

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 September 30, 2022

OR

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

For the transition period from _____ to _____

Commission File Number 001-37345

CHINOOK THERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

94-3348934
(I.R.S. Employer
Identification No.)

400 Fairview Avenue North, Suite 900
Seattle, WA 98109

(Address of principal executive offices including zip code)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	KDNY	The Nasdaq Stock Market LLC (The Nasdaq Global Select Market)

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 November 4, 2022 was 63,940,620.

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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)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 126,072	\$ 181,724
Marketable securities	247,211	105,113
Accounts receivable	2,919	10,061
Prepaid expenses and other current assets	5,468	3,741
Total current assets	381,670	300,639
Marketable securities	24,412	68,215
Property and equipment, net	16,827	18,935
Restricted cash	2,074	2,074
Operating lease right-of-use assets	50,546	55,385
Investment in equity securities	41,200	41,200
Equity method investment	5,118	8,205
Intangible assets, net	24,720	26,009
In-process research & development	36,550	36,550
Goodwill	117	117
Other assets	7,102	6,474
Total assets	<u>\$ 590,336</u>	<u>\$ 563,803</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	11,843	8,580
Accrued and other current liabilities	25,583	17,104
Operating lease liabilities	4,810	4,401
Contingent value rights liability	2,500	10,000
Total current liabilities	44,736	40,085
Contingent value rights liability - non-current	30,430	24,591
Contingent consideration liability	4,040	5,160
Deferred tax liabilities	735	735
Operating lease liabilities, net of current maturities	35,759	39,589
Total liabilities	<u>115,700</u>	<u>110,160</u>
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000 shares authorized as of September 30, 2022 and December 31, 2021; no shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock, \$0.0001 par value; 300,000 shares authorized as of September 30, 2022 and December 31, 2021; 63,822 and 54,761 shares issued and outstanding at September 30, 2022 and December 31, 2021	6	5
Additional paid-in capital	835,330	685,459
Accumulated deficit	(357,077)	(231,766)
Accumulated other comprehensive loss	(3,623)	(55)
Total stockholders' equity	474,636	453,643
Total liabilities and stockholders' equity	<u>\$ 590,336</u>	<u>\$ 563,803</u>

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

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Collaboration and license revenue	\$ 2,501	\$ 4	\$ 5,616	\$ 389
Operating expenses:				
Research and development	41,984	23,573	98,259	72,057
General and administrative	10,023	6,847	26,526	24,158
Change in fair value of contingent consideration and contingent value rights liabilities	7,741	167	4,719	21,563
Amortization of intangible assets	431	423	1,289	1,265
Total operating expenses	60,179	31,010	130,793	119,043
Gain on sale of assets to equity method investment	—	—	—	7,227
Loss from operations	(57,678)	(31,006)	(125,177)	(111,427)
Other income (expense), net	1,690	(69)	2,362	(175)
Loss before income taxes and equity method investment gain (loss)	(55,988)	(31,075)	(122,815)	(111,602)
Income tax benefit	—	463	—	1,204
Equity method investment gain (loss)	9	(84)	(2,496)	(84)
Net loss	<u>\$ (55,979)</u>	<u>\$ (30,696)</u>	<u>\$ (125,311)</u>	<u>\$ (110,482)</u>
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.83)	\$ (0.69)	\$ (2.00)	\$ (2.54)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	67,779	44,661	62,736	43,563
Other comprehensive income (loss):				
Foreign currency translation adjustments, net of tax of \$0	(550)	202	(944)	339
Unrealized gain (loss) on marketable debt securities, net of tax of \$0	(542)	(1)	(2,624)	23
Total other comprehensive income (loss)	(1,092)	201	(3,568)	362
Comprehensive loss	<u>\$ (57,071)</u>	<u>\$ (30,495)</u>	<u>\$ (128,879)</u>	<u>\$ (110,120)</u>

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

Chinook Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(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, 2021	54,761	\$ 5	\$ 685,459	\$ (231,766)	\$ (55)	\$ 453,643
Issuance of common stock upon exercise of stock options and vesting of restricted stock units	356	1	2,048	—	—	2,049
Stock-based compensation expense	—	—	4,269	—	—	4,269
Other comprehensive loss	—	—	—	—	(1,482)	(1,482)
Net loss	—	—	—	(31,684)	—	(31,684)
Balance at March 31, 2022	55,117	\$ 6	\$ 691,776	\$ (263,450)	\$ (1,537)	\$ 426,795
Issuance of common stock upon exercise of stock options, issuance of common stock under Employee Stock Purchase Plan, and vesting of restricted stock units	202	—	1,136	—	—	1,136
Issuance of common stock and accompanying pre-funded warrants in underwritten public offering, net of issuance costs	7,554	—	113,082	—	—	113,082
Stock-based compensation expense	—	—	4,760	—	—	4,760
Other comprehensive loss	—	—	—	—	(994)	(994)
Net loss	—	—	—	(37,648)	—	(37,648)
Balance at June 30, 2022	62,873	\$ 6	\$ 810,754	\$ (301,098)	\$ (2,531)	\$ 507,131
Issuance of common stock upon exercise of stock options and vesting of restricted stock units	94	—	453	—	—	453
Issuance of common stock under the at-the-market sales agreement, net of offering costs	855	—	18,804	—	—	18,804
Stock-based compensation expense	—	—	5,319	—	—	5,319
Other comprehensive loss	—	—	—	—	(1,092)	(1,092)
Net loss	—	—	—	(55,979)	—	(55,979)
Balance at September 30, 2022	63,822	\$ 6	\$ 835,330	\$ (357,077)	\$ (3,623)	\$ 474,636

	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
Issuance of common stock upon exercise of stock options and vesting of restricted stock units	54	—	259	—	—	259
Stock-based compensation expense	—	—	3,287	—	—	3,287
Other comprehensive income	—	—	—	—	201	201
Net loss	—	—	—	(30,696)	—	(30,696)
Balance at September 30, 2021	44,830	\$ 4	\$ 508,714	\$ (239,311)	\$ 373	\$ 269,780

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

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

	Nine Months Ended September 30,	
	2022	2021
Cash Flows from Operating Activities		
Net loss	\$ (125,311)	\$ (110,482)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	2,540	2,243
Loss on disposal of property and equipment	256	—
Amortization of intangible assets	1,289	1,265
Non-cash operating lease expense	4,676	4,134
Stock-based compensation expense	14,348	9,360
Change in fair value of contingent consideration and contingent value rights liabilities	4,719	21,563
Accretion of discounts and amortization of premiums on marketable securities	579	63
Deferred income tax	—	(1,204)
Gain on sale of assets to equity method investment	—	(7,227)
Equity method investment gain (loss)	2,496	84
Changes in operating assets and liabilities:		
Accounts receivable	7,142	250
Prepaid expenses and other assets	(2,400)	2,153
Accounts payable	3,696	1,822
Accrued and other liabilities	8,555	(1,968)
Operating lease liabilities	(3,238)	(2,204)
Deferred revenue	—	(95)
Net cash used in operating activities	(80,653)	(80,243)
Cash Flows from Investing Activities		
Purchases of marketable securities	(234,191)	(128,984)
Proceeds from marketable securities	132,695	95,315
Purchases of property and equipment	(970)	(1,497)
Proceeds from sale of property and equipment	—	267
Net cash used in investing activities	(102,466)	(34,899)
Cash Flows from Financing Activities		
Proceeds from issuance of common stock and accompanying pre-funded warrants in underwritten public offering, net of issuance costs	113,082	—
Proceeds from exercise of stock options and warrants and from Employee Stock Purchase Plan	3,638	2,027
Proceeds from at-the-market sales agreement, net of issuance costs	18,804	33,891
Previously incurred issuance costs related to an underwritten public offering paid during period	(286)	—
Payment of contingent value rights liability	(7,500)	—
Net cash provided by financing activities	127,738	35,918
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(271)	320
Net decrease in cash, cash equivalents and restricted cash	(55,652)	(78,904)
Cash, cash equivalents and restricted cash at beginning of period	183,798	189,500
Cash, cash equivalents and restricted cash at end of period	<u>\$ 128,146</u>	<u>\$ 110,596</u>
Reconciliation of Cash, Cash Equivalents and Restricted Cash		
Cash and cash equivalents	\$ 126,072	\$ 108,522
Restricted cash	2,074	2,074
Total cash, cash equivalents and restricted cash	<u>\$ 128,146</u>	<u>\$ 110,596</u>
Supplemental Cash Flow Information		
Cash paid for amounts included in the measurement of lease liabilities	\$ 5,581	\$ 4,491
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	\$ 59	\$ 116
Right-of-use asset for office space acquired through leases	\$ —	\$ 5,406

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

Chinook Therapeutics, Inc.
Notes to Unaudited 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. On October 5, 2020, Aduro Biotech, Inc. (“Aduro”) completed its merger with Chinook Therapeutics U.S., Inc. (“Private Chinook”), pursuant to the terms of a merger agreement dated as of June 1, 2020, and amended on August 17, 2020, by which a wholly owned subsidiary of Aduro merged with and into Private Chinook, with Private Chinook continuing as a wholly owned subsidiary of Aduro (the “Merger”). Immediately following the Merger, Aduro changed its name to “Chinook Therapeutics, Inc.” and the business conducted by Private Chinook became the primary business conducted by the Company. Refer to Note 3 “Reverse Merger and Contingent Value Rights” for more information.

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

2. 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 (“U.S. GAAP”) and follow the requirements of the Securities and Exchange Commission (“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 nine months ended September 30, 2022 are not necessarily indicative of the results to be expected for the year ending December 31, 2022 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, 2021 included in our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 17, 2022.

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 (“CVR”) liability, contingent consideration 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.

Risks and Uncertainties

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

commercialization. These efforts will require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance and reporting.

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

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

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

Recent Accounting Pronouncements

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

3. Reverse Merger and Contingent Value Rights

We completed our Merger with Aduro on October 5, 2020. At the effective time of the Merger, we also entered into an agreement pursuant to which Aduro’s common stockholders of record as of the close of business on October 2, 2020 received one CVR for each outstanding share of Aduro common stock held by such stockholder on such date (the “CVR Agreement”). Each CVR represents the contractual right to receive payments from us upon the receipt of consideration resulting from milestones and royalties from certain pre-existing agreements and the disposition or licensing of certain of Aduro’s non-renal assets, net of deductions permitted under the CVR Agreement, including taxes and certain other expenses.

4. Cash, Cash Equivalents and Marketable Securities

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

	September 30, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Cash and cash equivalents:				
Cash	\$ 21,199	\$ —	\$ —	\$ 21,199
Money market funds	36,755	—	—	36,755
Commercial paper	32,575	—	(4)	32,571
U.S. government and agency securities	34,547	4	(1)	34,550
Corporate debt securities	998	—	(1)	997
Total cash and cash equivalents	<u>\$ 126,074</u>	<u>\$ 4</u>	<u>\$ (6)</u>	<u>\$ 126,072</u>
Marketable securities:				
Commercial paper	\$ 49,671		\$ (37)	\$ 49,634
U.S. government and agency securities	151,654	1	(1,802)	149,853
Corporate debt securities	73,051		(915)	72,136
Total marketable securities	<u>\$ 274,376</u>	<u>\$ 1</u>	<u>\$ (2,754)</u>	<u>\$ 271,623</u>

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

The amortized cost and estimated fair value of our available-for-sale marketable securities by contractual maturity are summarized below as of September 30, 2022 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Mature in one year or less	\$ 249,289	\$ 1	\$ (2,079)	\$ 247,211
Mature after one year through two years	25,087	—	(675)	24,412
Total available-for-sale marketable securities	<u>\$ 274,376</u>	<u>\$ 1</u>	<u>\$ (2,754)</u>	<u>\$ 271,623</u>

For all securities with a fair value less than its amortized cost basis, we determined the decline in fair value below amortized cost basis to be non-credit related. As of September 30, 2022, there were no investments in our portfolio that were other-than-temporarily impaired.

5. Fair Value Measurements

We record 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. We consider observable data to be market data which is readily available, regularly distributed or updated, reliable and verifiable, not proprietary, and provided by independent sources that are actively involved in the relevant market.

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

September 30, 2022				
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and cash equivalents:				
Cash and money market funds	\$ 57,954	\$ —	\$ —	\$ 57,954
Commercial paper	—	32,571	—	32,571
U.S. government and agency securities	—	34,550	—	34,550
Corporate debt securities	—	997	—	997
Total cash and cash equivalents	57,954	68,118	—	126,072
Marketable securities:				
Commercial paper	—	49,634	—	49,634
U.S. government and agency securities	—	149,853	—	149,853
Corporate debt securities	—	72,136	—	72,136
Total marketable securities	—	271,623	—	271,623
Total fair value of assets	\$ 57,954	\$ 339,741	\$ —	\$ 397,695
Liabilities:				
Contingent value rights liability	\$ —	\$ —	\$ 32,930	\$ 32,930
Contingent consideration liability	—	—	4,040	4,040
Total fair value of liabilities	\$ —	\$ —	\$ 36,970	\$ 36,970

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

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

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

	Contingent Value Rights Liability	Contingent Consideration Liability
Balance at December 31, 2021	\$ 34,591	\$ 5,160
Net change in fair value upon remeasurement	5,839	(1,120)
Payment of contingent value rights liability	(7,500)	—
Balance at September 30, 2022	\$ 32,930	\$ 4,040

The fair values of the CVR and contingent consideration liabilities are based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy. In determining the fair value of the CVR and the contingent consideration liabilities, we used the income approach, primarily discounted cash flow models. The discounted cash flow models require the use of significant judgment, estimates and assumptions, including estimated revenues and costs, the probability of technical and regulatory success, and discount rates. The fair value of the CVR liability decreased during the nine months ended September 30, 2022 by \$1.7 million. The decrease primarily resulted from a payment of \$7.5 million to the CVR holders in the second quarter of 2022, partially offset by a net increase from remeasuring the CVR liability at fair value. The payment to the CVR holders resulted from a development milestone recognized in the fourth quarter of 2021 under the license agreement with Merck for MK-5890. The CVR liability increased in the third quarter of 2022 from remeasuring the value of our preferred shares in Sairopa at estimated fair value, as a result of the expectation that Sairopa might execute a license agreement for its SIRPa inhibitor ADU-1805. Sairopa executed a license agreement with Exelixis, Inc. in November 2022. This increase was partially offset by a decrease in the contingent consideration liability due to higher discount rates in 2022 driven by changes in market interest rates, which lowered the present value of future cash flows. We will hold the shares in Sairopa until there is a liquidation event, at which time, in accordance with the CVR agreement, 50% of any net proceeds will accrue to the benefit of the CVR holders, net of deductions permitted under the CVR Agreement, including taxes and certain other expenses. Refer to Note 10 “Equity Method Investment” for more information.

6. Property and Equipment, Net

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

	September 30, 2022	December 31, 2021
Research and lab equipment	\$ 3,167	\$ 3,366
Computer equipment and software	1,613	1,497
Furniture and fixtures	1,340	1,224
Leasehold improvements	17,023	16,976
Total property and equipment	23,143	23,063
Total accumulated depreciation	(6,316)	(4,128)
Property and equipment, net	\$ 16,827	\$ 18,935

Depreciation and amortization expense for property and equipment for both the three months ended September 30, 2022 and 2021 was \$0.8 million, and was \$2.5 million and \$2.3 million for the nine months ended September 30, 2022 and 2021, respectively. Approximately \$2.3 million of our property and equipment, net as of September 30, 2022 is located in Canada.

7. Goodwill and Intangible Assets

Goodwill

The gross carrying amount and net book value of goodwill was \$0.1 million at September 30, 2022, all of which resulted from the Merger. We test goodwill for impairment on an annual basis or more frequently if an impairment indicator exists. 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):

	September 30, 2022		
	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Intangible assets with finite lives:			
Acquired license agreement	\$ 26,685	\$ 3,145	\$ 23,540
In-place lease	1,433	253	1,180
Total intangible assets with finite lives	28,118	3,398	24,720
Acquired in-process research & development ("IPR&D") assets	36,550	—	36,550
Total intangible and acquired IPR&D assets	<u>\$ 64,668</u>	<u>\$ 3,398</u>	<u>\$ 61,270</u>

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

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

Amortization expense was \$0.4 million for both the three months ended September 30, 2022 and 2021, and was \$1.3 million for both the three and nine months ended September 30, 2022 and 2021. Based on finite-lived intangible assets recorded as of September 30, 2022, the estimated future amortization expense for the next five years is as follows (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2022 (remaining three months)	\$ 433
2023	1,733
2024	1,733
2025	1,733
2026	1,733
Thereafter	17,355

8. Accrued and Other Current Liabilities

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

	September 30, 2022	December 31, 2021
Research and development costs	\$ 16,927	\$ 8,397
Compensation and benefits	7,811	6,455
Sublease rent and security deposit	249	1,067
Business taxes and licensing fees	—	421
Consulting and outside services	576	424
Other	20	340
Total accrued and other current liabilities	<u>\$ 25,583</u>	<u>\$ 17,104</u>

9. Investment in Equity Securities

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

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

We account for the investment in SanReno in accordance with the provisions of ASC Topic 321, *Investments – Equity Securities*, and elect to use the measurement alternative therein. As such, the investment is valued at \$41.2 million as of September 30, 2022, which was the total of the aggregate cost value of the 40.0 million preferred shares in SanReno received by us on the date of the closing of the formation of SanReno and the grant date value of the warrant. The investment will be re-measured upon future observable price changes(s) in orderly transaction(s) or upon impairment, if any. There were no impairments of this investment during the three and nine months ended September 30, 2022.

Pursuant to the terms of the Series A preferred stock, we are entitled to non-cumulative dividends at 8% of our initial investment, payable when and if declared by the board of directors of SanReno. Dividends from our investment in equity securities, if declared, are reflected in the consolidated statements of operations and comprehensive loss. There were no dividends declared during the three and nine months ended September 30, 2022.

10. Equity Method Investment

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

As of September 30, 2022, we own a 36% interest in Sairopa. We determined that we have the ability to exercise significant influence over Sairopa but do not have a controlling interest. Therefore, the investment in Sairopa was accounted for using the equity method. Judgment regarding the level of influence over each equity method investment includes considering key factors such as ownership interest, representation on the board of directors, and participation in policy-making decisions. The Sairopa Investors provided an initial capitalization of 12.5 million Euros. We recorded the equity method investment at \$10.0 million, which is the fair value of the equity received by us in exchange for the non-renal assets.

Our equity method investment was recorded at cost at inception and is adjusted each period for our share of the investee’s income or loss, which is reported in our consolidated statements of operations and comprehensive loss on a one quarter lag. Our equity method investment is also adjusted each period for gains or losses from changes in our ownership interest in Sairopa, if any. We recorded a gain of \$1.1 million in our equity method investment in the third quarter of 2022 resulting from changes in our ownership interest in Sairopa due to additional shares issued by Sairopa. 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.

11. Collaboration and License Agreements

SanReno Therapeutics

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

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

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

The estimated standalone selling price for the Technology Transfers was determined by estimating the costs of satisfying the performance obligation, plus an appropriate margin for such services. Pursuant to the China License Agreement, SanReno will reimburse the manufacturing and supply services at cost plus a mark-up and will reimburse the opt-in global studies at cost, which represent pass-through fees from third-party vendors, including clinical research organization. Revenue attributable to the manufacturing and supply services and opt-in global studies will be recognized as incurred. For the three months ended September 30, 2022, we recognized revenue of \$0.6 million under the China License Agreement for costs reimbursed related to manufacturing and supply services. For the nine months ended September 30, 2022, we recognized revenue of \$3.7 million under the China License Agreement for costs reimbursed related to opt-in global studies and manufacturing and supply services.

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

The potential progress-dependent cash milestone payment that we are eligible to receive was excluded from the total transaction price, as the milestone amount is fully constrained based on the probability of achievement. Accordingly, any future milestone payment received under the agreement will be recorded upon or over a period following receipt. Further, we will apply the exception under ASC Topic 606 for variable consideration related to sales-or-usage based royalties received in exchange for licensed intellectual property associated with atrasentan, therefore the royalties are not included in the transaction price until the licensee sells product. No progress-dependent milestone payments and royalties were earned during the three and nine months ended September 30, 2022.

AbbVie Ireland Unlimited Company

In December 2019, we entered into a license agreement (the “License Agreement”) with AbbVie Ireland Unlimited Company (“AbbVie”), which granted us an exclusive license to develop and commercialize atrasentan, an endothelin receptor antagonist. Under the agreement, we assumed all global development and commercialization responsibilities for atrasentan. In consideration of the license and rights granted under the License Agreement, we made an upfront cash payment and issued 2.0 million shares of common stock for total consideration of \$6.7 million to AbbVie. We concluded that this transaction should be accounted for as an asset purchase, and as such, recorded the associated expense within research and development expense in the 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 nine months ended September 30, 2022 and 2021. As of September 30, 2022 and December 31, 2021, we did not have any payable or receivable balances associated with the License Agreement.

Merck

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

Eli Lilly and Company

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

For the three and nine months ended September 30, 2022, we recognized revenue of \$1.9 million under the Lilly agreement. For the three and nine months ended September 30, 2021, we recognized revenue of less than \$0.1 million and \$0.4 million, respectively, under the Lilly agreement.

12. Commitments and Contingencies

Leases

We have a total of four operating leases as of September 30, 2022 with remaining lease terms of approximately 4 to 7 years.

In June 2021, we entered into a sublease agreement for office space in Seattle, Washington ("Seattle Sublease"), which we use as our corporate headquarters. The Seattle Sublease commenced on July 1, 2021 and continues for a period of 58 months. The aggregate estimated base rent payments due over the remaining term of the Seattle Sublease is approximately \$4.5 million.

As of September 30, 2022, we are subleasing approximately 112,000 square feet in one of our facilities. Sublease income was \$2.0 million and \$1.7 million for the three months ended September 30, 2022 and 2021, respectively, which was netted against rent expense and is recorded as a component of general and administrative expenses in the condensed consolidated statement of operations and comprehensive loss. Sublease income was \$6.0 million and \$4.4 million for the nine months ended September 30, 2022 and 2021, respectively, which was netted against rent expense. Total sublease income to be earned, in aggregate, will be approximately \$59.1 million over the remaining term of the sublease agreement.

We maintain a letter of credit as security for a facility lease that expires in 2029. The letter of credit is collateralized by a certificate of deposit in the amount of \$1.8 million, which is classified as long-term restricted cash in our condensed consolidated balance sheet as of September 30, 2022. Additionally, we maintain a letter of credit as a security deposit for a facility lease that expires in 2026. The letter of credit is collateralized by a certificate of deposit in the amount of \$0.3 million, which is classified as long-term restricted cash in our condensed consolidated balance sheet as of September 30, 2022.

The maturity of our operating lease liabilities as of September 30, 2022 is as follows (in thousands):

Undiscounted Lease Payments	Amounts
2022 (remaining three months)	\$ 1,892
2023	7,655
2024	7,810
2025	7,969
2026	7,117
Thereafter	18,891
Total undiscounted lease payments	51,334
Present value adjustment	(10,765)
Total net lease liability	\$ 40,569
Net lease liability – current	\$ 4,810
Net lease liability – non-current	35,759
Total net lease liability	\$ 40,569

Rent expense recognized for operating leases was \$2.4 million for both the three months ended September 30, 2022 and 2021, and was \$7.1 million and \$6.4 million for the nine months ended September 30, 2022 and 2021, respectively. Variable lease payments, including non-lease components such as common area maintenance fees, recognized as rent expense for operating leases were \$0.8 million and less than \$0.5 million for the three months ended September 30, 2022 and 2021, respectively, and were \$2.4 million and \$1.7 million for the nine months ended September 30, 2022 and 2021, respectively.

The following summarizes additional information related to our operating leases:

	September 30, 2022	December 31, 2021
Weighted-average remaining lease terms (in years)		
Operating leases	6.7	7.4
Weighted-average discount rate		
Operating leases	7.4%	7.5%

Indemnification Agreements

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

Legal Proceedings

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

Other Commitments

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

13. Common Stock

Issuance of Securities through an Underwritten Public Offering

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

We evaluated the Pre-Funded Warrants for liability or equity classification in accordance with the provisions of ASC Topic 480, *Distinguishing Liabilities from Equity*, and determined that equity treatment was appropriate because the Pre-Funded Warrants did not meet the definition of liability instruments. The Pre-Funded Warrants are classified as a component of permanent equity because they are freestanding financial instruments that are legally detachable and separately exercisable from the share of common stock with which they were issued, are immediately exercisable, do not include repurchase rights, cash settlement, or other put provisions, and permit the holders to receive a fixed number of shares of common stock upon exercise. In addition, the Pre-Funded Warrants do not provide any guarantee of value or return. We valued the Pre-Funded Warrants to purchase 1.1 million shares of common stock at an aggregate value of \$15.0 million. The value of \$13.9999 per pre-funded warrant was measured on the grant date based on the common stock price in the underwritten public offering of \$14.00 per share, less the \$0.0001 per share exercise price of the warrant. As of September 30, 2022, none of the Pre-Funded Warrants have been exercised. Additionally, as of September 30, 2022, none of the 3.6 million pre-funded warrants to purchase common stock, issued in connection with the November 2021 public offering, have been exercised. Refer to Note 13 "Common Stock" in our Annual Report on Form 10-K for more information.

At-the-Market Sales Agreement

In April 2021, we entered into an “at-the-market” sales agreement (the “2021 Sales Agreement”), with Cantor Fitzgerald & Co. and SVB Securities LLC, previously known as SVB Leerink LLC, through which we may offer and sell shares of our common stock having an aggregate offering of up to \$75.0 million through our sales agents, Cantor Fitzgerald & Co. and SVB Securities LLC. Additionally, in November 2022, we amended the 2021 Sales Agreement to provide for offerings of up to \$150.0 million. We will pay the sales agents a commission of up to 3% of the gross proceeds of sales made through the 2021 Sales Agreement. In the first quarter of 2021, we sold 2.2 million shares for \$33.9 million in net proceeds under the 2021 Sales Agreement and in the third quarter of 2022, we sold 0.9 million shares for \$18.8 million in net proceeds under the 2021 Sales Agreement. As of November 10, 2022, we have \$150.0 million remaining under the 2021 Sales Agreement, which is subject to the continued effectiveness of our automatic shelf registration statement on Form S-3 ASR (Registration No. 333-265168), or upon an effective replacement shelf registration statement.

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, 2021	99	\$ 0.00034
Vested	(68)	0.00034
Cancelled or forfeited	(6)	0.00034
Balance—September 30, 2022	25	\$ 0.00034

The fair value of RSAs vested during both the nine months ended September 30, 2022 and 2021 was \$1.1 million.

14. Stock-Based Compensation

Equity Incentive Plans

In February 2019, Private Chinook adopted the 2019 Equity Incentive Plan (the “2019 Plan”). In connection with the Merger, we assumed Aduro’s two equity incentive plans, the 2015 Equity Incentive Plan (the “2015 Plan”) and the 2009 Stock Incentive Plan (the “2009 Plan,” and collectively the “Aduro Plans” and together with the 2019 Plan, the “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. As of September 30, 2022 and December 31, 2021, there were 1.5 million and 1.4 million shares available for future grant, respectively.

In connection with the Merger, we assumed Aduro’s 2015 employee stock purchase plan (“2015 ESPP”). As of September 30, 2022 and December 31, 2021, there were 1.2 million and 0.7 million shares available for future issuance under the 2015 ESPP, respectively.

During the third quarter of 2022, our board of directors approved the 2022 Employment Inducement Incentive Award Plan (the “2022 Inducement Plan”). We reserved 1.5 million shares of our common stock for issuance pursuant to awards to be granted under the 2022 Inducement Plan. The terms of the 2022 Inducement Plan are substantially similar to the terms of the Plans with the exception that awards may only be made to an employee who has not previously been an employee or member of our board of directors if the award is in connection with commencement of employment. As of September 30, 2022, 1.5 million shares are available for future issuance under the 2022 Inducement Plan.

Stock option activity under the Plans is set forth below:

	Number of Shares Underlying Options (in thousands)	Weighted- Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance—December 31, 2021	5,842	\$ 12.73	\$ 7.00	\$ 34,928
Granted	2,233	14.02		
Exercised	(429)	7.08		
Canceled or forfeited	(608)	12.94		
Balance—September 30, 2022	7,038	\$ 13.46	\$ 7.35	\$ 54,520
Options exercisable—September 30, 2022	3,000	\$ 14.21	\$ 5.38	\$ 27,201
Options vested and expected to vest—September 30, 2022	7,038	\$ 13.46	\$ 7.35	\$ 54,520

The aggregate intrinsic values of options outstanding, exercisable, and vested and expected to vest were calculated as the difference between the exercise price of the options and the market price for shares of our common stock as of September 30, 2022. Options for 0.4 million and 0.3 million shares of our common stock were exercised during the nine months ended September 30, 2022 and 2021, respectively, with an intrinsic value of \$3.8 million and \$2.9 million, respectively.

Restricted stock unit (“RSU”) activity under the Plans is set forth below:

	RSUs Outstanding	
	Number of RSUs (in thousands)	Weighted- Average Grant Date Fair Value Per Share
Balance—December 31, 2021	823	\$ 14.76
Granted	890	14.78
Vested	(181)	15.12
Cancelled or forfeited	(124)	14.77
Balance—September 30, 2022	1,408	\$ 14.72

The total fair value of RSUs that vested in the nine months ended September 30, 2022 and 2021 was \$2.7 million and \$0.4 million, respectively. The fair value of RSUs is determined on the date of grant based on the market price of our common stock on that date.

Valuation Assumptions

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Assumptions:				
Expected term (in years)	6.3	6.2	6.2	6.1
Volatility	76.2%	77.6%	77.5%	79.0%
Risk-free interest rate	3.1%	1.0%	2.1%	0.8%
Dividend yield	—	—	—	—

	Nine Months Ended September 30,	
	2022	2021
Fair Value:		
Weighted-average grant date fair value per share	\$ 9.65	\$ 10.53

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Assumptions:				
Expected term (in years)	—	—	0.5	0.5
Volatility	0.0%	0.0%	57.1%	60.9%
Risk-free interest rate	0.0%	0.0%	1.5%	0.0%
Dividend yield	—	—	—	—

	Nine Months Ended September 30,	
	2022	2021
Fair Value:		
Weighted-average grant date fair value per share	\$ 4.29	\$ 5.36

Stock-Based Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	\$ 2,869	\$ 1,522	\$ 7,409	\$ 4,282
General and administrative	2,450	1,765	6,939	5,078
Total stock-based compensation expense	\$ 5,319	\$ 3,287	\$ 14,348	\$ 9,360

Total unrecognized stock-based compensation expense and the expected period over which such expense will be recognized are as follows (\$ in millions):

	As of September 30, 2022
Stock options	
Unrecognized stock compensation expense	\$ 33.2
Weighted-average remaining vesting period (years)	2.7
RSU	
Unrecognized stock compensation expense	\$ 16.1
Weighted-average remaining vesting period (years)	2.1
ESPP	
Unrecognized stock compensation expense	\$ 0.1
Weighted-average remaining vesting period (years)	0.1

15. Income Taxes

No income tax benefit or expense was recorded for the three and nine months ended September 30, 2022. We recorded income tax benefit of \$0.5 million and \$1.2 million for the three and nine months ended September 30, 2021, respectively. Our effective tax rate was 1.5% and 1.1% for the three and nine months ended September 30, 2021. Our 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.

16. 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Numerator:				
Net loss attributable to common stockholders	\$ (55,979)	\$ (30,696)	\$ (125,311)	\$ (110,482)
Denominator:				
Weighted-average shares outstanding	67,814	44,797	62,794	43,722
Less: weighted-average unvested restricted shares and shares subject to repurchase	(35)	(136)	(58)	(159)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	<u>67,779</u>	<u>44,661</u>	<u>62,736</u>	<u>43,563</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.83)</u>	<u>\$ (0.69)</u>	<u>(2.00)</u>	<u>(2.54)</u>

As of September 30, 2022, 3.6 million and 1.1 million pre-funded warrants to purchase common stock, issued in connection with the November 2021 public offering and the May 2022 public offering, respectively, were included in the weighted-average shares outstanding used in the calculation of basic and diluted net loss per share. Refer to Note 13 “Common Stock” in our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 17, 2022 and Note 13 “Common Stock” for more information.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Unvested RSUs	1,408	902	1,408	902
Unvested RSAs	25	124	25	124
Options to purchase common stock	7,038	6,209	7,038	6,209
Total	<u>8,471</u>	<u>7,235</u>	<u>8,471</u>	<u>7,235</u>

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, 2021, 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

Chinook is a clinical-stage biopharmaceutical company focused on discovering, developing and commercializing precision medicines for kidney diseases. Our pipeline is focused on rare, severe chronic kidney diseases with well-defined clinical pathways. Our lead clinical program is atrasentan, a potent and selective endothelin A receptor antagonist. We are currently conducting the phase 3 ALIGN trial of atrasentan for IgA nephropathy, or IgAN, and the phase 2 AFFINITY basket trial for proteinuric glomerular diseases. We most recently presented interim data from the IgAN patient cohort of the AFFINITY trial at the American Society of Nephrology, or ASN, Kidney Week in November 2022. Our second product candidate, BION-1301, is an anti-APRIL monoclonal antibody also in development for patients with IgAN. We most recently presented interim results from the ongoing phase 1/2 trial at ASN Kidney Week in November 2022. We plan to maintain commercial rights for atrasentan and BION-1301 in North America and possibly Europe. In November 2021, we established SanReno, a joint venture to develop, manufacture and commercialize kidney disease therapies in mainland China, Hong Kong, Macau, Taiwan and Singapore. We believe that a strong local presence in East Asia may allow us to accelerate the clinical development and maximize the commercial potential of atrasentan and BION-1301 in the region. Our third product candidate is CHK-336, an oral small molecule LDHA inhibitor for the treatment of primary and idiopathic hyperoxaluria that is currently in a phase 1 clinical trial in healthy volunteers. In addition, we are conducting research programs in several other rare, severe chronic kidney diseases. We seek to build our pipeline by leveraging insights from kidney single cell RNA sequencing, 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 an ongoing strategic collaboration with Evotec SE, or Evotec, to jointly identify, characterize and validate novel mechanisms and discover precision medicines for lupus nephritis, IgAN, polycystic kidney disease, or PKD, and other primary glomerular diseases.

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

Atrasentan

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

IgAN is the leading cause of primary glomerulonephritis worldwide, with an estimated incidence of 1.29 per 100,000 individuals per year in the United States. The global incidence of IgAN is approximately 2.5 per 100,000 individuals per year. Variations in disease incidence and prevalence are, in part, due to regional differences in urine screening, referral patterns and indications for biopsy.

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

Activation of the 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 conducted in over 5,000 diabetic kidney disease patients. We presented new preclinical data elucidating the mechanism of action of atrasentan in IgAN at multiple nephrology congresses in 2021 and 2022, including most recently at ASN Kidney Week in November 2022. In preclinical studies, atrasentan rapidly reduced albuminuria and downregulated intra-renal transcriptional proliferative, inflammatory and fibrotic signaling in the gddY mouse IgAN model. The data also showed that atrasentan attenuated human renal mesangial cell activation induced by endothelin-1 or IgAN patient immune-derived immune complexes in a translational model system. Additionally, preclinical data was presented at ASN Kidney Week in November 2022 on single-cell RNA-seq of a mouse model of IgAN, revealing a prominent expansion of failed repair proximal tubular epithelial cells, which was reversed by atrasentan but not ACE inhibition.

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 a new drug application, or NDA, seeking accelerated approval based on surrogate endpoints, including proteinuria. In April 2021 we initiated the phase 2 AFFINITY trial in proteinuric glomerular diseases, including cohorts of patients with lower proteinuria IgAN, focal segmental glomerulosclerosis, or FSGS, and Alport syndrome, as well as diabetic kidney disease combined with sodium glucose co-transporter 2, or SGLT2, inhibitors, such as canagliflozin or dapagliflozin, which have recently been shown to provide clinical benefit in patients with multiple types of chronic kidney disease.

We most recently presented interim data from the IgAN patient cohort of the AFFINITY trial in a poster presentation at ASN Kidney Week in November 2022 demonstrating consistent and clinically meaningful proteinuria reductions at weeks six, 12 and 24 of treatment in patients with IgAN already on a maximally tolerated and stable dose of a RAS inhibitor. Specifically, atrasentan demonstrated mean reductions in 24-hour urine protein creatinine ratio, or UPCR, of 38.1% at six weeks of treatment, 48.3% at 12 weeks of treatment and 54.7% at 24 weeks of treatment. After 24 weeks of treatment, 15 of the 19 patients (79%) who had completed this visit had greater than a 40% reduction in proteinuria. Atrasentan was well-tolerated, with no treatment-related serious or severe adverse events. The mean treatment duration was 45 weeks, with time on treatment ranging from 13 to 52 weeks. There were no meaningful changes in blood pressure or acute eGFR effects, suggesting proteinuria reductions were not primarily due to hemodynamic effects of atrasentan. There were no increases in brain natriuretic peptide, or BNP, or mean bodyweight, suggesting minimal fluid retention.

We expect to present additional data from the AFFINITY trial during 2023. Enrollment of the phase 3 ALIGN trial of atrasentan continues to advance at more than 160 sites in 21 countries. We expect to report topline data from the six-month interim proteinuria endpoint analysis in the third quarter of 2023 to potentially support an application for accelerated approval under Subpart H in the United States.

BION-1301

We are also developing BION-1301, an investigational humanized IgG4 monoclonal antibody that blocks APRIL, a soluble factor that is believed to be implicated in IgAN and other indications, from binding to its receptors.

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

The data presented at ASN demonstrated BION-1301's disease-modifying potential in IgAN by generating rapid and durable reductions in mechanistic biomarkers and corresponding clinically meaningful proteinuria reductions within three months of initiating treatment, which was consistent across both cohorts. In Cohort 1, reductions in IgA and Gd-IgA1 were maintained beyond 52 weeks of treatment. Reductions in IgM, and to a lesser extent IgG, were also observed. In Cohort 1, BION-1301 demonstrated mean reductions in 24-hour UPCR of 30.4% in seven patients at 12 weeks of treatment, 48.8% in all eight patients at 24 weeks of treatment, 66.9% in all eight patients at 52 weeks of treatment, 67.4% in four patients at 76 weeks of treatment and 71.0% in two patients at 100 weeks of treatment. In Cohort 2, SC BION-1301 treatment resulted in rapid and sustained reductions in IgA and Gd-IgA1, IgM, and to a lesser extent IgG, through 24 weeks of treatment, highly consistent with Cohort 1. BION-1301 also demonstrated mean reductions in 24-hour UPCR of 28.7% in 15 patients at 12 weeks of treatment and 53.8% in 9 patients at 24 weeks of treatment, similar to reductions observed at the same timepoints in Cohort 1. In both cohorts, BION-1301 was well-tolerated, with no serious adverse events or treatment discontinuations due to adverse events and no anti-drug antibodies observed.

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

CHK-336

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

Research and Discovery Programs

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

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

Components of Operating Results

Collaboration and License Revenue

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

SanReno Therapeutics

In November 2021, we entered into a License Agreement with SanReno, or the China License Agreement. The China License Agreement includes the transfer of intellectual property rights in the form of a development and commercialization license in the Territory; manufacturing and supply services; and participation in opt-in global studies with the collaboration party. The terms of the China License Agreement also include potential payment to us for the following: progress-dependent milestone payment; royalties on the net sales of a licensed product and reimbursement for certain expenses incurred. As of September 30, 2022, these potential payments are not considered probable of being achieved and they relate to promised goods or services for which revenue will be recognized upon our satisfaction of the underlying performance obligations.

Pre-existing Collaboration Agreements

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

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

For additional information, refer to Note 11 "Collaboration and License Agreements" in our condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Research and Development Expenses

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

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

General and Administrative Expenses

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

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

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

Amortization of Intangible Assets

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

Gain on Sale of Assets to Equity Method Investment

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 and comprehensive loss during the three and nine months ended September 30, 2021.

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.

Equity Method Investment Gain (Loss)

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

Results of Operations

Comparison of the Three Months Ended September 30, 2022 and 2021

	Three Months Ended September 30,		Change
	2022	2021	
	(In thousands)		
Collaboration and license revenue	\$ 2,501	\$ 4	\$ 2,497
Operating expenses:			
Research and development	\$ 41,984	\$ 23,573	\$ 18,411
General and administrative	10,023	6,847	3,176
Change in fair value of contingent consideration and contingent value rights liabilities	7,741	167	7,574
Amortization of intangible assets	431	423	8
Total operating expenses	60,179	31,010	29,169
Loss from operations	(57,678)	(31,006)	(26,672)
Other income (expense), net	1,690	(69)	1,759
Loss before income taxes and equity method investment gain (loss)	(55,988)	(31,075)	(24,913)
Income tax benefit	—	463	(463)
Equity method investment gain (loss)	9	(84)	93
Net loss	\$ (55,979)	\$ (30,696)	\$ (25,283)

Collaboration and License Revenue

Total revenue was \$2.5 million for the three months ended September 30, 2022, an increase of \$2.5 million compared to less than \$0.1 million for the three months ended September 30, 2021. The increase was due to revenue recognized in the 2022 period related to a development milestone of \$1.9 million recognized under our collaboration agreement with Eli Lilly and Company, or Lilly, and services provided under our license agreement with SanReno.

Research and Development Expenses

The following tables summarize our research and development expenses by program and by category incurred during the three months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		Change
	2022	2021	
	(In thousands)		
Product Candidates			
Atrasentan	\$ 16,865	\$ 10,753	\$ 6,112
BION-1301	11,160	3,148	8,012
CHK-336	1,484	2,062	(578)
Other discovery, research and development programs	3,222	3,820	(598)
Subtotal	32,731	19,783	12,948
Stock-based compensation expense	2,869	1,522	1,347
Facility and depreciation costs	1,785	1,235	550
Other general research and development expenses	4,599	1,033	3,566
Total research and development expenses	\$ 41,984	\$ 23,573	\$ 18,411

	Three Months Ended September 30,		Change
	2022	2021	
	(In thousands)		
Licensing and contract research and manufacturing	\$ 21,189	\$ 10,796	\$ 10,393
Employee-related costs	11,045	6,537	4,508
Supplies used in research and development	792	948	(156)
Stock-based compensation expense	2,869	1,522	1,347
Facility and depreciation costs	1,785	1,235	550
Consulting and outside services	3,061	2,216	845
Other	1,243	319	924
Total research and development expenses	<u>\$ 41,984</u>	<u>\$ 23,573</u>	<u>\$ 18,411</u>

Research and development expenses were \$42.0 million for the three months ended September 30, 2022, an increase of \$18.4 million compared to \$23.6 million for the three months ended September 30, 2021. The increase in research and development expenses was primarily due to an increase in licensing and contract research and manufacturing costs; higher employee-related costs, including salaries, benefits and stock-based compensation expense; increased spending for consulting and outside services costs; and an increase in facilities and other costs to continue the progression of our research and clinical programs.

General and Administrative Expenses

The following table summarizes our general and administrative expenses incurred during the three months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		Change
	2022	2021	
	(In thousands)		
Consulting and outside services	\$ 3,074	\$ 1,944	\$ 1,130
Employee-related costs	3,315	2,212	1,103
Stock-based compensation expense	2,450	1,765	685
Facility and depreciation costs	184	376	(192)
Other	1,000	550	450
Total general and administrative expenses	<u>\$ 10,023</u>	<u>\$ 6,847</u>	<u>\$ 3,176</u>

General and administrative expenses were \$10.0 million for the three months ended September 30, 2022, an increase of \$3.2 million compared to \$6.8 million for the three months ended September 30, 2021. The increase in general and administrative expenses was primarily due to higher employee-related costs, including salaries, benefits and stock-based compensation expense resulting from new grants and higher consulting and outside services costs to support our operations.

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

Change in fair value of contingent consideration and contingent value rights liabilities expense was \$7.7 million for the three months ended September 30, 2022, an increase of \$7.6 million compared to \$0.2 million the three months ended September 30, 2021. The increase primarily resulted from remeasuring the value of our preferred shares in Sairopa at estimated fair value, as a result of the expectation that Sairopa might execute a license agreement for its SIRPa inhibitor, ADU-1805. Sairopa executed a license agreement with Exelixis, Inc. in November 2022. This increase was partially offset by a decrease in the contingent consideration liability due to higher discount rates in 2022 driven by changes in market interest rates, which lowered the present value of future cash flows.

Amortization of intangible assets

Amortization of intangible assets expense was \$0.4 million for both the three months ended September 30, 2022 and 2021 and was related to normal amortization of finite-lived intangible assets acquired in the Merger.

Benefit for income taxes

We recorded a benefit for income taxes of \$0.5 million for the three months ended September 30, 2021, primarily resulting from deferred tax benefits related to foreign exchange losses of our wholly-owned subsidiaries in the Netherlands.

Equity method investment gain (loss)

Equity method investment gain (loss) decreased by \$0.1 million for the three months ended September 30, 2022 compared to the three months ended September 30, 2021, due to a gain of \$1.1 million recorded in the third quarter of 2022, which resulted from changes in our ownership interest in Sairopa due to additional shares issued by Sairopa. This decrease was offset by \$1.0 million for our share of net losses in the Sairopa investment, net of any taxes.

Comparison of the Nine months Ended September 30, 2022 and 2021

	Nine Months Ended September 30,		
	2022	2021	Change
	(In thousands)		
Collaboration and license revenue	\$ 5,616	\$ 389	\$ 5,227
Operating expenses:			
Research and development	98,259	72,057	26,202
General and administrative	26,526	24,158	2,368
Change in fair value of contingent consideration and contingent value rights liabilities	4,719	21,563	(16,844)
Amortization of intangible assets	1,289	1,265	24
Total operating expenses	130,793	119,043	11,750
Gain on sale of assets to equity method investment	—	7,227	(7,227)
Loss from operations	(125,177)	(111,427)	(13,750)
Other income (expense), net	2,362	(175)	2,537
Loss before income taxes and equity method investment loss	(122,815)	(111,602)	(11,213)
Income tax benefit	—	1,204	(1,204)
Equity method investment loss	(2,496)	(84)	(2,412)
Net loss	<u>\$ (125,311)</u>	<u>\$ (110,482)</u>	<u>\$ (14,829)</u>

Collaboration and License Revenue

Total revenue was \$5.6 million for the nine months ended September 30, 2022, an increase of \$5.2 million compared to \$0.4 million for the nine months ended September 30, 2021. The increase was primarily due to \$3.7 million revenue recognized in the 2022 period related to services provided under our license agreement with SanReno and due to a development milestone of \$1.9 million recognized under our collaboration agreement with Lilly.

Research and Development Expenses

The following tables summarize our research and development expenses by program and by category incurred during the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,		
	2022	2021	Change
	(In thousands)		
Product Candidates			
Atrasentan	\$ 40,654	\$ 29,807	\$ 10,847
BION-1301	20,085	9,323	10,762
CHK-336	5,593	7,092	(1,499)
Other discovery, research and development programs	9,555	14,129	(4,574)
Subtotal	75,887	60,351	15,536
Stock-based compensation expense	7,409	4,282	3,127
Facility and depreciation costs	4,801	2,746	2,055
Other general research and development expenses	10,162	4,678	5,484
Total research and development expenses	<u>\$ 98,259</u>	<u>\$ 72,057</u>	<u>\$ 26,202</u>

	Nine Months Ended September 30,		Change
	2022	2021	
	(In thousands)		
Licensing and contract research and manufacturing	\$ 43,640	\$ 37,880	\$ 5,760
Employee-related costs	30,086	17,581	12,505
Supplies used in research and development	1,697	2,380	(683)
Stock-based compensation expense	7,409	4,282	3,127
Facility and depreciation costs	4,801	2,746	2,055
Consulting and outside services	7,851	6,237	1,614
Other	2,775	951	1,824
Total research and development expenses	<u>\$ 98,259</u>	<u>\$ 72,057</u>	<u>\$ 26,202</u>

Research and development expenses were \$98.3 million for the nine months ended September 30, 2022, an increase of \$26.2 million compared to \$72.1 million for the nine months ended September 30, 2021. The increase in research and development expenses was primarily due to higher employee-related costs, including salaries, benefits and stock-based compensation expense; an increase in licensing and contract research and manufacturing costs; an increase in facilities and other costs to continue the progression of our research and clinical programs; and increased spending for consulting and outside services costs.

General and Administrative Expenses

The following table summarizes our general and administrative expenses incurred during the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,		Change
	2022	2021	
	(In thousands)		
Consulting and outside services	\$ 8,202	\$ 7,195	\$ 1,007
Employee-related costs	8,353	8,153	200
Stock-based compensation expense	6,939	5,078	1,861
Facility and depreciation costs	995	2,095	(1,100)
Other	2,037	1,637	400
Total general and administrative expenses	<u>\$ 26,526</u>	<u>\$ 24,158</u>	<u>\$ 2,368</u>

General and administrative expenses were \$26.5 million for the nine months ended September 30, 2022, an increase of \$2.4 million compared to \$24.2 million for the nine months ended September 30, 2021. The increase in general and administrative expenses was primarily due to higher employee-related costs, including salaries, benefits and stock-based compensation expense resulting from new grants and higher consulting and outside services costs to support our operations. These increases were offset by a decrease in facilities costs, which are allocable from general and administrative to research and development expenses based on headcount.

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

Change in fair value of contingent consideration and contingent value rights liabilities expense was \$4.7 million for the nine months ended September 30, 2022, a decrease of \$16.8 million compared to \$21.6 million for the nine months ended September 30, 2021. The decrease primarily resulted from a change in estimate of the potential future proceeds derived from Aduro's license agreement with Merck for MK-5890, which included the impact of Merck informing us in the second quarter of 2021 that they intended to explore the potential benefits of the product candidate MK-5890 in a phase 2 clinical study for a new indication, and a change in the fair value resulting from the sale of certain of our non-renal assets in exchange for preferred shares in Sairopa during the second quarter of 2021. The decrease was partially offset by a net increase in the CVR liability in the third quarter of 2022 from remeasuring the value of our preferred shares in Sairopa at estimated fair value, as a result of the expectation that Sairopa could enter into a license agreement, which was completed in November 2022.

Amortization of intangible assets

Amortization of intangible assets expense was \$1.3 million for both the nine months ended September 30, 2022 and 2021, respectively, and was related to normal amortization of finite-lived intangible assets acquired in the Merger.

Gain on sale of assets to equity method investment

Gain on sale of assets to equity method investment decreased \$7.2 million for the nine months ended September 30, 2022, 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.

Benefit for income taxes

We recorded a benefit for income taxes of \$1.2 million for the nine months ended September 30, 2021, primarily resulting from deferred tax benefits associated with the sale of certain non-renal assets and foreign exchange losses of our wholly-owned subsidiaries in the Netherlands.

Equity method investment loss

Equity method investment loss increased by \$2.4 million for the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021 due to our share of net loss in the Sairopa investment, net of any taxes. This increase was offset by a \$1.1 million gain recorded in the third quarter of 2022, which resulted from changes in our ownership interest in Sairopa due to additional shares issued by Sairopa.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2022, we had \$397.7 million in cash, cash equivalents and marketable securities. We expect that our research and development and general and administrative expenses will increase, and, as a result, we anticipate that we will continue to incur increasing losses in the foreseeable future. We believe that our cash, cash equivalents and marketable securities as of September 30, 2022 will enable us to fund our operating expenses and capital expenditure requirements for at least the next 24 months.

In May 2022, we completed an underwritten public offering of 7.6 million shares of our common stock at a price to the public of \$14.00 per share, which included the exercise in full of the underwriters' option to purchase an additional 1.1 million shares of our common stock in June 2022. As part of this offering, we also sold to certain investors pre-funded warrants (the "Pre-Funded Warrants") to purchase up to an aggregate of 1.1 million shares of common stock at a purchase price of \$13.9999 per pre-funded warrant. The underwritten public offering in May 2022 resulted in gross proceeds to us of \$120.7 million, before \$7.7 million of underwriting discounts and commissions and estimated offering expenses.

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

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

In April 2021, we entered into an "at-the-market" sales agreement (the "2021 Sales Agreement") with Cantor Fitzgerald & Co. and SVB Securities LLC, previously known as SVB Leerink LLC, through which we may offer and sell shares of our common stock having an aggregate offering of up to \$75.0 million through our sales agents, Cantor Fitzgerald & Co. and SVB Securities LLC. Additionally, in November 2022, we amended the 2021 Sales Agreement to provide for offerings of up to \$150.0 million. We will pay the sales agents a commission of up to 3% of the gross proceeds of sales made through the 2021 Sales Agreement. In the third quarter of 2022, we sold 0.9 million shares for \$18.8 million in net proceeds under the 2021 Sales Agreement. As of November 10, 2022, we have \$150.0 million remaining under the 2021 Sales Agreement.

Funding Requirements

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 September 30, 2022, our material cash requirements from known contractual and other obligations primarily relate to our contractual obligations related to our operating leases. For additional information on our operating lease commitments, refer to Note 12 “Commitments and Contingencies” in our condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q. 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, including through our at-the-market offering program or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market our product candidates to third parties that we would otherwise prefer to develop and market ourselves.

Cash Flows

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

	Nine Months Ended September 30,	
	2022	2021
	(In thousands)	
Net cash provided by (used in):		
Operating activities	\$ (80,653)	\$ (80,243)
Investing activities	(102,466)	(34,899)
Financing activities	127,738	35,918
Effect of exchange rate changes	(271)	320
Net change in cash, cash equivalents, and restricted cash	<u>\$ (55,652)</u>	<u>\$ (78,904)</u>

Operating Activities

Net cash used in operating activities was \$80.7 million for the nine months ended September 30, 2022, an increase of \$0.4 million compared to \$80.2 million for the nine months ended September 30, 2021. The increase was primarily due to an increased operating loss, primarily resulting from research and development and general and administrative spending, offset in part by changes in net working capital usage.

Investing Activities

Net cash used in investing activities was \$102.5 million for the nine months ended September 30, 2022, an increase of \$67.6 million compared to \$34.9 million cash used for the nine months ended September 30, 2021. The increase in cash used was primarily due to purchases of marketable securities, net of proceeds from maturities of marketable securities.

Financing Activities

Net cash provided by financing activities was \$127.7 million for the nine months ended September 30, 2022, an increase of \$91.8 million compared to \$35.9 million for the nine months ended September 30, 2021. The increase was primarily due to increased net proceeds from the sale of common stock in the May 2022 underwritten public offering and the at-the-market sales agreement, as well as an increase in proceeds from option exercises and the employee stock purchase plan. The increase was partially offset by \$7.5

million paid to the CVR holders in the second quarter of 2022, which resulted from a development milestone recognized in the fourth quarter of 2021 under the license agreement with Merck for MK-5890.

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 nine months ended September 30, 2022, 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, 2021 filed with the SEC on March 17, 2022.

Recently Adopted Pronouncements

For information with respect to recently issued accounting standards and the impact of these standards on our condensed 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 September 30, 2022, which our management views as an integral part of our disclosure controls and procedures.

Material Weaknesses:

Management’s assessment identified the following material weaknesses in our internal control over financial reporting:

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

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

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

These material weaknesses could result in a misstatement of accounts or disclosures that would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected.

Remediation Efforts

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 have updated 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. During the second quarter of 2022, we started using a third-party system to perform certain information technology general controls associated with our accounting general ledger, such as system user access reviews. Additionally, during the third quarter of 2022, we executed several controls associated with our accounting general ledger, such as reviews of underlying database user access, program change management, and password configurations.
- (iv) We have assigned responsibilities among our expanded staff to enable improved segregation of duties. Additionally, during the fourth quarter of 2021, we implemented a third-party system which is being leveraged in our procurement process and has contributed to certain automated system controls supporting segregation of duties within the procurement process. During the second quarter of 2022, we started using this system to perform certain information technology general controls associated with our procurement process, such as system user access reviews. Additionally, during the third quarter of 2022, we performed user access reviews and program change management reviews associated with this system. During the first half of 2022, we implemented user access reviews within and across several other systems that support our financial reporting, such as stock administration, payroll, and disbursements.

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. During the first half of 2022, we engaged an additional third-party service provider to assess and provide feedback on the design of our controls within key process areas impacting financial reporting, including information technology general controls. We implemented relevant design feedback across several process areas during the second and third quarters of 2022 and implemented documentation enhancements related to control operation. During the first half of 2022, in collaboration with this third-party service provider, we evaluated key systems supporting financial reporting and implemented several information technology general controls across these systems, including user access provisioning, deprovisioning, and user access monitoring. We also continued the evaluation of systems and processes for proper segregation of duties during the second and third quarter of 2022.

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.

The third quarter of 2022 remediation activities described above are changes in our internal control over financial reporting during the quarter ended September 30, 2022 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.

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 continued presence of COVID-19, or the outbreak of a similar public health crises, could have a material adverse impact on our business, financial condition and results of operations, including the execution of our planned clinical trials and could cause potential supply chain disruptions.
- 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 U.S. Food and Drug Administration, or FDA, approval of atrasentan and our other product candidates through the accelerated approval pathway. If we are unable to obtain accelerated approval, we may be required to conduct additional clinical trials beyond those that we currently contemplate.
- Actual or perceived failure to comply with privacy and data protection laws or to adequately secure the personal information we hold could result in significant legal liability or reputational harm, and, in turn, create a material adverse effect on our potential future revenue and research & testing efforts.
- Our success depends in part on our ability to obtain, maintain and protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Risks Related to Our Financial Position

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

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

We have incurred net losses in each year since our inception. We incurred a net loss of \$125.3 million for the nine months ended September 30, 2022. As September 30, 2022, we had an accumulated deficit of \$357.1 million. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses over the next several years and for the foreseeable future as we intend to continue to conduct research and development, clinical testing, regulatory compliance activities, manufacturing activities, and, if any of our product candidates are approved, sales and marketing activities that, together with anticipated general and administrative expenses, will likely result in us incurring significant losses for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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

We will require substantial future capital in order to complete planned and future preclinical and clinical development for atrasentan and other product candidates and potentially commercialize these product candidates. Based upon our current operating plan, we believe that our existing cash, cash equivalents, and marketable securities held as of September 30, 2022 will enable us to fund our operating expenses and capital expenditure requirements for at least the next 24 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, 2021 and 2020, 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.

In 2021, we hired additional accounting personnel with appropriate experience, certification, education and training as a component of our plans to remediate the material weaknesses. In 2022 we have performed several additional reviews in seeking to remediate the material weaknesses. To the extent that these remediation efforts are not successful, 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.

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, 2021 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 candidates, atrasentan, a potent and selective endothelin receptor antagonist, and BION-1301, an anti-APRIL monoclonal antibody. With atrasentan, we are currently conducting the ALIGN phase 3 clinical trial for the treatment of IgAN and the phase 2 AFFINITY clinical trial for certain proteinuric glomerular diseases. With BION-1301, we are currently conducting a phase 1/2 clinical trial for the treatment of IgAN, and planning to initiate a phase 3 trial in 2023. We are also developing CHK-336 for the treatment of kidney stone disease, or hyperoxaluria, and have received rare pediatric disease designation from the FDA for CHK-336 for the treatment of primary hyperoxaluria. In addition, we are conducting research programs in several other rare, severe chronic kidney diseases. Our ability to generate product revenue will depend heavily on the successful development and eventual commercialization of atrasentan and our other product candidates, which may never occur. We currently generate no revenue from sales of any product, and we may never be able to develop or commercialize a marketable product.

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

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

- successful completion of preclinical studies, including those compliant with GLP, or GLP toxicology studies, biodistribution studies and minimum effective dose studies in animals, and successful enrollment and completion of clinical trials compliant with current GCPs;
- effective investigational new drug applications, or INDs, and Clinical Trial Authorizations, or CTAs, that allow commencement of our planned clinical trials or future clinical trials for our product candidates in relevant territories;
- establishing and maintaining relationships with contract research organizations, or CROs, and clinical sites for the clinical development of our product candidates, both in the United States and internationally;
- maintenance of arrangements with third-party contract manufacturing organizations, or CMOs, for key materials used in our manufacturing processes and to establish backup sources for clinical and large-scale commercial supply;
- positive results from our clinical programs that are supportive of safety and efficacy and provide an acceptable risk-benefit profile for our product candidates in the intended patient populations;
- receipt of regulatory approvals from applicable regulatory authorities, including those necessary for pricing and reimbursement of our product candidates;

- establishment and maintenance of patent and trade secret protection and regulatory exclusivity for our product candidates;
- commercial launch of our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of our product candidates, if and when approved, by patients, patient advocacy groups, third-party payors and the general medical community;
- our effective competition against other therapies available in the market;
- establishment and maintenance of adequate reimbursement from third-party payors for our product candidates;
- our ability to acquire or in-license additional product candidates;
- prosecution, maintenance, enforcement and defense of intellectual property rights and claims;
- maintenance of a continued acceptable safety profile of our product candidates following approval, including meeting any post-marketing commitments or requirements imposed by or agreed to with applicable regulatory authorities;
- political factors surrounding the approval process, such as government shutdowns or political instability; or
- disruptions in enrollment of our clinical trials due to the COVID-19 pandemic.

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

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

Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Success in preclinical studies and early clinical trials may not be predictive of results in later-stage clinical trials, and successful results from early or small clinical trials may not be replicated or show as favorable an outcome in later-stage or larger clinical trials, even if successful. We will be required to demonstrate through adequate and well-controlled clinical trials that our product candidates are safe and effective for their intended uses before we can seek regulatory approvals for their commercial sale. The conduct of phase 3 trials and the submission of an NDA or biologics license application, 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 2 and phase 3 trials. Based on the data from the SONAR trial, we believe that atrasentan, combined with current standard of care, may have benefits compared to treatment with current standard of care. However, we cannot assure that any potential advantages that we believe atrasentan may have for treatment of patients with proteinuric glomerular diseases will be substantiated by our planned clinical trials or included in the product's labeling should we obtain approval. Without head-to-head data, we will not be able to make comparative claims with respect to any other treatments. In addition, the patient populations under investigation with atrasentan have many co-morbidities that may cause severe illness or death, which may be attributed to atrasentan in a manner that negatively affects its safety profile. If the results of our clinical trials for atrasentan are inconclusive with respect to efficacy, if we do not meet our clinical endpoints with statistical significance, or if there are unanticipated safety concerns or adverse events that emerge during clinical trials, we may have to conduct further preclinical studies and/or clinical trials before obtaining marketing approval, or we may be prevented from or delayed in obtaining marketing approval.

Though atrasentan has been evaluated by AbbVie in late-stage clinical trials, our other product candidates, such as BION-1301 and CHK-336, have only been evaluated in early-stage clinical trials, and we may experience unexpected or negative results in the future as our other product candidates are evaluated in clinical trials. Any positive results we have observed in preclinical animal models may not be predictive of our future clinical trials in humans, as animal models carry inherent limitations relevant to all preclinical studies. Our product candidates may also fail to show the desired safety and efficacy in later stages of clinical development

even if they successfully advance through initial clinical trials. Even if our clinical trials demonstrate acceptable safety and efficacy of atrasentan or our other product candidates and such product candidates receive regulatory approval, the labeling we obtain through negotiations with the FDA or foreign regulatory authorities may not include data on secondary endpoints and may not provide us with a competitive advantage over other products approved for the same or similar indications.

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

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

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

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

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

Even if our product candidates meet their pre-specified safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner and may not consider the clinical trial results sufficient to grant, or we may not be able to obtain, regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process.

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

The ongoing COVID-19 pandemic, 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 and could cause potential supply chain disruptions.

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

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

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

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

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

While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and 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 1.29 per 100,000 individuals per year in the United States. The global incidence of IgAN is approximately 2.5 per 100,000 individuals per year. Variations in disease incidence and prevalence are, in part, due to regional differences in urine screening, referral patterns and indications for biopsy. IgAN is associated with progressive loss of kidney function leading to ESKD in approximately 30% to 45% of IgAN patients over 20 to 25 years, representing a significant unmet need for new treatment options. We are also developing CHK-336 for the treatment of primary hyperoxaluria, which is an ultra orphan disease with an even smaller number of patients. We have received rare pediatric disease designation from the FDA for CHK-336 for the treatment of PH. Small target patient populations could pose obstacles to the timely recruitment and enrollment of a sufficient number of eligible patients in our trials, or limit a product candidate's commercial potential. Patient enrollment may be affected by other factors including:

- the ability to identify and enroll patients that meet study eligibility criteria in a timely manner for clinical trials;
- the severity of the disease under investigation;
- design of the study protocol;

- the perceived risks, benefits and convenience of administration of the product candidate being studied;
- the patient referral practices of providers;
- the proximity and availability of clinical trial sites to prospective patients; and
- the availability of approved or investigational alternative treatment options.

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

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

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

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

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

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

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

Our product candidates and the activities associated with their development and potential commercialization, including their testing, manufacturing, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to

comprehensive regulation by the FDA and other U.S. and international regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, including current Good Manufacturing Practices, or cGMPs, quality control, quality assurance and corresponding maintenance of records and documents, including periodic inspections by the FDA and other regulatory authorities and requirements regarding the distribution of samples to providers and recordkeeping. In addition, manufacturers of drug 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, or FD&C, Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws and similar laws in international jurisdictions.

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

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

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

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

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

To market and sell atrasentan and our other product candidates in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time and data required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory

authorities will approve the product for sale in that country. Failure to obtain foreign regulatory approvals or non-compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries.

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

Risks Related to Commercialization and Manufacturing

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

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

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

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

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

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

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

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered and reimbursed. The Medicare program covers certain individuals aged 65 or older, disabled or suffering from ESKD. The Medicaid program, which varies from state-to-state, covers certain individuals and families who have limited financial means. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. One payor's determination to provide coverage for a drug 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 us to repeat clinical trials, which could delay or prevent the receipt of regulatory approvals. Any such event could have an adverse effect on our business, financial condition, results of operations and prospects.

We 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 is one approved drug for IgAN, as well as a variety of additional 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 Alnylam Pharmaceuticals, Inc., AstraZeneca PLC, Calliditas Therapeutics AB, Ionis Pharmaceuticals, Inc., F. Hoffman-La Roche Ltd., Novartis AG, Omeros Corporation, Travele Therapeutics, Inc., Vera 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 have and intend to continue to establish manufacturing relationships with a limited number of suppliers to manufacture raw materials, the drug substance and finished product of any product candidate for which we are responsible for preclinical or clinical development. Pursuant to our license agreement with AbbVie, we received a substantial amount of drug product and drug substance to support initiation of our clinical trials of atrasentan; however, we do not yet have a long-term commercial manufacturing agreement for atrasentan with AbbVie or any other CMO. We will need to establish manufacturing relationships for the production of sufficient atrasentan for any potential commercialization. Each supplier may require licenses to manufacture such components if such processes are not owned by the supplier or in the public domain. As part of any marketing approval, a manufacturer and our processes are required to be qualified by the FDA prior to regulatory approval. If supply from the approved vendor is interrupted, there could be a significant disruption in commercial supply. An alternative vendor would need to be qualified through an NDA 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, we are responsible for ensuring compliance with applicable laws and regulations, including cGMPs.

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

We believe that we will rely upon a limited number of manufacturers for our product candidates, including atrasentan, for which we have identified single-source suppliers for the various steps of manufacture. This reliance on a limited number of manufacturers and the complexity of drug manufacturing and the difficulty of scaling up a manufacturing process could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our product candidates successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production in a timely manner at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

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

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

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

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

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

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

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

The success of any potential collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of such collaboration arrangements. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to

expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

Risks Related to Government Regulation

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

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

The accelerated approval pathway may be used in cases in which the advantage of a new 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 the standard of care were to evolve or if any of our competitors were to receive full approval for an indication for which we are seeking accelerated approval before we receive accelerated approval, the indication we are seeking may no longer qualify as a condition for which there is an unmet medical need and accelerated approval of our product candidate would not occur without a showing of benefit over available therapy.

In addition, the FDA may terminate the accelerated approval program or change the standards under which accelerated approvals are considered and granted in response to public pressure or other concerns regarding the accelerated approval program. Changes to or termination of the accelerated approval program could prevent or limit our ability to obtain accelerated approval of any of our clinical development programs. Recently, the accelerated approval pathway has come under scrutiny within the FDA and by Congress. The FDA has put increased focus on ensuring that confirmatory studies are conducted with diligence and, ultimately, that such studies confirm the benefit. Congress is also considering various proposals to potentially make changes to the accelerated approval pathway, including proposals to increase the likelihood of withdrawal of approval in such circumstances.

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

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

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

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

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

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

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

The Rare Pediatric Disease Voucher Program is intended to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Although there are existing incentive programs to encourage the development and study of drugs for rare diseases, pediatric populations, and unmet medical needs, this program provides an additional incentive for the development of drugs for rare pediatric diseases, which may be used alone or in combination with other incentive programs. A rare pediatric disease is defined as a disease that is a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; and is a rare disease or condition as defined in the FD&C Act, which includes diseases and conditions that affect fewer than 200,000 persons in the 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.

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 voucher program was most recently re-authorized by Congress in the Consolidated Appropriations Act of 2021, extending the rare pediatric disease program through September 30, 2024, with the potential for priority review vouchers to be granted through September 30, 2026. Although we have obtained designation of CHK-336 for the treatment of PH as a rare pediatric disease, we may not meet the eligibility requirements for a priority voucher at the time we seek approval of CHK-336 or we may not meet the current deadline for receiving a priority review voucher, in which case we would not be able to use priority review for a subsequent product of ours or be able to sell such voucher to a third party.

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. The law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

There have been executive, legislative and judicial efforts to modify, repeal or otherwise invalidate all or certain aspects of the ACA. By way of example, the Tax Cuts and Jobs Act, or the TCJA, was enacted, 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 to reduce healthcare expenditures, including aggregate reductions to Medicare payments to providers of 2 percent per fiscal year, which went into effect April 1, 2013 and will stay in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, unless additional Congressional action is taken. The Medicare reductions phased back in starting with a 1% reduction in effect from April 1, 2022 to June 30, 2022 before increasing to the full 2% reduction. In addition, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

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

On September 9, 2021, the Biden administration published a wide-ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. The U.S. Department of Health and Human Services, or HHS, plan includes, among other reform measures, proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. These initiatives recently culminated in the enactment of the Inflation Reduction Act, or IRA, in August 2022, which will, among other things, allow HHS to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although this will only apply to high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics). The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price beginning in October 2023, and penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be

subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges.

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.

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

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

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

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which

payment may be made under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

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

- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us.

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

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

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

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. For example, while our patent applications are pending, we may be subject to a third party preissuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or become involved in interference or derivation proceedings, or equivalent proceedings in foreign jurisdictions. Even if patents do successfully issue, third parties may challenge their inventorship, validity, enforceability or scope, including through opposition, revocation, reexamination, post-grant and *inter partes* review proceedings. An adverse determination in any such submission, proceeding or litigation may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. Moreover, some of our owned and in-licensed patents and patent applications may be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in development, testing, and regulatory review of new product candidates, the period of time during which we could market our product candidates under patent protection would be reduced or eliminated.

Since patent applications in the United States and other countries are confidential for a period of time after filing, at any moment in time, we cannot be certain that we were in the past or will be in the future the first to file any patent application related to our product candidates. In addition, some patent applications in the United States may be maintained in secrecy until the patents are issued. As a result, there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim, and we may be subject to priority disputes. We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that, if challenged, our patents would be declared by a court, patent office or other governmental authority to be valid or enforceable or that even if found valid and enforceable, a competitor's technology or product would be found by a court to infringe our patents. We may analyze patents or patent applications of our competitors that we believe are relevant in our activities, and consider that we are free to

operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, that block our efforts or potentially result in our product candidates or our activities infringing such claims. It is possible that our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to our own products or technology. Those patent applications may have priority over our owned and in-licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. The possibility also exists that others will develop products that have the same effect as our product candidates on an independent basis that do not infringe our patents or other intellectual property rights, or will design around the claims of patents that we have had issued that cover our product candidates or their use.

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

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

- others may be able to make or use compounds that are similar to the active compositions of our product candidates but that are not covered by the claims of our patents;
- the APIs in our current product candidates will eventually become commercially available in generic drug products, and no patent protection may be available with regard to formulation or method of use;
- our licensors, as the case may be, may fail to meet our obligations to the U.S. government regarding any in-licensed patents and patent applications funded by U.S. government grants, leading to the loss or unenforceability of patent rights;
- our licensors, as the case may be, might not have been the first to file patent applications for certain inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our currently pending or future patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our owned or in-licensed patents, as the case may be, or parts of our owned or in-licensed patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished patent applications or patent applications maintained in secrecy that may later issue with claims covering our product candidates or technology similar to ours;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not adequately cover our product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes that design around our patents, or become hostile to the Company or the patents or patent applications on which they are named as inventors;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable or such omitted individuals may grant licenses to third parties;
- we have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing products that are outside the scope of our patent claims;
- we may not develop additional proprietary technologies for which we can obtain patent protection;

- it is possible that product candidates or diagnostic tests we develop may be covered by third parties' patents or other exclusive rights; or
- the patents of others may have an adverse effect on our business.

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

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

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

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

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

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

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

It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with the Company. These agreements provide that all confidential information concerning our research and development, business, or financial affairs developed or made known to the individual or entity during the course of the party's relationship with Chinook Therapeutics are to be kept confidential and not disclosed to third parties, except in certain specified circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and that are related in our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information (or as otherwise permitted by applicable law), are our exclusive property. In the case of consultants and other third parties, the agreements provide that all inventions conceived in connection with the services provided are our exclusive property. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We have also adopted policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our secrets. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information through other appropriate precautions, such as physical and technological security measures. However, trade secrets and know-how can be difficult to protect. These measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and any recourse we might take against this

type of misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent us from receiving legal recourse. If any of our confidential or proprietary information, such as the Company's trade secrets, were to be disclosed or misappropriated, such as through a data breach, or if any of that information was independently developed by a competitor, our competitive position could be harmed. Additionally, certain trade secrets and proprietary information may be required to be disclosed in submissions to regulatory authorities. If such authorities do not maintain the confidential basis of such information or disclose it as part of the basis of regulatory approval, our competitive position could be adversely affected.

In addition, courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. Even if we are successful, these types of lawsuits may consume our time and other resources. Although we take steps to protect our proprietary information and trade secrets, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access 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 have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our product candidates in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

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

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at universities or other biopharmaceutical or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. We may then have to pursue litigation to defend against these claims. If we fail in defending any claims of this nature, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these types of claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or

investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities, and we may not have sufficient financial or other resources to adequately conduct this type of litigation or proceeding. For example, some of our competitors may be able to sustain the costs of this type of litigation or proceeding more effectively than we can because of their substantially greater financial resources. In any case, uncertainties resulting from the initiation and continuation of intellectual property litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

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

The growth of our business may depend in part on our ability to acquire, in-license or use third-party proprietary rights. For example, our product candidates may require specific formulations to work effectively and efficiently, we may develop product candidates containing pre-existing pharmaceutical compounds, or we may be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our product candidates, any of which could require us to obtain rights to use intellectual property held by third parties. In addition, with respect to any patents we may co-own with third parties, we may require licenses to such co-owners' interest in such patents. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties we identify as necessary or important in our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, which means 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 to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the case, *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to DNA molecules are not patent-eligible.

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

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

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

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

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during clinical trials and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent per product may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. U.S. and ex-U.S. law concerning patent term extensions and foreign equivalents continue to evolve. Even if we were to seek a patent term extension, it may not be granted because of, for example, the failure to exercise due diligence during the testing phase or regulatory review process, the failure to apply within applicable deadlines, the failure to apply prior to expiration of relevant patents, or any other failure to satisfy applicable requirements. Moreover, the applicable time period of extension or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or 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. Aduro experienced and Private Chinook likely experienced an ownership change under Section 382 as a result of the Merger. Any such limitation may significantly reduce our ability to utilize net operating loss carryforwards and tax credit carryforwards before they expire. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of Private Chinook's or Aduro's net operating loss carryforwards and other tax attributes, which could have a material adverse effect on our cash flow and results of operations. There is also a risk that due to regulatory changes, such as suspensions on the use of net operating losses, or NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

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

Risks Related to the CVRs

Our outstanding CVRs may expire valueless.

The right of the holders of our contingent value rights, or CVRs, issued prior to the closing of the Merger will be contingent solely upon the occurrence of 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 the second quarter of 2022, we paid \$7.5 million to CVR holders following receipt of a development milestone under our license agreement with Merck for MK-5890. In April 2021, prior to the disposition period set forth in the CVR Agreement, we entered into an agreement with Sairopa, a private company created by Van Herk Royalty B.V. and D.S. Chahal to acquire certain of our non-renal assets in exchange for stock in Sairopa. We will hold our equity interests in Sairopa until there is a liquidity event, upon which 50% of any proceeds, net of deductions permitted under the CVR Agreement, including taxes and certain other expenses, will be distributed to CVR holders, provided such liquidity event occurs during the 10-year CVR period. 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 additional payments will be made under the CVR Agreement, and the CVRs will expire valueless.

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

The tax treatment of the CVRs is unclear.

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

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

Risks Related to our Common Stock

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

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

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

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

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

We will incur significant legal, accounting and other expenses as a public company that we did not incur as a private company, including costs associated with public company reporting obligations under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our management team consists, among others, of the executive officers of Private Chinook prior to the Merger, some of whom have not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise related to public company reporting requirements and compliance with applicable laws and regulations to ensure that we comply with all of these requirements. Any changes we make to comply with these obligations may not be sufficient to allow 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.

We expect to no longer be a smaller reporting company as of December 31, 2022, and will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results.

We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition as well as other disclosure and corporate governance requirements. 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 of the Sarbanes-Oxley Act of 2002 and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We expect to no longer be a smaller reporting company or otherwise qualify for these exemptions as of December 31, 2022 and 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, whether due to terrorism, armed conflict (such as the current conflict between Russia and Ukraine), natural disasters or health crises (such as COVID-19) could cause extreme volatility and disruptions in the capital and credit markets, as well as rising interest rates and inflation. A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive such difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our

business. Furthermore, our stock price may decline due in part to the volatility of the stock market and any general economic downturn.

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

We are subject to numerous environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also may produce hazardous waste products. We generally anticipate contracting with third parties for the disposal of these materials and wastes. We will not be able to eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from any use by us of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

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

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

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

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

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

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

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

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

We must attract and retain highly skilled employees to succeed.

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

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

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

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

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

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

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

Federal, state, and foreign government requirements include obligations of companies to notify regulators and/or individuals of security breaches involving personally identifiable information, which could result from breaches experienced by us or by our

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

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

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

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

Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. California recently enacted legislation, the California Consumer Privacy Act, or CCPA, which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information 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. A ballot initiative from privacy rights advocates intended to augment and expand the CCPA called the California Privacy Rights Act, or CPRA, was passed in November 2020 and will take effect in January 2023 (with a look back to January 2022). The CPRA will significantly modify the CCPA, including by expanding consumers' rights with respect to certain sensitive personal data. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. Potential uncertainty surrounding the CCPA and CPRA may increase our compliance costs and potential liability, particularly in the event of a data breach, and could have a material adverse effect on our business. Other states have followed California's lead. The Virginia Consumer Data Protection Act, or VCDPA, which will go into effect in 2023, gives new data protection rights to Virginia residents and imposes additional obligations on controllers and processors of personal data. Colorado has also adopted a new state data

protection act titled the Colorado Privacy Act, which is set to take effect on July 1, 2023. As of January 2022, fourteen states have pending consumer privacy legislation under review, which if enacted would add additional costs and expense of resources to maintain compliance.

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

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

The GDPR, as well as law in the United Kingdom, or the UK, and Switzerland, also prohibits the international transfer of personal data from the EEA/UK/Switzerland to countries outside of those jurisdictions unless made to a country deemed to have adequate data privacy laws by the European Commission or where a data transfer mechanism has been put in place. We rely on a mixture of mechanisms to transfer personal data to countries outside of the EEA, Switzerland, and the UK, including to the United States and therefore are continuing to evaluate the guidance and mechanisms required to establish adequate safeguards for personal data. Until recently, one such data transfer mechanism was the EU-US Privacy Shield. However, in July 2020 the Court of Justice of the European Union, or CJEU, declared the Privacy Shield to be invalid. The CJEU upheld the validity of the standard contractual clauses, or SCCs, as a legal mechanism to transfer personal data but companies relying on SCCs will continually be subject to guidance from regulators in the EEA and need to evaluate and implement supplementary measures that provide privacy protections additional to those provided under SCCs. In turn, the findings of the CJEU will have significant implications for cross-border data flows. On June 4, 2021, the European Commission adopted new SCCs to apply to international transfers of data. We will have until December 27, 2022 to update any existing agreements, or any new agreements executed before September 27, 2021, that rely on the former SCCs. If we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we conduct our operations, and we may find it necessary to establish systems in the EEA, Switzerland, and the UK to maintain personal data originating from the EEA and the UK, which may involve substantial expense and distraction from other aspects of our business. As supervisory authorities continue to issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used and/or what safeguards must be implemented, or start taking enforcement action, there will be uncertainty as to how we comply with EEA, Switzerland, and UK privacy laws and we could suffer additional costs, complaints, or regulatory investigations or fines. For example, German and Irish supervisory authorities have indicated that the Standard Contractual Clauses alone provide inadequate protection for EU-U.S. data transfers. Use of the data transfer mechanisms must now be assessed on a case-by-case basis, taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals. We may need to implement additional safeguards to further enhance the security of data transferred out of the EEA/Switzerland/UK, conduct data transfer impact assessments, and review existing agreements which could increase our compliance costs, expose us to further regulatory scrutiny and liability, and adversely affect our business. Further, the GDPR provides that countries in the EEA may establish their own laws and regulations further restricting the processing of certain personal data, including genetic data, biometric data, and health data.

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

Further, as a consequence of the UK's departure from the EU, the UK is free to diverge from EU data privacy laws. The UK's Data Reform Bill, containing proposals for the UK GDPR to diverge from the EU GDPR, is currently progressing through the UK Parliament and is expected to be finalized this year. We may therefore be subject in the future to separate and additional data

protection obligations to those that we are already subject to. This may result in substantial costs and may necessitate changes to our business practices, which in turn may adversely affect our business, reputation, legal exposures, and financial condition.

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

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

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

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

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. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

In April 2021, we entered into an “at-the-market” sales agreement (the “2021 Sales Agreement”) with Cantor Fitzgerald & Co. and SVB Securities LLC, previously known as SVB Leerink LLC, through which we may offer and sell shares of our common stock having an aggregate offering of up to \$75.0 million through our sales agents, Cantor Fitzgerald & Co. and SVB Securities LLC. In November 2022, we amended the 2021 Sales Agreement to provide for offerings of up to \$150.0 million.

Item 6. Exhibits.

EXHIBIT INDEX

Exhibit No	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
5.1	Opinion of Fenwick & West LLP					X
10.1	2022 Equity Inducement Plan and forms of award agreements thereunder	S-8	333-268295	99.1	11/10/2022	
10.2	Amendment No. 1 to Sales Agreement, dated April 7, 2021, by and between the Registrant and SVB Securities LLC (formerly known as SVB Leerink LLC) and Cantor Fitzgerald & Co., as amended on November 10, 2022					X
23.1	Consent of Fenwick & West LLP (included in Exhibit 5.1)					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: November 10, 2022

By: /s/ Eric L. Dobmeier

Eric L. Dobmeier

President and Chief Executive Officer

(principal executive officer)

Chinook Therapeutics, Inc.

Date: November 10, 2022

By: /s/ Eric H. Bjerkholt

Eric H. Bjerkholt

Chief Financial Officer

(principal financial and accounting officer)

November 10, 2022

Chinook Therapeutics, Inc.
400 Fairview Avenue North
Suite 900
Seattle, WA 98109

Ladies and Gentlemen:

We deliver this opinion with respect to certain matters in connection with the offering by Chinook Therapeutics, Inc., a Delaware corporation (the “**Company**”), of the Company’s Common Stock, \$0.0001 par value per share (the “**Common Stock**”), with an aggregate maximum offering price of up to \$150,000,000 (the “**Placement Shares**”), to be issued from time to time pursuant to that certain Sales Agreement, dated as of April 7, 2021, as amended by Amendment No. 1 to the Sales Agreement, dated November 10, 2022 (the “**Offering Agreement**”), by and among Company, SVB Securities LLC, formerly known as SVB Leerink LLC, and Cantor Fitzgerald & Co. The Placement Shares will be registered pursuant to the automatically effective Registration Statement on Form S-3ASR (File No. 333-265168) filed by the Company with the Securities and Exchange Commission (the “**Commission**”) on May 24, 2022 (the “**Registration Statement**”) under the Securities Act of 1933, as amended (the “**Securities Act**”), the base prospectus dated May 24, 2022 included therein (the “**Base Prospectus**”), and the related prospectus supplement to be filed with the Commission pursuant to Rule 424(b) under the Securities Act on November 10, 2022 (the “**Prospectus Supplement**,” and together with the Base Prospectus, the “**Prospectus**”). The offering of the Placement Shares is referred to herein as the “**Offering**.” The Placement Shares are to be sold by the Company as described in the Registration Statement, the Prospectus and the Offering Agreement.

In connection with our opinion expressed below, we have examined originals or copies of the Company’s current Certificate of Incorporation and Bylaws, as amended (the “**Charter Documents**”), certain corporate proceedings of the Company’s board of directors (the “**Board**”) and stockholders relating to the Registration Statement, the Charter Documents, and such other agreements, documents, certificates and statements of the Company, its transfer agent and public or government officials, as we have deemed advisable, and have examined such questions of law as we have considered necessary. We have assumed, and express no opinion as to, the genuineness of all signatures on documents submitted to us, the authenticity and completeness of all documents submitted to us as originals, the conformity to originals and completeness of all documents submitted to us as copies, the legal capacity of all persons or entities executing the same, the absence of any undisclosed termination, modification, waiver or amendment to any document reviewed by us, the absence of any other extrinsic agreements or documents that might change or affect the interpretation or terms of documents we have reviewed, and the due authorization, execution and delivery of all such documents where due authorization, execution and delivery are prerequisites to the effectiveness thereof. In giving our opinion, we have also relied upon a good standing certificate regarding the Company issued by the Delaware Secretary of State dated November 10, 2022 and a management certificate addressed to us and dated of even date herewith executed by the Company containing certain factual representations (the “**Management Certificate**”).

As to matters of fact relevant to this opinion, we have relied solely upon our examination of the documents referred to above and the Management Certificate and have assumed the current accuracy and completeness of the information obtained from the documents referred to above and the representations and warranties made by representatives of the Company to us, including but not limited to those set forth in the Management Certificate. We have made no independent investigation or other attempt to verify the accuracy of any of such information or to determine the existence or non-existence of any other factual matters.

We render this opinion only with respect to, and express no opinion herein concerning the application or effect of the laws of any jurisdiction other than the existing laws of the Delaware General Corporation Law (the “**Applicable Laws**”). Without limitation, we express no opinion with respect to the federal laws of the United States of America or the securities or “blue sky” laws of any state or any local or regional laws.

In connection with our opinions expressed below, we have assumed that, (i) at or prior to the time of the delivery of any of the Placement Shares, there will not have occurred any change in the law or the facts affecting the validity of the Placement Shares, (ii) at the time of the offer, issuance and sale of any Placement Shares, no stop order suspending the Registration Statement’s effectiveness will have been issued and remain in effect, (iii) no future amendments will be made to the Charter Documents that would be in conflict with or inconsistent with the Company’s right and ability to issue the Placement Shares, (iv) at the time of each offer, issuance and sale of any Placement Shares, the Company will have a sufficient number of authorized and unissued and unreserved shares of the applicable class or series of its capital stock included in (or purchasable upon exercise or conversion of) the Placement Shares so issued and sold (after taking into account all other outstanding securities of the Company which may require the Company to issue shares of such applicable class or series) to be able to issue all such shares, and (v) the purchaser of the Placement Shares will timely pay in full to the Company all amounts they have agreed to pay to purchase such Placement Shares, as approved by the Board or a duly authorized committee thereof, and that the purchase price of any Placement Shares will not be less than the par value thereof.

The Company has informed us that the Company intends to issue the Placement Shares, from time to time on a delayed or continuous basis. This opinion is limited to the Applicable Laws, including the rules and regulations thereunder, as in effect on the date hereof.

Based upon the foregoing, we are of the opinion that the Placement Shares to be issued and sold by the Company, when issued, sold and delivered in the manner and for the consideration stated in the Registration Statement and the Prospectus and in accordance with the resolutions adopted and to be adopted by the Board or a committee thereof, will be validly issued, fully paid and nonassessable.

We consent to the use of this opinion as an exhibit to the Quarterly Report on Form 10-Q and further consent to all references to us, if any, in the Registration Statement, the Prospectus constituting a part thereof and any amendments or supplements thereto. We do not thereby admit that we are within the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission thereunder.

[Concluding Paragraph Follows on Next Page]

This opinion is intended solely for use in connection with the issuance and sale of the Placement Shares subject to the Offering Agreement and is not to be relied upon for any other purpose. In providing this letter, we are opining only as to the specific legal issues expressly set forth above, and no opinion shall be inferred as to any other matter or matters. This opinion is rendered on, and speaks only as of, the date of this letter first written above, is based solely on our understanding of facts in existence as of such date after the aforementioned examination and does not address any potential changes in facts, circumstance or law that may occur after the date of this opinion letter. We assume no obligation to advise you of any fact, circumstance, event or change in the law or the facts that may hereafter be brought to our attention whether or not such occurrence would affect or modify any of the opinions expressed herein

Very truly yours,

/s/ Fenwick & West LLP

FENWICK & WEST LLP

AMENDMENT NO. 1 TO SALES AGREEMENT

November 10, 2022

Chinook Therapeutics, Inc.
400 Fairview Avenue North, Suite 900
Seattle, WA 98109

Ladies and Gentlemen:

Chinook Therapeutics, Inc., a Delaware corporation (the “**Company**”), together with SVB Securities LLC (formerly SVB Leerink LLC) (“**SVB Securities**”) and Cantor Fitzgerald & Co. (“**Cantor**”; each individually an “**Agent**” and together, the “**Agents**”), are parties to that certain Sales Agreement dated April 7, 2021 (the “**Original Agreement**”). All capitalized terms not defined herein shall have the meanings ascribed to them in the Original Agreement. The Company and the Agents desire to amend the Original Agreement as set forth in this Amendment No. 1 thereto (this “**Amendment**”) as follows:

1. The first paragraph of Section 1 of the Original Agreement shall be deleted in its entirety, and the following shall be inserted in lieu thereof:

“The Company agrees that, from time to time during the term of this Agreement, on the terms and subject to the conditions set forth herein, it may issue and sell through or to the Agents up to an aggregate of \$225,000,000 of shares of common stock, \$0.0001 par value per share, of the Company (the “**Common Stock**”), as sales agent or principal, subject to the limitations set forth in Section 5(c) (the “**Placement Shares**”); *provided* that the Company may only may issue and sell through or to the Agents up to an aggregate of \$150,000,000 of Placement Shares after November 10, 2022. Notwithstanding anything to the contrary contained herein, the parties hereto agree that compliance with the limitation set forth in this Section 1 on the aggregate gross sales price of Placement Shares that may be issued and sold under this Agreement from time to time shall be the sole responsibility of the Company, and that the Agents shall have no obligation in connection with such compliance. The issuance and sale of Placement Shares through the Agents will be effected pursuant to the Registration Statement (as defined below) filed by the Company with the Securities and Exchange Commission (the “**Commission**”), although nothing in this Agreement shall be construed as requiring the Company to issue any Placement Shares. ”

2. The second paragraph of Section 1 of the Original Agreement shall be deleted in its entirety, and the following shall be inserted in lieu thereof:

“The Company shall file, or has filed, in accordance with the provisions of the Securities Act of 1933, as amended, and the rules and regulations thereunder (collectively, the “**Securities Act**”), with the Commission (a) a registration statement on Form S-3, including a base prospectus (the “**Base Prospectus**”), relating to certain securities, including the Common Stock, to be issued from time to time by the Company, and which incorporates by reference documents that the Company has filed or will file in accordance with the provisions of the Securities Exchange Act of 1934, as amended, and the rules and

regulations thereunder (collectively, the “**Exchange Act**”), and (b) a prospectus supplement to the Base Prospectus specifically relating to the Placement Shares to be issued from time to time pursuant to this Agreement (such prospectus supplement, together with the Base Prospectus, the “**ATM Prospectus**”). The Company will furnish to the Agents, for use by the Agents, copies of the ATM Prospectus. The Company may file one or more additional registration statements from time to time that will contain a base prospectus and related prospectus or prospectus supplement, if applicable, with respect to the Placement Shares. Except where the context otherwise requires, such registration statement(s), including all documents filed as part thereof or incorporated by reference therein, and including any information contained in a Prospectus (as defined below) subsequently filed with the Commission pursuant to Rule 424(b) under the Securities Act or deemed to be a part of such registration statement pursuant to Rule 430B or Rule 462(b) under the Securities Act, is herein called the “**Registration Statement**.” The ATM Prospectus, including all documents incorporated therein by reference, as it may be supplemented by any prospectus supplement, in the form most recently been filed by the Company with the Commission pursuant to Rule 424(b) under the Securities Act, together with any “issuer free writing prospectus” (as used herein, as defined in Rule 433 under the Securities Act (“**Rule 433**”)), relating to the Placement Shares that (i) is required to be filed with the Commission by the Company or (ii) is exempt from filing pursuant to Rule 433(d)(5)(i), in each case, in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company’s records pursuant to Rule 433(g), is herein called the “**Prospectus**.””

3. The second sentence of the third paragraph of Section 1 of the Original Agreement shall be deleted in its entirety, and the following shall be inserted in lieu thereof:

“Any reference herein to the terms “amend,” “amendment” or “supplement” with respect to the Registration Statement or the Prospectus shall be deemed to refer to and include the filing after the execution hereof of any document with the Commission deemed to be incorporated by reference therein on or after the most recent effective date of the Registration Statement, or the date of the Prospectus, as the case may be.”

4. The eighth sentence of Section 6(a) of the Original Agreement shall be deleted in its entirety, and the following shall be inserted in lieu thereof:

“At the time of the initial filing of the Registration Statement, or the applicable Prospectus Supplement, as the case may be, the Company paid the required Commission filing fees relating to the securities covered by the Registration Statement, including the Shares that may be sold pursuant to this Agreement, in accordance with Rule 457(o) under the Securities Act.”

5. All references to “April 7, 2021” set forth in Schedule 1 and Exhibit 7(m) of the Original Agreement are revised to read “April 7, 2021 (as amended by Amendment No. 1, dated November 10, 2022)”.

6. Except as specifically set forth herein, all other provisions of the Original Agreement shall remain in full force and effect.

7. The Company will pay reasonable and documented out-of-pocket fees and disbursements of counsel to the Agents up to \$75,000 in the aggregate incurred in connection with this Amendment No. 1 and other related documents.

8. This Amendment together with the Original Agreement (including all exhibits attached hereto) constitutes the entire agreement and supersedes all other prior and contemporaneous agreements and undertakings, both written and oral, among the parties hereto with regard to the subject matter hereof. Neither this Amendment nor any term hereof may be amended except pursuant to a written instrument executed by the Company and the Agents. In the event that any one or more of the provisions contained herein, or the application thereof in any circumstance, is held invalid, illegal or unenforceable as written by a court of competent jurisdiction, then such provision shall be given full force and effect to the fullest possible extent that it is valid, legal and enforceable, and the remainder of the terms and provisions herein shall be construed as if such invalid, illegal or unenforceable term or provision was not contained herein, but only to the extent that giving effect to such provision and the remainder of the terms and provisions hereof shall be in accordance with the intent of the parties as reflected in this Amendment. No implied waiver by a party shall arise in the absence of a waiver in writing signed by such party. No failure or delay in exercising any right, power, or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any right, power, or privilege hereunder. All references in the Original Agreement to the "Agreement" shall mean the Original Agreement as amended by this Amendment; *provided, however*, that all references to "date of this Agreement" in the Original Agreement shall continue to refer to the date of the Original Agreement.

9. EACH OF THE COMPANY AND THE AGENTS HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AMENDMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.

10. THIS AMENDMENT SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF, THE STATE OF NEW YORK WITHOUT REFERENCE TO ITS PRINCIPLES OF CONFLICTS OF LAW.

11. Each of the Company and the Agents agree that any legal suit, action or proceeding arising out of or based upon this Amendment or the transactions contemplated hereby ("Related Proceedings") shall be instituted in (i) the federal courts of the United States of America located in the City and County of New York, Borough of Manhattan or (ii) the courts of the State of New York located in the City and County of New York, Borough of Manhattan (collectively, the "Specified Courts"), and irrevocably submits to the exclusive jurisdiction (except for proceedings instituted in regard to the enforcement of a judgment of any Specified Court, as to which such jurisdiction is non-exclusive) of the Specified Courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to a party's address set forth in Section 11 of the Original Agreement, as amended by this Amendment, shall be effective service of process upon such party for any suit, action or proceeding brought in any Specified Court. Each of the Company and the Agents irrevocably and unconditionally waives any objection to the laying

of venue of any suit, action or proceeding in the Specified Courts and irrevocably and unconditionally waives and agrees not to plead or claim in any Specified Court that any such suit, action or proceeding brought in any Specified Court has been brought in an inconvenient forum.

12. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Delivery of an executed amendment by one party to the other may be made by facsimile transmission or electronic transmission (e.g., PDF).

[Remainder of Page Intentionally Blank]

If the foregoing correctly sets forth the understanding between the Company and each Agent, please so indicate in the space provided below for that purpose, whereupon this Amendment shall constitute a binding amendment to the Original Agreement between the Company and each Agent.

Very truly yours,

SVB SECURITIES LLC

By: /s/ Peter M. Fry
Name: Peter M. Fry
Title: Head of Alt Equities

CANTOR FITZGERALD & CO.

By: /s/ Sage Kelly
Name: Sage Kelly
Title: Senior Managing Director, Head of Investment Banking

[Signature Page to Amendment No. 1 to Sales Agreement]

**ACCEPTED as of the date
first-above written:**

CHINOOK THERAPEUTICS, INC.

By: /s/ Eric Bjerkholt

Name: Eric Bjerkholt

Title: Chief Financial Officer

[Signature Page to Amendment No. 1 to Sales Agreement]

**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: November 10, 2022

/s/ Eric L. Dobmeier

Eric L. Dobmeier

President, Chief Executive Officer and Director
(Principal Executive Officer)

**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: November 10, 2022

/s/ Eric H. Bjerkholt

Eric H. Bjerkholt

Chief Financial Officer

(Principal Accounting and Financial Officer)

**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 September 30, 2022 (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: November 10, 2022

/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.