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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2021

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)

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The number of shares of Registrant's Common Stock outstanding as of August 10, 2021 was 44,799,736.

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Chinook Therapeutics, Inc., (the "Company" or "Chinook"), is a clinical-stage biopharmaceutical company. On October 5, 2020, Aduro Biotech, Inc. ("Aduro"), completed its business combination with Private Chinook, as defined below, in accordance with the terms of a merger agreement dated June 1, 2020 and amended on August 17, 2020 (the "Merger"). In this Quarterly Report on Form 10-Q, the term "Private Chinook" refers to Chinook Therapeutics U.S., Inc. prior to the consummation of the merger described in this report and references to the terms "Chinook", the "Company", "we", "our" and "us" refer to Private Chinook, prior to the consummation of the Merger described in this report and Chinook Therapeutics, Inc. (formerly known as Aduro Biotech, Inc.) and its subsidiaries upon the consummation of the merger described in this report. The term "Aduro" refers to the Aduro Biotech, Inc. and its subsidiaries prior to the Merger described in this report.

PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (unaudited)

Chinook Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(In thousands, except per share amounts)
(Unaudited)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 135,466	$ 187,750
Marketable securities	61,684	59,622
Accounts receivable	467	262
Prepaid expenses and other current assets	5,710	6,447
Total current assets	203,327	254,081
Marketable securities	32,682	3,000
Property and equipment, net	19,359	20,626
Restricted cash	2,074	1,750
Operating lease right-of-use assets	53,157	55,673
Equity method investment	9,972	—
Intangible assets, net	26,854	27,696
In process research & development	36,550	39,295
Goodwill	18,541	22,441
Other assets	5,349	4,440
Total assets	$ 407,865	$ 429,002
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	9,221	3,995
Accrued and other current liabilities	11,269	15,674
Operating lease liabilities	3,280	3,045
Deferred revenue	—	95
Total current liabilities	23,770	22,809
Contingent value rights liability	29,050	13,780
Contingent consideration liability	4,780	1,800
Deferred tax liabilities	15,635	16,377
Operating lease liabilities, net of current maturities	37,147	38,709
Other long-term liabilities	754	905
Total liabilities	111,136	94,380
Commitments and contingencies (Note 10)		
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000 shares authorized as of June 30, 2021 and December 31, 2020; no shares issued and outstanding at June 30, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value; 300,000 shares authorized as of June 30, 2021 and December 31, 2020; 44,776 and 42,282 shares issued and outstanding at March 31, 2021 and December 31, 2020	4	4
Additional paid-in capital	505,168	463,436
Accumulated deficit	(208,615)	(128,829)
Accumulated other comprehensive income	172	11
Total stockholders' equity	296,729	334,622
Total liabilities and stockholders' equity	$ 407,865	$ 429,002

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Collaboration and license revenue	$ 34	$ —	$ 385	$ —
Operating expenses:				
Research and development	22,787	3,870	48,484	6,688
General and administrative	7,768	3,879	17,311	5,150
Change in fair value of contingent consideration and contingent value rights liabilities	19,557	—	21,396	—
Amortization of intangible assets	422	—	842	—
Total operating expenses	50,534	7,749	88,033	11,838
Gain on sale of assets to equity method investment	7,227	—	7,227	—
Loss from operations	(43,273)	(7,749)	(80,421)	(11,838)
Other income (expense):				
Other income (expense), net	(39)	(4)	(106)	115
Change in fair value of redeemable convertible preferred stock tranche liability	—	10	—	(1,169)
Loss before income taxes	(43,312)	(7,743)	(80,527)	(12,892)
Income tax benefit	741	—	741	—
Net loss	$ (42,571)	$ (7,743)	$ (79,786)	$ (12,892)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.97)	$ (1.87)	$ (1.86)	$ (3.12)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	43,861	4,151	43,004	4,128
Other comprehensive income (loss):				
Foreign currency translation adjustments, net of tax of $0	99	49	137	(166)
Unrealized gain on marketable securities, net of tax of $0	8	—	24	—
Total other comprehensive income (loss)	107	49	161	(166)
Comprehensive loss	$ (42,464)	$ (7,694)	$ (79,625)	$ (13,058)

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

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2020	42,282	$ 4	$ 463,436	$ (128,829)	$ 11	334,622
Issuance of common stock upon exercise of stock options and warrants and vesting of restricted stock units	100	—	580	—	—	580
Stock-based compensation expense	—	—	2,478	—	—	2,478
Other comprehensive loss	—	—	—	—	54	54
Net loss	—	—	—	(37,215)	—	(37,215)
Balance at March 31, 2021	42,382	$ 4	$ 466,494	$ (166,044)	$ 65	$ 300,519
Issuance of common stock upon exercise of stock options and warrants, issuance of common stock under Employee Stock Purchase Plan, and vesting of restricted stock units	178	—	1,188	—	—	1,188
Issuance of common stock under the at-the-market sales agreement, net of offering costs	2,216	—	33,891	—	—	33,891
Stock-based compensation expense	—	—	3,595	—	—	3,595
Other comprehensive income	—	—	—	—	107	107
Net loss	—	—	—	(42,571)	—	(42,571)
Balance at June 30, 2021	44,776	$ 4	$ 505,168	$ (208,615)	$ 172	$ 296,729

	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				
Balance at December 31, 2019	7,597	$ 19,835	4,502	$ —	$ 6,095	$ (47,207)	$ (7)	$ (41,119)
Issuance of common stock upon exercise of stock options	—	—	4	—	1	—	—	1
Repurchase of unvested restricted stock awards	—	—	(40)	—	—	—	—	—
Issuance of Series A redeemable convertible preferred stock, net of issuance costs of $21	4,237	14,479	—	—	—	—	—	—
Exercise of redeemable convertible preferred stock tranche liability	—	9,723	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	100	—	—	100
Other comprehensive loss	—	—	—	—	—	—	(215)	(215)
Net loss	—	—	—	—	—	(5,149)	—	(5,149)
Balance at March 31, 2020	11,834	$ 44,037	4,466	$ —	$ 6,196	$ (52,356)	$ (222)	$ (46,382)
Stock-based compensation expense	—	—	—	—	299	—	—	299
Other comprehensive income	—	—	—	—	—	—	49	49
Net loss	—	—	—	—	—	(7,743)	—	(7,743)
Balance at June 30, 2020	11,834	$ 44,037	4,466	$ —	$ 6,495	$ (60,099)	$ (173)	$ (53,777)

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

Chinook Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Six Months Ended June 30,	
	2021	2020
Cash Flows from Operating Activities		
Net loss	$ (79,786)	$ (12,892)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	1,552	162
Amortization of finance lease right-of-use asset	—	22
Amortization of intangible assets	842	—
Non-cash operating lease expense	2,596	124
Stock-based compensation expense	6,073	399
Change in fair value of redeemable convertible preferred stock tranche liability	—	1,169
Change in fair value of contingent consideration and contingent value rights liabilities	21,396	—
Accretion of discounts and amortization of premiums on marketable securities	(6)	
Deferred income tax	(741)	—
Gain on sale of assets to equity method investment	(7,227)	—
Changes in operating assets and liabilities:		
Accounts receivable	(205)	—
Prepaid expenses and other assets	(153)	(188)
Accounts payable	5,610	1,362
Accrued and other liabilities	(3,956)	2,752
Operating lease liabilities	(1,413)	(116)
Deferred revenue	(95)	—
Net cash used in operating activities	(55,513)	(7,206)
Cash Flows from Investing Activities		
Purchases of marketable securities	(105,328)	—
Proceeds from marketable securities	73,615	—
Purchases of property and equipment	(744)	(400)
Proceeds from sale of property and equipment	267	—
Net cash used in investing activities	(32,190)	(400)
Cash Flows from Financing Activities		
Proceeds from issuance of common stock, net of offering costs	—	1
Proceeds from exercise of stock options and warrants	1,768	—
Proceeds from at-the-market sales agreement, net of offering costs	33,891	
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	14,479
Repayment of finance lease liability-related party	—	(31)
Net cash provided by financing activities	35,659	14,449
Effect of exchange rate changes on cash, cash equivalents and restricted cash	84	(152)
Net increase (decrease) in cash, cash equivalents and restricted cash	(51,960)	6,691
Cash, cash equivalents and restricted cash at beginning of period	189,500	11,357
Cash, cash equivalents and restricted cash at end of period	$ 137,540	$ 18,048
Supplemental Disclosure of Non-Cash Investing and Financing Activities		
Purchases of property and equipment included in accounts payable and in accrued and other current liabilities	$ 129	$ 15
Right-of-use asset for office space acquired through leases	$ —	$ 199
Reconciliation of Cash, Cash Equivalents and Restricted Cash		
Cash and cash equivalents	$ 135,466	$ 17,901
Restricted cash	2,074	147
Total cash, cash equivalents and restricted cash	$ 137,540	$ 18,048

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

1. Description of Business

Chinook Therapeutics, Inc. (the "Company", "Chinook", "we", "our", or "us") is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing precision medicines for kidney diseases. Our lead clinical program is atrasentan, an endothelin receptor antagonist that was in-licensed from AbbVie in late 2019. In March 2021, we initiated the phase 3 ALIGN trial of atrasentan for IgA nephropathy ("IgAN") and in April 2021, we initiated the phase 2 AFFINITY basket trial of atrasentan for proteinuric glomerular diseases. Our pipeline also includes BION-1301, an anti-APRIL monoclonal antibody that is being evaluated in a phase 1b trial for IgAN, as well as CHK-336, an oral small molecule LDHA inhibitor in preclinical development for the treatment of primary hyperoxaluria. In addition, we are building our precision medicine pipeline through research and discovery programs for other rare, severe chronic kidney diseases. We were incorporated in Delaware and are headquartered in Seattle, Washington.

The Company as used in the accompanying notes to the unaudited condensed consolidated financial statements, refers to Private Chinook prior to the completion of the Merger and Public Chinook subsequent to the completion of the Merger. See the note "Reverse Merger and Contingent Value Rights" in the accompanying notes to the condensed consolidated financial statements.

2. Basis of Presentation and Consolidation, Use of Estimates and Recent Accounting Pronouncements

Basis of Presentation and Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP, and follow the requirements of the Securities and Exchange Commission, or the SEC, for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP have been condensed or omitted, and accordingly the unaudited condensed consolidated financial statements do not include all of the information and notes required by U.S. GAAP for complete financial statements. These financial statements have been prepared on the same basis as our annual financial statements and, in the opinion of management, reflect all adjustments (consisting only of normal recurring adjustments) that are necessary for a fair presentation of financial information. The results of operations for the three and six months ended June 30, 2021 are not necessarily indicative of the results to be expected for the year ending December 31, 2021 or for any other interim period or for any other future year.

The accompanying condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2020 included in our Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC on April 7, 2021.

The condensed consolidated financial statements include the accounts of Chinook Therapeutics, Inc. and our wholly-owned subsidiaries. All intercompany transactions and balances have been eliminated.

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.

Recent Accounting Pronouncements, Not Yet Adopted

In June 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standard Update ("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. We do not plan to early adopt ASU No. 2016-13 and are currently evaluating the impact the adoption of this ASU will have on our consolidated financial statements.

Recently Adopted Accounting Pronouncements

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. We adopted the standard on January 1, 2021 and concluded that adoption of the standard did not have a material impact on our consolidated financial statements.

3. Reverse Merger and Contingent Value Rights

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

At the effective time of the Merger, we 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 us upon the receipt of consideration resulting from milestones and royalties from certain pre-existing agreements and the disposition or licensing of any of Aduro's non-renal assets, net of any tax, and certain other expenses that could be deducted by us.

4. Cash, Cash Equivalents and Marketable Securities

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

	June 30, 2021			
	Amortized cost	Unrealized gains	Unrealized losses	Estimated Fair Value
Cash and cash equivalents:				
Cash	$ 15,545	$ —	$ —	$ 15,545
Money market funds	114,921	—	—	114,921
Certificate of deposit	—	—	—	—
Commercial paper	5,000	—	—	5,000
U.S. government and agency securities	—	—	—	—
Total cash and cash equivalents	$ 135,466	$ —	$ —	$ 135,466
Marketable securities:				
Commercial paper	$ 52,665	$ 4	$ (5)	$ 52,664
U.S. government and agency securities	35,677	5	—	35,682
Corporate debt securities	6,021	—	(1)	6,020
Total marketable securities	$ 94,363	$ 9	$ (6)	$ 94,366

	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

The amortized cost and estimated fair value of our available-for-sale marketable securities by contractual maturity are summarized below as of June 30, 2021 (in thousands):

	Amortized cost	Unrealized gains	Unrealized losses	Estimated Fair Value
Mature in one year or less	$ 61,685	$ 4	$ (5)	$ 61,684
Mature after one year through two years	32,678	5	(1)	32,682
Total available-for-sale marketable securities	$ 94,363	$ 9	$ (6)	$ 94,366

None of our marketable securities were in a continuous unrealized loss position as of June 30, 2021. We review individual securities in our portfolio to determine whether a decline in a security's fair value below the amortized cost basis is other-than-temporary. We determined that as of June 30, 2021, 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 Accounting Standards Codification ("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 our financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	June 30, 2021			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and cash equivalents:				
Cash and money market funds	$ 130,466	$ —	$ —	$ 130,466
Commercial paper	—	—	—	—
U.S. government and agency securities	—	5,000	—	5,000
Total cash and cash equivalents	130,466	5,000	—	135,466
Marketable securities:				
Commercial paper	—	52,664	—	52,664
U.S. government and agency securities	—	35,682	—	35,682
Corporate debt securities	—	6,020	—	6,020
Total marketable securities	—	94,366	—	94,366
Total fair value of assets	$ 130,466	$ 99,366	$ —	$ 229,832
Liabilities:				
Contingent value rights liability	$ —	$ —	$ 29,050	$ 29,050
Contingent consideration liability	—	—	4,780	4,780
Total fair value of liabilities	$ —	$ —	$ 33,830	$ 33,830

	December 31, 2020			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and cash equivalents:				
Cash and money market funds	$ 119,251	$ —	$ —	$ 119,251
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	119,251	68,499	—	187,750
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	$ 119,251	$ 131,121	$ —	$ 250,372
Liabilities:				
Contingent value rights liability	$ —	$ —	$ 13,780	$ 13,780
Contingent consideration liability	—	—	1,800	1,800
Total fair value of liabilities	$ —	$ —	$ 15,580	$ 15,580

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 our Level 3 financial instruments (in thousands):

	Contingent Value Rights Liability	Contingent Consideration Liability
Balance at December 31, 2020	$ 13,780	$ 1,800
Net change in fair value upon remeasurement	15,270	2,980
Balance at June 30, 2021	$ 29,050	$ 4,780

The fair values of the CVR and contingent consideration liabilities related to the Merger are based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy. In determining the fair value of the CVR and the contingent consideration liabilities related to the Merger, we used a probability-adjusted, scenario-based income approach. For the three and six months ended June 30, 2021, the change in fair value of the CVR and the contingent value rights liabilities related to the Merger was $16.4 million and $18.3 million, respectively, and was recorded in the consolidated statement of operations and comprehensive loss. The change in the fair value during the periods, resulted from a change in estimate of the potential future proceeds derived from Aduro's license agreement with Merck and from the sale of certain of our non-renal assets in exchange for preferred shares in Sairopa during the three months ended June 30, 2021. We will hold the shares in Sairopa until there is a liquidation event at which time, in accordance with the CVR agreement, 50% of any net proceeds will accrue to the benefit of the CVR holders. Refer to Note 15, "Equity Method Investment," for more information. In addition, we identified measurement period adjustments, which reduced the CVR liability. Refer to Note 7, "Goodwill and Intangible Assets" for more information.

6. Property and Equipment, Net

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

	June 30, 2021	December 31, 2020
Research and lab equipment	$ 3,446	$ 3,616
Computer equipment	1,151	921
Computer software	44	27
Furniture and fixtures	1,106	1,099
Leasehold improvements	16,189	16,111
Total property and equipment	21,936	21,774
Total accumulated depreciation	(2,577)	(1,148)
Property and equipment, net	$ 19,359	$ 20,626

Approximately $3.4 million of our property and equipment as of June 30, 2021 is located in Canada.

7. Goodwill and Intangible Assets

Goodwill

The gross carrying amount and net book value of goodwill was $18.5 million at June 30, 2021, all of which resulted from the Merger. During the second quarter of 2021, we identified and recorded measurement period adjustments for taxes related to the merger, which reduced goodwill by $3.9 million from the preliminary purchase price allocation and reduced our deferred tax liabilities by $0.8 million and reduced the CVR liability by $3.1 million. The measurement period adjustments were the result of additional analysis performed and information identified during the second quarter of 2021 based on facts and circumstances that existed as of the merger date. As of June 30, 2021, the preliminary purchase price allocation for the merger with Aduro is subject to change as we use the measurement period, not to exceed one-year, to adequately analyze all the factors used in establishing the asset and liability fair values as of the merger date.

We test goodwill for impairment on an annual basis or more frequently if an impairment indicator exists. To determine if an impairment has occurred, we perform a quantitative test in which the fair value of a single reporting unit is compared to its carrying value. If the carrying value of the reporting unit exceeds the fair value of the reporting unit, we record an impairment loss equal to that difference.

Intangible assets

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

	June 30, 2021		
	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Intangible assets with finite lives:			
Acquired license agreement	$ 26,685	$ 1,182	$ 25,503
In-place lease	1,433	82	1,351
Total intangible assets with finite lives	28,118	1,264	26,854
Acquired in-process research and development assets ("IPR&D")	36,550	—	36,550
Total intangible and acquired IPR&D assets	$ 64,668	$ 1,264	$ 63,404

	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 a period of 9 to 17 years, with a weighted average period of 16.7 years, and the amortization expense is recorded in operating expenses. We test our Acquired IPR&D assets for impairment on an annual basis, or more frequently if an impairment indicator exists.

Acquired IPR&D decreased by $2.7 million from the sale of certain of our non-renal assets in exchange for stock during the three months ended June 30, 2021. Refer to Note 15, “Equity Method Investment,” for more information.

Amortization expense was $0.4 million and $0 for the three months ended June 30, 2021 and 2020, respectively, and was $0.8 million and $0 for the six months ended June 30, 2021 and 2020, respectively. Based on finite-lived intangible assets recorded as of June 30, 2021, the estimated future amortization expense for the next five years is as follows (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2021 (remaining six months)	$ 845
2022	1,722
2023	1,733
2024	1,733
2025	1,733
Thereafter	19,088

8. Accrued Liabilities and Other

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

	June 30 2021	December 31, 2020
Research and development costs	$ 5,426	$ 8,135
Compensation and benefits	3,489	4,530
Sublease rent and security deposit	675	1,400
Business taxes and licensing fees	1,052	898
Consulting and outside services	306	499
Other	321	212
Total accrued expenses and other liabilities	$ 11,269	$ 15,674

9. Collaboration and License Agreements

AbbVie Ireland Unlimited Company

On December 16, 2019, we entered into a license agreement (the "License Agreement") with AbbVie Ireland Unlimited Company ("AbbVie"), which granted us 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, we assumed all global development and commercialization responsibilities for atrasentan. In consideration of the license and rights granted under the License Agreement, we made an upfront cash payment and issued 1,999,415 shares of common stock for total consideration of $6.7 million to AbbVie. We concluded that this transaction should be accounted for as an asset purchase, and as such, recorded the associated expense within research and development expense in the statements of operations and comprehensive loss, as the product has not reached technological feasibility and does not have alternative future use. Under the License Agreement, we are obligated to make contingent development, regulatory and commercial milestone payments of up to a maximum of $135 million in the aggregate, as well as pay royalties on the worldwide net sales of licensed products ranging from upper-single-digit to high-teen percentages.

We did not recognize any milestone payments for the three and six months ended June 30, 2021 and 2020. As of June 30, 2021 and December 31, 2020, we did not have any payable or receivable balances associated with the License Agreement.

Merck

In connection with the Merger, we became party to an agreement with Merck. The agreement sets forth the parties' respective obligations for development, commercialization, regulatory and manufacturing and supply activities for antibody product candidates. All performance obligations of Aduro were completed prior to the Merger. We are eligible to receive future contingent payments, including up to $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, we are eligible to receive royalties at percentages in the mid-single digits to low teens based on net sales of the product. Future milestone payments and royalties will be recognized as revenue when earned as we have no performance obligations under this agreement. Any such milestones and royalties earned prior to October 4, 2030 will be payable by us to the holders of the CVRs, net of tax and certain other expenses that could be deducted by us.

Eli Lilly and Company

In connection with the Merger, we assumed an ongoing research collaboration and exclusive license agreement with Eli Lilly and Company ("Lilly") for the research and development of novel immunotherapies for autoimmune and other inflammatory diseases. Our only remaining performance obligation under the agreement is to perform research services through 2021, for which we will be reimbursed up to a specified amount.

For the three and six months ended June 30, 2021, we recognized revenue of less than $0.1 million and $0.4 million, respectively, under the Lilly agreement.

Novartis Pharmaceuticals Corporation

In connection with the Merger, we 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. On April 1, 2021, we received notice that Novartis terminated for convenience the Collaboration and License Agreement, dated March 12, 2015.

As a result of the termination, the only remaining activity under this agreement is reimbursement resulting from development costs that are shared between us and Novartis. We 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. For the three and six months ended June 30, 2021, the amounts recognized under the agreement with Novartis were not material.

10. Commitments and Contingencies

Redeemable Convertible Preferred Stock Tranche Liability

In February 2019, as amended in July 2019, we entered into a Series A financing transaction, pursuant to which we were authorized to issue up to 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 terms of the Series A redeemable convertible preferred stock agreement include provisions requiring the investors to purchase, and obligating us to deliver, additional shares of redeemable convertible preferred stock at a specified price in the future based on the achievement of certain development-based milestones by us. The investors are also able to waive the milestone requirements, which provides the investors with an option to purchase additional Series A redeemable convertible preferred stock if the milestone is not met. The rights to purchase additional shares were recorded as a tranche liability at the estimated fair value of the obligation on the date of issuance with the carrying values adjusted at each reporting date for any changes in the estimated fair values. For the three and six months ended June 30, 2020, we recorded less than a $0.1 million and $1.2 million, respectively, for the change in the fair value of the redeemable convertible preferred stock tranche liability.

Upon closing of the Merger, the outstanding redeemable convertible preferred stock tranche rights terminated and all redeemable convertible preferred stock that had been issued converted to common stock.

Leases

We have a total of five operating leases as of June 30, 2021 with remaining lease terms of approximately 6 months to 9 years.

In June 2021, we entered into a sublease agreement for office space in Seattle, Washington (“Seattle Sublease”), which we expect to use as our corporate headquarters. The Seattle Sublease commenced on July 1, 2021 and continues for a period of 58 months. The aggregate estimated base rent payments due over the term of the Seattle Sublease is approximately $5.7 million.

As of June 30, 2021, we are subleasing approximately 100,000 square feet in one of our facilities. Sublease income was $1.4 million and $0 for the three months ended June 30, 2021 and 2020, respectively, which was netted against rent expense. Sublease income was $2.6 million and $0 for the six months ended June 30, 2021, respectively, which was netted against rent expense. Total sublease income to be earned, in aggregate, will be approximately $69.2 million over the remaining term of the sublease agreement.

We maintain a letter of credit as security for one of our leases in the amount of $1.8 million, which is collateralized by a certificate of deposit that is included in restricted cash in our Condensed Consolidated Balance Sheet as of June 30, 2021. Additionally, in connection with the Seattle Sublease, we posted a security deposit of $0.3 million in the form of a letter of credit, which was collateralized by a certificate of deposit and is included in restricted cash in our Condensed Consolidated Balance Sheet as of June 30, 2021.

The maturity of our operating lease liabilities as of June 30, 2021 is as follows (in thousands):

Undiscounted Lease Payments	Amounts
2021 (remaining six months)	$ 2,980
2022	6,124
2023	6,250
2024	6,361
2025	6,475
Thereafter	25,538
Total undiscounted lease payments 1)	53,728
Present value adjustment	13,301
Total net lease liability	$ 40,427
Net lease liability - current	$ 3,280
Net lease liability - non-current	37,147
Total net lease liability	$ 40,427

1) Excludes future operating lease payments under the Seattle Sublease entered into in June 2021, in addition to future operating lease payments associated with another lease agreement entered into in June 2021, both of which have not commenced. The undiscounted future operating lease payments related to these agreements are approximately $6.9 million. Undiscounted future operating lease payments including these agreements are $ 60.6 million.

Rent expense recognized for operating leases was $2.1 million and $0.1 million for the three months ended June 30, 2021 and 2020, respectively, and was $4.1 million and $0.3 million for the six months ended June 30, 2021 and 2020, respectively. Variable lease payments, including non-lease components such as common area maintenance fees, recognized as rent expense for operating leases were $0.6 million and less than $0.1 million for the three months ended June 30, 2021 and 2020, respectively, and were $1.2 million and $0.1 million for the six months ended June 30, 2021 and 2020, respectively.

The following summarizes additional information related to operating leases:

	June 30, 2021	December 31, 2020
Weighted-average remaining lease terms (in years)		
Operating leases	8.3	8.8
Weighted-average discount rate		
Operating leases	7.1%	7.1%

Indemnification

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

Legal Proceedings

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

Other Commitments

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

11. Common Stock

Warrants

At June 30, 2021, warrants outstanding were not material.

Restricted Stock Awards ("RSAs")

The following table summarizes RSA activity:

	RSAs Outstanding	
	Number of RSAs (in thousands)	Weighted-Average Grant Date Fair Value Per Share
Balance—December 31, 2020	196	$ 0.00034
Vested	(48)	0.00034
Balance—June 30, 2021	148	$ 0.00034

The fair value of RSAs vested during the six months ended June 30, 2021 was $0.8 million.

At-the-Market Sales Agreement

In April 2021, we entered into an "at-the-market" sales agreement (the "2021 Sales Agreement"), with Cantor Fitzgerald & Co. and SVB Leerink LLC, through which we may offer and sell shares of our common stock having an aggregate offering of up to $75.0 million through Cantor Fitzgerald & Co. and SVB Leerink LLC, as our sales agents. We will pay the sales agents a commission of up to 3% of the gross proceeds of sales made through the 2021 Sales Agreement. In April 2021, we sold 2.2 million shares for $33.9 million in net proceeds under the 2021 Sales Agreement. We have $40.0 million remaining under the 2021 Sales Agreement, which is subject to the continued effectiveness of our shelf registration statement on Form S-3 (Registration No. 333-255099) that expires on April 7, 2024, or upon an effective replacement shelf registration statement.

12. Stock-Based Compensation

Equity Incentive Plan

In February 2019, Private Chinook adopted the 2019 Equity Incentive Plan (the "2019 Plan"). In connection with the Merger, we assumed Aduro's two equity incentive plans, the 2015 Equity Incentive Plan (the "2015 Plan") and the 2009 Stock Incentive Plan (the "2009 Plan," and collectively the "Aduro Plans"). No additional grants may be made from the 2009 Plan; however, shares subject to awards granted under the 2009 Plan remain subject to the terms of the 2009 Plan. The number of shares subject to and the exercise prices applicable to these awards were adjusted to reflect the one-for-five reverse stock split.

As of June 30, 2021 and December 31, 2020, there were 1.2 million and 0.9 million shares available for future grant, respectively.

Stock Options

The following table summarizes stock option activity:

	Number of Shares Underlying Options (in thousands)	Weighted-Average Exercise Price	Aggregate Intrinsic Value (In thousands)
Balance—December 31, 2020	5,514	$ 13.24	$ 38,433
Granted	1,280	15.66	
Exercised	(236)	6.23	$ 2,515
Canceled	(144)	35.77	
Balance—June 30, 2021	6,414	$ 13.48	$ 29,740
Options exercisable—June 30, 2021	2,385	$ 17.91	$ 13,672
Options vested and expected to vest—June 30, 2021	6,414	$ 13.48	$ 29,740

The aggregate intrinsic value represents the difference between the exercise price of the options and the closing price of our common stock for stock options that were in-the-money at June 30, 2021.

The weighted average grant-date fair value of options granted was $10.65 and $3.64 for the six months ended June 30, 2021 and 2020, respectively. As of June 30, 2021, the total unrecognized compensation expense related to unvested options was $29.1 million, which is expected to be recognized over a weighted-average period of 3.1 years.

We estimate the fair value of stock options using the Black Scholes option-pricing model. The fair value of stock options is amortized on a straight-line basis over the requisite service period of the awards. The fair value of stock options is estimated at the date of grant using a Black-Scholes option-pricing model with the following weighted-average assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Expected term (in years)	6.1	6.1	6.1	6.1
Volatility	78.6%	80.3%	79.0%	79.5%
Risk-free interest rate	1.1%	0.4%	0.8%	0.8%
Dividend yield	—	—	—	—

Restricted Stock Units ("RSUs")

The following table summarizes RSU activity:

	RSUs Outstanding	
	Number of RSUs (in thousands)	Weighted-Average Grant Date Fair Value Per Share
Balance—December 31, 2020	441	$ 14.51
Granted	466	15.43
Vested	(15)	14.74
Forfeited	(16)	14.81
Balance—June 30, 2021	876	$ 14.99

The total fair value of RSUs that vested in the six months ended June 30, 2021 was $0.2 million. The fair value of RSUs is determined on the date of grant based on the market price of our common stock on that date. As of June 30, 2021, there was $11.1 million of unrecognized stock-based compensation expense related to RSUs, which is expected to be recognized over a weighted-average period of 2.5 years.

2015 Employee Stock Purchase Plan ("ESPP")

We had 0.7 million shares available for future issuance under the 2015 ESPP as of June 30, 2021.

The fair value of our common stock to be issued under the 2015 ESPP is estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Expected term (in years)	0.5	—	0.5	—
Volatility	60.9%	0%	60.9%	0%
Risk-free interest rate	0.0%	0%	0.0%	0%
Dividend yield	—	—	—	—

As of June 30, 2021, the unrecognized stock-based compensation expense related to the ESPP was $0.1 million, 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):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development	$ 1,732	$ 143	$ 2,760	$ 183
General and administrative	1,863	156	3,313	216
Total stock-based compensation expense	$ 3,595	$ 299	$ 6,073	$ 399

13. Income Taxes

We recorded income tax benefit of $0.7 million for the three and six months ended June 30, 2021. No income tax benefit or expense was recorded for the three and six months ended June 30, 2020. Our effective tax rate was 1.7% and 0.9% for the three and six months ended June 30, 2021, respectively. The effective tax rate is lower than the statutory tax rate of 21% primarily due to us maintaining a full valuation allowance against our net deferred tax assets, offset by deferred tax benefits associated with the sale of certain non-renal assets.

14. Net Loss per Common 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 us (in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Numerator:				
Net loss	$ (42,571)	$ (7,743)	$ (79,786)	$ (12,892)
Denominator:				
Weighted-average shares outstanding	44,021	4,466	43,176	4,465
Less: weighted-average unvested restricted shares and shares subject to repurchase	(160)	(315)	(172)	(337)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	43,861	4,151	43,004	4,128
Net loss per share attributable to common stockholders, basic and diluted	$ (0.97)	$ (1.87)	(1.86)	(3.12)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the period presented because including them would have been antidilutive (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Redeemable convertible preferred stock	—	11,834	—	11,834
Conversion of redeemable convertible preferred stock issuable upon settlement of the redeemable convertible preferred stock tranche liability	—	7,159	—	7,159
Unvested restricted stock units	876	—	876	—
Unvested restricted stock awards	148	297	148	297
Options to purchase common stock	6,414	2,007	6,414	2,007
Total	7,438	21,297	7,438	21,297

15. Equity Method Investment

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

As of June 30, 2021, we own a 44% interest in Sairopa. We determined that we have the ability to exercise significant influence over Sairopa but do not have a controlling interest. Therefore, the investment in Sairopa was accounted for using the equity method. Judgment regarding the level of influence over each equity method investment includes considering key factors such as ownership interest, representation on the board of directors, participation in policy-making decisions and material intercompany transactions. The Sairopa Investors provided an initial capitalization of 12.5 million Euros. We recorded the equity method investment at $10.0 million, which is the fair value of the equity received by us in exchange for the non-renal assets. The sale of the non-renal assets to Sairopa resulted in a $7.2 million gain, which is the difference between the fair value of the equity received and the carrying value of the non-renal assets. The gain is reported in our Condensed Consolidated Statements of Operations during the three and six months ended June 30, 2021.

Our equity method investment is reported at cost and adjusted each period for our share of the investee's income or loss, which are reported in our Condensed Consolidated Statement of Operations on a one quarter lag. We assess our equity method investment for impairment whenever events or changes in circumstances indicate that the carrying value of the investment may not be recoverable

Item 2. 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 unaudited condensed consolidated financial statements and related notes included in Part I, Item 1 of this report and with our audited consolidated financial statements and related notes thereto for the year ended December 31, 2020, included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission.

Forward-Looking Statements

This discussion and other parts of this report contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are identified by words such as "believe," "will," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "could," "potentially" or the negative of these terms or similar expressions. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our future plans, strategies, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this report in Part II, Item 1A — "Risk Factors" and elsewhere in this report. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

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 results from the ongoing phase 1b trial at future nephrology conferences, including ASN in November 2021. We are also advancing our third program, CHK-336, which is currently in IND-enabling studies, towards an expected start of a phase 1 clinical trial in the first quarter of 2022 for the treatment of primary hyperoxaluria, or 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 SE, or Evotec, to jointly identify, characterize and validate novel mechanisms and discover precision medicines for lupus nephritis, IgAN, polycystic kidney disease, or PKD, and other primary glomerular diseases. 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, the leading cause of primary glomerulonephritis, 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 – 150,000 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 and 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. We presented new preclinical data elucidating the mechanism of action of atrasentan in IgAN at the ISN World Congress of Nephrology in April 2021, or WCN ’21. In this preclinical study, atrasentan rapidly reduced albuminuria and downregulated intra-renal transcriptional proliferative, inflammatory and fibrotic signaling in the gddY mouse IgAN model. The data also showed that atrasentan attenuated human renal mesangial cell activation induced by endothelin-1 or IgAN patient immune-derived immune complexes in a translational model system.

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 potential 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 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. Recently analyzed data in healthy volunteers from this trial were presented at WCN’21. In this trial, BION-1301 produced dose-dependent reductions in serum Gd-IgA1 levels that were greater in magnitude than previously reported for total IgA concentrations.

In addition, we have completed a phase 1 intravenous, or IV, to subcutaneous, or SC, bioavailability study in healthy volunteers. Results from the bioavailability study were presented at WCN’21. In this study, BION-1301 was well-tolerated when administered by both IV and SC routes in healthy volunteers, the pharmacokinetic profile of BION-1301 was consistent with previous clinical studies, the absorption rate of BION-1301 was typical of a monoclonal antibody and the magnitude of pharmacodynamic responses were largely retained with SC dosing compared to IV dosing.

We are currently enrolling patients with IgAN in Part 3 of this trial, and we presented a subset of interim data from this trial at the 58th ERA-EDTA conference in June 2021. The interim data presented was from the first several patients with IgAN enrolled in Cohort 1 of Part 3, in which patients were dosed with 450 mg of BION-1301 IV every two weeks. The preliminary data that were presented at the conference demonstrate that BION-1301 was generally well-tolerated to date in patients with IgAN, with no serious adverse events or treatment discontinuations due to adverse events. The pharmacokinetics of BION-1301 observed in patients with IgAN are consistent with those previously reported in healthy volunteers and are sufficient to drive rapid and sustained reductions in free APRIL levels. BION-1301 has durably reduced Gd-IgA1, IgA, IgM, and to a lesser extent, IgG levels in patients with IgAN.

BION-1301 demonstrated a clinically meaningful mean reduction in 24-hour proteinuria (UPCR) in the first several patients enrolled in the study, providing initial proof-of-concept for BION-1301 in IgAN.

We expect to complete enrollment of Cohort 1 in the third quarter of 2021, and then transition to SC dosing for future cohorts of the study. Patients in Cohort 2 will receive a SC dose of 600 mg of BION-1301 every two weeks for up to 52 weeks. Recent amendments to the design of Part 3 also include the option for a third cohort of patients to receive a SC dose of BION-1301 at a dose and schedule that would be determined based on data generated from Cohort 2. Moving forward with Cohort 3 may help us better understand the SC dose-response relationship prior to the next phase of development.

We have taken a number of actions this year to improve enrollment dynamics in this study, including streamlining the protocol, adding new experienced nephrology investigative sites, and increasing physician and patient awareness and enthusiasm about BION-1301. Going forward, we also expect to benefit from improved COVID-19 environments in many geographies. We plan to present additional and more mature data from this study at future nephrology conferences, including ASN in November 2021.

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 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 guidance on target selection, prioritization and validation strategies, as well as access to technology platforms that support target validation efforts through deep biological insights into human disease mechanisms and translational cellular and animal model systems.

In March 2021, we announced a strategic collaboration with Evotec focused on the joint identification, characterization and validation of novel mechanisms as well as the discovery of precision medicines for lupus nephritis, IgAN, PKD and other primary glomerular diseases. The collaboration 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

Collaboration and License Revenue

We have not generated any revenue from product sales. Prior to the completion of the Merger, Aduro generated revenue from collaboration and license agreements. These collaboration agreements may have included the transfer of intellectual property rights in the form of licenses, promises to provide research and development services and promises to participate on certain development committees with the collaboration party. The terms of such agreements included payment to Aduro of one or more of the following: nonrefundable upfront fees, payment for research and development services, development, regulatory and commercial milestone payments, and royalties on net sales of licensed products.

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 employee-related costs; licensing costs; materials and supplies; contracted research and manufacturing; consulting arrangements; allocated costs, such as facility costs; and other expenses incurred to advance our research and development activities. We recognize all research and development costs as they are incurred. Clinical trial costs, contract manufacturing and other development costs incurred by third parties are expensed as the contracted work is performed.

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

General and Administrative Expenses

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

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

At the effective time of the Merger, we also entered into an agreement pursuant to which Aduro's common stockholders of record as of the close of business on October 2, 2020 received one contingent value right, or CVR for each outstanding share of Aduro common stock held by such stockholder on such date. Each CVR represents the contractual right to receive payments from us upon the receipt of consideration resulting from milestones and royalties from certain pre-existing agreements and the disposition or licensing of any of Aduro's non-renal assets, net of any tax, and certain other expenses that could be deducted by us. Change in the fair value of the contingent consideration and CVR liability at each reporting consists of the changes in this contractual right.

Amortization of Intangible Assets

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

Gain on Sale of Assets to Equity Method Investment

We entered into an agreement with Sairopa B.V., or Sairopa, to acquire certain of our non-renal assets in exchange for preferred stock in Sairopa during the second quarter of 2021. The sale of the non-renal assets to Sairopa resulted in a $7.2 million gain, which is the difference between the fair value of the equity received and the carrying value of the non-renal assets. The gain is reported in our Condensed Consolidated Statements of Operations during the three and six months ended June 30, 2021.

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.

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 Three Months Ended June 30, 2021 and 2020

	Three Months Ended June 30,		
	2021	2020	Change
	(In thousands)		
Collaboration and license revenue	$ 34	$ —	$ 34
Operating expenses:			
Research and development	22,787	3,870	18,917
General and administrative	7,768	3,879	3,889
Change in fair value of contingent consideration and contingent value rights liabilities	19,557	—	19,557
Amortization of intangible assets	422	—	422
Total operating expenses	50,534	7,749	42,785
Gain on sale of assets to equity method investment	7,227	—	7,227
Loss from operations	(43,273)	(7,749)	(35,524)
Other expense, net	(39)	(4)	(35)
Change in fair value of redeemable convertible preferred stock tranche liability	—	10	(10)
Loss before income taxes	(43,312)	(7,743)	(35,569)
Income tax benefit	741	—	741
Net loss	$ (42,571)	$ (7,743)	$ (34,828)

Collaboration and License Revenue

Collaboration and license revenue was less than $0.1 million for the three months ended June 30, 2021 compared to $0 for the three months ended June 30, 2020. Revenue recognized was related to the research and development services provided under our collaboration agreement with Lilly, which was acquired through the Merger.

Research and Development Expenses

The following table summarizes our research and development costs by program and by category incurred during the three months ended June 30, 2021 and 2020:

	Three Months Ended June 30,		
	2021	2020	Change
	(In thousands)		
Product Candidates			
Atrasentan	$ 10,327	$ 1,436	$ 8,891
BION-1301	2,094	—	2,094
CHK-336	2,432	753	1,679
Other	3,221	194	3,027
Discovery research and other development costs	2,484	971	1,513
Subtotal	20,558	3,354	17,204
Stock-based compensation expense	1,732	143	1,589
Facility costs and depreciation	497	373	124
Total research and development	$ 22,787	$ 3,870	$ 18,917

The following table summarizes our research and development expenses incurred during the three months ended June 30, 2021 and 2020:

	Three Months Ended June 30,		
	2021	2020	Change
	(In thousands)		
Contract research and manufacturing	$ 11,248	$ 1,388	$ 9,860
Employee-related costs	5,728	1,576	4,152
Supplies used in research and development	726	243	483
Stock-based compensation expense	1,732	143	1,589
Facility costs and depreciation	497	373	124
Consulting and outside services	2,526	29	2,497
Other	330	118	212
Total research and development	$ 22,787	$ 3,870	$ 18,917

Research and development expenses were $22.8 million for the three months ended June 30, 2021, an increase of $18.9 million compared to $3.9 million for the three months ended June 30, 2020. The increase was primarily due to external clinical and manufacturing expenses related to the atrasentan and BION-1301 clinical programs; higher employee-related costs, including salaries, benefits and stock-based compensation expense, associated with hiring staff to build out our clinical and development capabilities; increased spending for consulting and outside services; and higher facilities and other costs.

General and Administrative Expenses

The following table summarizes our general and administrative expenses incurred during the three months ended June 30, 2021 and 2020:

	Three Months Ended June 30,		
	2021	2020	Change
	(In thousands)		
Consulting and outside services	$ 2,084	$ 3,191	$ (1,107)
Employee-related costs	2,574	570	2,004
Stock-based compensation expense	1,863	156	1,707
Facility costs and depreciation	809	(102)	911
Other	438	64	374
Total general and administrative	$ 7,768	$ 3,879	$ 3,889

General and administrative expenses were $7.8 million for the three months ended June 30, 2021, an increase of $3.9 million compared to $3.9 million for the three months ended June 30, 2020. The increase was primarily due to higher employee-related costs, including salaries, benefits and stock-based compensation expenses associated with the addition of administrative staff to build out our public company infrastructure and an increase in facilities and other costs.

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

Change in fair value of contingent consideration expense increased by $19.6 million for the three months ended June 30, 2021 compared to the three months ended June 30, 2020. The increase primarily resulted from a change in estimate of the potential future proceeds derived from Aduro's license agreement with Merck and from the sale of certain of our non-renal assets in exchange for preferred shares in Sairopa. During the second quarter of 2021, Merck informed us that they intend to explore the potential benefit of the product candidate MK-5890, previously out-licensed to Merck by Aduro, in a phase 2 clinical study for a new indication. This could result in potential milestone and royalty payments for the benefit of the CVR holders.

Amortization of intangible assets

Amortization of intangible assets expense increased by $0.4 million for the three months ended June 30, 2021 compared to the three months ended June 30, 2020, due to amortization of finite-lived intangible assets acquired in the Merger.

Gain on sale of assets to equity method investment

Gain on sale of assets to equity method investment increased $7.2 million for three months ended June 30, 2021 resulting from the agreement to sell certain non-renal assets of ours in exchange for stock in Sairopa during the second quarter of 2021. The gain is the difference between the fair value of the equity received and the carrying value of the non-renal assets.

Change in fair value of redeemable convertible preferred stock tranche liability

Change in fair value of redeemable convertible preferred stock tranche liability decreased by less than $0.1 million for the three months ended June 30, 2021 compared to the three months ended June 30, 2020, due to the termination of the convertible preferred stock tranche rights pursuant to the terms of the merger agreement.

Benefit for income taxes

We recorded a benefit for income taxes of $0.7 million for the three months ended June 30, 2021, primarily resulting from deferred tax benefits associated with the sale of certain non-renal assets.

Comparison of the Six Months Ended June 30, 2021 and 2020

	Six Months Ended June 30,		
	2021	2020	Change
	(In thousands)		
Collaboration and license revenue	$ 385	$ —	$ 385
Operating expenses:			
Research and development	48,484	6,688	41,796
General and administrative	17,311	5,150	12,161
Change in fair value of contingent consideration and contingent value rights liabilities	21,396	—	21,396
Amortization of intangible assets	842	—	842
Total operating expenses	88,033	11,838	76,195
Gain on sale of assets to equity method investment	7,227	—	7,227
Loss from operations	(80,421)	(11,838)	(68,583)
Other income (expense), net	(106)	115	(221)
Change in fair value of redeemable convertible preferred stock tranche liability	—	(1,169)	1,169
Loss before income taxes	(80,527)	(12,892)	(67,635)
Income tax benefit	741	—	741
Net loss	$ (79,786)	$ (12,892)	$ (66,894)

Collaboration and License Revenue

Collaboration and license revenue was $0.4 million for the six months ended June 30, 2021 compared to $0 for the six months ended June 30, 2020. Revenue recognized was related to the research and development services provided under our collaboration agreement with Lilly, which was acquired through the Merger.

Research and Development Expenses

The following table summarizes our research and development costs by program and by category incurred during the six months ended June 30, 2021 and 2020:

	Six Months Ended June 30,		
	2021	2020	Change
	(In thousands)		
Product Candidates			
Atrasentan	$ 19,054	$ 2,271	$ 16,783
BION-1301	6,175	—	6,175
CHK-336	5,030	1,617	3,413
Other	6,716	1,045	5,671
Discovery research and other development costs	7,238	1,139	6,099
Subtotal	44,213	6,072	38,141
Stock-based compensation expense	2,760	183	2,577
Facility costs and depreciation	1,511	433	1,078
Total research and development	$ 48,484	$ 6,688	$ 41,796

The following table summarizes our research and development expenses incurred during the six months ended June 30, 2021 and 2020:

	Six Months Ended June 30,		
	2021	2020	Change
	(In thousands)		
Contract research and manufacturing	$ 27,084	$ 2,600	$ 24,484
Employee-related costs	11,044	2,440	8,604
Supplies used in research and development	1,432	524	908
Stock-based compensation expense	2,760	183	2,577
Facility costs and depreciation	1,511	433	1,078
Consulting and outside services	4,021	328	3,693
Other	632	180	452
Total research and development	$ 48,484	$ 6,688	$ 41,796

Research and development expenses were $48.5 million for the six months ended June 30, 2021, an increase of $41.8 million compared to $6.7 million for the six months ended June 30, 2020. The increase was primarily due to external clinical and manufacturing expenses related to the atrasentan and BION-1301 clinical programs; higher employee-related costs, including salaries, benefits and stock-based compensation expense, associated with hiring staff to build out our clinical and development capabilities; increased spending for consulting and outside services; and higher facilities and other costs. The six months ended June 30, 2021 also includes an upfront fee of $3.3 million due to Evotec International GmbH under a research collaboration and license agreement entered into in February 2021.

General and Administrative Expenses

The following table summarizes our general and administrative expenses incurred during the six months ended June 30, 2021 and 2020:

	Six Months Ended June 30,		
	2021	2020	Change
	(In thousands)		
Consulting and outside services	$ 5,251	$ 3,531	$ 1,720
Employee-related costs	5,941	1,134	4,807
Stock-based compensation expense	3,313	216	3,097
Facility costs and depreciation	1,719	117	1,602
Other	1,087	152	935
Total general and administrative	$ 17,311	$ 5,150	$ 12,161

General and administrative expenses were $17.3 million for the six months ended June 30, 2021, an increase of $12.2 million compared to $5.2 million for the six months ended June 30, 2020. The increase was primarily due to higher employee-related costs, including salaries, benefits and stock-based compensation expenses associated with the addition of administrative staff to build out our public company infrastructure; higher legal, consulting and other professional services costs; and an increase in facilities and other costs.

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

Change in fair value of contingent consideration and contingent value rights liabilities expense increased by $21.4 million for the six months ended June 30, 2021 compared to the six months ended June 30, 2020. The increase primarily resulted from a change in estimate of the potential future proceeds derived from Aduro's license agreement with Merck and from the sale of certain of our non-renal assets in exchange for preferred shares in Sairopa. During the second quarter of 2021, Merck informed us that they intend to explore the potential benefit of the product candidate MK-5890, previously out-licensed to Merck by Aduro, in a phase 2 clinical study for a new indication. This could result in potential milestone and royalty payments for the benefit of the CVR holders.

Amortization of intangible assets

Amortization of intangible assets expense increased by $0.8 million for the six months ended June 30, 2021 compared to the six months ended June 30, 2020, due to amortization of finite-lived intangible assets acquired in the Merger.

Gain on sale of assets to equity method investment

Gain on sale of assets to equity method investment increased $7.2 million for six months ended June 30, 2021, resulting from the agreement to sell certain non-renal assets of ours in exchange for stock in Sairopa during the second quarter of 2021. The gain is the difference between the fair value of the equity received and the carrying value of the non-renal assets.

Change in fair value of redeemable convertible preferred stock tranche liability

Change in fair value of redeemable convertible preferred stock tranche liability decreased by $1.2 million for the six months ended June 30, 2021 compared to the six months ended June 30, 2020, due to the termination of the convertible preferred stock tranche rights pursuant to the terms of the merger agreement.

Benefit for income taxes

We recorded a benefit for income taxes of $0.7 million for the six months ended June 30, 2021, primarily resulting from deferred tax benefits associated with the sale of certain non-renal assets.

Liquidity and Capital Resources

As of June 30, 2021, we had $229.8 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 based on our current business plan, our cash, cash equivalents and marketable securities as of June 30, 2021 will enable us to fund our operating expenses and capital expenditure requirements through 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. As of June 30, 2021, our material cash requirements from known contractual and other obligations include our contractual obligations related to our operating leases. 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:

	Six Months Ended June 30,	
	2021	2020
	(In thousands)	
Net cash provided by (used in):		
Operating activities	$ (55,513)	$ (7,206)
Investing activities	(32,190)	(400)
Financing activities	35,659	14,449
Effect of exchange rate changes	84	(152)
Net change in cash, cash equivalents, and restricted cash	$ (51,960)	$ 6,691

Operating Activities

Net cash used in operating activities was $55.5 million for the six months ended June 30, 2021, an increase of $48.3 million compared to $7.2 million for the six months ended June 30, 2020. The increase was primarily due to an increased operating loss resulting from increased research and development and general and administrative spending.

Investing Activities

Net cash used in investing activities was $32.2 million for the six months ended June 30, 2021, an increase of $31.8 million compared $0.4 million cash used for the six months ended June 30, 2020. The increase was primarily due to net purchases of marketable securities.

Financing Activities

Net cash provided by financing activities was $35.7 million for the six months ended June 30, 2021, an increase of $21.2 million compared to $14.4 million for the six months ended June 30, 2020. The increase was primarily due to net proceeds received from the sales of shares of our common stock through the at-the-market sales agreement during the six months ended June 30, 2021.

In April 2021, we entered into the 2021 Sales Agreement with Cantor Fitzgerald & Co. and SVB Leerink LLC, through which we may offer and sell shares of our common stock having an aggregate offering of up to $75.0 million through Cantor Fitzgerald & Co. and SVB Leerink LLC, as our sales agents. We will pay the sales agents a commission of up to 3% of the gross proceeds of sales made through the 2021 Sales Agreement. During the six months ended June 30, 2021, we sold 2.2 million shares for $33.9 million in net proceeds under the 2021 Sales Agreement. We have $40.0 million remaining under the 2021 Sales Agreement. In addition, proceeds from the exercise of stock options and warrants totaled $1.8 million during the six months ended June 30, 2021, an increase of $1.8 million compared to zero for the six months ended June 30, 2020.

Critical Accounting Policies and Significant Judgments and Estimates

Our condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP. The preparation of these unaudited condensed 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.

There have been no material changes in our critical accounting policies during the six months ended June 30, 2021, as compared to those disclosed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting

Policies and Estimates" in our Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC on April 7, 2021.

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.

Recently Adopted Pronouncements

For information with respect to recently issued accounting standards and the impact of these standards on our consolidated financial statements, refer to Note 2 "Basis of Presentation and Consolidation, Use of Estimates and Recent Accounting Pronouncements" in our condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures.

Our management, with the participation of our President and Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) prior to the filing of this Quarterly Report on Form 10-Q. Based on that evaluation, our President and Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were not effective at a reasonable assurance level due to the material weaknesses identified in our internal control over financial reporting as of December 31, 2020, which our management views as an integral part of our disclosure controls and procedures. Management's assessment identified the following material weaknesses in our internal control over financial reporting: lack of segregation of duties due to lack of sufficient accounting and finance personnel, lack of sufficient entity level controls and lack of a sufficient technology infrastructure to support the financial reporting function.

Our management, under the supervision of our President and Chief Executive Officer and our Chief Financial 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. This individual has significant experience in technical accounting matters and internal controls commensurate with public company reporting requirements. During the second quarter of 2021, we hired additional qualified personnel to critical accounting leadership roles, who we expect to significantly contribute to the remediation of our material weaknesses.

(iii) We 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. During the second quarter of 2021, we implemented procedures for the preparation and review of reconciliations and journal entries, in addition to implementing procedures over several other areas that support our financial reporting. We will continue to enhance or modify these procedures and controls in future periods as needed. We also engaged third-party service providers, who we plan to utilize in the future to implement certain information technology general controls associated with our accounting general ledger.

(iv) We have assigned responsibilities among our expanded staff to enable improved segregation of duties. During the second quarter of 2021, we also began evaluating systems and processes for proper segregation of duties.

In addition to the items above, during the second quarter of 2021, we engaged a third-party service provider to complete an independent risk assessment of our internal control over financial reporting to evaluate sources of potential risks to our financial

statements. This also included an assessment of key systems supporting financial reporting in order to improve the design and operating effectiveness of information technology general controls. As a result of this risk assessment, we identified and designed key controls across several processes supporting internal control over financial reporting and developed a workplan for remediation of the enhancements identified.

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, which will help facilitate the remediation of the material weaknesses identified above. As we continue to evaluate and work to improve our internal control over financial reporting, we will take additional measures to address control deficiencies, or we may modify certain of the remediation measures described above. 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.

Other than the changes described above, there were no changes in our internal control over financial reporting during the quarter ended June 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent limitation on the effectiveness of internal control.

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurances. In addition, 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. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but cannot assure you that such actions will be sufficient to provide us with effective internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

We are not party to any material legal proceedings at this time. From time to time, we may become involved in various legal proceedings that arise in the ordinary course of our business.

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 Quarterly Report on Form 10-Q, including our unaudited condensed 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 $42.6 million and $79.8 million for the three and six months ended June 30, 2021, respectively. As of June 30, 2021, we had an accumulated deficit of $208.6 million. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses over the next several years and for the foreseeable future as we intend to continue to conduct research and development, clinical testing, regulatory compliance activities, manufacturing activities, and, if any of our product candidates are approved, sales and marketing activities that, together with anticipated general and administrative expenses, will likely result in us incurring significant losses for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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

We will require substantial future capital in order to complete planned and future preclinical and clinical development for atrasentan and other product candidates and potentially commercialize these product candidates. Based upon our current operating plan, we believe that our existing cash and cash equivalents held as of June 30, 2021 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 our business and share price.

Following the merger, our management is required to report on the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation.

In preparing our 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 us, or at all, and/or that there will not be additional material weaknesses or significant deficiencies in our 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 our 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 our financial reports, the market price of our common stock could decline, and we 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.

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 later in 2021. We also plan to advance our CHK-336 program in primary hyperoxaluria towards a phase 1 clinical trial expected to begin in the first quarter of 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 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 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 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 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 – 150,000 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, atrasentan may not show a sufficient treatment benefit on the expected surrogate endpoint to satisfy the FDA that the anticipated benefit on loss of renal function will be confirmed in the planned post-marketing phase of the trial. If we decide to submit an NDA seeking accelerated approval or receive an expedited regulatory designation for atrasentan or any of our other product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. If 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 June 2021, the U.S. Supreme Court held that plaintiffs did not have standing to challenge constitutionality of the individual mandate. It is unclear whether 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 that could be deducted by us under the CVR Agreement. In April 2021, prior to the disposition period set forth in the CVR agreement, we entered into an agreement with Sairopa, a private company created by Van Herk Royalty B.V. and D.S. Chahal to acquire certain of our non-renal assets in exchange for stock in Sairopa. We will hold our equity interests in Sairopa until there is a liquidity event, upon which 50% of any proceeds, net of any tax, and certain other expenses that could be deducted by us, will be distributed to CVR holders, provided such liquidity event occurs during the 10-year CVR period. In the event that no CVR milestones occur within the 10-year CVR period specified in the CVR Agreement or the consideration received is not greater than the amounts that could be deducted by us, no 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.

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 our existing or future collaborators;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- 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. We currently qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Exchange Act, which allows 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, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially and adversely affect our business, financial condition and results of operations.

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

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

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

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

General Risk Factors

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, a global economic downturn 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 our cash and cash equivalents. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. Our failure to apply these resources effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. You may not have the opportunity to influence our decisions on how to use our cash resources.

We must attract and retain highly skilled employees to succeed.

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

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

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

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

Our internal computer and information systems, or those used by our CROs, CMOs or other contractors or consultants, may fail or suffer security 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 2. Recent Sales of Unregistered Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

EXHIBIT INDEX

Exhibit No	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.24	Sublease between the Registrant and Wireless Advocates LLC dated May 24, 2021.					X
31.1	Certification of the Chief Executive Officer Pursuant to Securities Exchange Act Rules 13A-14(A) and 15D-14(A).					X
31.2	Certification of the Chief Financial Officer Pursuant to Securities Exchange Act Rules 13A-14(A) and 15D-14(A).					X
32.1*	Certification Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL 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 (formatted as inline XBRL and contained in Exhibit 101)					X

* The certifications attached as Exhibit 32.1 accompany this Quarterly Report on Form 10-Q 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Chinook Therapeutics, Inc.

Date: August 12, 2021

By: /s/ Eric L. Dobmeier
Eric L. Dobmeier
President and Chief Executive Officer
(principal executive officer)

Chinook Therapeutics, Inc.

Date: August 12, 2021

By: /s/ Eric H. Bjerkholt
Eric H. Bjerkholt
Chief Financial Officer
(principal financial and accounting officer)

SUBLEASE

1. PARTIES.

This Sublease (this "**Sublease**"), dated May 24, 2021, is made by and between Wireless Advocates LLC, a Washington limited liability company ("**Sublandlord**"), and Chinook Therapeutics, Inc., a Delaware corporation ("**Subtenant**").

2. MASTER LEASE.

400 Fairview Avenue LLC, a Delaware limited liability company, as successor-in-interest to 400 Fairview LLC, a Delaware limited liability company ("**Master Landlord**"), as landlord, and Sublandlord, as tenant, entered into that certain Office Lease dated May 13, 2015, as amended by that certain First Amendment to Lease dated July 27, 2015; that certain Second Amendment to Lease dated February 2, 2016; and that certain Third Amendment to Lease dated May 8, 2020 (collectively, the "**Master Lease**"), pursuant to which Master Landlord leased to Sublandlord approximately 52,371.48 rentable square feet of space (the "**Office Space**"), which is comprised of the entire 9th and 10th floors of the building located at 400 Fairview Avenue, Seattle, Washington 98109 (the "**Building**") and legally described in the Master Lease, and (ii) approximately 520.83 rentable square feet of space (the "**Storage Space**"), which is comprised of 3 separate areas on the P2, P3 and P4 levels of the Building's parking garage. The Office Space and the Storage Space are together referred to herein as the "**Master Premises**." A copy of the Master Lease is attached hereto as Exhibit A. Capitalized terms used but not otherwise defined in this Sublease shall have the meanings assigned to such terms in the Master Lease.

3. SUBLEASE PREMISES.

Sublandlord hereby subleases to Subtenant, on the terms and conditions set forth in this Sublease, the entire 9th floor of the Master Premises, except as set forth in Section 15 regarding Sublandlord's retained Server space, which floor consists of approximately 25,903 rentable square feet of space (the "**Sublease Premises**"). For purposes of this Sublease, "**Subtenant's Share**" of the Master Premises shall be 49.46%. The Sublease Premises is depicted on Exhibit B attached hereto.

4. WARRANTY BY SUBLANDLORD.

Sublandlord warrants and represents to Subtenant that the Master Lease has not been amended or modified except as expressly set forth herein, that Sublandlord is not now, and as of the Commencement Date shall not be, in default or breach of any of the provisions of the Master Lease, and that Sublandlord has no knowledge of any claim by Master Landlord that Sublandlord is in default or breach of any of the provisions of the Master Lease.

5. TERM.

The term of this Sublease (the "**Term**") shall commence on July 1, 2021 (the "**Commencement Date**"), or 3 business days following the date upon which Master Landlord consents in writing to this Sublease, whichever shall last occur. The Term shall expire on April 30, 2026 (the "**Expiration Date**"), unless otherwise sooner terminated in accordance with the provisions of this Sublease. In the event that the Term commences on a date other than the Commencement Date, Sublandlord and Subtenant shall execute a memorandum setting forth the actual date of commencement of the Term. Possession of the Sublease Premises ("**Possession**") shall be delivered to Subtenant on the Commencement Date. If, for any reason, Sublandlord does not deliver Possession to Subtenant on the Commencement Date, (i) Sublandlord shall not be subject to any liability for such failure, (ii) the Expiration Date shall not be extended by the delay, and (iii) the validity of this Sublease shall not be impaired, but Base Rent shall abate per diem until delivery of Possession. Notwithstanding the foregoing, if Sublandlord has not delivered Possession to Subtenant within 30 days after the Commencement Date, then, at any time thereafter and before delivery of Possession, Subtenant may give written notice to Sublandlord of Subtenant's intention to cancel this Sublease. Said notice shall set forth an effective date for such cancellation which shall be not less than 10 days after delivery of said notice to Sublandlord. If Sublandlord fails to deliver Possession to Subtenant on or before such

effective date, then (i) this Sublease shall be cancelled on such effective date, (ii) all consideration previously paid by Subtenant to Sublandlord on account of this Sublease shall promptly be refunded to Subtenant, (iii) this Sublease shall thereafter be of no further force or effect, and (iv) Sublandlord shall have no further liability to Subtenant on account of such delay or cancellation. If Sublandlord permits Subtenant to take possession prior to the Commencement Date ("**Early Possession**"), such Early Possession shall not advance the Expiration Date and shall be subject to the provisions of this Sublease other than the obligation to pay Base Rent.

6. RENT.

Subtenant shall pay to Sublandlord, without deduction, setoff, notice or demand (except as otherwise set forth herein), at Sublandlord's address designated below or at such other place as Sublandlord shall designate from time to time by written notice to Subtenant, the sum of $55,625.00 per month for months 1 through 4 (July 1, 2021 through and including October 31, 2021); $74,166.67 per month for months 5 through 8 (November 1, 2021 through and including February 28, 2022); and $96,056.96 per month for months 9 through 12 (March 1, 2022 through and including June 30, 2022), in advance on the first day of each month of the Term (the "**Base Rent**"). Beginning on July 1, 2022, and on the 1st day of July of every year thereafter for the duration of the Term, the Base Rent shall increase by 3% on an annual basis. If the Term commences or expires on a day other than the first or last day of a month, the Base Rent for the partial months shall be prorated on a per diem basis. Except as set forth below, the Base Rent as described above shall constitute the total amount due from Subtenant to Sublandlord under this Sublease. Sublandlord is and shall remain responsible for all amounts owing under the Master Lease, including, without limitation, Base Rent and all "**Additional Rent**" as that term is defined in the Master Lease.

If the Base Rent or any other amounts due under this Lease (collectively, the "Additional Rent") are not received by Sublandlord when due, Subtenant shall pay to Sublandlord an amount equal to the sum which would be payable by Sublandlord to Master Landlord for an equivalent default under the Master Lease or 5% of the delinquent amount for the cost of collecting and handling such late payment in addition to the amount due and as Additional Rent, whichever is greater. All delinquent sums not paid by Subtenant within five (5) days of when due shall incur interest at the rate the Subtenant would pay the Master Landlord under the Master Lease or an equivalent default at the highest rate of interest allowable by law, whichever is less. Interest on all delinquent amounts shall be calculated from the original due date to the date of payment.

Sublandlord's acceptance of less than the full amount of any payment due from Subtenant shall not be deemed an accord and satisfaction or compromise of such payment unless Sublandlord specifically consents in writing to payment of such lesser sum as an accord and satisfaction or compromise of the amount which Subtenant claims. Any portion that remains to be paid by Subtenant shall be subject to the late charges and default interest provisions of this Section.

For purposes of this Sublease, the "**Base Year**" shall be calendar year 2021. Beginning January 1, 2022, Subtenant shall pay to Sublandlord, as additional rent, monthly and in advance on the first day of each month during the Term thereafter, an amount equal to 1/12th of Subtenant's Share of the actual increase in Operating Costs for each calendar year during the Term over the Operating Costs for the Base Year, as reasonably estimated by Sublandlord. If Subtenant's portion of said estimate of Operating Costs shows an increase for subsequent calendar years over the Base Year, Subtenant shall pay to Sublandlord, as additional rent, such estimated increase in monthly installments of 1/12th beginning on January 1 of the forthcoming calendar year, and 1/12th on the first day of each succeeding calendar month. As soon as practical, but not more than 30 days following the receipt of an accounting from the Master Landlord for each calendar year, Sublandlord shall provide to Subtenant, a written accounting of actual Operating Costs incurred during the prior calendar year, and such accounting shall reflect Subtenant's Share of Operating Costs. If the additional rent paid by Subtenant under this Section 6 during the preceding calendar year was less than the actual amount of Subtenant's Share of Operating Costs, Sublandlord shall so notify Subtenant and Subtenant shall pay such amount to Sublandlord within 30 days of receipt of such notice. Such amount shall be deemed to have accrued during the prior calendar year and shall be due and payable from Subtenant even though the Term of this Sublease has expired or this Sublease has been terminated prior to Subtenant's receipt of this notice. If Subtenant's payments were greater than the actual amount, then such overpayment shall be credited (or refunded, as applicable) by Sublandlord to all present additional rent due under this Section 6. For purposes

of this Sublease, the Base Rent and any additional rent that may be due under this Section 6 may collectively be referred to as the "**Rent**."

7. ADDITIONAL PROVISIONS.

(a) **Parking.** Subtenant shall have the right, but no obligation, to lease up to 33 unreserved and 1 reserved stall during the Term at the Building garage operator's parking rate. If Sublandlord receives any discounts for parking, such discounts shall be passed on to Subtenant. Beginning September 1, 2021, and for such period of time during the Term that the Master Lease is structured as "must take" parking, Subtenant shall commit to lease 1/2 of the parking allotment above (16 stalls) at the Building garage operator's parking rate (less any discounts received by Sublandlord under the Master Lease).

(b) **Condition of Sublease Premises.** Subtenant accepts the Sublease Premises in its current, "as-is" condition. Sublandlord shall have no obligation to furnish or supply any work, services, furniture, fixtures, equipment, or decorations, except as set forth below and Sublandlord shall deliver the Subleased Premises in broom clean condition. Subtenant acknowledges that neither Sublandlord nor Sublandlord's agents have made any representation or warranty as to the condition of the Sublease Premises or the suitability of the Sublease Premises for the conduct of Subtenant's business. At no additional charge to Subtenant, all furniture, equipment and fixtures currently located in the Sublease Premises shall remain for Subtenant's use during the Term, including, without limitation, existing data cabling, patch panels, white boards, server racks, filing cabinets and kitchen equipment (the "**Existing Furniture**"); provided, however, that Subtenant may (at its option and cost and with no liability to Sublandlord) dispose of any Existing Furniture that Subtenant does not desire to use during the Term after notifying Sublandlord and providing Sublandlord the opportunity to remove any unwanted items within 10 business days following such notification. Notwithstanding the above, Sublandlord shall have the right, prior to the Commencement Date, to remove up to 28 workstations, 4 lobby chairs and 2 lunch tables from the Sublease Premises.

(c) **Alterations.** Subtenant intends to make certain alterations, additions, improvements, modifications and decorations to the Sublease Premises (including, but not limited to, the construction of a large conference room, 3-4 private offices, paint, carpet, and modifications to the current mechanical and electrical systems required to make such improvements) (the "**Planned Alterations**") at Subtenant's sole cost and expense. Sublandlord hereby approves of the Planned Alterations as described in Exhibit C attached hereto, provided, however, that Master Landlord also approves of such Planned Alterations. Subtenant shall be responsible for preparation of working drawings prepared with respect to the Planned Alterations for review and approval by Subtenant and Master Landlord. Subtenant shall also obtain Master Landlord's approval for Planned Alterations at Subtenant's sole cost and expense. If Sublandlord incurs any expense in attempting to obtain Master Landlord's approval for the Planned Alterations or any other matter in which Master Landlord's consent is required on Subtenant's behalf, Subtenant shall promptly reimburse Sublandlord for such expense. Unless otherwise agreed in writing by Sublandlord and Subtenant, all such Planned Alterations that are a part of, or that are permanently affixed to, the Sublease Premises shall be installed at the sole cost and expense of Subtenant and shall become the property of Sublandlord and shall remain upon and be surrendered with the Sublease Premises at the end of the Term. Notwithstanding the foregoing sentence, if Master Landlord requires the removal of the Planned Alterations at the end of the Term, Subtenant shall be solely responsible for their removal and shall, at its sole cost and expense, repair any damage caused to the Sublease Premises by the removal of the Planned Alterations.

(d) **Prepaid Rent**. Upon execution of the Sublease, Subtenant shall deliver to Sublandlord the sum of $55,625.00 (or such other amount as prorated for less than a full first month) as prepaid rent to be applied to Rent due for month 1 of the Sublease Term; provided, however that if the Sublease becomes of null effect pursuant to Section 23 herein, such prepaid rent will be returned to Subtenant within five (5) business days.

(e) **Letter of Credit.**

1. **Form of Letter of Credit.** Within five (5) business days after Master Landlord's consent to this Sublease, Subtenant shall deliver to Sublandlord, as security for the faithful performance of all Subtenant's obligations under this Sublease, an irrevocable standby letter of credit (the "Letter of Credit") in the amount of $324,435.08 for the account of Subtenant and for the benefit of Sublandlord and issued by a bank reasonably acceptable to Sublandlord (the "Issuer"). Provided however, if Subtenant has a cash, or cash equivalent balance exceeding $125,000,000.00 for the fiscal quarter preceding month 36 of the sublease term, the Letter of Credit amount shall be reduced to $216,290.05 at month 36 for the remainder of the Term. Subtenant will provide a copy of such Letter of Credit. Subtenant shall maintain the Letter of Credit in effect until thirty (30) days after the later of (x) the expiration of the Sublease Term or earlier termination of this Sublease, or (y) vacation of the Sublease Premises by Subtenant. If the Letter of Credit shall expire prior to said date, Subtenant shall renew the Letter of Credit prior to its expiration or arrange for issuance of a new Letter of Credit in accordance with the terms hereof. If Subtenant fails to give Sublandlord evidence of renewal of the Letter of Credit or issuance of a new Letter of Credit at least ten (10) days prior to the expiration of the Letter of Credit then in effect, Sublandlord shall be entitled to draw down the full amount of the Letter of Credit and the amount so drawn ("Draw Proceeds"), although not a cash security deposit, shall be held and maintained by Sublandlord and may be applied in the same manner as set forth in Section 4.6.5 below with respect to a Security Deposit.

2. **Draws on the Letter of Credit.** Sublandlord shall be entitled to draw upon a portion or the entire amount of the Letter of Credit from time to time, with notice to Subtenant and without prejudice to any other remedy Sublandlord may have, for any of the following reasons: (x) upon or following the occurrence of a Sublease event of default, (A) to pay any amounts payable by Subtenant to Sublandlord hereunder, and (B) to compensate Sublandlord for any expense, loss or damage actually incurred or suffered by Sublandlord in connection with the default; or (y) if Subtenant fails to give Sublandlord evidence of renewal of the Letter of Credit or issuance of a new Letter of Credit at least ten (10) days prior to the expiration of the Letter of Credit then in effect as provided above; or (z) upon the expiration or earlier termination of this Sublease, to pay any amount then due and payable by Subtenant to Sublandlord. If the entire Draw Proceeds are not used or applied by Sublandlord, the balance of the Draw Proceeds, although not a cash security deposit, shall be held and maintained by Sublandlord and may be applied in the manner set forth in Section 7(e)5 below with respect to a Security Deposit.

3. **Restoration of Letter of Credit.** If Sublandlord draws upon the Letter of Credit as provided above, Subtenant shall, in each instance, within ten (10) days after its receipt of written demand therefore, either (x) deposit cash with Sublandlord in an amount that, when added to the amount remaining under the Letter of Credit and the amount of any Security Deposit (as defined in Section 7(e)5 below), shall equal the Letter of Credit amount required under this Section 7(e)3, or (y) deliver written documentation issued by Issuer confirming that the Letter of Credit has been reinstated to the amount required under this Section 7(e). If Subtenant so reinstates the Letter of Credit, Sublandlord shall promptly return to Subtenant any unused Draw Proceeds.

4. **Transfer.** Sublandlord may transfer the Letter of Credit to any successor in interest of Sublandlord's interest under the Master Lease or this Sublease, but no such transfer shall release Sublandlord of its liability with respect to the return of the Letter of Credit or refund of unused Draw Proceeds as required by this Sublease. In connection with any such transfer of the Letter of Credit by Sublandlord, Subtenant shall execute and submit to the bank such applications, documents and instruments as may be necessary to effectuate such transfer. Sublandlord shall be responsible for paying the bank's transfer and processing fees in connection with any transfer, provided that Subtenant shall have the right (in its sole

discretion), but not the obligation, to pay such fees on behalf of Sublandlord, in which case Sublandlord shall reimburse Subtenant within ten (10) business days after Sublandlord's receipt of an invoice from Subtenant therefor.

5. **Security Deposit.** In the event Sublandlord holds any cash security deposit (the "Security Deposit") from time to time during the Sublease Term, as security for the faithful performance by Subtenant of all the terms, covenants, and conditions of this Sublease to be kept and performed by Subtenant during the Sublease Term and if Subtenant fails to pay sums due hereunder, or otherwise is in breach with respect to any provisions of this Sublease, Sublandlord may use, apply or retain all or any portion of the Security Deposit for the payment of any past due sum or for the payment of any other sum to which Sublandlord may become obligated by reason of Subtenant's breach, or to compensate Sublandlord for any loss or damage which Sublandlord may suffer thereby. If Sublandlord so uses or applies all or any portion of the Security Deposit, Subtenant shall within ten (10) days after demand therefor deposit cash with Sublandlord in an amount sufficient to restore the Security Deposit to the full amount thereof and Subtenant's failure to do so shall be a material breach of this Sublease. If Subtenant performs all of Subtenant's obligations hereunder, the Security Deposit, or so much thereof as has not theretofore been applied by Sublandlord, shall be returned, without interest, to Subtenant (or, at Sublandlord's option, to the last assignee, if any, of Subtenant's interest hereunder) within thirty (30) days following the later to occur of (a) the expiration of the Term, and (b) Subtenant's vacation from the Sublease Premises and completion of all removal, repair and restoration obligations. No trust relationship is created herein between Sublandlord and Subtenant with respect to the Security Deposit. Sublandlord and Subtenant agree that Sublandlord may, in addition, claim those sums reasonably necessary to compensate Sublandlord for any other foreseeable or unforeseeable loss or damage caused by the act or omission of Subtenant or Subtenant's officers, agents, employees, independent contractors, or invitees.

8. SURRENDER OF SUBLEASE PREMISES.

At the expiration or sooner termination of this Sublease, Subtenant, without notice to Sublandlord, shall peacefully quit and surrender the Sublease Premises in the same condition in which it was received, excepting ordinary wear and tear, damage by fire or other casualty (including foreign or domestic terrorism), insured losses, damage caused by Sublandlord or Sublandlord's agents, contractors or employees, and repairs or maintenance for which Subtenant is not responsible under the Sublease. Notwithstanding anything to the contrary contained herein or in the Master Lease, Subtenant shall have no obligation to remove any Existing Furniture (and any such obligation shall belong solely to Sublandlord); provided, however, Subtenant shall be responsible for removal of any personal property that is not part of or related to the Planned Alterations and/or Existing Furniture.

9. USE OF SUBLEASE PREMISES.

The Sublease Premises shall be used and occupied for general office purposes only and for no other use or purpose without the prior written consent of Sublandlord and Master Landlord, which consent shall not be unreasonably withheld, conditioned or delayed.

10. ASSIGNMENT AND SUBLETTING.

Subtenant shall not assign the Sublease or further sublet all or any part of the Sublease Premises without the prior written consent of Sublandlord (and the consent of Master Landlord, if such consent is required under the terms of the Master Lease), which consent shall not be unreasonably withheld, conditioned or delayed.

11. CONDEMNATION.

If all of the Sublease Premises is condemned by eminent domain, inversely condemned or sold in lieu of condemnation, for any public or a quasi-public use or purpose (a "**Condemnation**"), this Sublease shall terminate and Subtenant shall not have any obligation hereunder, including the payment of Rent, subsequent to such date of termination. If there is a Condemnation of any material part of the Sublease Premises, Subtenant may terminate this Sublease by providing written notice of termination to the Sublandlord within

30 days after Subtenant first receives notice of the Condemnation. If Subtenant does not terminate the Sublease pursuant to the preceding sentence and the Sublease is not terminated under the terms of the Master Lease, the Rent shall be appropriately adjusted to account for any reduction in the square footage of the Sublease Premises. Any termination pursuant to this Section 11 shall be effective as of the effective date of any order granting possession to, or vesting legal title in, the condemning authority or party.

12. SUBTENANT DEFAULTS.

If Subtenant fails (i) to pay any sum payable under the Sublease when due, and such failure shall continue for a period of 5 business days after its due date, or (ii) to perform or comply with any non-monetary term, covenant or condition under this Sublease within 15 days after written notice from Sublandlord to Subtenant describing the failure to perform or comply, then Sublandlord may make such payment or perform such other obligation of Subtenant in such manner and to such extent as Sublandlord shall deem necessary, and in exercising this right Sublandlord may pay any incidental costs and expenses, employ attorneys and other professionals, and incur and pay attorneys' fees and other costs reasonably required in connection therewith (collectively, "**Remedy Costs**"). Subtenant shall pay to Sublandlord upon demand all Remedy Costs paid by Sublandlord in exercising its rights pursuant to this Section 12, together with interest thereon at the lesser of 12% or the highest amount permitted by law. Notwithstanding the foregoing, where any Subtenant failure under subpart (ii) above cannot reasonably be cured within such 15-day period, Subtenant shall not be in default if Subtenant commences to cure the failure within the 15-day period and thereafter diligently prosecutes such cure to completion, which completion shall occur not later than the time permitted for such cure under the Master Lease.

13. SUBLANDLORD DEFAULTS.

If Sublandlord receives any notice from Master Landlord regarding a default of Sublandlord under the Master Lease, Sublandlord shall immediately provide Subtenant written notice of the same, including a copy of the notice from Master Landlord. If such default under the Master Lease concerns any obligation of Sublandlord to pay monies under the Master Lease, Subtenant shall have the right, but not the obligation, upon written notice to Sublandlord, and without waiving or releasing Sublandlord from any obligations of Sublandlord hereunder, to make such payment directly to Master Landlord if Sublandlord does not pay the same within 30 days after Sublandlord receives written demand therefor from Master Landlord. Sublandlord shall pay to Subtenant upon demand all sums so paid by Subtenant pursuant to this Section 13. Subtenant shall have the right to apply any amounts owing to Subtenant pursuant to the foregoing sentence against Subtenant's obligation to pay Rent hereunder.

14. INDEMNIFICATION.

Each of Sublandlord and Subtenant, as applicable, shall defend, indemnify and hold harmless the other party, its affiliates and their respective members, officers, directors, shareholders, Personnel (defined below), successors and assigns from and against any loss, damage, settlement, cost, expense and any other liability (including but not limited to reasonable attorneys' fees incurred and/or those necessary to successfully establish the right to indemnification) arising out of or relating to (i) any damage to tangible property, to the extent caused by the gross negligence or willful misconduct of, or breach of this Sublease by, the indemnifying party or its agents, contractors or employees ("**Personnel**"), or (ii) the indemnifying party's failure to comply with any applicable law, rule, regulation or this Sublease.

15. SERVER ROOM.

Sublandlord shall retain exclusive possession and use of the existing MDF server room in the Sublease Premises. Sublandlord shall remove all existing equipment from the IDF closet in the Sublease Premises and Subtenant shall have the exclusive use of the existing IDF closet on the 9th floor for Subtenant's server equipment and racks during the Term. Sublandlord shall retain secured access to the existing server room on the 9th floor as well as entrance to the 9th floor. Sublandlord will limit the number of personnel who maintain this access to no more than five (5) persons. Sublandlord shall prior to or upon the Commencement Date provide notice to Subtenant of the identification of those five (5) persons and provide forty-eight hours (48) advance notice of a change in such authorized persons. Sublandlord shall have 24/7 access in the case of an emergency. The parties agree that "emergency access" shall mean access required in response to an urgent and material threat to Sublandlord's business operations (including a breach of privacy, breach of

security or a customer facing system down). In the case of non-emergency access, Sublandlord's IT representative shall provide not less than 48 non-business hours advance written or verbal notice to Subtenant's IT representative for access to the MDF server room and shall avoid planned repairs and maintenance during normal business hours in order to avoid disruption to Subtenant's business.

16. OTHER PROVISIONS OF SUBLEASE.

All applicable terms and conditions of the Master Lease are incorporated into and made a part of this Sublease as if Sublandlord were the Master Landlord hereunder. Subtenant assumes and agrees to perform the Sublandlord's obligations under the Master Lease during the Term to the extent that such obligations are applicable to the Sublease Premises, including, but not limited to, procuring and maintaining the insurance policies required under the Master Lease, except that the obligation to pay rent to Master Landlord under the Master Lease shall be considered performed by Subtenant to the extent Rent is paid to Sublandlord in accordance with Section 6 of this Sublease. Subtenant shall not commit or suffer any act or omission that would violate any of the provisions of the Master Lease. Sublandlord shall exercise due diligence in attempting to cause Master Landlord to perform its obligations under the Master Lease for the benefit of Subtenant but shall not be required to expend any cost or expense to do so without reimbursement. If the Master Lease terminates, this Sublease shall terminate and the parties shall be relieved of any further liability or obligation under this Sublease, provided however that if the Master Lease terminates as a result of a default or breach by Sublandlord or Subtenant under this Sublease and/or the Master Lease, then the defaulting party shall be liable to the non-defaulting party for the damage suffered as a result of such termination. Notwithstanding the foregoing, if the Master Lease gives Sublandlord any right to terminate the Master Lease in the event of the partial or total damage, destruction, or condemnation of the Master Premises or the Building or project of which the Master Premises are a part, the exercise of such right by Sublandlord shall not constitute a default or breachhereunder.

17. BROKER PARTICIPATION.

Sublandlord and Subtenant warrant and represent that they have dealt with no real estate broker in connection with this Sublease other than Newmark Knight Frank (representing Sublandlord) and Kidder Mathews (representing Subtenant), and that no other broker is entitled to any commission on account of this Sublease. Sublandlord shall pay Subtenant's broker a commission equal to $1.25/sf/year of the Term, 1/2 of which commission shall be payable within 10 business days after the receipt of Master Landlord's consent, and the balance shall be payable within 10 business days following the Commencement Date. Sublandlord shall pay Sublandlord's broker pursuant to a separate agreement.

18. ATTORNEYS' FEES.

If Sublandlord or Subtenant shall commence an action against the other arising out of or in connection with this Sublease, the prevailing party shall be entitled to recover its actual and reasonable attorneys' fees and other actual and reasonable costs of suit from the non-prevailing party.

19. NOTICE.

All notice and demands which may be or are required or permitted to be given by either party to the other hereunder shall be in writing. All notices and demands by either party to the other shall be sent by United States Mail, postage prepaid, addressed to the applicable address identified below, and to such other person or place as the parties may from time to time designate in a notice to the other.

TO SUBLANDLORD:

Wireless Advocates LLC
400 Fairview Ave. N, Suite 1000
Seattle, WA 98109
Attn: Chief Financial Officer w/a copy to Chief Executive Officer

TO SUBTENANT:

Chinook Therapeutics, Inc.
400 Fairview Ave. N, Suite 900
Seattle, WA 98109
Attention: General Counsel

20. **QUIET ENJOYMENT.** So long as Subtenant pays all of the Rent due hereunder and performs all of Subtenant's other obligations hereunder, Sublandlord shall do nothing to affect Subtenant's right to peaceably and quietly have, hold and enjoy the Sublease Premises as against Sublandlord, Master Landlord and/or anyone claiming by, through or under either of them.

21. **SUBLESSOR-SUBLESSEE RELATIONSHIP.** Nothing contained in this Sublease shall be deemed or construed by the parties to create the relationship of principal and agent, partnership, joint venture, or any association between Sublandlord and Subtenant. Nothing in this Sublease shall be deemed to create any relationship between the parties other than the relationship of sublessor and sublessee.

22. **ENTIRE AGREEMENT.**

This Sublease contains all agreements between the parties with respect to any matter mentioned herein, and no other prior or contemporaneous agreement or understanding shall be effective.

23. **CONSENT BY MASTER LANDLORD.**

This Sublease shall be of no force or effect unless consented to by Master Landlord within 10 business days after mutual execution hereof.

IN WITNESS WHEREOF, the parties have caused this instrument to be executed on the day and year first above written.

SUBLANDLORD:

Wireless Advocates LLC,
a Washington limited liability company

By: /s/ Dan Brettler
Dan Brettler, Chairman and CEO

SUBTENANT:

Chinook Therapeutics, Inc.,
a Delaware corporation

By: /s/ Eric Dobmeier
Eric Dobmeier, President and CEO

Exhibit 31.1

Certification of the Chief Executive Officer
Pursuant to
Securities Exchange Act Rules 13A-14(A) and 15D-14(A)

I, Eric Dobmeier, certify that:

1. I have reviewed this quarterly report on Form 10-Q 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 13(a)-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: August 12, 2021

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

Exhibit 31.2

Certification of the Chief Financial Officer
Pursuant to
Securities Exchange Act Rules 13A-14(A) and 15D-14(A)

I, Eric H. Bjerkholt, certify that:

1. I have reviewed this quarterly report on Form 10-Q 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 13(a)-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: August 12, 2021

/s/ Eric H. Bjerkholt
Eric H. Bjerkholt
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

In connection with the Quarterly Report of Chinook Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2021 (the "Report"), Eric L. Dobmeier, President, Chief Executive Officer and Director of the Company, and Eric H. Bjerkholt, Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 12, 2021

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

/s/ Eric H. Bjerkholt
Eric H. Bjerkholt
Chief Financial Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Chinook Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.