	Contingent Consideration Related to Acquisition
Fair Value as of January 1, 2019	$ —	$ —	$ —
Recognition of redeemable convertible preferred stock tranche liability	5,914	—	—
Change in fair value	26,819	—	—
Fair Value as of December 31, 2019	32,733	—	—
Exercise	(9,723)	—	—
Change in fair value	27,696	—	—
Terminated in connection with the Merger	(50,706)	—	—
Assumed in the Merger	—	12,270	1,800
Change in fair value	—	1,510	—
Fair Value as of December 31, 2020	$ —	$ 13,780	$ 1,800

The fair values of the redeemable convertible preferred stock tranche liability, contingent value rights liability, and contingent consideration related to acquisition are based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy. In determining the fair value of the redeemable convertible preferred stock tranche liability, the Company used the Probability-Weighted Expected Return Method, "PWERM" (see Note 10). In determining the fair value of the contingent value rights liability and the contingent consideration related to acquisition, the Company used a probability-adjusted, scenario-based income approach. For the year ended December 31, 2020, the change in fair value of the contingent value rights liability and the contingent consideration related to acquisition, totaling $1.5 million, was recorded in the statement of operations.

6. Property and Equipment, Net and Finance Lease Right-of-Use Asset

Property and equipment, net and finance lease right-of-use asset consisted of the following (in thousands):

	December 31,	
	2020	2019
Research and lab equipment	$ 3,616	$ 640
Computer equipment	921	57
Computer software	27	10
Furniture and fixtures	1,099	84
Leasehold improvements	16,111	464
	21,774	1,255
Total accumulated depreciation	(1,148)	(139)
Property and equipment, net	20,626	1,116
Finance lease right-of-use asset	—	195
Property and equipment, net and finance lease right-of use asset	$ 20,626	$ 1,311

Depreciation and amortization expense for property and equipment for the years ended December 31, 2020 and 2019 was $1.1 million and $0.1 million, respectively. Approximately $2.1 million of the Company's property and equipment as of December 31, 2020 is located at Chinook Canada.

Amortization of finance lease right-of-use assets for the years ended December 31, 2020 and 2019, was $1.2 million and $0.1 million, respectively. The finance lease right-of-use assets obtained in exchange for finance lease liabilities were $0.3 million.

7. Intangible Assets and Goodwill

Goodwill

The gross carrying amount and net book value of goodwill was $22.4 million at December 31, 2020, all of which resulted from the Merger. Refer to Note 3 for more information. The Company tests goodwill for impairment on an annual basis or more frequently if an impairment indicator exists. To determine if an impairment has occurred, the Company performs a quantitative test in which the Company compares the fair value of its single reporting unit to its carrying value. If the carrying value of the reporting unit exceeds the fair value of the reporting unit, the Company records 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, 2020		
	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Intangible assets with finite lives:			
Acquired license agreement	$ 26,685	$ 398	$ 26,287
In-place lease	1,433	24	1,409
Total intangible assets with finite lives	28,118	422	27,696
Acquired IPR&D assets	39,295	—	39,295
Total intangible and acquired IPR&D assets	$ 67,413	$ 422	$ 66,991

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

Amortization expense was $0.4 million and $0 for the years ended December 31, 2020, and 2019, respectively. Based on finite-lived intangible assets recorded as of December 31, 2020, the estimated future amortization expense for the next five years is as follows (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2021	$ 1,688
2022	1,722
2023	1,733
2024	1,733
2025	1,733

8. Accrued Liabilities and Other

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

	December 31,	
	2020	2019
Clinical trial accruals	$ 8,004	$ —
Personnel costs	4,530	621
Sublease rent and security deposit	1,400	—
Business taxes and licensing fees	898	67
Consulting and outside services	499	73
External research services	131	—
Property and equipment	—	489
Other	212	—
Total accrued and other current liabilities	$ 15,674	$ 1,250

9. Collaboration and License Agreements

AbbVie Ireland Unlimited Company

On December 16, 2019, the Company entered into a license agreement (the "License Agreement") with AbbVie Ireland Unlimited Company ("AbbVie"), which granted the Company an exclusive license to atrasentan, an endothelin receptor antagonist, under AbbVie's patent rights to develop and commercialize licensed products for the treatment of rare, severe chronic kidney diseases. Under the agreement, the Company assumes all global development and commercialization responsibilities for atrasentan. In consideration of the license and rights granted under the License Agreement, the Company made an upfront cash payment and issued 1,999,415 shares of common stock for total consideration of $6.7 million to AbbVie. The Company concluded that this transaction should be accounted for as an asset purchase, and as such, recorded the associated expense within research and development expense on the Company's 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, the Company is obligated to make contingent development, regulatory and commercial milestone payments, of up to a maximum of $135 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. Prior to entering this License Agreement, AbbVie was not a related party.

The Company did not recognize any milestone payments for the years ended December 31, 2020 and 2019. As of December 31, 2020 and 2019, the Company did not have any payable or receivable balances associated with the License Agreement.

Merck

In connection with Merger, the Company 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. The Company is eligible to receive future contingent payments, including up to $297.0 million in potential development milestone payments, and up to $135.0 million in commercial and net sales milestones for a product candidate. In addition, the Company is 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 the Company has no performance obligations under this agreement. Any such milestones and royalties earned will be payable by the Company to the holders of the CVRs, after deduction for any associated expenses.

Eli Lilly and Company

In connection with the Merger, the Company 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. The Company's only remaining performance obligation under the agreement is to perform research services through 2021, for which it is reimbursed up to a specified amount each year. The Company is eligible to receive future contingent milestone payments of up to approximately $620.0 million per licensed product and tiered royalties on net sales at percentages in the single to low-double digits.

For revenue recognition purposes, the Company evaluated the agreement as of the date of the Merger and estimated it would incur research costs of $1.0 million over the remaining performance period, for which it would receive reimbursement of $0.4 million from Lilly. The Company applied ASC 606 by analogy, such that deferred revenue was recognized related to the non-reimbursable research services and collaboration revenue was recognized as services were delivered and for reimbursements received. The Company determined that the potential milestone payments are not considered probable of being achieved and, accordingly, such milestones will be recognized as revenue when earned. For the year ended December 31, 2020, the Company recognized revenue of $0.8 million under the Lilly agreement.

Novartis Pharmaceuticals Corporation

In connection with the Merger, the Company assumed an ongoing collaboration and license agreement with Novartis Pharmaceuticals Corporation ("Novartis") for the development and potential commercialization of product candidates in the field of oncology. Under this agreement, the Company and Novartis intend to jointly develop product candidates and share commercialization rights geographically. The Company is responsible for 38 percent of the joint development costs worldwide and Novartis is responsible for the remaining 62 percent of the joint development costs worldwide; provided that either party may opt out of early-stage clinical trials subject to an obligation to fund and participate in any pivotal trials and reimburse certain early development costs if development of the product progresses into pivotal trials.

The Company is eligible to receive up to $215.0 million in future development milestones and up to an additional $250.0 million in regulatory approval milestones. The Company will be entitled to 50 percent of gross profits on sales of any products commercialized pursuant to this collaboration in the United States and 45 percent of gross profits for specified European countries and Japan. For each of these profit share countries, each party will be responsible for its respective commercial sharing percentage of all joint commercialization costs incurred in that country. For all other countries where the Company is not sharing profits, Novartis will be responsible for all commercialization costs and will pay the Company a royalty in the mid-teens on all net sales.

With respect to the profit share countries, the Company may elect for any region to reduce by 50 percent its development and commercialization cost sharing obligation, in which case its profit share in such region will also be reduced by 50 percent. Alternatively, the Company may elect for any region to eliminate its development cost sharing obligation, in which case Novartis will owe the Company royalties in the mid-teens on any net sales of product for such region.

The Company evaluated the agreement as of the date of the Merger and concluded that its only undelivered unit of account was development cost sharing, which is outside the scope of ASC 606. The Company will record any amounts paid to Novartis under the agreement as research and development expense and any amounts received from Novartis as an offset to research and development expense. The Company determined that the potential milestone payments are not considered probable of being achieved and, accordingly, such milestones will be analogized to ASC 606 and recognized as revenue when earned. For the year ended December 31, 2020, the Company recognized $0.1 million payable to Novartis under the agreement as research and development expense.

10. Redeemable Convertible Preferred Stock Tranche Liability

The terms of the Series A redeemable convertible preferred stock agreement include provisions requiring the investors to purchase, and obligating the Company to deliver, additional shares of redeemable convertible preferred stock at a specified price in the future based on the achievement by the Company of certain development-based milestones (see Note 11). 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, in accordance with guidance applicable to freestanding instruments to issue shares that are redeemable, at the estimated fair value of the obligation on the date of issuance with their carrying values adjusted at each reporting date for any changes in their estimated fair values.

The Company estimated the fair value of the redeemable convertible preferred stock tranche liability related to each milestone utilizing the income approach using unobservable inputs including (a) future per share value of Series A redeemable convertible preferred stock upon achievement of the milestone, (b) estimated term until date of milestone achievement, and (c) probability of milestone achievement. The future per share value of Series A redeemable convertible preferred stock upon achievement of the milestone and the probability of milestone achievement for each tranche were calculated on a probability-weighted basis giving equal weighting to public offering and private exit scenarios. The future cash flows were discounted to their fair values as of the valuation date using one or more discount rates, depending on the number of probability-weighted scenarios employed. The redeemable convertible preferred stock tranche liability was valued as of the dates indicated using the following weighted, where applicable, assumptions:

	Value of Future Series A Redeemable Convertible Preferred Stock	Term	Probability
February 6, 2019 (upon issuance)	$1.05 – $2.49	1.15 – 3.40 years	39% – 75%
December 31, 2019	$1.69 – $2.61	0.17 – 0.75 years	71% – 93%

For the February 6, 2019 valuation date, the Company utilized a discount rate of 10 percent. For the December 31, 2019 valuation date, the Company used multiple discount rates of 10 percent. and 40 percent.

Upon issuance, the fair value of the redeemable convertible preferred stock tranche liability was recorded as a reduction in the amounts paid by investors for the purchase of Series A redeemable convertible preferred stock.

Upon closing of the Merger, the outstanding redeemable convertible preferred stock tranche rights terminated pursuant to the terms of the merger agreement. 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.

11. Redeemable Convertible Preferred Stock

In February 2019, as amended in July 2019, the Company entered into a Series A financing transaction, pursuant to which the Company was authorized to issue up to 18,992,220 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 issuance consisted of four tranches:

- The first tranche consisted of two closings, the first in February 2019 resulting in the issuance of 5,843,760 shares at $3.4225 per share, for total gross proceeds of $20.0 million, out of which 3,895,840 shares were issued to an existing common stock shareholder at $3.4225 per share, for total gross proceeds of $13.3 million. The second closing occurred in July 2019, resulting in the issuance of 1,753,126 shares at $3.4225 per share, for total gross proceeds of $6.0 million.
- The second tranche is for 4,236,726 shares and initially required either (i) the Company's delivery of a written certification by the Board, including at least two of the Preferred Directors (the "Preferred Director Approval"), of nomination by the Company's management of one development candidate for initiation of investigational new drug ("IND")-enabling development in any indication, or (ii) the waiver by the Requisite Purchasers (as defined in the Series A stock purchase agreement) of the satisfaction of the above closing condition. Commensurate with the third tranche financing in February 2020, the Board revised the second tranche so it requires the Company's delivery of a written certification by the Board, including the Preferred Director Approval, of the Company's cash and cash equivalents being less than or equal to $10.0 million. Upon closing of the Merger, and conversion of all redeemable convertible preferred stock to common stock, the second tranche had not closed and the rights terminated.
- The third tranche is for 4,236,726 shares and requires either (i) the Company's delivery of a written certification by the Board, including the Preferred Director Approval, of (A) achievement of one of the following milestone events of (a) nomination by the Company's management and approval by the Board, including the Preferred Director Approval, of a second development candidate (which may be a Board approved in-licensed compound) for initiation of IND-enabling development in any indication other than that addressed by the development candidate that satisfied the second closing milestone, or (b) filing of an IND by the Company with no hold placed on the program after the 30-day waiting period, or (c) closing of a strategic partnership, acceptable to the Board, that either (1) yields at least $20.0 million in upfront consideration, or (2) results in the in-license by the Company of an IND-ready or clinical-stage program in any indication, and (B) the Company's cash and cash equivalents balance being less than or equal to $5.0 million, or (ii) the waiver by the Requisite Purchasers of the satisfaction of the above closing conditions. This tranche closed on February 5, 2020 resulting in the issuance of 4,236,724 shares at $3.4225 per share, for total gross proceeds of $14.5 million.
- The fourth tranche is for 2,921,880 shares and requires either (i) the Company's delivery of a written certification by the Board, including the Preferred Director Approval, of (A) achievement of one of the following milestone events of (a) a clinical study in any program has provided evidence of pharmacologic activity or efficacy that constitutes clinical proof of concept sufficient to justify further development of that program and there are no safety findings that prevent commercially reasonable further development of that program, or (ii) filing of a second IND in any indication except that addressed by the Company's first IND if such lead program still is successfully progressing, or (iii) closing of a strategic partnership, acceptable to the Board that either yields at least $50.0 million in upfront consideration or results in the in-license by the Company of an IND-ready or clinical-stage program in any indication not already under active development, and (B) the Company's cash and cash equivalents balance being less than or equal to $5.0 million, or (ii) the waiver by the Requisite Purchasers of the satisfaction of the above closing conditions. Upon closing of the Merger, and conversion of all redeemable convertible preferred stock to common stock, the fourth tranche had not closed and the rights terminated.

As of December 31, 2020, all redeemable convertible preferred stock had been converted to common stock. As of December 31, 2019, redeemable convertible preferred stock consisted of the following (in thousands, except per share and share amounts):

	Shares Authorized	Original Issue Price	Shares Issued and Outstanding	Carrying Value	Liquidation Preference
Series A	65,000,000	$ 3.4225	7,596,886	$ 19,835	$ 26,000

The rights, preferences, privileges and restrictions granted to or imposed on the respective classes of the Company's capital stock or the holders thereof are as follows:

Voting

The Series A redeemable convertible preferred stockholders vote with the common stockholders on an as converted basis into common stock and as a single class.

The holders of shares of Series A redeemable convertible preferred stock shall be entitled, voting separately as a single class, to elect four directors of the Company (the "Series A Directors"). The holders of shares of common stock shall be entitled, voting separately as a single class, to elect one director of the Company. The holders of shares of common stock and redeemable convertible preferred stock shall be entitled, voting together, to elect the remaining directors of the Company.

Dividends

Holders of the Series A redeemable convertible preferred stock are entitled to noncumulative dividends at an annual rate of $0.2738 per share, when and if declared by the Board.

The Company shall not declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Company in any fiscal year unless the holders of the Series A redeemable convertible preferred stock then outstanding shall first receive, or simultaneously receive, a dividend on each outstanding share of Series A redeemable convertible preferred stock in an amount at least equal to (i) all declared but unpaid dividends with respect to all outstanding shares of Series A redeemable convertible preferred stock, (ii) in the case of a dividend on common stock or any class or series that is convertible into common stock, that dividend per share of Series A redeemable convertible preferred stock as would equal the product of (A) the dividend payable on each share of such class or series determined on an as-converted basis, if applicable, and (B) the number of shares of common stock issuable upon conversion of a share of Series A redeemable convertible preferred stock, in each case calculated on the record date for determination of holders entitled to receive such dividend or (iii) in the case of a dividend on any class or series that is not convertible into common stock, at a rate per share of Series A redeemable convertible preferred stock determined by (A) dividing the amount of the dividend payable on each share of such class or series of capital stock by the original issuance price of such class or series of capital stock subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to such class or series ("recapitalizations") and (B) multiplying such fraction by an amount equal to the Series A original issue price.

No dividends have been declared or paid to date.

Conversion

Each share of Series A redeemable convertible preferred stock shall be convertible, at the option of the holder, at any time and from time to time, and without the payment of additional consideration, into such number of fully paid and non-assessable shares of common stock as is determined by dividing the Series A redeemable convertible preferred stock original issue price by the Series A redeemable convertible preferred stock conversion price in effect at the time of conversion. The Series A conversion price shall initially be equal to $3.4225. If, after the issuance date of the Series A redeemable convertible preferred stock, the Company issues or sells, or is deemed to have sold, additional shares of common stock without consideration or for a consideration per share less than the conversion price of Series A redeemable convertible preferred stock in effect immediately prior to the issuance of such additional shares of common stock, except for certain exceptions allowed, the conversion price of Series A redeemable convertible preferred stock would be adjusted. All shares of Series A redeemable convertible preferred stock converted into the Company's shares of common stock on a one-for-one basis prior to closing of the Merger.

Liquidation

In the event of any (i) voluntary or involuntary liquidation, dissolution or winding up of the Company; or (ii) a merger, acquisition or consolidation of the Company, any transaction or series of transactions in which more than 50 percent of the voting power of the Company is transferred, or a sale, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, of all or substantially all of the assets of the Company (each of such events a "Deemed Liquidation Event"), the holders of shares of Series A redeemable convertible preferred stock then outstanding shall be entitled to be paid before any payment shall be made to the holders of common stock an amount per share equal to the Series redeemable convertible preferred stock's original issue price of $3.4225 per share, plus any dividends declared but unpaid thereon.

If upon any such liquidation, dissolution or winding up of the Company or Deemed Liquidation Event, the assets of the Company available for distribution to its stockholders shall be insufficient to pay the holders of shares of Series A redeemable convertible preferred stock the full amount to which they shall be entitled, the holders of shares of Series A redeemable convertible preferred stock shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

After the payment to the holders of Series A redeemable convertible preferred stock of the full preferential amounts specified above, all of the remaining assets of the Company available for distribution to stockholders shall be distributed among the holders of Series A redeemable convertible preferred stock and common stock pro rata based on the number of shares of common stock held by each such holder on an as-converted basis.

Redemption and Balance Sheet Classification

The redeemable convertible preferred stock is recorded within mezzanine equity on the balance sheets because while it is not mandatorily redeemable, it becomes redeemable at the option of the stockholders upon the occurrence of certain deemed liquidation events that are considered not solely within the Company's control.

12. Common Stock

The Company is authorized to issue common stock, with a par value of $0.0001 per share. As of December 31, 2020, and 2019, there were 300,000,000 shares of common stock authorized.

Common stockholders are entitled to dividends if and when declared by the Board of Directors (the "Board") subject to the prior rights of preferred stockholders, if any. As of December 31, 2020, and 2019, no dividends on common stock had been declared by the Board.

The Company had the following shares of common stock reserved for future issuance:

	December 31,	
	2020	2019
Conversion of redeemable convertible preferred stock	—	7,596,886
Conversion of redeemable convertible preferred stock issuable upon settlement of the redeemable convertible preferred stock tranche liability	—	11,395,332
Common stock warrants	10,032	—
Restricted stock units	440,540	—
Employee stock purchase plan	298,840	—
Stock options issued and outstanding	5,513,581	730,116
Stock options available for future grant	894,227	500,535
Total shares of common stock reserved for future issuance	7,157,220	20,222,869

Warrants

The Company assumed certain common stock warrants in the Merger. At December 31, 2020, there were warrants outstanding on 10,032 shares of common stock with a weighted average exercise price of $0.52 per share and expiration dates ranging from 2021 to 2023.

Restricted Stock

The Company has sold 556,490 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 the Company has the option to repurchase unvested shares at the lower of the amount paid at grant or the fair market value as of repurchase date.

Given the absence of a public trading market for the Company's common stock when the restricted stock was issued, the Company exercised reasonable judgment and considered numerous objective and subjective factors to determine the best estimate of the fair value of the common stock at each issuance date.

Activity with respect to restricted stock was as follows:

	Number of Shares Underlying Outstanding Restricted Stock	Weighted Average Grant Date Fair Value
Unvested, January 1, 2020	415,809	$ 0.00034
Repurchased	(71,951)	$ 0.00034
Vested	(147,939)	$ 0.00034
Unvested, December 31, 2020	195,919	$ 0.00034

The fair value of restricted stock vested during the years ended December 31, 2020 was less than $0.1 million.

13. 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, all stock options outstanding under the 2019 Plan converted into options to purchase shares of Aduro common stock, as renamed Chinook, and the applicable share amounts and exercise prices were adjusted to reflect the Exchange Ratio. Under the 2019 Plan, up to 13,559 shares of the Company's common stock, in the form of incentive and nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, and other stock awards, may be granted to eligible employees, directors, and consultants.

In connection with the Merger, the Company assumed Aduro's two equity incentive plans, the 2015 Equity Incentive Plan (the "2015 Plan") and the 2009 Stock Incentive Plan (the "2009 Plan") (together, the "Aduro Plans"). Options are outstanding under both Aduro Plans, and restricted stock units are outstanding under the 2015 Plan. No additional grants may be made from the 2009 Plan; however, shares subject to awards granted under the 2009 Plan that cancel or expire unexercised revert to and become available for re-grant under the 2015 Plan, which provides for the granting of incentive and nonqualified stock options and other forms of stock awards to its employees, directors and consultants. 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. Upon assumption of the Aduro Plans, a total of 880,668 shares of common stock were authorized for future issuance. 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. The Company intends that the 2015 Plan will be its primary equity incentive plan in the future.

Because Private Chinook is considered to be the acquirer for accounting purposes, the pre-Merger vested stock options granted by Aduro under the Aduro Plans are deemed to have been exchanged for equity awards of the Company and as such the portion of the acquisition date fair value of these equity awards attributable to pre-Merger service to Aduro were accounted for as a component of the Merger consideration. The exchange of Private Chinook stock options for options to purchase Company common stock was accounted for as a modification of the Private Chinook stock options; however, the modification did not result in any incremental compensation expense as the modification did not increase the fair value of the stock options.

The 2019 Plan and the Aduro Plans (the "Plans") are administered by the Board of Directors, or a committee of the 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 the Company's 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. Vested options can be exercised at any time.

Stock Options

A summary of stock option activity is set forth below (aggregate intrinsic value in thousands):

		Outstanding Awards			
	Number of Shares Available for Grant	Number of Shares Underlying Outstanding Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding, January 1, 2020	500,535	730,120	$ 0.34	9.41	$ 1,872
Options authorized	1,245,282	—			
Options granted	(3,019,582)	3,019,582	$ 8.47		
Restricted stock units granted	(434,240)	—			
Options assumed in the Merger	2,478,581	1,969,885	$ 24.63		
Options exercised	—	(82,287)	$ 5.39		$ 811
Options forfeited or cancelled	123,651	(123,719)	$ 7.22		
Outstanding, December 31, 2020	894,227	5,513,581	$ 13.24		
Options exercisable December 31, 2020		2,067,406	$ 22.08		$ 10,829
Vested and expected to vest, December 31, 2020		5,513,580	$ 13.24		$ 38,433

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock for stock options that were in-the-money at December 31, 2020.

The weighted average grant-date fair value of options granted was $9.99 and $0.23 for the year ended December 31, 2020 and December 31, 2019, respectively. As of December 31, 2020, the total unrecognized stock-based compensation expense related to unvested stock options was $20.1 million, which is expected to be recognized over the remaining weighted-average vesting period of 3.2 years.

The Company estimated the fair value of stock options using the Black Scholes option-pricing model. The fair value of stock options is being amortized on a straight-line basis over the requisite service period of the awards. The fair value of stock options was estimated using the following assumptions:

	Years Ended December 31,	
	2020	2019
Expected term (in years)	0.0 – 6.1	5.1 – 6.1
Volatility	78% – 90%	74% – 78%
Risk-free interest rate	0.1% – 0.9%	1.5% – 2.5%
Dividend yield	0%	0%

The assumptions were determined as follows:

- *Expected volatility.* The expected volatility was determined by examining the historical volatilities for comparable publicly traded companies within the biotechnology and pharmaceutical industry using an average of historical volatilities of the Company's industry peers. Prior to the Merger, due to the lack of company-specific historical and implied volatility data, the Company based its 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, the Company is using historical volatility of Aduro's and the combined 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.
- *Risk-free interest rate.* The risk-free interest rate was based on the U.S. Treasury yield with a maturity equal to the expected term of the option in effect at the time of grant.
- *Dividend yield.* The expected dividend was assumed to be zero as dividends have never been paid and there are no current plans to pay any dividends on common stock.
- *Expected term.* The expected term represents the period that the stock-based awards are expected to be outstanding. The expected term was determined using the simplified method.

Restricted Stock Units (RSUs)

In connection with the Merger, the Company assumed Aduro's outstanding unvested RSUs. The following table summarizes RSU activity:

	RSUs Outstanding	
	Number of Restricted Stock Units	Weighted-Average Grant Date Fair Value Per Share
Outstanding, January 1, 2020	—	$ —
Assumed in Merger	11,289	—
Granted	440,990	$ 14.52
Vested	(4,989)	$ 15.42
Forfeited	(6,750)	$ 14.77
Outstanding, December 31, 2020	440,540	$ 14.51

The total fair value of RSUs that vested in the year ended December 31,2020 was $0.1 million. The fair value of RSUs is determined on the date of grant based on the market price of Aduro's or the Company's common stock on that date. As of December 31, 2020, there was $5.9 million of unrecognized stock-based compensation expense related to RSUs which is expected to be recognized over a weighted-average period of 2.7 years.

Employee Stock Purchase Plan

In connection with the Merger, the Company assumed the Aduro employee stock purchase plan ("ESPP"), which is intended to qualify as an employee stock purchase plan under Section 423 of the Code and is administered by the Company's Board of Directors or a committee of the Board of Directors. Upon assumption of the ESPP, there were 305,651 shares reserved for future issuance. 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. As of December 31, 2020, there were 298,840 shares reserved for issuance under the ESPP. Employees purchased 6,811 shares for $0.1 million under the ESPP from the time of the Merger through December 31, 2020.

The following table summarizes the assumptions used in the Black-Scholes option-pricing model to determine fair value of the Company's common shares to be issued under the ESPP:

	Year Ended December 31, 2020
Expected term (in years)	0.5
Volatility	82% – 128%
Risk-free interest rate	0.1% – 0.2%
Dividend yield	—%

As of December 31, 2020, there was $0.1 million of unrecognized stock-based compensation expense related to the ESPP, which is expected to be recognized over a weighted-average period of 0.4 years.

Stock-Based Compensation Expense

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

	Years Ended December 31,	
	2020	2019
Research and development	$ 1,759	$ 44
General and administrative	1,852	51
Total stock-based compensation expense	$ 3,611	$ 95

14. Net Loss Per Share

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders, which excludes unvested restricted shares and shares which are legally outstanding, but subject to repurchase by the Company (in thousands, except share and per share data):

	Years Ended December 31,	
	2020	2019
Numerator:		
Net loss attributable to common stockholders	$ (81,622)	$ (46,519)
Denominator:		
Weighted-average shares outstanding	13,463,477	2,343,157
Less: weighted-average unvested restricted shares and shares subject to repurchase	(295,334)	(517,441)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	13,168,143	1,825,716
Net loss per share attributable to common stockholders, basic and diluted	$ (6.20)	$ (25.48)

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:

	December 31,	
	2020	2019
Redeemable convertible preferred stock	—	7,596,886
Conversion of redeemable convertible preferred stock issuable upon settlement of the redeemable convertible preferred stock tranche liability	—	11,395,332
Options to purchase common stock	5,513,581	730,116
Common stock warrants	10,032	—
Unvested restricted stock units	440,540	—
Unvested restricted stock awards	195,919	415,809
Total	6,160,072	20,138,143

15. Income Taxes

Income (loss) before taxes was derived from domestic (United States) and Foreign (Canada and the Netherlands) sources as follows (in thousands):

	Years ended December 31,	
	2020	2019
Domestic	$ (68,636)	$ (34,713)
Foreign	(14,989)	(11,806)
Total	$ (83,625)	$ (46,519)

The income tax benefit consists of the following:

	Years ended December 31,	
	2020	2019
Current:		
U.S. – Federal	$ —	$ —
U.S. – State	—	—
Foreign	—	—
Total current	—	—
Deferred:	—	—
U.S. – Federal	(1,607)	—
U.S. – State	(234)	—
Foreign	(162)	—
Total deferred	(2,003)	—
Total income tax benefit	$ (2,003)	$ —

The Company recorded an income tax benefit of $2.0 million for the year ended December 31, 2020 due to a deferred tax liability generated in connection with the Merger that was used to realize certain deferred tax assets, which previously had a full valuation allowance.

The effective tax rate of the provision for income taxes differed from the federal statutory rate as follows:

	Years ended December 31,	
	2020	2019
U.S. statutory rate	21.0%	21.0%
Other	(0.7%)	(0.0%)
Change in valuation allowance	(12.0%)	(10.4%)
Foreign rate differential	1.0%	1.5%
Redeemable convertible preferred stock tranche liability	(7.0%)	(12.1%)
Effective income tax rate	2.3%	0.0%

On December 22, 2017, H.R.1, commonly referred to as the Tax Cuts and Jobs Act (TCJA) (“Tax Act”) was enacted into law in the United States of America. The Company continues to consider the impact of the Base Erosion and Anti-Abuse Tax ("BEAT"), Global Intangible Low-Taxed Income (“GILTI”), the deduction for foreign derived intangible income and other provisions of the Tax Act on an on-going basis. The Company has elected to treat taxes due on future U.S. inclusions in taxable income under the GILTI provision as a current-period expense when incurred. As such and to the extent relevant, expected future GILTI inclusions have not been factored into the measurement of our deferred taxes.

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):

	December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 16,781	$ 4,901
Accruals and reserves	928	64
Fixed asset basis	—	37
Stock-based compensation	2,134	9
Business tax credits	1,372	—
Lease liabilities	10,010	563
Gross deferred tax assets	31,225	5,574
Valuation allowance	(15,020)	(5,014)
Total deferred tax assets, net of valuation allowance	16,205	560
Deferred tax liabilities:		
Fixed asset basis	(2,541)	—
Right of use asset	(13,318)	(560)
Intangible asset basis	(16,726)	—
Total deferred tax liabilities	(32,585)	(560)
Net deferred tax assets and liabilities	$ (16,380)	$ —

In connection with the Merger, the Company recorded $67.0 million of acquired intangible assets and IPR&D. The Company has recorded a deferred tax liability of $16.4 million resulting from the difference between the financial reporting basis of $67.0 million and the tax basis of zero for these assets.

The Company is required to reduce its deferred tax assets by a valuation allowance if it is more likely than not that some or all of its deferred tax assets will not be realized. Management 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, the Company assesses the likelihood that it will be able to recover its deferred tax assets using historical levels of income, estimates of future income and tax planning strategies. As a result of historical consolidated cumulative losses, the Company determined that, based on all available evidence, there was substantial uncertainty as to whether it will recover a majority of its recorded net deferred taxes in future periods. As a result, the Company recorded a valuation allowance against the U.S. net deferred tax assets at December 31, 2020 and 2019. The valuation allowance increased by $10.0 million and $4.8 million during the years ended December 31, 2020 and 2019, respectively.

At December 31, 2020, the Company has generated net operating loss, or NOL, carryforwards (before tax effects) for federal, state and foreign income tax purposes of $14.4 million, $0.5 million and $21.4 million, respectively. The federal NOL carryforwards do not expire and the state and foreign NOL carryforwards will begin to expire in 2040 and 2026, respectively, if not utilized. In addition, the Company has foreign business tax credit of $1.3 million to offset future income tax liabilities, which will start to expire in 2039, if not utilized.

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 may 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. Private Chinook and Aduro may have experienced ownership changes in the past and likely experienced ownership change under Section 382 as a result of the Merger. Any such limitation may significantly reduce the Company’s ability to utilize net operating loss carryforwards and tax credit carryforwards before they expire. Consequently, if the Company achieves profitability, it may not be able to utilize a material portion of Private Chinook’s or Aduro’s net operating loss carryforwards.

The Company has determined that its ability to utilize the U.S. tax carryforward attributes of Aduro were likely significantly limited under Section 382 of the U.S. Internal Revenue Service and as such, no related U.S. deferred tax attributes have been recorded in connection with the Merger. A similar determination was made with respect to the Aduro Dutch tax carryforwards, which are subject to similar change of control provisions. As a result, no related Dutch tax carryforward attributes have been recorded in connection with the Merger.

The Company's material income tax jurisdictions are the United States (Federal), Canada and the Netherlands (foreign), and California (state). Federal and state income tax returns are open under the statute of limitations and subject to audit for tax years 2016 and forward. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the IRS or state tax authorities to the extent utilized in a future period. For Canada, the Company is subject to audit for tax years 2018 and forward. For the Netherlands, the tax administration can impose an additional assessment within five years from the year in which the tax debt originated.

Uncertain Tax Positions

The Company accounts for uncertainty in income taxes in accordance with ASC 740. Tax positions are evaluated in a two-step process, whereby the Company first determines 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.

A reconciliation of the Company's unrecognized tax benefits follows (in thousands):

	Year Ended December 31,	
	2020	2019
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	—	—
Additions based on tax positions related to current year	—	—
Reductions based on tax positions related to current year	—	—
Balance at end of year	$ 753	$ 753

The Company does not foresee material changes to its gross uncertain income tax position liability within the next 12 months.

The Company will recognize accrued interest and penalties related to unrecognized tax benefits as income tax expense in its consolidated statements of operations. At December 31, 2020, the Company has recorded no interest and penalties.

16. Defined Contribution Plans

In 2019, the Company implemented a defined contribution plan (the "401(k) Plan") for its 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 Internal Revenue Service guidelines for such plans. The 401(k) Plan provides for matching and discretionary contributions by the Company, which are made in the subsequent year. Matching contributions were less than $0.1 million, respectively for the years ended December 31, 2020 and 2019.

In 2019, the Company implemented a defined contribution plan (the "RRSP Matching Program") for its full-time, Canadian employees, with eligibility commencing on the employee's hire date. Employee contributions to the RRSP Matching 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 Matching Program provides for matching contributions by the Company on a 1-to-1 basis within a prescribed limit for each calendar year. Matching contributions were less than $0.1 million, respectively for the years ended December 31, 2020 and 2019.

In 2020, in connection with the Merger, the Company 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 are based on a percentage of the employee's gross compensation, limited by Internal Revenue Service guidelines for such plans. The Aduro 401(k) Plan provides for matching and discretionary contributions, which are 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.

17. Commitments and Contingencies

Leases

In December 2018, the Company entered into a services agreement with a related party under which office space of approximately 12,265 square feet is leased in Vancouver, Canada. The underlying lease of the premises has an expiration date of August 31, 2027, with current base lease payments of $0.3 million per year. In addition, the Company is responsible for certain other costs, such as insurance, taxes, utilities, and maintenance, which were $0.1 million and $0.2 million for the years ended December 31, 2020 and 2019, respectively. The Company assumed the underlying lease in April 2020, which is treated as an operating lease for accounting purposes.

Under the above services agreement the Company also leased $0.3 million of equipment and furniture located at its office space. Pursuant to the terms of the agreement, the Company leased these assets for the same term as the office space for less than $0.1 million per month with purchase rights. In April 2020, the Company purchased these assets. For accounting purposes, the lease of these assets is treated as a finance lease (a capital lease before the adoption of ASC Topic 842).

In December 2019, the Company entered into a non-cancelable lease agreement to lease approximately 3,000 square feet of office space located in Seattle, Washington. The term of the lease is 2 years commencing on January 1, 2020. The total base lease payments over the life of the lease is $0.2 million. The Company has an option to extend the lease term for 24 months after expiration of the initial lease term.

In connection with the Merger, the Company assumed two operating leases, one for a facility in Berkeley, California that has a remaining lease term of approximately 9 years, and another for a facility in Oss, the Netherlands, that expired in December 2020. Both leases contain an option to extend for an additional term, however, the option was not exercised for the expired lease, and the Company is not reasonably certain to exercise the option for the Berkeley lease.

Under a sublease agreement assumed in the Merger, the Company is subleasing approximately 88,883 square feet of the Berkeley facility at December 31, 2020 and is committed to sublease the remainder of the space under the agreement, which expires at the same time as the underlying lease. Sublease income was $1.4 million and $0 for the years ended December 31, 2020 and 2019, respectively, which was netted against rent expense. Total sublease income to be earned, in aggregate, will be approximately $71.4 million over the remaining term of the sublease agreement.

As of the date of the Merger, the market rental rate for the Berkeley facility was determined to be higher than the contractual rental rate and, accordingly, was determined to be favorable to the Company. Additionally, the Company is required to share the sublease income with its landlord to the extent it exceeds the rent payable under the underlying lease. These payments to the landlord were deemed to be a feature of the acquired lease and factored into the determination of the favorable lease value, which was estimated based on an income approach with-and-without analysis. The fair value of the favorable lease was estimated to be $15.0 million, which is included in the value of the operating lease right-of-use asset on the Company’s balance sheets.

The Company maintains a letter of credit as security for the Berkeley lease in the amount of $1.8 million, which is collateralized by a certificate of deposit that is included in restricted cash in the consolidated balance sheet as of December 31, 2020.

The Company recognizes rent expense on a straight-line basis over the lease period. Rent expense recognized under all operating leases was $2.9 million and $0.4 million for the years ended December 31, 2020 and 2019, respectively, including variable lease costs of $0.8 million and $0.2 million, respectively.

Weighted average remaining lease term and the weighted average discount rate for operating leases was 8.8 years and 7.1 percent, respectively, at December 31, 2020.

The maturities of the Company's operating lease liabilities at December 31, 2020 were as follows (in thousands):

Undiscounted Lease Payments	Amounts
2021	$ 5,832
2022	6,106
2023	6,232
2024	6,343
2025	6,457
2026 and thereafter	25,507
Total undiscounted lease payments	56,477
Less: imputed interest	14,722
Total lease liability	41,755
Less: current portion	3,045
Lease liability, net of current portion	$ 38,709

Indemnification Agreements

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company 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 the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that require the Company, 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. The Company currently maintains directors' and officers' liability insurance.

Legal Proceedings

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

18. Related Party Transactions

During the years ended December 31, 2020 and 2019, the Company subleased part of its office space to an affiliate of a stockholder, at approximately $25,500 per annum base rent plus operating costs. For each of the years ended December 31, 2020 and 2019, the Company received less than $0.1 million from such related party for rent and operating expenses. As of December 31, 2020, and 2019, the Company had no amounts receivable from such related party.

Under a services agreement with an affiliate of a stockholder, such related party has provided the Company with office space, equipment, furniture, and other services, including outsourced personnel and support services, which are billed to the Company at cost plus 10 percent markup. Certain payments for office space and equipment are accounted for as leases and disclosed in Note 17. For the years ended December 31, 2020 and 2019, the Company paid $0.8 million and $4.1 million, respectively, to the related party for office space, equipment, and other support services. The Company owed this related party $0.2 million and $0.7 million, which were included in accounts payable and accrued and other current liabilities, as of December 31, 2020, and 2019, respectively.

In 2019, the Company entered into an agreement with a stockholder to purchase intellectual property. The Company issued 438,282 shares of common stock with a value of approximately $0.2 million for such intellectual property in 2019, and there were no related accounts payable to this stockholder as of December 31, 2020 or 2019.

In 2019, the Company entered into an asset purchase agreement with an affiliate of a stockholder to acquire certain research and development assets. The Company paid this related party $2.0 million for these assets on December 31, 2019 and paid $0.1 million in January 2020 for the associated sales taxes.

19. Subsequent Events

On April 1, 2021, the Company received notice that Novartis terminated for convenience the Collaboration and License Agreement, dated March 12, 2015.

On April 2, 2021, the Company entered into a definitive agreement with Sairopα B.V. (“Sairopα”), a private company created by Van Herk Royalty B.V. and D.S. Chahal to acquire certain non-renal assets of Chinook in exchange for stock in Sairopα. The Company will hold such shares until such time as there is a liquidation event in Sairopα. In accordance with the CVR agreement, 50% of any net proceeds received from this transaction by way of a liquidation event of Sairopα by October 4, 2030 will accrue to the benefit of the CVR holders.

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.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934, as amended ("Exchange Act"), is recorded, processed, summarized, and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our President and Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure. 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 Exchange Act) as of December 31, 2020. Based on that evaluation, our President and Chief Executive Officer and our Chief Financial Officer have concluded that, our disclosure controls and procedures were not effective as of December 31, 2020, due to the material weaknesses identified in our internal control over financial reporting described below.

Following identification of the material weaknesses and prior to filing this Annual Report on Form 10-K, we completed substantive procedures for the year ended December 31, 2020. Based on these procedures, management concluded that our consolidated financial statements included in this Form 10-K have been prepared in accordance with U.S. GAAP. Our Chief Executive Officer and Chief Financial Officer have certified that, based on their knowledge, the financial statements, and other financial information included in this Form 10-K, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this Form 10-K.

Management's 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.

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. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2020. 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)*. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. We have identified the following control deficiencies that constituted material weaknesses in our internal control over financial reporting as of December 31, 2020:

(i) We did not design or maintain an effective control environment commensurate with our financial reporting requirements due to lack of sufficient accounting professionals with the appropriate level of skill, experience and training commensurate with its financial reporting requirements. Additionally, the limited personnel resulted in our inability to consistently establish appropriate authorities and responsibilities in pursuit of its financial reporting objectives, as demonstrated by, among other things, insufficient segregation of duties in its finance and accounting functions. This contributed to additional material weaknesses;

(ii) We did not design and maintain formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting reporting and disclosures, including controls over the preparation and review of account reconciliations, journal entries and period end financial reporting; and

(iii) We did not design and maintain controls over the operating effectiveness of information technology general controls for information systems that are relevant to the preparation of our financial statements, specifically including controls over program change management; user access, including segregation of duties; and computer operations.

The material weaknesses identified above did not result in any identified misstatements to our annual or interim financial statements. Additionally, these material weaknesses could result in a misstatement of accounts or disclosures that would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected.

Based on these material weaknesses, management concluded that the Company did not maintain effective internal control over financial reporting as of December 31, 2020.

This Annual Report on Form 10-K does not include a report of our independent registered public accounting firm on the effectiveness of internal control over financial reporting due to an exemption for smaller reporting companies established by the rules of the Securities and Exchange Commission

Remediation Efforts

Our management, under the supervision of our President and Chief Executive Officer, has undertaken a plan to remediate the material weaknesses identified above. The remediation efforts summarized below, which are in the process of being implemented, are intended to address the identified material weaknesses.

(i) In November 2020, we hired a permanent Chief Financial Officer with substantial experience in the biotechnology industry, whose responsibilities include working with existing employees and third-party consultants to improve the design, implementation, execution and supervision of the company's internal control over financial reporting.

(ii) We have hired additional finance, accounting and information technology employees with appropriate experience, certification, education and training. This includes a senior information technology leader and additional accounting staff, who are already onboard, as well as a senior accounting leader who joined us in March 2021.

(iii) We have integrated the accounting systems of Private Chinook and Aduro in 2021, and are updating our formal accounting policies, procedures and controls, including preparation and review of account reconciliations, review of journal entries and controls over period end financial reporting, as well as information technology general controls.

(iv) We have assigned responsibilities among our expanded staff to enable improved segregation of duties.

We believe that the implementation of the above steps has already allowed us to make progress on addressing a number of the deficient controls within our internal control environment. However, we require additional time to complete the design and implementation of our remediation plans and demonstrate the effectiveness of our remediation efforts. The material weaknesses cannot be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

Changes in internal control over financial reporting.

On October 5, 2020, we consummated our reverse merger with Aduro Biotech. Upon closing, the historical consolidated financial statements of private Chinook became the historical consolidated financial statements of the registrant. During the quarter ended December 31, 2020, following becoming a public company as a result of the reverse merger, we hired a Chief Financial Officer, integrated our financial reporting processes of the business with Aduro's processes, and implemented additional closing procedures to enable our financial reporting process. Other than such changes, there were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.]

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers and Directors of the Company

The company's board of directors consists of seven members. The board of directors has determined that each of the directors other than Mr. Dobmeier meet the Nasdaq independence requirements.

The following table lists the names and ages, as of January 31, 2021, and positions of the individuals who serve as our executive officers and directors:

Name	Age	Position
Executive Officers:		
Eric L. Dobmeier	52	President, Chief Executive Officer and Director
Eric Bjerkholt	61	Chief Financial Officer
Tom Frohlich	45	Chief Business Officer
Alan Glicklich, M.D.	59	Chief Medical Officer
Andrew King, BVMS, Ph.D.	41	Head of Renal Discovery and Translational Medicine
Non-Employee Directors:		
Srinivas Akkaraju, M.D., Ph.D.	52	Director
Jerel Davis, Ph.D.	44	Director
William M. Greenman	54	Director
Michelle Griffin	55	Director
Ross Haghighat	57	Director
Dolca Thomas	50	Director

Executive Officers

Eric L. Dobmeier has served as our President, Chief Executive Officer and member of the board of directors since April 2019. From January 2018 to June 2018, Mr. Dobmeier served as President and Chief Executive Officer of Silverback Therapeutics, Inc. Prior to joining Silverback Therapeutics, from 2002 to December 2017, Mr. Dobmeier held positions of increasing responsibility at Seattle Genetics, Inc., a publicly traded biotechnology company, most recently as Chief Operating Officer from June 2011 to December 2017. Prior to joining Seattle Genetics, Mr. Dobmeier was an attorney with the law firms of Venture Law Group and Heller Ehrman LLP, where he represented technology companies in connection with public and private financings, mergers and acquisitions and corporate partnering transactions. Mr. Dobmeier currently serves on the boards of directors of Atara Biotherapeutics, Inc., a publicly traded biotechnology company, where he has served since 2015. Mr. Dobmeier previously served on the boards of directors of Adaptive Biotechnologies from 2016 to 2021, Stemline Therapeutics from 2012 to 2018 and Versartis from 2017 to 2018, each a publicly traded biopharmaceutical company. He received an A.B. in History from Princeton University and a J.D. from the University of California, Berkeley School of Law. We believe Mr. Dobmeier's legal, business development and operating experience, knowledge of our business, years of senior management experience at a public biotechnology company and his service as a director of other biopharmaceutical companies provide him with the qualifications and skills to serve as a director of the Company.

Eric Bjerkholt has served as our Chief Financial Officer since November 2020. Mr. Bjerkholt served as the Chief Financial Officer of Aimmune Therapeutics, Inc., a biotechnology company developing treatments for food allergies from April 2017 to October 2020. From 2004 until April 2017, Mr. Bjerkholt held various roles at Sunesis Pharmaceuticals, Inc., a biopharmaceutical company developing oncology therapeutics, including as Executive Vice President, Corporate Development and Finance and Chief Financial Officer. Mr. Bjerkholt has served as a member of the board of directors of Graybug Vision, Inc., a biopharmaceutical company, since September 2020, and as a member of the board of directors of Cerus Corporation, a biotechnology company, since October 2018 and as chair of Cerus Corporation's audit committee from March 2019 until February 2021. Mr. Bjerkholt holds a Cand. Oecon degree in Economics from the University of Oslo and an M.B.A. from Harvard Business School.

Tom Frohlich has served as our Chief Business Officer since January 2019. Since April 2018, Mr. Frohlich has also served as an Operating Principal and subsequently as an Entrepreneur in Residence at Versant Ventures, a healthcare investment firm. From April 2018 to December 2018, Mr. Frohlich served as the Senior Vice President of Business Development at Inception Sciences, Inc., a drug discovery engine co-founded with Versant Ventures. Prior to joining Inception Sciences, from 2014 to 2018, Mr. Frohlich held positions of increasing responsibility at Arbutus Biopharma (formerly Tekmira Pharmaceuticals), a publicly traded biopharmaceutical company, most recently as Vice President of Business Development from January 2016 through March 2018. Prior to joining Arbutus Biopharma, Mr. Frohlich worked internationally at Johnson & Johnson, a publicly traded pharmaceutical and consumer packaged goods company, from September 2007 through January 2014, and at Merck & Co., a publicly traded pharmaceutical company, from June 1998 through June 2006, in various roles leading commercial strategy across all stages of product development. Mr. Frohlich received a B.Sc. in Biochemistry from the University of Victoria and an M.B.A. from the University of Oxford.

Alan Glicklich,

M.D. has served as our Chief Medical Officer since April 2020. From June 2015 through April 2020, Dr. Glicklich served as the Chief Medical Officer at Bird Rock Bio, a private biotechnology company focused on clinical development of monoclonal antibodies. Prior to joining Bird Rock Bio, Dr. Glicklich served as the Vice President of Clinical Development at Arena Pharmaceuticals, a publicly traded biopharmaceutical company, from January 2014 through September 2015, and as the Vice President of Clinical Affairs of Savient Pharmaceuticals from January 2013 through October 2013. Dr. Glicklich has also served in senior clinical roles at Mitsubishi-Tanabe Development America, Bristol Myers Squibb, Sanofi-Aventis and Regeneron. Dr. Glicklich received a B.A. in Biology from the University of Chicago, an M.D. from the University of Wisconsin-Madison and an M.B.A. from Emory University.

Andrew King, BVMS, Ph.D. has served as our Head of Renal Discovery and Translational Medicine of Chinook Therapeutics, Inc. since May 2019. From August 2018 through May 2019, Dr. King served as the Executive Vice President of Discovery at BIOAGE Labs, a private biotechnology company. From August 2015 through August 2018, Dr. King served as the Senior Director of Discovery and Translational Biology at Ardelyx, Inc., a publicly traded biotechnology company, where he focused on delivering small molecule candidates for the treatment of cardio-renal diseases. Prior to Ardelyx, Inc., Dr. King was a Principal Research Scientist at AbbVie Inc., a publicly traded biopharmaceutical, from January 2013 through August 2015, where he led the Renal Discovery scientific strategy to treat chronic kidney disease. From March 2008 to December 2012, Dr. King held positions of increasing responsibility at Abbott Laboratories, a publicly traded biotechnology company. Andrew received a B.Sc. in Veterinary Biology from Murdoch University in Australia, a BVMS from Murdoch University in Australia and a Ph.D. in Pharmacology from Michigan State University.

Non-Employee Directors

Srinivas Akkaraju, M.D., Ph.D. has served as a member of our board of directors since July 2019. Dr. Akkaraju is currently the Managing General Partner and Founder of Samsara BioCapital, a venture capital company focused on innovative therapeutics, and has held such positions since Samsara Capital's founding in March 2017. From April 2013 to June 2016, Dr. Akkaraju served as a General Partner and then a Senior Advisor of Sofinnova Ventures, a venture capital firm focused on the life sciences industry. From January 2009 until April 2013, Dr. Akkaraju served as Managing Director of New Leaf Venture Partners. Prior to New Leaf Venture Partners, Dr. Akkaraju served as a Managing Director at Panorama Capital, LLC, a private equity firm which he co-founded. Prior to Panorama Capital, Dr. Akkaraju held several executive and management positions with J.P. Morgan Partners, which he joined in 2001 and of which he became a Partner in 2005. From October 1998 to April 2001, Dr. Akkaraju was in Business and Corporate Development at Genentech, Inc. (now a wholly owned member of The Roche Group), a publicly traded biotechnology company, most recently as Senior Manager. Dr. Akkaraju has served as a director of Seattle Genetics, Inc. since June 2003, Intercept Pharmaceuticals, Inc. since October 2012 and Syros Pharmaceuticals, Inc. since June 2017, each a publicly traded biotechnology company. During the prior five years, Dr. Akkaraju served as a director on the boards of Aravive, Inc. (formerly Versartis, Inc.), aTyr Pharma, Inc., Principia Biopharma Inc. and ZS Pharma, Inc., each a publicly traded biotechnology company. Dr. Akkaraju received a B.S. in Biochemistry and Computer Science from Rice University and an M.D. and Ph.D. in Immunology from Stanford University. We believe Dr. Akkaraju's extensive experience in the biotechnology industry as an executive officer and director provides him with the qualifications and skills to serve on our board of directors.

Jerel Davis, Ph.D. has served as a member of our board of directors since December 2018. Since June 2011, Dr. Davis has been at Versant Venture Management, LLC, a healthcare investment firm, where he has been a Managing Director since April 2016. Prior to Versant, Dr. Davis was an associate principal at McKinsey & Company from January 2006 through June 2011, working in the U.S., Canada, Europe and China healthcare markets. Dr. Davis has served on the board of directors of Repare Therapeutics, a publicly traded precision oncology company, since September 2016. Dr. Davis currently serves on the board of directors of several private companies. Dr. Davis received a B.S. in Mathematics and Biology from Pepperdine University and a Ph.D. in Population Genetics from Stanford University. We believe that Dr. Davis' broad experience in the life sciences industry as an investor qualifies him to serve on our board of directors.

William M. Greenman has served as a member of our board of directors since June 2010. Mr. Greenman has served as the President, Chief Executive Officer and a member of the board of directors of Cerus Corporation, a publicly traded biomedical products company, since April 2011. Since joining Cerus Corporation in 1995, Mr. Greenman has served in several executive and management positions, including as the Chief Business Officer and President of Cerus Europe. Prior to Cerus Corporation, Mr. Greenman worked in various marketing and business development positions in the Biotech Division of Baxter International Inc., a publicly traded medical equipment company, from 1991 to 1995. Mr. Greenman received a B.A.S. in Biological Sciences and Economics from Stanford University. We believe Mr. Greenman's extensive experience holding executive positions and knowledge of the biomedical industry provides him with the qualifications and skills to serve on our board of directors.

Michelle Griffin has served as a member of our board of directors since October 2020. Ms. Griffin currently serves on the board of directors of Adaptive Biotechnologies Corporation, a publicly traded life sciences equipment company, including as chair of the audit committee, where she has served since March 2019, Acer Therapeutics, Inc., a publicly traded company, including as chair of the audit committee, where she has served since September 2017 and HTG Molecular Diagnostics, Inc., a publicly traded company, including as chair of the audit committee, where she has served since August 2018. Ms. Griffin previously served on the board of directors and as chair of the audit committee of PhaseRx, Inc., formerly a publicly traded company, from 2016 to 2018, OncoGenex Pharmaceuticals Inc. (now Achieve Life Sciences, Inc.) from 2008 to 2011 and Sonus Pharmaceuticals, Inc. (now Achieve Life Sciences, Inc.), from 2004 to 2008. Ms. Griffin served as the Executive Vice President, Operations and Chief Financial Officer at OncoGenex Pharmaceuticals, Inc. from 2011 to 2013, the Acting Chief Executive, Senior Vice President and Chief Operating Officer at Trubion Pharmaceuticals, Inc. from 2009 until its acquisition in 2010 and as its Chief Financial Officer from 2006 to 2009 and served as Senior Vice President and Chief Financial Officer of Dendreon Corp. from 2005 to 2006, and served as the Controller of Corixa Corp., from 1994 to 1997 and was its Chief Financial Officer from 1997 to 2005. Ms. Griffin holds a B.S. in Marketing from George Mason University, an M.B.A. from Seattle University and has passed the certified public accountant exam. We believe Ms. Griffin is qualified to serve as a member of our board of directors based on her extensive operational experience in the biotechnology industry and deep experience in public company financial matters.

Ross Haghighat has served as a member of our board of directors since 2009. Mr. Haghighat founded Triton Systems, Inc., a product venturing company, in May 1992, and has served as its the Chairman and Chief Executive Officer and member of the board of directors since 2009. Mr. Haghighat has served as a member of the board of directors of CITIC Capital Acquisition Corp. since May 2020, and currently serves on the board of directors of several private companies. Mr. Haghighat received a B.S. in Material Science and a M.S. in Organometallic Chemistry from Rutgers University and an M.B.A. from Boston College. We believe Mr. Haghighat's extensive experience in the biotechnology field as an executive officer and director provides him with the qualifications and skills to serve on our board of directors.

Dolca Thomas, M.D. has served as a member of our board of directors since October 2020. Dr. Thomas has served as the Executive Vice President, Head of Research and Development and Chief Medical Officer of Equillium, Inc. since January 2021. Dr. Thomas previously served as the Chief Medical Officer of Principia Biopharma Inc. from October 2018 to December 2020. From June 2016 to September 2018, Dr. Thomas was Vice President and Global Head of Translational Medicine for Immunology, Inflammation, and Infectious Disease at Roche Group, where she was responsible for advancing multiple product candidates through clinical development. Prior to Roche Group, Dr. Thomas held roles of increasing responsibility at Pfizer from 2012 to May 2016, including as Vice President of Clinical Development and Clinical Immunophenotyping, and Vice President and Chief Development Officer of the Biosimilars Research and Development Unit where she was responsible for all stages of development of multiple assets. From 2008 to 2012, Dr. Thomas began her industry career at Bristol-Myers Squibb as Director of Global Clinical Development. Prior to her career in drug development, Dr. Thomas was a faculty member at Weill Cornell Medicine's Department of Nephrology and Transplantation Medicine. Dr. Thomas received her B.A. in sociology and her M.D. from Cornell University. We believe Dr. Thomas is qualified to serve as a member of our board of directors based on her academic and clinical research experience, her nephrology expertise and her extensive operational experience in the biotechnology industry.

Family Relationships

There are no family relationships among any of our directions or executive officers.

Delinquent Section 16(a) Reports

Based solely on its review of the copies of such forms furnished to Chinook and written representations from the directors and executive officers, Chinook believes that all Section 16(a) filing requirements were timely met in the year ended December 31, 2020, except that a Form 4 for Eric Bjerkholt for two transactions on November 30, 2020, was filed on December 18, 2020.

INDEPENDENCE OF THE BOARD OF DIRECTORS

The Nasdaq Stock Market LLC ("Nasdaq") listing standards require that a majority of the members of a listed company's Board of Directors must qualify as "independent," as affirmatively determined by the Board of Directors. The Board consults with the Company's counsel to ensure that the Board's determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of Nasdaq, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his or her family members, and the Company, its senior management and its independent auditors, the Board has affirmatively determined that, other than Mr. Isaacs, by virtue of his position as President and Chief Executive Officer, each of the Company's directors is independent within the meaning of the applicable Nasdaq listing standards. In making this determination, the Board found that none of these directors or nominees for director had a material or other disqualifying relationship with the Company.

BOARD LEADERSHIP STRUCTURE

Our Board of Directors is currently chaired by Mr. Dobmeier. We believe that combining the positions of Chief Executive Officer and Board Chair helps to ensure that the Board and management act with a common purpose. Our corporate governance guidelines provide that one of our independent directors may be designated by the Board to serve as lead independent director. Accordingly, the Board has appointed Dr. Davis to serve as the Board's lead independent director. As lead independent director, Dr. Davis: establishes, with the Board Chair, the agenda for regular Board meetings and serves as the chair of Board meetings in the absence of the Board Chair; establishes the agenda for meetings of the independent directors; coordinates with committee chairs regarding meeting agendas and informational requirements; presides over meetings of the independent directors; presides over any portions of meetings of the Board at which evaluation or compensation of the Chief Executive Officer is presented or discussed; presides over any portions of meetings of the Board at which the performance of the Board is presented or discussed; and coordinates the activities of other independent directors and performs such other duties as may be established or delegated by the Board Chair.

MEETINGS OF THE BOARD OF DIRECTORS

The Board of Directors met 21 times during the last fiscal year. Each Board member attended 75 percent or more of the aggregate number of meetings of the Board and of the committees on which he or she served, held during the portion of the last fiscal year for which he or she was a director or committee member. As required under applicable Nasdaq listing standards, in fiscal 2020, our independent directors met 21 times in regularly scheduled executive sessions at which only independent directors were present. Dr. Davis, as our lead independent director, presided over the executive sessions occurring after October 5, 2020. We do not have a formal policy requiring the members of our Board of Directors to attend our annual meetings of stockholders, although directors are encouraged to attend annual meetings. One of our then current directors attended our 2020 annual meeting of stockholders.

INFORMATION REGARDING COMMITTEES OF THE BOARD OF DIRECTORS

Audit Committee

The Audit Committee of the Board of Directors is composed of Ms. Griffin, Mr. Greenman and Mr. Haghighat. The chair of our Audit Committee is Ms. Griffin. The Audit Committee met two times during the fiscal year. The Board has adopted a written Audit Committee charter that is available to stockholders on the Company's website at https://investors.chinooktx.com/corporate-governance/highlights.

The Board of Directors has determined that each member of the Audit Committee satisfies the applicable Nasdaq rules and regulations regarding "independence" and each member is free of any relationship that would impair his or her individual exercise of independent judgment with regard to the Company.

In addition, the Board of Directors reviews the Nasdaq listing standards definition of independence for Audit Committee members on an annual basis and has determined that all members of our Audit Committee satisfy the independence standards for audit committee members (as independence is currently defined in Rule 5605(c)(2)(A)(i) of the Nasdaq listing standards and Rule 10A-3 of the Securities Exchange Act of 1934, as amended (the "Exchange Act")). The Board of Directors has also determined that Ms. Griffin qualifies as an "audit committee financial expert," as defined in applicable SEC rules.

The Audit Committee was established by the Board in accordance with Section 3(a)(58)(A) of the Exchange Act, to oversee our corporate accounting and financial reporting processes and audits of its financial statements. For this purpose, the Audit Committee performs several functions. Among other matters, the audit committee:

- appoints our independent registered public accounting firm;
- evaluates the independent registered public accounting firm's qualifications, independence and performance;
- determines the engagement of the independent registered public accounting firm;
- reviews and approves the scope of the annual audit and the audit fee;
- discusses with management and the independent registered public accounting firm the results of the annual audit and the review of our quarterly consolidated financial statements;
- approves the retention of the independent registered public accounting firm to perform any proposed permissible non-audit services;
- monitors the rotation of partners of the independent registered accounting firm on our engagement team in accordance with requirements established by the SEC;

- is responsible for reviewing our consolidated financial statements and its management's discussion and analysis of financial condition and results of operations to be included in our annual and quarterly reports to be filed with the SEC;
- reviews our critical accounting policies and estimates;
- reviews, with our independent registered public accounting firm and management, significant issues that may arise regarding our accounting principles and financial statement presentation, as well as matters concerning the scope, adequacy and effectiveness of our financial controls;
- considers and approves or disapproves all related party transactions;
- reviews the audit committee charter and the committee's and its member's performance at least annually; and
- establishes procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters.

Compensation Committee

The Compensation Committee is composed of three directors: Mr. Greenman, Dr. Davis and Dr. Akkaraju. The chair of our compensation committee is Mr. Greenman. The Compensation Committee met four times during the fiscal year. The Board has adopted a written Compensation Committee charter that is available to stockholders on the Company's website at https://investors.chinooktx.com/corporate-governance/highlights.

Our Board of Directors has determined that each member of the Compensation Committee is independent under Nasdaq listing standards and the rules and regulations of the SEC and is a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act.

Among other matters, the Compensation Committee:

- determines the compensation and other terms of employment of our executive officers and reviews and recommends to the independent directors corporate performance goals and objectives relevant to such compensation;
- reviews and recommends to the independent directors the compensation, performance goals, objects relevant to compensation and other terms of employment for our Chief Executive Officer;
- reviews and recommends to the full board the compensation for our directors;
- evaluates and administers the equity incentive plans, compensation plans and similar programs advisable for us, as well as reviews and recommends to its board of directors the adoption, modification or termination of such plans and programs;
- establishes policies with respect to equity compensation arrangement;
- reviews with management disclosures under the caption "Compensation Discussion and Analysis," when and as required by applicable rules and regulations of the SEC, and recommends to the full board its inclusion in our periodic reports to be filed with the SEC;
- administers our equity compensation plans, pension and profit-sharing plans, deferred compensation and other similar plans and program; and
- reviews and evaluates, at least annually, the performance of the compensation committee and its members, including compliance by the compensation committee with its charter.

Compensation Committee Processes and Procedures

Typically, the Compensation Committee meets as often as its members deem necessary or appropriate. The agenda for each meeting is usually developed by the Chair of the Compensation Committee, in consultation with the Company's Chief Executive Officer. The Compensation Committee meets regularly in executive session. However, from time to time, various members of management and other employees as well as outside advisors or consultants may be invited by the Compensation Committee to make presentations, to provide financial or other background information or advice or to otherwise participate in Compensation Committee meetings. The Chief Executive Officer may not participate in, or be present during, any deliberations or determinations of the Compensation Committee regarding his compensation or individual performance objectives. The charter of the Compensation Committee grants the Compensation Committee full access to all books, records, facilities and personnel of the Company. In addition, under the charter, the Compensation Committee has the authority to obtain, at the expense of the Company, advice and assistance from compensation consultants and internal and external legal, accounting or other advisors and other external resources that the Compensation Committee considers necessary or appropriate in the performance of its duties. The Compensation Committee has direct responsibility for the oversight of the work of any consultants or advisers engaged for the purpose of advising the Committee. In

particular, the Compensation Committee has the sole authority to retain, in its sole discretion, compensation consultants to assist in its evaluation of executive and director compensation, including the authority to approve the consultant's reasonable fees and other retention terms. Under the charter, the Compensation Committee may select, or receive advice from, a compensation consultant, legal counsel or other adviser to the compensation committee, other than in-house legal counsel and certain other types of advisers, only after taking into consideration six factors, prescribed by the SEC and Nasdaq, that bear upon the adviser's independence.

The Compensation Committee engaged an independent executive compensation consulting firm, Radford, which is part of the Rewards Solutions practice at Aon plc, to evaluate our executive compensation and Board of Directors compensation program and practices and to provide advice and ongoing assistance on these matters following the merger of Chinook and Aduro. Specifically, Radford was engaged to:

- provide compensation-related data for a peer group of companies to serve as a basis for assessing competitive compensation practices;
- review and assess our current Board of Directors, Chief Executive Officer and other executive officer compensation policies and practices and equity profile, relative to market practices;
- review and assess our current executive compensation program relative to market to identify any potential changes or enhancements to be brought to the attention of the Compensation Committee; and
- review market practices regarding base salary, bonus and equity programs.

Representatives of Radford met informally with the Chair of the Compensation Committee and attended the regular meetings of the Compensation Committee, including executive sessions from time to time without any members of management present. Radford worked directly with the Compensation Committee (and not on behalf of management) to assist the committee in satisfying its responsibilities and undertook no projects for management without the committee's prior approval. The Compensation Committee has determined that none of the work performed by Radford during the fiscal year ended December 31, 2020 raised any conflict of interest.

The Compensation Committee may form and delegate authority to subcommittees as it deems appropriate, including, but not limited to, a subcommittee composed of one or more members of the Board or officers of the Company to grant stock awards under the Company's equity incentive plans to persons who are not then subject to Section 16 of the Exchange Act.

Nominating and Corporate Governance Committee

Our Nominating and Corporate Governance Committee consists of Dr. Akkaraju, Mr. Haghighat and Dr. Thomas. The chair of our Nominating and Corporate Governance Committee is Mr. Akkaraju. The Nominating and Corporate Governance Committee met once during the fiscal year. The Board has adopted a written Nominating and Corporate Governance Committee charter that is available to stockholders on the Company's website at https://investors.chinooktx.com/corporate-governance/highlights.

Our Board of Directors has determined that each member of our Nominating and Corporate Governance Committee is independent under Nasdaq listing standards and the rules and regulations of the SEC.

The Nominating and Corporate Governance Committee:

- interviews, evaluates, nominates and recommends to the board of directors candidates for directorships;
- performs periodic reviews of the performance of each member of the entire board of directors and its committees and recommends areas for improvement to the board and management;
- oversees the corporate governance policies and reporting and makes recommendations to the board of directors concerning governance matters; and
- reviews and evaluates, at least annually, the performance of the nominating and corporate governance committee and its members, including compliance by the nominating and corporate governance committee with its charter.

The Nominating and Corporate Governance Committee is responsible for identifying, considering and recommending candidates to the Board of Directors for Board membership. A variety of methods are used to identify and evaluate director nominees, with the goal of maintaining and further developing a diverse, experienced and highly qualified Board of Directors. Candidates may come to our attention through current members of our Board of Directors, professional search firms, stockholders or other persons.

The Nominating and Corporate Governance Committee will recommend to the Board of Directors for selection all nominees to be proposed by the Board of Directors for election by the stockholders, including approval or recommendation of a slate of director

nominees to be proposed by the Board of Directors for election at each annual meeting of stockholders, and will recommend all director nominees to be appointed by the Board of Directors to fill interim director vacancies.

Our Board of Directors encourages selection of directors who will contribute to the company's overall corporate goals. The Nominating and Corporate Governance Committee may from time to time review and recommend to the Board of Directors the desired qualifications, expertise and characteristics of directors, including such factors as business experience, diversity and personal skills in life sciences and biotechnology, finance, marketing, financial reporting and other areas that are expected to contribute to an effective Board of Directors. Exceptional candidates who do not meet all of these criteria may still be considered. In evaluating potential candidates for the Board of Directors, the Nominating and Governance Committee considers these factors in the light of the specific needs of the Board of Directors at that time.

In addition, under our Corporate Governance Guidelines, a director is expected to spend the time and effort necessary to properly discharge such director's responsibilities. Accordingly, a director is expected to regularly attend meetings of the Board of Directors and committees on which such director sits, and to review prior to meetings material distributed in advance for such meetings. Thus, the number of other public company boards and other boards (or comparable governing bodies) on which a prospective nominee is a member, as well as his or her other professional responsibilities, will be considered. Also, under our Corporate Governance Guidelines, there are no limits on the number of three-year terms that may be served by a director. However, in connection with evaluating recommendations for nomination for reelection, the Nominating and Corporate Governance Committee considers director tenure. We value diversity on a company-wide basis but have not adopted a specific policy regarding Board diversity.

The Nominating and Corporate Governance Committee will consider director candidates recommended by stockholders. The Nominating and Corporate Governance Committee does not intend to alter the manner in which it evaluates candidates, including the minimum criteria set forth above, based on whether or not the candidate was recommended by a stockholder. A stockholder of record can nominate a candidate for election to the Board of Directors by complying with the procedures in Article I, Section 1.12 of our bylaws. Stockholders who wish to recommend individuals for consideration by the Nominating and Corporate Governance Committee to become nominees for election to the Board may do so by delivering a written recommendation to the Nominating and Corporate Governance Committee at the following address: Chinook Therapeutics, Inc., c/o Corporate Secretary 1600 Fairview Ave E, Suite #100, Seattle WA 98102, at least 120 days prior to the anniversary date of the mailing of the Company's proxy statement for the last Annual Meeting of Stockholders. Submissions must include the full name of the proposed nominee, complete biographical information, a description of the proposed nominee's qualifications as a director, other information specified in our bylaws, and a representation that the nominating stockholder is a beneficial or record holder of our stock. Any such submission must be accompanied by the written consent of the proposed nominee to be named as a nominee and to serve as a director if elected. These candidates are evaluated at meetings of the Nominating and Corporate Governance Committee and may be considered at any point during the year. If any materials are provided by a stockholder in connection with the recommendation of a director candidate, such materials are forwarded to the Nominating and Corporate Governance Committee.

CODE OF ETHICS

Our Board of Directors has adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including our Chief Executive Officer, Chief Financial Officer and other executive and senior financial officers. We intend to disclose future amendments to certain provisions of our code of conduct, or waivers of these provisions, on our website or in public filings. The full text of our code of conduct is posted on the investor relations section of our website https://investors.chinooktx.com/corporate-governance/highlights.

CORPORATE GOVERNANCE GUIDELINES

The Board of Directors documented the governance practices followed by the Company by adopting Corporate Governance Guidelines to assure that the Board will have the necessary authority and practices in place to review and evaluate the Company's business operations as needed and to make decisions that are independent of the Company's management. The guidelines are also intended to align the interests of directors and management with those of the Company's stockholders. The Corporate Governance Guidelines set forth the practices the Board intends to follow with respect to board composition and selection, board meetings and involvement of senior management, Chief Executive Officer performance evaluation and succession planning, and board committees and compensation. The Corporate Governance Guidelines, as well as the charters for each committee of the Board, may be viewed at https://investors.chinooktx.com/corporate-governance/highlights.

Item 11. Executive Compensation.

Compensation Committee Interlocks and Insider Participation

None of the members of the compensation committee is currently or has been at any time one of our officers or employees. None of our executive officers currently serves, or has served during the last year, as a member of the board of directors or

compensation committee of any entity that has one or more executive officers serving as a member of our Board of Directors or Compensation Committee.

SUMMARY COMPENSATION TABLE

The following table sets forth information regarding compensation awarded to or earned by the executive officers listed below during the years ended December 31, 2020 and 2019. We comply with the executive compensation disclosure rules applicable to "smaller reporting companies," as such term is defined in the rules promulgated under the Securities Act, which require compensation disclosure for all individuals who served as our principal executive officer during the year, and the two most highly compensated executive officers other than our principal executive officer. These officers are referred to as our named executive officers.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)(1)	Option Awards ($)(2)	Non-equity Incentive Plan Compensation ($)(3)	All Other Compensation ($)(4)	Total($)
Eric Dobmeier								
President and Chief Executive Officer	2020	437,802	—	1,364,586	4,181,817	256,113	2,000	6,242,318
Stephen T. Isaacs								
Former President and Chief Executive Officer	2020	488,861	562,500	—	1,035,294	976,876	1,120,313 (5)	4,183,844
	2019	625,000	75,938	—	2,244,330	318,750	—	3,264,018
Tom Frohlich								
Chief Business Officer	2020	307,413	—	601,774	1,537,975	117,529	1,488	2,566,179
Alan Glicklich, M.D.								
Chief Medical Officer	2020	266,288	75,000	314,763	1,656,680	95,760	—	2,408,491

(1) The amounts reported in the Stock Awards column represent the aggregate grant date fair value of restricted stock granted under our equity incentive plans to our named executive officers during the year ended December 31, 2020 and 2019 as computed in accordance with ASC 718. The assumptions used in calculating the grant date fair value of the restricted stock reported in the Stock Awards column are set forth in Note 11 to the Chinook audited financial statements included elsewhere in this annual report. Note that the amounts reported in this column reflect the aggregate accounting cost for these stock awards, and do not necessarily correspond to the actual economic value that may be received by the named executive officers from the awards.

(2) The amounts reported in the Option Awards column represent the aggregate grant date fair value of stock options granted under our equity incentive plans to our named executive officers during the year ended December 31, 2020 and 2019 as computed in accordance with ASC 718. The assumptions used in calculating the grant date fair value of the stock options reported in the Option Awards column are set forth in Note 11 to the Chinook audited financial statements included elsewhere in this annual report. Note that the amounts reported in this column reflect the aggregate accounting cost for these stock options, and do not necessarily correspond to the actual economic value that may be received by the named executive officers from the options.

(3) Represents the bonuses paid to the named executive officers in cash performance pursuant to our annual incentive program based on achievement of pre-established corporate goals.

(4) Represents contributions to each officer's 401(k) Plan or other retirement plan. Mr. Frohlich's retirement contribution was converted to U.S. dollars from Canadian dollars based on the average exchange rate of $1.4332.

(5) Mr. Isaacs's 2020 other compensation included (i) $970,313 in severance pay and (ii) $150,000 of consulting services rendered.

Outstanding Equity Awards at December 31, 2020

The following table provides information regarding each unexercised stock option granted pursuant to our equity incentive plans held by our named executive officers as of December 31, 2020:

		Option Awards				Stock Awards	
Name	Grant Date	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares of Restricted Stock That Have Not Vested (#)	Market Value of Shares of Restricted Stock That Have Not Vested ($)
Eric Dobmeier	10/5/2020(1)	173,065	443,358	0.35	6/5/2029	—	—
	10/5/2020(2)	—	423,555	0.42	3/17/2030	—	—
	10/6/2020(3)	—	271,647	14.77	10/5/2030	—	—
	10/5/2020(4)	—	—	—	—	27,031	428,711
	10/6/2020(5)	—	—	—	—	92,389	1,465,289
Tom Frohlich	10/5/2020(6)	—	98,847	0.42	3/17/2030	—	—
	10/6/2020(7)	—	119,793	14.77	10/5/2030	—	—
	10/5/2020(8)	—	—	—	—	76,700	1,216,462
	10/6/2020(9)	—	—	—	—	40,743	646,183
Alan Glicklich, M.D.	10/5/2020(10)	—	242,662	0.42	4/21/2030	—	—
	10/6/2020(11)	—	62,660	14.77	10/5/2030	—	—
	10/5/2020(12)	—	—	—	—	21,311	337,992
Stephen T. Isaacs	06/10/2016(13)	2,810	—	59.95	10/3/2022	—	—
	06/12/2017(13)	1,860	—	53.75	10/3/2022	—	—
	02/08/2018(13)	3,135	—	30.25	10/3/2022	—	—
	02/19/2019(13)	5,420	—	19.40	10/3/2022	—	—
	01/10/2015(13)	4,343	—	7.25	10/3/2022	—	—
	10/24/2011(13)	27,765	—	2.60	10/3/2022	—	—
	10/24/2011(13)	80,547	—	2.60	10/3/2022	—	—
	10/24/2011(13)	24,195	—	2.60	10/3/2022	—	—
	07/31/2014(13)	57,815	—	5.00	10/3/2022	—	—
	07/31/2014(13)	19,999	—	5.00	10/3/2022	—	—
	02/21/2020(13)	42,496	—	18.25	10/3/2022	—	—
	06/10/2016(13)	11,329	—	59.95	10/3/2022	—	—
	12/12/2016(13)	13,820	—	55.75	10/3/2022	—	—
	02/08/2018(13)	72,114	—	30.25	10/3/2022	—	—
	02/19/2019(13)	174,580	—	19.40	10/3/2022	—	—
	01/10/2015(13)	204,153	—	7.25	10/3/2022	—	—
	12/10/2015(13)	7,450	—	150.80	10/3/2022	—	—
	06/12/2017(13)	15,819	—	53.75	10/3/2022	—	—
	07/31/2014(13)	46,174	—	5.00	10/3/2022	—	—
	07/31/2014(13)	28,793	—	5.00	10/3/2022	—	—

(1) 25 percent of the shares underlying the option vested on April 1, 2020, and 1/48th of the total shares underlying the option vest in equal monthly installments thereafter, subject to the executive's continued service. This stock option was received in connection with the Merger in exchange for an existing stock option award for shares of Chinook Therapeutics U.S., Inc.

(2) 25 percent of the shares underlying the option vest on March 6, 2021, and 1/48th of the total shares underlying the option vest in equal monthly installments thereafter, subject to the executive's continued service. This stock option was received in connection with the Merger in exchange for an existing stock option award for shares of Chinook Therapeutics U.S., Inc.

(3) 25 percent of the shares underlying the option vest on October 6, 2021, and 1/36th of the total shares underlying the option vest in equal monthly installments thereafter, subject to the executive's continued service.

(4) Represents shares of common stock purchased by Mr. Dobmeier pursuant to the Chinook 2019 Plan, which are subject to a company repurchase right that lapsed with respect to 25 percent of the purchased shares on April 1, 2020, and with respect to 1/48th of the total purchased shares in equal monthly installments thereafter, subject to Mr. Dobmeier's continued service. These shares were received in connection with the Merger in exchange for existing restricted stock of Chinook Therapeutics U.S., Inc.

(5) 1/3 of the restricted stock units vest in equal annual installments beginning on October 6, 2021.

(6) 25 percent of the shares underlying the option vest on March 6, 2021, and 1/48th of the total shares underlying the option vest in equal monthly installments thereafter, subject to the executive's continued service. This stock option was received in connection with the Merger in exchange for an existing stock option award for shares of Chinook Therapeutics U.S., Inc.
(7) 25 percent of the shares underlying the option vest on October 6, 2021, and 1/36th of the total shares underlying the option vest in equal monthly installments thereafter, subject to the executive's continued service.
(8) Represents shares of common stock purchased by Mr. Frohlich pursuant to the Chinook 2019 Plan, which are subject to a company repurchase right that lapsed with respect to 25 percent of the purchased shares on April 1, 2020, and with respect to 1/48th of the total purchased shares in equal monthly installments thereafter, subject to Mr. Frohlich's continued service. These shares were received in connection with the Merger in exchange for existing restricted stock of Chinook Therapeutics U.S., Inc.
(9) 1/3 of the restricted stock units vest in equal annual installments beginning on October 6, 2021.
(10) 25 percent of the shares underlying the option vest on April 20, 2021, and 1/48th of the total shares underlying the option vest in equal monthly installments thereafter, subject to the executive's continued service. This stock option was received in connection with the Merger in exchange for an existing stock option award for shares of Chinook Therapeutics U.S., Inc.
(11) 25 percent of the shares underlying the option vest on October 6, 2021, and 1/36th of the total shares underlying the option vest in equal monthly installments thereafter, subject to the executive's continued service.
(12) 1/3 of the restricted stock units vest in equal annual installments beginning on October 6, 2021.
(13) 100 percent of Mr. Isaacs outstanding options vested upon the Merger and pursuant to his separation agreement the exercise period for all such options was extended until October 3, 2022.

Employment Arrangements

Each of our named executive officers' employment is "at will" and may be terminated at any time. Below is a description of our employment agreements or offer letters, as applicable, with each of our named executive officers for the year ended December 31, 2020.

Eric Dobmeier

In October 2020, following the closing of the Merger, we entered into a new employment agreement with Mr. Dobmeier setting forth the terms of his employment. Pursuant to his employment agreement, Mr. Dobmeier will receive an annual base salary of $437,800 and will be eligible to receive an annual performance bonus with a target amount equal to 45 percent of his base salary. In the event that Mr. Dobmeier experiences a termination of his employment without "cause" or he resigns for "good reason" outside of the "change in control period" (as such terms are defined in Mr. Dobmeier's employment agreement), provided that he executes and makes effective a release of claims against the Company and its affiliates, Mr. Dobmeier will become entitled to (i) an amount equal to twelve months' annual base salary, payable in a lump sum, (ii) an amount equal to any annual bonus for any completed calendar year, to the extent earned but not yet paid at the time of such termination, and (iii) premium payments for continued healthcare coverage for a period of twelve months.

In the event that Mr. Dobmeier experiences a termination of his employment without cause or he resigns for good reason during the change in control period, provided that he executes and makes effective a release of claims against the Company and its affiliates, Mr. Dobmeier will become entitled to (i) an amount equal to eighteen months' annual base salary and 150 percent of his target annual performance bonus, payable in a lump sum, (ii) an amount equal to any annual bonus for any completed calendar year, to the extent earned but not yet paid at the time of such termination; (iii) premium payments for continued healthcare coverage for a period of eighteen month; and (iv) accelerated vesting of each outstanding unvested equity award, provided that any performance-based vesting criteria will be treated in accordance with the applicable award agreement or other applicable equity incentive plan governing the terms of such equity award.

Tom Frohlich

In October 2020, following the closing of our merger with Aduro, we entered into a new employment agreement with Mr. Frohlich setting forth the terms of his employment. Pursuant to his employment agreement, Mr. Frohlich will receive an initial annual base salary of 412,100 Canadian Dollars (CAD), and will be eligible to receive annual performance bonuses with target amounts equal to 30 percent of his base salary. In the event that Mr. Frohlich experiences a termination of his employment without "cause" or resigns for "good reason" outside of the "change in control period" (as such terms are defined in Mr. Frohlich's employment agreement), provided that he executes and makes effective a release of claims against the Company and its affiliates, Mr. Frohlich will become entitled to (i) an amount equal to twelve months' annual base salary, payable in a lump sum, (ii) an amount equal to any annual bonus for any completed calendar year, to the extent earned but not yet paid at the time of such termination, and (iii) premium payments for continued healthcare coverage for a period of twelve months.

In the event that Mr. Frohlich experiences a termination of his employment without cause or resigns for good reason during the change in control period, provided that he executes and makes effective a release of claims against the Company and its affiliates, Mr.

Frohlich will become entitled to an amount equal to (i) eighteen months' annual base salary and 100 percent of his target annual performance bonus, payable in a lump sum, (ii) an amount equal to any annual bonus for any completed calendar year, to the extent earned but not yet paid at the time of such termination; (iii) premium payments for continued healthcare coverage for a period of eighteen months; and (iv) accelerated vesting of each outstanding unvested equity award, provided that any performance-based vesting criteria will be treated in accordance with the applicable award agreement or other applicable equity incentive plan governing the terms of such equity award.

Alan Glicklich

In October 2020, following the closing of the Merger, we entered into a new employment agreement with Dr. Glicklich setting forth the terms of his employment. Dr. Glicklich will receive an initial annual base salary of $380,000 and will be eligible to receive an annual performance bonus with a target amount equal to 30% of his base salary. In the event that Dr. Glicklich experiences a termination of his employment without "cause" or resigns for "good reason" outside of the "change in control period" (as such terms are defined in Dr. Glicklich's employment agreement), provided that he executes and makes effective a release of claims against the Company and its affiliates, Dr. Glicklich will become entitled to (i) an amount equal to twelve months' annual base salary, payable in a lump sum, (ii) an amount equal to any annual bonus for any completed calendar year, to the extent earned but not yet paid at the time of such termination, and (iii) premium payments for continued healthcare coverage for a period of twelve months.

In the event that Dr. Glicklich experiences a termination of his employment without cause or resigns for good reason during the change in control period, provided that he executes and makes effective a release of claims against the Company and its affiliates, Dr. Glicklich will become entitled to an amount equal to (i) eighteen months' annual base salary and 100% of his target annual performance bonus, payable in a lump sum, (ii) an amount equal to any annual bonus for any completed calendar year, to the extent earned but not yet paid at the time of such termination; (iii) premium payments for continued healthcare coverage for a period of eighteen months; and (iv) accelerated vesting of each outstanding unvested equity award, provided that any performance-based vesting criteria will be treated in accordance with the applicable award agreement or other applicable equity incentive plan governing the terms of such equity award.

Stephen Isaacs

On October 6, 2020, following the closing of our merger with Aduro, we entered into consulting agreements with Mr. Isaacs pursuant to which he agreed to provide consulting services to us to support the disposition of our non-renal assets. We paid a $75,000 flat monthly fee for Mr. Isaacs services through November 30, 2020, plus reimbursement of reasonable expenses.

Other Benefits

Chinook's named executive officers are eligible to participate in employee benefit plans on the same basis as Chinook's other employees, including a 401(k) plan and health and welfare plans.

Chinook 2019 Equity Incentive Plan

We maintain the Chinook 2019 Plan, which was approved by Private Chinook's stockholders and adopted by its board of directors on February 6, 2019, and assumed by us upon the closing of the Merger. The purposes of the Chinook 2019 Plan is to secure and retain the services of eligible award recipients, provide incentives for such persons to exert maximum efforts for the success of Chinook. The material terms of the Chinook 2019 Plan are summarized below:

Share Reserve. Subject to adjustment as provided in the Chinook 2019 Plan, the maximum number of shares of Chinook common stock which may be issued under the Chinook 2019 Plan is 3,311,647 shares, or the Share Reserve. In addition, effective immediately following the completion of each of the Second Closing, Third Closing and the Fourth Closing (each as defined in that certain Amended and Restated Series A Preferred Stock Purchase Agreement, dated July 3, 2019, by and among Chinook and the purchasers listed on the schedule of purchasers attached thereto, as may be amended from time to time), the Share Reserve shall automatically increase such that, as of immediately following such increase, the aggregate number of shares that may be issued equals 15.0 percent of Chinook's fully diluted capitalization.

Administration. The Chinook 2019 Plan is administered by Chinook's board of directors, or a committee created and appointed by Chinook's board of directors for such administration. Subject to the terms of the Chinook 2019 Plan, Chinook's board of directors has the authority to, among other things, select the persons to whom awards will be granted, construe and interpret the Chinook 2019 Plan as well as to prescribe, amend, expand, modify and rescind rules and regulations relating to the Chinook 2019 Plan.

Eligibility. Pursuant to the Chinook 2019 Plan, Chinook may grant incentive stock options to employees of Chinook or a "parent corporation" or "subsidiary corporation" thereof, as such terms are defined in the Code. Stock awards other than incentive stock options may be granted to employees, director and consultants, subject to certain restrictions.

Options. The Chinook 2019 Plan provides for the grant of both (i) incentive stock options, which are intended to qualify for tax treatment as set forth under Section 422 of the Code and (ii) non-statutory stock options to purchase shares of Chinook common stock, each at a stated exercise price. The exercise price of each stock option must be at least equal to the fair market value of Chinook's common stock on the date of grant. However, the exercise price of any incentive stock option granted to an individual who owns more than 10 percent of the total combined voting power of all classes of Chinook's capital stock must be at least equal to 110 percent of the fair market value of Chinook's common stock on the date of grant.

The maximum permitted term of options granted under the Chinook 2019 Plan is ten years from the date of grant, except that the maximum permitted term of incentive stock options granted to an individual who owns more than ten percent of the total combined voting power of all classes of Chinook capital stock is five years from the date of grant.

Restricted Stock Awards. The Chinook 2019 Plan also provides for the issuance of restricted stock awards pursuant to which the holder may purchase restricted shares of Chinook common stock. Among other terms and conditions, Chinook may retain an option to repurchase the unvested restricted stock at any time following the holder's termination of service.

Restricted Stock Units. The Chinook 2019 Plan also provides for the issuance of RSUs that may be settled in cash, by issuance of Chinook common stock or by a combination thereof. The terms will be generally determined by Chinook's board of directors and be set forth in an award agreement.

Stock Appreciation Rights. In addition, the Chinook 2019 Plan provides for the issuance of stock appreciation rights that may be settled in cash, by issuance of Chinook common stock, restricted stock awards or RSUs, or by a combination thereof, with the value equal to the value determined by multiplying the difference between the fair market value on the date of exercise over the exercise price thereof, and the number of shares to which the stock appreciation rights are being exercised. The terms will be generally determined by Chinook's board of directors and be set forth in an award agreement.

Limited Transferability. Unless otherwise determined by Chinook's board of directors, awards granted under the Chinook 2019 Plan generally may not be transferred or assigned in any manner other than by will or the laws of descent and distribution.

Corporate Transaction. In the event of a Corporate Transaction (as defined in the Chinook 2019 Plan), the Chinook 2019 Plan provides that its board of directors has the discretion to take (or arrange for) any of the following actions with respect to some or all outstanding equity awards under the Chinook 2019 Plan: continuation of such awards if Chinook is the successor entity, assumption or substitution of awards by a successor or acquiring corporation, immediate termination of the awards if not exercised and/or vested within a specified time frame, cash payment and consequent cancellation of the awards, partial or full accelerated vesting of such equity awards, or the lapse or assignment of any reacquisition or repurchase rights to a successor or acquiring corporation.

Adjustments. In the event of a stock dividend, recapitalization, stock split, reverse stock split, subdivision, combination, reclassification or other similar transaction, Chinook's board of directors may adjust the number and class of shares reserved for issuance under Chinook 2019 Plan, or the prices of and number and class of shares covered by each outstanding award, in order to prevent diminution or enlargement of benefits or potential benefits intended to be made available under the Chinook 2019 Plan or otherwise as required by applicable law.

EQUITY COMPENSATION PLAN INFORMATION

The following table provides certain information with respect to all of the Company's equity compensation plans in effect as of December 31, 2020:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options and RSUs	Weighted-Average Exercise Price of Outstanding Options	Number of Securities Remaining for Issuance under Equity Compensation Plans	
Equity compensation plans approved by stockholders (1)	5,368,793	$ 13.22	894,227	(2) (3)
Equity compensation plans not approved by stockholders	144,787	13.98	—	(4)
Total	5,513,580	$ 13.24	894,227	

(1) Includes securities issuable under our 2009 Stock Incentive Plan (the "2009 Plan"), the 2015 Plan and our 2019 Plan.

(2) Includes 13,599 and 880,668 shares of common stock available for issuance under the 2019 Plan and the 2019 Plan, respectively, as of December 31, 2020. Shares under the 2009 Plan that expire, terminate or are forfeited prior to exercise or settlement automatically become available for issuance under the 2015 Plan.

(3) The number of shares of common stock reserved for issuance pursuant to equity awards under the 2015 Plan will automatically increase January 1 of each year for a period of up to ten years, commencing on January 1, 2016 and continuing through and including January 1, 2025 by the lesser of (i) the amount equal to 4 percent of the number of shares issued and outstanding on December 31 immediately prior to the date of increase or (ii) such lower number of shares as may be determined by the Board of Directors.

(4) On November 30, 2020, the Board of Directors granted an option to purchase 144,787 shares of Company common stock to our Chief Financial Officer, as inducement to his employment with us pursuant to Nasdaq Listing Rule 5635(c)(4).

Limitation on Liability and Indemnification Matters

Our amended and restated certificate of incorporation and restated bylaws provide that we will indemnify our directors and officers, and may indemnify our employees and other agents, to the fullest extent permitted by the Delaware General Corporation Law. However, Delaware law prohibits us from limiting the liability of our directors for the following:

- any breach of a director's duty of loyalty to us or to our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or unlawful stock repurchases or redemptions; and
- any transaction from which a director derived an improper personal benefit.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our amended and restated certificate of incorporation does not eliminate a director's duty of care and, in appropriate circumstances, equitable remedies, such as injunctive or other forms of nonmonetary relief, remain available under Delaware law. It also does not affect a director's responsibilities under any other laws, such as the federal securities laws or other state or federal laws. Under our amended and restated bylaws, we will also be empowered to enter into indemnification agreements with our directors, officers, employees and other agents and to purchase insurance on behalf of any person whom we are required or permitted to indemnify.

In addition to the indemnification required in our amended and restated certificate of incorporation and amended and restated bylaws, we have entered into indemnification agreements with each of our current directors and executive officers. These agreements provide for the indemnification of such persons for all reasonable expenses and liabilities incurred in connection with any action or proceeding brought against them by reason of the fact that they are or were serving in such capacity. We believe that these certificate of incorporation and bylaws provisions and indemnification agreements are necessary to attract and retain qualified persons as directors, officers and employees. Furthermore, we have obtained director and officer liability insurance to cover liabilities our directors and officers may incur in connection with their services to us.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended (the "Securities Act"), may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

NON-EMPLOYEE DIRECTOR COMPENSATION

The following table shows for the fiscal year ended December 31, 2020 certain information with respect to the compensation of all non-employee directors of the Company:

Name	Fees Earned or Paid in Cash	Option Awards(1)	Total
Srinivas Akkaraju, M.D., Ph.D.	$ 13,500	$ 234,411	$ 247,911
Jerel Davis, Ph.D.	$ 17,750	$ 234,411	$ 252,161
William M. Greenman	$ 57,246	$ 259,971	$ 317,217
Michelle Griffin	$ 15,000	$ 234,411	$ 249,411
Ross Haghighat	$ 50,138	$ 374,969	$ 425,107
Dolca Thomas	$ 11,000	$ 234,411	$ 245,411
Frank Karbe (2)	$ 45,570	$ 25,560	$ 71,130
David H. Mack (2)	$ 38,172	$ 25,560	$ 63,732
Stephanie Monaghan O'Brien (2)	$ 60,035	$ 25,560	$ 85,595
Stephen A. Sherwin, M.D. (2)	$ 45,806	$ 25,560	$ 71,366

(1) The amounts in the "Option Awards" column reflect the aggregate grant date fair value of stock options granted during the calendar year computed in accordance with the provisions of ASC 718, Compensation-Stock Compensation. The assumptions that we used to calculate these amounts are discussed in the notes to our audited consolidated financial statements included in this annual report on Form 10 K for the year ended December 31, 2020. These amounts may not reflect the actual economic value that will be realized by the non-employee director upon the exercise of the stock options or the sale of the common stock acquired upon such exercise. For information regarding the number of stock options held by each non-employee director as of December 31, 2020, see the table below.

(2) Directors of Aduro who left the board of directors at the conclusion of the merger.

	Number of shares underlying options held as of December 31, 2020
Srinivas Akkaraju, M.D., Ph.D.	23,522
Jerel Davis, Ph.D.	23,522
William M. Greenman	57,985
Michelle Griffin	23,522
Ross Haghighat	57,722
Dolca Thomas	23,522
Frank Karbe (1)	24,000
David H. Mack (1)	20,000
Stephanie Monaghan O'Brien (1)	43,431
Stephen A. Sherwin, M.D. (1)	29,167

(1) Directors of Aduro who left the Board of Directors upon the closing of the Merger.

Following completion of the Merger, non-employee directors receive the following cash compensation for service on our Board of Directors and committees of our Board of Directors, as applicable, payable in equal monthly installments, in arrears:

- $40,000 per year for service as a member of our Board of Directors;
- $25,000 per year for service as our Lead Independent Director;
- $20,000 per year for service as the chair of the Audit Committee and $7,500 per year for service as a member (other than as chair) of the Audit Committee;
- 12,000 per year for service as the chair of the Compensation Committee and $6,000 per year for service as a member (other than as chair) of the Compensation Committee; and
- 8,000 per year for service as the chair of the Nominating and Corporate Governance Committee and $4,000 per year for service as a member (other than as chair) of the Nominating and Corporate Governance Committee

In addition, each newly appointed non-employee director will be granted an option to purchase shares of our common stock with a grant date value of $200,000. These options will vest on a three-year, monthly vesting schedule. Additionally, on the date of each annual meeting, each person who is elected or appointed and each director who continues to serve as a director immediately after such annual meeting shall be granted options to purchase shares of our common stock with a grant date value of $100,000. These options will vest on the one-year anniversary of granting.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth certain information regarding the ownership of the Company's common stock as of January 31, 2021 by: (i) each of our directors and named executive officers; (ii) all executive officers and directors of the Company as a group; and (iii) all those known by the Company to be beneficial owners of more than five percent of its common stock.

Beneficial ownership is determined according to the rules of the SEC and generally means that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power of that security, including options and warrants that are currently exercisable or exercisable within 60 days of January 31, 2021. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons named in the table below have sole voting and investment power with respect to all shares of common stock shown that they beneficially own, subject to community property laws where applicable. Common stock subject to options and warrants currently exercisable or exercisable within 60 days of January 31, 2021, is deemed to be outstanding for computing the percentage ownership of the person holding these options or warrants and the percentage ownership of any group of which the holder is a member but is not deemed outstanding for computing the percentage of any other person.

Our calculation of the percentage of beneficial ownership is based on shares of our common stock outstanding at January 31, 2021. Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Chinook Therapeutics, Inc., 1600 Fairview Ave E, Suite #100, Seattle WA 98102.

	Beneficial Ownership	
Name of Beneficial Owner	Number	Percent
Directors and Named Executive Officers:		
Eric Dobmeier (1)	394,403	*
Tom Frohlich (2)	178,109	*
Alan Glicklich	-	*
Jerel Davis (3)	7,891,639	18.65%
Srinivas Akkaraju (4)	3,171,654	7.50%
Ross Haghighat (5)	55,396	*
William M. Greenman (6)	41,695	*
Michelle Griffin (7)	3,266	*
Dolca Thomas (8)	3,266	*
Stephen Isaacs (9)	846,109	2.00%
All executive officers and directors as a group (11 persons) (10)	12,585,537	29.75%
5% or Greater Stockholders:		
Versant Entities (11)	7,888,373	18.65%
Apple Tree Partners IV, L.P. (12)	4,028,938	9.52%
Samsara BioCapital, L.P. (13)	3,168,388	7.49%
Morningside Venture Entities (14)	2,984,605	7.05%

* Represents beneficial ownership of less than one percent.

(1) Represents (i) 76,837 shares of common stock, of which 23,169 shares are unvested and subject to repurchase by us if Mr. Dobmeier ceases to provide service to us prior to the vesting of the shares and (ii) 317,566 shares of common stock subject to options that are exercisable within 60 days of January 31, 2021.

(2) Represents 153,398 shares of common stock, of which 67,112 shares are unvested and subject to repurchase by us if Mr. Frohlich ceases to provide service to us prior to the vesting of the shares and (ii) 24,711 shares of common stock subject to options that are exercisable within 60 days of January 31, 2021.

(3) Represents (i) 4,733,024 shares of common stock held by Versant Venture Capital VII, L.P., (ii) 722,248 shares of common stock held by Versant Voyageurs I Parallel, L.P.,(iii) 2,433,101 common shares held by Versant Voyageurs I, L.P and (iv) 3,266 shares of common stock subject to options held by Dr. Davis that are exercisable within 60 days of January 31, 2021. Dr. Davis is a managing director of Versant Ventures VII GP-GP, LLC, the ultimate general partner of Versant Venture Capital VII, L.P. and shares voting and investment power over the shares held by such fund with Bradley Bolzon, Robin Praeger, Thomas Woiwode and Clare Ozawa. Dr. Davis is a managing director of Versant Ventures VI GP-GP, LLC, the ultimate general partner of Versant Voyageurs I, L.P. and Versant Voyageurs I Parallel, L.P. and shares voting and investment power over the shares held by such funds with Bradley Bolzon, Robin Praeger, Thomas Woiwode and Clare Ozawa. The address for each of these entities and individuals is One Sansome, Suite 3630, San Francisco, CA 94104.

(4) Represents (i) 3,168,388 shares of common stock held by Samsara BioCapital, L.P., or Samsaraand 3,266 shares of common stock subject to options held by Dr. Akkaraju that are exercisable within 60 days of January 31, 2021. Dr. Akkaraju is the managing general partner of Samsara BioCapital, LLC, the general partner of Samsara and may be deemed to have voting and investment power over the shares held by Samsara. Dr. Akkaraju disclaims beneficial ownership of the shares held by Samsara except to the extent of his pecuniary interest therein. The address for Samsara is 628 Middlefield Road, Palo Alto, CA 94301.

(5) Represents (i) 17,930 shares of common stock and (ii) 37,466 shares underlying options to purchase common stock that are exercisable within 60 days of January, 2021.

(6) Represents (i) 3,966 shares of common stock and (ii) 37,729 shares of common stock subject to options that are exercisable within 60 days of January 31, 2021.

(7) Represents 3,266 shares of common stock subject to options that are exercisable within 60 days of January 31, 2021.

(8) Represents 3,266 shares of common stock subject to options that are exercisable within 60 days of January 31, 2021.

(9) Represents 1,492 shares of common stock held by the Isaacs Family Trust and 844,617 shares of common stock subject to options that are exercisable within 60 days of January 31, 2021.

(10) Includes 1,365,434 shares of common stock issuable upon exercise of options that are exercisable within 60 days of January 31, 2021 or shares that are unvested and subject to repurchase by us if such person ceases to provide service to us prior to the vesting of the shares.

(11) Represents (i) 4,733,024 shares of common stock held by Versant Venture Capital VII, L.P., (ii) 722,248 shares of common stock held by Versant Voyageurs I Parallel, L.P., and (iii) 2,433,101 common shares held by Versant Voyageurs I, L.P. Dr. Davis, a member of Chinook's board of directors, is a managing director of Versant Ventures VII GP-GP, LLC, the ultimate general partner of Versant Venture Capital VII, L.P. and shares voting and investment power over the shares held by such fund with Bradley Bolzon, Robin Praeger, Thomas Woiwode and Clare Ozawa. Dr. Davis is a managing director of Versant Ventures VI GP-GP, LLC, the ultimate general partner of Versant Voyageurs I, L.P. and Versant Voyageurs I Parallel, L.P. and shares voting and investment power over the shares held by such funds with Bradley Bolzon, Robin Praeger, Thomas Woiwode and Clare Ozawa. The address for each of these entities and individuals is One Sansome, Suite 3630, San Francisco, CA 94104.

(12) Represents 4,028,938 shares of common stock held by Apple Tree Partners IV, L.P. The general partner of Apple Tree Partners IV, L.P. is ATP III GP, Ltd., the sole owner and director of which is Seth L. Harrison. The address for Apple Tree Partners IV, L.P. is 230 Park Avenue, Suite 2800, New York, New York 10169.

(13) Represents 3,168,388 shares of common stock held by Samsara BioCapital, L.P., or Samsara. Dr. Akkaraju, a member of Chinook's board of directors, is the managing general partner of Samsara BioCapital, LLC, the general partner of Samsara and may be deemed to have voting and investment power over the shares held by Samsara. Dr. Akkaraju disclaims beneficial ownership of the shares held by Samsara except to the extent of his pecuniary interest therein. The address for Samsara is 628 Middlefield Road, Palo Alto, CA 94301.

(14) Based solely on a Schedule 13D/A filed by Morningside Venture (VI) Investments Limited ("MV(VI)IL") on February 16, 2021. Consists of (a) 1,861,106 shares held by Morningside Venture (VI) Investments Limited ("MV(VI)IL"); (b) 1,120,499 shares held by Ultimate Keen Limited ("UKL"); and (c) 3,000 shares held by Golwyn Capital Appreciation Limited ("GCAL"). Frances Anne Elizabeth Richard, Jill Marie Franklin and Wong Yuk Lan, the directors of MV(VI)IL, share voting and dispositive control over the shares held by MV(VI)IL. Cheung Ka Ho and Jill Marie Franklin, the directors of UKL, share voting and dispositive control over the shares held by UKL. Frances Anne Elizabeth Richard and Jill Marie Franklin, the directors of GCAL, share voting and dispositive control over the shares held by UKL. The business address of each of MV(VI)IL, UKL and GCAL is 2nd Floor, Le Prince De Galles, 3-5 Avenue Des Citronniers, MC 98000, Monaco.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

RELATED-PERSON TRANSACTIONS POLICY AND PROCEDURES

We have adopted a policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5 percent of any class of our common stock and any members of the immediate family of any of the foregoing persons are not permitted to enter into a related person transaction with us without the prior consent of our audit committee. Any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5 percent of any class of our voting securities or any member of the immediate family of any of the foregoing persons, in which the amount involved exceeds $120,000 and such person would have a direct or indirect interest, must first be presented to our Audit Committee for review, consideration and approval. In approving or rejecting any such proposal, our Audit Committee is to consider the material facts of the transaction, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction.

CERTAIN RELATIONSHIPS AND RELATED-PERSON TRANSACTIONS

There were no transactions since January 1, 2020 in which we have participated whereby the amount involved exceeded or will exceed $120,000, and in which any of our directors, executive officers or holders of more than 5 percent of our capital stock or any members of their immediate family had or will have a direct or indirect material interest, other than compensation arrangements which are described under "Executive Compensation" and "Director Compensation."

Equity Grants to Executive Officers and Directors

We have granted stock options to our executive officers and certain directors, as more fully described in the sections titled "*Executive Compensation*" and "*Non-Employee Director Compensation*," respectively.

Director and Executive Officer Compensation

Please see the sections titled "*Non-Employee Director Compensation*" and "*Executive Compensation*" for information regarding the compensation of Chinook's directors and executive officers.

Employment Agreements

Chinook has entered into employment agreements with certain of its executive officers. For more information regarding these agreements, see the section titled "*Executive Compensation—Employment Arrangements*."

Indemnification Agreements

We entered into new indemnification agreements with each of our directors and executive officers following completion of the Merger. The indemnification agreements, our amended and restated certificate of incorporation and our amended and restated bylaws require us to indemnify our directors to the fullest extent not prohibited by Delaware law. Subject to certain limitations, our amended and restated bylaws also require us to advance expenses incurred by our directors and officers.

Item 14. Principal Accounting Fees and Services.

The following table represents aggregate fees billed to the Company for the fiscal years ended December 31, 2020 and 2019 by PricewaterhouseCoopers, our independent registered public accounting firm.

	Fiscal Year Ended	
	2020	2019
Audit Fees(1)	$ 1,386,230	$ 611,025
Tax Fees(2)	43,399	62,031
Total Fees	$ 1,429,629	$ 673,056

(1) "Audit Fees" consist of fees for professional services rendered in connection with the audit of our annual consolidated financial statements, review of our quarterly financial statements presented in our quarterly reports on Form 10-Q, and services that are normally provided by our independent registered public accounting firm in connection with statutory and regulatory filings or engagements for those fiscal years.

(2) "Tax Fees" consist of international and domestic tax studies, consulting and compliance.

PRE-APPROVAL POLICIES AND PROCEDURES

Our Audit Committee generally pre-approves all audit and permissible non-audit services provided by the independent registered public accounting firm. These services may include audit services, audit-related services, tax services and other services. Pre-approval is detailed as to the particular service or category of services and is generally subject to a specific budget. The independent registered public accounting firm and management are required to periodically report to the Audit Committee regarding the extent of services provided by the independent registered public accounting firm in accordance with this pre-approval, and the fees for the services performed to date. Our Audit Committee may also pre-approve particular services on a case-by-case basis. All of the services relating to the fees described in the table above were approved by our Audit Committee.

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.	S-1/A	333-202667	3.5	04/06/2015	
3.5	Amendment to Amended and Restated Bylaws, dated July 16, 2020	8-K	001-37345	3.1	07/17/2020	
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.					X
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+	Executive Employment Agreement between Aduro Biotech, Inc. and Stephen T. Isaacs, dated February 26, 2010.	S-1	333-202667	10.12	03/11/2015	
10.9+	Amendment to Executive Employment Agreement between Aduro Biotech, Inc. and Stephen T. Isaacs, dated July 31, 2014.	S-1	333-202667	10.13	03/11/2015	
10.10+	Amendment No. 2 to Executive Employment Agreement dated January 13, 2020, between the Company and Stephen T. Isaacs.	10-K	001-37345	10.37+	03/09/2020	
10.11+	Retention Bonus Agreement dated January 10, 2020, between the Company and Stephen T. Isaacs.	10-K	001-37345	10.38+	03/09/2020	
10.12+	Amended and Restated Executive Employment Agreement by and between the Company and Stephen T. Isaacs, dated July 2, 2020.	8-K	001-37345	10.1	7/2/2020	
10.13+	Form of Separation Agreement (Stephen T. Isaacs).	8-K	001-35890	10.3	10/7/2020	
10.14+	Form of Consulting Agreement.	8-K	001-35890	10.4	10/7/2020	
10.15	Form of Indemnification Agreement.	8-K	001-35890	10.5	10/7/2020	
10.16+	Form of Employment Agreement (US).	8-K	001-35890	10.6	10/7/2020	
10.17+	Form of Employment Agreement (Canada).	8-K	001-35890	10.7	10/7/2020	
10.18+	Amendment to the Aduro Biotech, Inc. Amended and Restated Severance Plan and Summary Plan Description.	8-K	001-37345	10.2	7/2/2020	
10.19#^	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	
10.20	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	
10.21†	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	
10.22#	Sublease between the Registrant and Perfect Day, Inc., dated August 25, 2020	10-Q	001-37345	10.9	11/5/2020	
10.23+	Form of Inducement Stock Option Agreement					X
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.**

† **Confidential treatment has been granted for a portion of this exhibit.**

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 7th day of April 2021.

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)	April 7, 2021
/s/ Eric H. Bjerkholt Eric H. Bjerkholt	Chief Financial Officer (principal financial and accounting officer)	April 7, 2021
/s/ Srinivas Akkaraju Srinivas Akkaraju	Director	April 7, 2021
/s/ Jerel Davis Jerel Davis	Director	April 7, 2021
/s/ William M. Greenman William M. Greenman	Director	April 7, 2021
/s/ Michelle Griffin Michelle Griffin	Director	April 7, 2021
/s/ Ross Haghighat Ross Haghighat	Director	April 7, 2021
/s/ Dolca Thomas Dolca Thomas	Director	April 7, 2021

Exhibit 4.2

DESCRIPTION OF REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2020, Chinook Therapeutics, Inc. ("we," "us" or "our") had common stock, $0.0001 par value per share, registered under Section 12 of the Securities Exchange Act of 1934, as amended, and listed on The Nasdaq Global Select Market under the trading symbol "KDNY."

DESCRIPTION OF CAPITAL STOCK

Our certificate of incorporation authorizes us to issue up to 300,000,000 shares of common stock, $0.0001 par value per share, and 10,000,000 shares of preferred stock, $0.0001 par value per share.

The following is a summary description of the material terms of our capital stock. The description of capital stock is intended as a summary and is qualified in its entirety by reference to our restated certificate of incorporation, as amended ("certificate of incorporation"), and our amended and restated bylaws, as amended ("bylaws"), copies of which are filed as exhibits to our most recent Annual Report on Form 10-K and are incorporated by reference herein. We encourage you to read our certificate of incorporation, our bylaws and the applicable provisions of the Delaware General Corporation Law (the "DGCL") for additional information.

Common Stock

Voting Rights

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Under our certificate of incorporation and bylaws, our stockholders do not have cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Dividends

Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock.

Rights and Preferences

Holders of common stock have no preemptive, conversion or subscription rights and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Anti-Takeover Provisions

Certificate of Incorporation and Bylaws

Our certificate of incorporation and bylaws provide that all stockholder actions must be effected at a duly called meeting of stockholders and not by written consent. A special meeting of stockholders may be called by the chairman of our board of directors, the majority of our whole board of directors, or our chief executive officer.

Our certificate of incorporation provides for our board of directors to be divided into three classes, with staggered three-year terms. As a result, only one class of directors is elected at each annual meeting of stockholders, with the other classes continuing for the remainder of their respective three-year terms. Stockholders have no cumulative voting rights, and the stockholders representing a majority of the shares of common stock entitled to vote in any election of directors may elect all of the directors standing for election. In addition, our certificate of incorporation provides that stockholders may remove directors only for cause and only by the affirmative vote of the holders of at least sixty-six and two-thirds percent (66-2/3%) in voting power of our stock entitled to vote thereon.

Our certificate of incorporation further provides that the affirmative vote of holders of at least sixty-six and two-thirds percent (66-2/3%) of the voting power of all of the then outstanding shares of voting stock, voting as a single class, will be required to amend certain provisions of our certificate of incorporation, including provisions relating to the size of the board, removal of directors, special meetings, actions by written consent and cumulative voting. The affirmative vote of holders of at least sixty-six and two-thirds percent (66-2/3%) of the voting power of all of the then outstanding shares of voting stock, voting as a single class, is required to amend or repeal our bylaws, although our bylaws may be amended by a simple majority vote of our board of directors.

The foregoing provisions make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to cause a change in control of us.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of us. These provisions are also designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging a change of control of our company or changes in our board of directors that our stockholders might consider favorable. As a consequence, these provisions also may inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the DGCL, which prohibits a Delaware corporation from engaging in a business combination with any interested stockholder for a period of three years following the date the person became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested holder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (a) by persons who are directors and also officers and (b) pursuant to employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; and

- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 of the DGCL defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to certain exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

Section 203 of the DGCL defines an "interested stockholder" as an entity or person who, together with the entity's or person's affiliates and associates, beneficially owns, or is an affiliate of the corporation and within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation. A Delaware corporation may "opt out" of these provisions with an express provision in its certificate of incorporation. We have not opted out of these provisions, which may as a result, discourage or prevent mergers or other takeover or change of control attempts of us.

Choice of Forum

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. Similarly, our bylaws provide that (a) the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL; or any action asserting a claim against us that is governed by the internal affairs doctrine, and (b) the federal district courts of the United Stated of America are the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. Although our bylaws contain the choice of forum provision described above, it is possible that a court could find that such provisions are inapplicable for a particular claim or action or that such provisions are unenforceable.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent and registrar's address is 250 Royall Street, Canton, Massachusetts 02021.

Exhibit 10.23

CHINOOK THERAPEUTICS, INC.

INDUCEMENT STOCK OPTION GRANT NOTICE

As a material inducement to the employment of Optionholder, Chinook Therapeutics, Inc. (the "***Company***"), hereby grants to Optionholder an option to purchase the number of shares of the Company's Common Stock set forth below. This option is granted separate and apart from, and outside of, the Aduro Biotech, Inc. 2015 Equity Incentive Plan (the "***Plan***") and shall not constitute an award granted under or pursuant to the Plan. However, except as otherwise expressly stated herein, this option is governed by terms and conditions identical to those of the Plan, which are incorporated herein by reference. In the event of any conflict between the terms and conditions of this Inducement Stock Option Grant Notice, the Option Agreement, and the Notice of Exercise and the terms and conditions of the Plan, the terms and conditions of this Inducement Stock Option Grant Notice, the Option Agreement and the Notice of Exercise shall govern. Capitalized terms not explicitly defined herein but defined in the Plan or the Option Agreement will have the same definitions as in the Plan or the Option Agreement.

Optionholder:	
Date of Grant:	
Vesting Commencement Date:	
Number of Shares:	
Exercise Price (Per Share)	
Total Exercise Price	
Expiration Date:	
Type of Grant:	Nonstatutory Stock Option
Exercise Schedule:	Same as Vesting Schedule
Vesting Schedule	25% of the number of shares subject to this option shall vest and become exercisable on the one-year anniversary of the Vesting Commencement Date, and 1/36th of the total number of shares subject to this option shall vest and become exercisable on a monthly basis thereafter, such that 100% of the shares subject to this option shall become vested and exercisable on the four-year anniversary of the Vesting Commencement Date, subject to Optionholder's Continuous Service on each applicable vesting date.
Payment:	By one or a combination of the following items (described in the Option agreement. ☐ By cash, check, bank draft or money order payable to the Company ☐ Pursuant to a Regulation T Program if the shares are publicly traded ☐ By delivery of already-owned shares if the shares are publicly traded ☐ Subject to the Company's consent at the time of exercise, by a "net exercise" arrangement

Additional Terms/Acknowledgements:	Optionholder acknowledges receipt of, and understands and agrees to, this Stock Option Grant Notice and the Option Agreement. Optionholder acknowledges and agrees that this Stock Option Grant Notice and the Option Agreement may not be modified, amended or revised except as provided in the Plan. Optionholder further acknowledges that as of the Date of Grant, this Inducement Stock Option Grant Notice and the Option Agreement set forth the entire understanding between Optionholder and the Company regarding this option award and supersede all prior oral and written agreements, promises and/or representations on that subject with the exception of (i) options previously granted and delivered to Optionholder, (ii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law and (iii) any written employment or severance arrangement that would provide for vesting acceleration of this option upon the terms and conditions set forth therein. By accepting this option, Optionholder consents to receive such documents by electronic delivery through an online or electronic system established and maintained by the Company or another third party designated by the Company.

CHINOOK THERAPEUTICS, INC.	**OPTIONHOLDER**
By:	
Signature	Signature
Title:	Date:
Date:	

ATTACHMENTS: Option Agreement and Notice of Exercise

ATTACHMENT I

OPTION AGREEMENT

CHINOOK THERAPEUTICS, INC.

INDUCEMENT STOCK OPTION AGREEMENT

Pursuant to your Inducement Stock Option Grant Notice ("***Grant Notice***") and this Inducement Stock Option Agreement (the "***Option Agreement***"), Chinook Therapeutics, Inc. (the "***Company***") has granted you an option to purchase the number of shares of the Company's Common Stock indicated in your Grant Notice at the exercise price indicated in your Grant Notice. The option is granted to you effective as of the date of grant set forth in the Grant Notice (the "***Date of Grant***").

The details of your option, in addition to those set forth in the Grant Notice, are as follows:

1. **NON-PLAN GRANT.** This option is granted to you as a stand-alone award, separate and apart from, and outside of, the Aduro Biotech, Inc. 2015 Equity Incentive Plan (the "***Plan***"), and shall not constitute an award granted under or pursuant to the Plan. However, except as otherwise expressly stated herein, this option is governed by terms and conditions identical to those of the Plan, which are incorporated herein by reference. In the event of any conflict between the terms and conditions of this Option Agreement and the terms and conditions of the Plan, the terms and conditions of this Option Agreement shall govern. Capitalized terms used and not otherwise defined herein shall have the meanings set forth in the Plan.

2. **EMPLOYMENT INDUCEMENT.** This option is intended to constitute an employment inducement award pursuant to Nasdaq Stock Market Listing Rule 5635(c)(4), and consequently is intended to be exempt from the Nasdaq listing rules regarding stockholder approval of equity compensation plans. This Option Agreement and the terms and conditions of this option shall be interpreted in accordance and consistent with such exemption.

3. **VESTING.** Subject to the provisions contained herein, your option will vest as provided in your Grant Notice. Vesting will cease upon the termination of your Continuous Service.

4. **NUMBER OF SHARES AND EXERCISE PRICE.** The number of shares of Common Stock subject to your option and your exercise price per share in your Grant Notice will be adjusted for Capitalization Adjustments.

5. **EXERCISE RESTRICTION FOR NON-EXEMPT EMPLOYEES.** If you are an Employee eligible for overtime compensation under the Fair Labor Standards Act of 1938, as amended (that is, a "***Non-Exempt Employee***"), and except as otherwise provided in the Plan, you may not exercise your option until you have completed at least six (6) months of Continuous Service measured from the Date of Grant, even if you have already been an employee for more than six (6) months. Consistent with the provisions of the Worker Economic Opportunity Act, you may exercise your option as to any vested portion prior to such six (6) month anniversary in the case of (i) your death or disability, (ii) a Corporate Transaction in which your option is not assumed, continued or substituted, (iii) a Change in Control or (iv) your termination of Continuous Service on your "retirement" (as defined in the Company's benefit plans).

6. **METHOD OF PAYMENT.** You must pay the full amount of the exercise price for the shares you wish to exercise. You may pay the exercise price in cash or by check, bank draft or money order payable to the Company or in any other manner permitted by your Grant Notice, which may include one or more of the following:

(a) Pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of Common Stock, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds. This manner of payment is also known as a "broker-assisted exercise", "same day sale", or "sell to cover".

(b) By delivery to the Company (either by actual delivery or attestation) of already-owned shares of Common Stock that are owned free and clear of any liens, claims, encumbrances or security interests, and that are valued at Fair Market Value on the date of exercise. "Delivery" for these purposes, in the sole discretion of the Company at the time you exercise your option, will include delivery to the Company of your attestation of

ownership of such shares of Common Stock in a form approved by the Company. You may not exercise your option by delivery to the Company of Common Stock if doing so would violate the provisions of any law, regulation or agreement restricting the redemption of the Company's stock.

(c) Subject to the consent of the Company at the time of exercise, by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issued upon exercise of your option by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price. You must pay any remaining balance of the aggregate exercise price not satisfied by the "net exercise" in cash or other permitted form of payment. Shares of Common Stock will no longer be outstanding under your option and will not be exercisable thereafter if those shares (i) are used to pay the exercise price pursuant to the "net exercise," (ii) are delivered to you as a result of such exercise, and (iii) are withheld to satisfy your tax withholding obligations.

7. **Whole Shares**. You may exercise your option only for whole shares of Common Stock.

8. **Securities Law Compliance**. In no event may you exercise your option unless the shares of Common Stock issuable upon exercise are then registered under the Securities Act or, if not registered, the Company has determined that your exercise and the issuance of the shares would be exempt from the registration requirements of the Securities Act. The exercise of your option also must comply with all other applicable laws and regulations governing your option, and you may not exercise your option if the Company determines that such exercise would not be in material compliance with such laws and regulations (including any restrictions on exercise required for compliance with Treas. Reg. 1.401(k)-1(d)(3), if applicable).

9. **Term**. You may not exercise your option before the Date of Grant or after the expiration of the option's term. The term of your option expires, subject to the provisions of Section 5(h) of the Plan, upon the earliest of the following:

(a) immediately upon the date on which the event giving rise to your termination of Continuous Service for Cause occurs (or, if required by law, the date of termination of Continuous Service for Cause);

(b) three (3) months after the termination of your Continuous Service for any reason other than Cause, your Disability or your death (except as otherwise provided in Section 9(d) below); *provided*, *however*, that if during any part of such three (3) month period your option is not exercisable solely because of the condition set forth in the section above relating to "Securities Law Compliance," your option will not expire until the earlier of the Expiration Date or until it has been exercisable for an aggregate period of three (3) months after the termination of your Continuous Service; provided further, if during any part of such three (3) month period, the sale of any Common Stock received upon exercise of your option would violate the Company's insider trading policy, then your option will not expire until the earlier of the Expiration Date or until it has been exercisable for an aggregate period of three (3) months after the termination of your Continuous Service during which the sale of the Common Stock received upon exercise of your option would not be in violation of the Company's insider trading policy. Notwithstanding the foregoing, if (i) you are a Non-Exempt Employee, (ii) your Continuous Service terminates within six (6) months after the Date of Grant, and (iii) you have vested in a portion of your option at the time of your termination of Continuous Service, your option will not expire until the earlier of (x) the later of (A) the date that is seven (7) months after the Date of Grant, and (B) the date that is three (3) months after the termination of your Continuous Service, and (y) the Expiration Date;

(c) twelve (12) months after the termination of your Continuous Service due to your Disability (except as otherwise provided in Section 9(d)) below;

(d) eighteen (18) months after your death if you die either during your Continuous Service or within three (3) months after your Continuous Service terminates for any reason other than Cause;

(e) the Expiration Date indicated in your Grant Notice; or

(f) the day before the tenth (10th) anniversary of the Date of Grant.

10. EXERCISE.

(a) You may exercise the vested portion of your option during its term by (i) delivering a Notice of Exercise (in a form designated by the Company) or completing such other documents and/or procedures designated by the Company for exercise and (ii) paying the exercise price and any applicable withholding taxes to the Company's Secretary, stock plan administrator, or such other person as the Company may designate, together with such additional documents as the Company may then require.

(b) By exercising your option you agree that, as a condition to any exercise of your option, the Company may require you to enter into an arrangement providing for the payment by you to the Company of any tax withholding obligation of the Company arising by reason of (i) the exercise of your option, (ii) the lapse of any substantial risk of forfeiture to which the shares of Common Stock are subject at the time of exercise, or (iii) the disposition of shares of Common Stock acquired upon such exercise.

11. TRANSFERABILITY. Except as otherwise provided in this Section 11, your option is not transferable, except by will or by the laws of descent and distribution, and is exercisable during your life only by you.

(a) Certain Trusts. Upon receiving written permission from the Board or its duly authorized designee, you may transfer your option to a trust if you are considered to be the sole beneficial owner (determined under Section 671 of the Code and applicable state law) while the option is held in the trust. You and the trustee must enter into transfer and other agreements required by the Company.

(b) Domestic Relations Orders. Upon receiving written permission from the Board or its duly authorized designee, and provided that you and the designated transferee enter into transfer and other agreements required by the Company, you may transfer your option pursuant to the terms of a domestic relations order, official marital settlement agreement or other divorce or separation instrument as permitted by Treasury Regulation 1.421-1(b)(2) that contains the information required by the Company to effectuate the transfer. You are encouraged to discuss the proposed terms of any division of this option with the Company prior to finalizing the domestic relations order or marital settlement agreement to help ensure the required information is contained within the domestic relations order or marital settlement agreement.

(c) Beneficiary Designation. Upon receiving written permission from the Board or its duly authorized designee, you may, by delivering written notice to the Company, in a form approved by the Company and any broker designated by the Company to handle option exercises, designate a third party who, on your death, will thereafter be entitled to exercise this option and receive the Common Stock or other consideration resulting from such exercise. In the absence of such a designation, your executor or administrator of your estate will be entitled to exercise this option and receive, on behalf of your estate, the Common Stock or other consideration resulting from such exercise.

12. OPTION NOT A SERVICE CONTRACT. Your option is not an employment or service contract, and nothing in your option will be deemed to create in any way whatsoever any obligation on your part to continue in the employ of the Company or an Affiliate, or of the Company or an Affiliate to continue your employment. In addition, nothing in your option will obligate the Company or an Affiliate, their respective stockholders, boards of directors, officers or employees to continue any relationship that you might have as a Director or Consultant for the Company or an Affiliate.

13. WITHHOLDING OBLIGATIONS.

(a) At the time you exercise your option, in whole or in part, and at any time thereafter as requested by the Company, you hereby authorize withholding from payroll and any other amounts payable to you, and otherwise agree to make adequate provision for (including by means of a "same day sale" pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board to the extent permitted by the Company), any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or an Affiliate, if any, which arise in connection with the exercise of your option.

(b) Upon your request and subject to approval by the Company, and compliance with any applicable legal conditions or restrictions, the Company may withhold from fully vested shares of Common Stock otherwise issuable to you upon the exercise of your option a number of whole shares of Common Stock having a Fair Market Value, determined by the Company as of the date of exercise, not in excess of the minimum amount of tax required to be withheld by law (or such lower amount as may be necessary to avoid classification of your option as a liability for financial accounting purposes). If the date of determination of any tax withholding obligation is deferred to a date later than the date of exercise of your option, share withholding pursuant to the preceding sentence shall not be permitted unless you make a proper and timely election under Section 83(b) of the Code, covering the aggregate number of shares of Common Stock acquired upon such exercise with respect to which such determination is otherwise deferred, to accelerate the determination of such tax withholding obligation to the date of exercise of your option. Notwithstanding the filing of such election, shares of Common Stock shall be withheld solely from fully vested shares of Common Stock determined as of the date of exercise of your option that are otherwise issuable to you upon such exercise. Any adverse consequences to you arising in connection with such share withholding procedure shall be your sole responsibility.

(c) You may not exercise your option unless the tax withholding obligations of the Company and/or any Affiliate are satisfied. Accordingly, you may not be able to exercise your option when desired even though your option is vested, and the Company will have no obligation to issue a certificate for such shares of Common Stock or release such shares of Common Stock from any escrow provided for herein, if applicable, unless such obligations are satisfied.

14. **Tax Consequences**. You hereby agree that the Company does not have a duty to design or administer this option or its other compensation programs in a manner that minimizes your tax liabilities. You will not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates related to tax liabilities arising from your option or your other compensation. In particular, you acknowledge that this option is exempt from Section 409A of the Code only if the exercise price per share specified in the Grant Notice is at least equal to the "fair market value" per share of the Common Stock on the Date of Grant and there is no other impermissible deferral of compensation associated with the option.

15. **Notices**. Any notices provided for in your Option Agreement will be given in writing (including electronically) and will be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. The Company may, in its sole discretion, decide to deliver any documents related to this option by electronic means. By accepting this option, you consent to receive such documents by electronic delivery through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

16. **Subject to Recoupment**. Your option (and any compensation paid or shares issued under your option) is subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law.

17. **Other Documents**. You hereby acknowledge receipt of and the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act, which includes any prospectus relating to the grant of this option. In addition, you acknowledge receipt of the Company's policy permitting certain individuals to sell shares only during certain "window" periods and the Company's insider trading policy, in effect from time to time.

18. **Effect On Other Employee Benefit Plans**. The value of this option will not be included as compensation, earnings, salaries, or other similar terms used when calculating your benefits under any employee benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company's or any Affiliate's employee benefit plans.

19. **Voting Rights**. You will not have voting or any other rights as a stockholder of the Company with respect to the shares to be issued pursuant to this option until such shares are issued to you. Upon such issuance,

you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in this option, and no action taken pursuant to its provisions, will create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

20. **SEVERABILITY**. If all or any part of this Option Agreement is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity will not invalidate any portion of this Option Agreement not declared to be unlawful or invalid. Any Section of this Option Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

21. **MISCELLANEOUS.**

(a) The rights and obligations of the Company under your option will be transferable to any one or more persons or entities, and all covenants and agreements hereunder will inure to the benefit of, and be enforceable by the Company's successors and assigns.

(b) You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your option.

(c) You acknowledge and agree that you have reviewed your option in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your option, and fully understand all provisions of your option.

(d) This Option Agreement will be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

(e) All obligations of the Company under this Option Agreement will be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

* **

This Option Agreement will be deemed to be signed by you upon the signing by you of the Grant Notice to which it is attached.

ATTACHMENT II

NOTICE OF EXERCISE

NOTICE OF EXERCISE

Chinook Therapeutics, Inc.
Attention: Stock Plan Administrator

Date of Exercise:

This constitutes notice to Chinook Therapeutics, Inc. (the "***Company***") under my stock option that I elect to purchase the below number of shares of Common Stock of the Company (the "***Shares***") for the price set forth below.

Type of option (check one):		Nonstatutory
Stock option dated:		
Number of Shares as to which option is exercised:		
Certificates to be issued in name of:		
Total exercise price:	$	$
Cash payment delivered herewith:	$	$
Value of Shares delivered herewith:	$	$
Value of Shares pursuant to net exercise:	$	$
Regulation T Program (cashless exercise):	$	$

By this exercise, I agree (i) to provide such additional documents as you may require pursuant to the terms of the Chinook Therapeutics, Inc. Inducement Stock Option Agreement, and (ii) to provide for the payment by me to you (in the manner designated by you) of your withholding obligation, if any, relating to the exercise of this option.

Very truly yours,

Signature

Print Name

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 and 333-249351) of Chinook Therapeutics, Inc. of our report dated April 7, 2021 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Seattle, Washington
April 7, 2021

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 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 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: April 7, 2021

/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 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 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: April 7, 2021

/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, 2020 (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: April 7, 2021

/s/ Eric L. Dobmeier
Eric L. Dobmeier
President, Chief Executive Officer and Director
(Principal Executive Officer)

Dated: April 7, 2021

/s/ Eric H. Bjerkholt
Eric H. Bjerkholt
Chief Financial Officer
(Principal Accounting and Financial Officer)