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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2023

OR

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

For the transition period from ______ to

Commission File Number 001-37345

CHINOOK THERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

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

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

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

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

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

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

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

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

The number of shares of Registrant's Common Stock outstanding as of August 4, 2023 was 71,804,977

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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)

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 127,149	$ 115,438
Marketable securities	170,016	262,887
Accounts receivable	3,102	1,091
Prepaid expenses and other current assets	5,150	6,176
Total current assets	305,417	385,592
Marketable securities	1,972	6,989
Property and equipment, net	16,235	16,908
Restricted cash	2,074	2,074
Operating lease right-of-use assets	42,874	48,970
Investment in equity securities	41,200	41,200
Equity method investment	4,784	4,071
Intangible assets, net	23,421	24,287
In-process research & development	36,550	36,550
Goodwill	117	117
Other assets	14,167	7,326
Total assets	$ 488,811	$ 574,084
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	16,362	9,751
Accrued and other current liabilities	29,342	33,636
Operating lease liabilities	4,268	4,948
Contingent value rights liability	2,500	2,500
Total current liabilities	52,472	50,835
Contingent value rights liability - non-current	40,217	37,318
Contingent consideration liability	4,290	4,420
Deferred tax liabilities	5,076	5,076
Operating lease liabilities, net of current maturities	29,717	34,494
Total liabilities	131,772	132,143
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000 shares authorized as of June 30, 2023 and December 31, 2022; no shares issued and outstanding at June 30, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value; 300,000 shares authorized as of June 30, 2023 and December 31, 2022; 67,079 and 65,471 shares issued and outstanding at June 30, 2023 and December 31, 2022	7	7
Additional paid-in capital	905,109	864,729
Accumulated deficit	(546,752)	(419,631)
Accumulated other comprehensive loss	(1,325)	(3,164)
Total stockholders' equity	357,039	441,941
Total liabilities and stockholders' equity	$ 488,811	$ 574,084

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)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Collaboration and license revenue	$ 1,008	$ 418	$ 2,836	$ 3,115
Operating expenses:				
Research and development	57,897	30,023	108,780	56,275
General and administrative	13,061	8,635	24,465	16,503
Change in fair value of contingent consideration and contingent value rights liabilities	2,243	(1,984)	2,769	(3,022)
Amortization of intangible assets	433	429	866	858
Total operating expenses	73,634	37,103	136,880	70,614
Loss from operations	(72,626)	(36,685)	(134,044)	(67,499)
Investment and other income, net	3,670	767	6,772	672
Loss before income taxes and equity method investment gain (loss)	(68,956)	(35,918)	(127,272)	(66,827)
Equity method investment gain (loss)	2,012	(1,730)	151	(2,505)
Net loss	$ (66,944)	$ (37,648)	$ (127,121)	$ (69,332)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.94)	$ (0.61)	$ (1.79)	$ (1.15)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	71,592	61,983	71,150	60,175
Other comprehensive income (loss):				
Foreign currency translation adjustments, net of tax of $0	(25)	(501)	445	(394)
Unrealized gain (loss) on marketable debt securities, net of tax of $0	411	(493)	1,394	(2,082)
Total other comprehensive income (loss)	386	(994)	1,839	(2,476)
Comprehensive loss	$ (66,558)	$ (38,642)	$ (125,282)	$ (71,808)

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	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Income (Loss)	Equity
Balance at December 31, 2022	65,471	$ 7	$ 864,729	$ (419,631)	$ (3,164)	441,941
Issuance of common stock upon exercise of stock options and vesting of restricted stock units	432	—	1,666	—	—	1,666
Issuance of common stock under the at-the-market sales agreement, net of issuance costs	919		19,600			19,600
Stock-based compensation expense	—	—	7,910	—	—	7,910
Other comprehensive loss	—	—	—	—	1,453	1,453
Net loss	—	—	—	(60,177)	—	(60,177)
Balance at March 31, 2023	66,822	$ 7	$ 893,905	$ (479,808)	$ (1,711)	$ 412,393
Issuance of common stock upon exercise of stock options, issuance of common stock under Employee Stock Purchase Plan, and vesting of restricted stock units	257	—	2,012	—	—	2,012
Stock-based compensation	—	—	9,192	—	—	9,192
Other comprehensive income	—	—	—	—	386	386
Net loss	—	—	—	(66,944)	—	(66,944)
Balance at June 30, 2023	67,079	$ 7	$ 905,109	$ (546,752)	$ (1,325)	$ 357,039

	Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Income (Loss)	Equity
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	—	—	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

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)

	Six Months Ended June 30,	
	2023	2022
Cash Flows from Operating Activities		
Net loss	$ (127,121)	$ (69,332)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	2,351	1,702
Loss on disposal of property and equipment	—	234
Amortization of intangible assets	866	858
Non-cash operating lease expense	3,062	3,092
Stock-based compensation expense	17,102	9,029
Change in fair value of contingent consideration and contingent value rights liabilities	2,769	(3,022)
Accretion of discounts and amortization of premiums on marketable securities	(2,704)	706
Equity method investment (gain) loss	(151)	2,505
Gain on termination of lease	(253)	—
Changes in operating assets and liabilities:		
Accounts receivable	(2,011)	6,946
Prepaid expenses and other assets	(5,807)	(2,503)
Accounts payable	6,523	(3,723)
Accrued and other liabilities	(4,314)	273
Operating lease liabilities	(2,175)	(2,105)
Net cash used in operating activities	(111,863)	(55,340)
Cash Flows from Investing Activities		
Purchases of marketable securities	(91,614)	(152,213)
Proceeds from marketable securities	193,600	63,479
Purchases of property and equipment	(1,546)	(601)
Net cash provided by (used in) investing activities	100,440	(89,335)
Cash Flows from Financing Activities		
Proceeds from exercise of stock options and warrants and from Employee Stock Purchase Plan	3,678	3,185
Proceeds from at-the-market-sales agreement, net of issuance costs	19,600	—
Proceeds from issuance of common stock and accompanying pre-funded warrants in underwritten public offering, net of issuance costs	—	113,505
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	23,278	108,904
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(144)	(26)
Net increase (decrease) in cash, cash equivalents and restricted cash	11,711	(35,797)
Cash, cash equivalents and restricted cash at beginning of period	117,512	183,798
Cash, cash equivalents and restricted cash at end of period	$ 129,223	$ 148,001
Reconciliation of Cash, Cash Equivalents and Restricted Cash		
Cash and cash equivalents	$ 127,149	$ 145,927
Restricted cash	2,074	2,074
Total cash, cash equivalents and restricted cash	$ 129,223	$ 148,001
Supplemental Cash Flow Information		
Cash paid for amounts included in the measurement of lease liabilities	$ 2,053	$ 3,686
Change in right-of-use assets obtained in exchange for operating lease liabilities	$ (3,077)	$ —
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	$ 344	$ 87
Issuance costs incurred but unpaid	$ —	$ 423
Receivable from option exercises	$ 31	$ —

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. Our lead clinical program is atrasentan, a potent and selective endothelin A receptor antagonist. We are currently conducting the phase 3 ALIGN trial of atrasentan for IgA nephropathy ("IgAN") and the phase 2 AFFINITY basket trial for proteinuric glomerular diseases. Our second product candidate, BION-1301, or zigakibart, is an anti-APRIL monoclonal antibody also in phase 3 development for patients with IgAN. Our third product candidate is CHK-336, an oral small molecule lactate dehydrogenase inhibitor for the treatment of primary and idiopathic hyperoxaluria that is currently in phase 1 development. 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.

Agreement and Plan of Merger

In June 2023, we entered into an Agreement and Plan of Merger (the "Merger Agreement") with Novartis AG, a company organized under the laws of Switzerland ("Novartis"), and Cherry Merger Sub Inc., a Delaware corporation and an indirect wholly owned subsidiary of Novartis ("Merger Sub"). Subject to the terms and conditions of the Merger Agreement, Merger Sub will be merged with and into Chinook (the "Merger"), with Chinook surviving the Merger as a wholly owned subsidiary of Novartis. The Merger Agreement provides that at the effective time of the Merger (the "Effective Time"), each outstanding share of Company common stock, par value $0.0001 per share, will automatically be converted into the right to receive (i) $40.00 in cash, without interest and less any applicable withholding taxes, and (ii) one contractual contingent value right ("New CVR") pursuant to the CVR Agreement to be entered into at or prior to the Effective Time of the Merger by Novartis and Computershare Trust Company, N.A. as rights agent (the "New CVR Agreement"). Following the consummation of the Merger, the Company will cease to be a publicly traded company.

The consummation of the Merger is subject to certain closing conditions, including (i) the adoption of the Merger Agreement by the holders of a majority of the outstanding shares of Company common stock, (ii) the expiration or termination of the applicable waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, with such waiting period having expired on July 31, 2023 and (iii) the absence of any legal restraints that have the effect of preventing the consummation of the Merger. Moreover, each party's obligation to consummate the Merger is subject to certain other conditions, including the accuracy of the other party's representations and warranties in the Merger Agreement (subject to certain materiality qualifiers), the other party's compliance in all material respects with its obligations under the Merger Agreement, the absence of any pending proceeding by a governmental entity and, to the extent required, certain other regulatory approvals. On August 2, 2023, our stockholders voted in favor of the adoption of the Merger Agreement. We expect to consummate the Merger on or about August 11, 2023.

2. Summary of Significant Accounting Policies

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 six months ended June 30, 2023 are not necessarily indicative of the results to be expected for the year ending December 31, 2023 or for any other interim period or for any other future year.

The accompanying unaudited 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, 2022 included in our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on February 27, 2023.

The unaudited 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.

Significant Accounting Policies

There have been no significant changes to the accounting policies during the six months ended June 30, 2023, as compared to the significant accounting policies described in Note 2 of the "Notes to Consolidated Financial Statements" in our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2022.

3. Reverse Merger and Contingent Value Rights

Chinook Therapeutics U.S., Inc. ("Private Chinook") completed a merger with Aduro Biotech, Inc. ("Aduro") on October 5, 2020 (the "Aduro Merger"). Refer to Note 1 "Description of Business" in our Annual Report on Form 10-K for the year ended December 31, 2022 for more information. At the effective time of the Aduro Merger, we also entered into an agreement pursuant to which Aduro's common stockholders of record as of the close of business on October 2, 2020 received one CVR for each outstanding share of Aduro common stock held by such stockholder on such date (the "CVR Agreement"). Each CVR represents the contractual right to receive payments from us upon the receipt of consideration resulting from certain events described in the CVR Agreement, 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):

	June 30, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Cash and cash equivalents:				
Cash	$ 3,828	$ —	$ —	$ 3,828
Money market funds	71,998	—	—	71,998
Commercial paper	14,461	—	(2)	14,459
U.S. government and agency securities	36,852	12	—	36,864
Total cash and cash equivalents	$ 127,139	$ 12	$ (2)	$ 127,149
Marketable securities:				
Commercial paper	$ 35,524	$ —	$ (39)	$ 35,485
U.S. government and agency securities	120,345	3	(538)	119,810
Corporate debt securities	16,785	—	(92)	16,693
Total marketable securities	$ 172,654	$ 3	$ (669)	$ 171,988

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

The amortized cost and estimated fair value of our available-for-sale marketable securities by contractual maturity are summarized below as of June 30, 2023 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Mature in one year or less	$ 170,659	$ 1	$ (644)	$ 170,016
Mature after one year through two years	1,995	2	(25)	1,972
Total available-for-sale marketable securities	$ 172,654	$ 3	$ (669)	$ 171,988

For all securities with a fair value less than its amortized cost basis, we determined the decline in fair value below amortized cost basis to be noncredit related. We have not recognized any impairment losses through June 30, 2023.

5. Fair Value Measurements

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

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

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

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

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

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

	June 30, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and cash equivalents:				
Cash and money market funds	$ 75,826	$ —	$ —	$ 75,826
Commercial paper	—	14,459	—	14,459
U.S. government and agency securities	—	36,864	—	36,864
Total cash and cash equivalents	75,826	51,323	—	127,149
Marketable securities:				
Commercial paper	—	35,485	—	35,485
U.S. government and agency securities	—	119,810	—	119,810
Corporate debt securities	—	16,693	—	16,693
Total marketable securities	—	171,988	—	171,988
Total fair value of assets	$ 75,826	$ 223,311	$ —	$ 299,137
Liabilities:				
Contingent value rights liability	$ —	$ —	$ 42,717	$ 42,717
Contingent consideration liability	—	—	4,290	4,290
Total fair value of liabilities	$ —	$ —	$ 47,007	$ 47,007

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

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, 2022	$ 39,818	$ 4,420
Net change in fair value upon remeasurement	2,899	(130)
Balance at June 30, 2023	$ 42,717	$ 4,290

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

The fair value of the CVR liability increased during the six months ended June 30, 2023 by $2.9 million primarily due to remeasuring the value of our preferred shares in Sairopa at estimated fair value mainly as a result of Sairopa executing a license agreement for its SIRPa inhibitor ADU-1805 with Exelixis, Inc. in November 2022. The contingent consideration liability did not change significantly during the six months ended June 30, 2023. In addition, 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):

	June 30, 2023	December 31, 2022
Research and lab equipment	$ 3,640	$ 3,212
Computer equipment and software	2,733	1,670
Furniture and fixtures	1,354	1,351
Leasehold improvements	17,750	16,957
Construction in progress	339	895
Total property and equipment	25,816	24,085
Total accumulated depreciation	(9,581)	(7,177)
Property and equipment, net	$ 16,235	$ 16,908

Depreciation and amortization expense for property and equipment was $1.5 million and $0.8 million for the three months ended June 30, 2023 and 2022, respectively, and was $2.4 million and $1.7 million for the six months ended June 30, 2023 and 2022, respectively. Approximately $2.9 million of our property and equipment as of June 30, 2023 is located in Canada.

7. Intangible Assets

Intangible assets

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

	June 30, 2023		
	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Intangible assets with finite lives:			
Acquired license agreement	$ 26,685	$ 4,322	$ 22,363
In-place lease	1,433	375	1,058
Total intangible assets with finite lives	28,118	4,697	23,421
Acquired in-process research & development ("IPR&D") assets	36,550	—	36,550
Total intangible and acquired IPR&D assets	$ 64,668	$ 4,697	$ 59,971

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

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 June 30, 2023 and 2022 and was $0.9 million for both the six months ended June 30, 2023 and 2022. Based on finite-lived intangible assets recorded as of June 30, 2023, the estimated future amortization expense for the next five years is as follows (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2023 (remaining six months)	$ 866
2024	1,733
2025	1,733
2026	1,733
2027	1,733
Thereafter	15,623

8. Accrued and Other Current Liabilities

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

	June 30, 2023	December 31, 2022
Research and development costs	$ 19,689	$ 21,970
Compensation and benefits	8,581	11,085
Sublease rent and security deposit	—	157
Business taxes and licensing fees	45	—
Consulting and outside services	971	403
Other	56	21
Total accrued and other current liabilities	$ 29,342	$ 33,636

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 zigakibart in the Territory for use in all human indications. In return, Chinook received 40.0 million Series A preferred shares in SanReno representing 50% ownership of the outstanding voting securities and a warrant to purchase a total of 5.0 million common shares of SanReno at an exercise price of $0.01 per share upon the attainment of regulatory exclusivity for atrasentan in the Territory. Such warrant will only be exercisable if and provided that SanReno obtains, before the 10-year anniversary of the closing of the formation of SanReno, the regulatory exclusivity for atrasentan in China for at least three years commencing from the New Drug Application approval by the National Medical Product Administration of China. The warrant will have a five-year exercise period after it becomes exercisable upon satisfaction of the exercise conditions and was valued at $1.2 million on the grant date based on the probability of exercise of the warrant and the market for such instruments. An investor syndicate led by Frazier Healthcare Partners and Pivotal bioVenture Partners China, along with existing Chinook investors Versant Ventures and Samsara BioCapital, invested $40.0 million in exchange for the remaining 50% of the outstanding voting securities of SanReno. Refer to Note 11 "Collaboration and License Agreements" for more information regarding the China License Agreement.

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

We account for the investment in SanReno in accordance with the provisions of ASC Topic 321, *Investments – Equity Securities*, and elect to use the measurement alternative therein. As such, the investment is valued at $41.2 million as of June 30, 2023, 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. We have not recognized any impairment losses through June 30, 2023.

Pursuant to the terms of the Series A preferred stock, we are entitled to non-cumulative dividends at 8% of our initial investment, payable when and if declared by the board of directors of SanReno. Dividends from our investment in equity securities, if declared, are reflected in the consolidated statements of operations and comprehensive loss. There were no dividends declared through June 30, 2023.

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 June 30, 2023, 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. In November 2022, Sairopa executed a license agreement with Exelixis, Inc (“Exelixis”). Under the terms of the agreement, Exelixis made an upfront payment of $40.0 million to obtain an exclusive, worldwide license to develop and commercialize ADU-1805 and other anti-SIRPα antibodies, and for certain expenses to be incurred by Sairopa in conducting phase 1 clinical studies of ADU-1805. Additionally, during the first quarter of 2023, Sairopa earned a $35.0 million milestone under the terms of the agreement. Sairopa is eligible to receive additional near-term development milestone payments totaling up to $62.5 million. Following the completion of certain clinical studies, Exelixis may exercise an option to continue the license agreement for $225.0 million based upon its evaluation of a pre-specified clinical data package to be delivered by Sairopa. Following the exercise of the option, Sairopa would be eligible to receive up to $465.0 million in additional development, commercial, and net sales milestone payments, as well as tiered royalties on future net sales of products.

Our equity method investment is also adjusted each period for gains or losses from changes in our ownership interest in Sairopa, if any. We assess our equity method investment for impairment whenever events or changes in circumstances indicate that the carrying value of the investment may not be recoverable. We have not recognized any impairment losses through June 30, 2023.

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 zigakibart 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 zigakibart; (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. Refer to Note 11 “Collaboration and License Agreements” in our Annual Report on Form 10-K for the year ended December 31, 2022.

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 June 30, 2023 and 2022, we recognized revenue of $0.7 million and $0.4 million, respectively, under the China License Agreement for costs reimbursed related to opt-in global studies and manufacturing and supply services. For the six months ended June 30, 2023 and 2022, we recognized revenue of $2.5 million and $3.1 million, respectively, 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 zigakibart. 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 zigakibart 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 zigakibart outside of the Territory.

The potential progress-dependent cash milestone payment that we are eligible to receive 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 six months ended June 30, 2023 and 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 $135.0 million in the aggregate, as well as pay royalties on the worldwide net sales of licensed products ranging from upper-single-digit to high-teen percentages.

We did not recognize any milestone payments for the three and six months ended June 30, 2023 and 2022. As of June 30, 2023 and December 31, 2022, we did not have any payable or receivable balances associated with the License Agreement.

Merck

In connection with the Aduro 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 Aduro 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.

Eli Lilly and Company

In connection with the Aduro 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.

We did not recognize revenue for the three and six months ended June 30, 2023 and 2022 under the Lilly agreement.

12. Commitments and Contingencies

Leases

We have a total of three operating leases as of June 30, 2023 with remaining lease terms of approximately 3 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 with an original lease term of 58 months. In April 2023, the sublandlord declared bankruptcy which terminated the Seattle Sublease. As a result, our Seattle Sublease term changed to a month-to-month basis with the landlord. Therefore, we derecognized the operating lease liabilities and assets related to this lease, which resulted in a gain of $0.3 million recorded in other income in the consolidated statements of operations and comprehensive loss. We also wrote-off $0.6 million of leasehold improvements related to this office space.

As of June 30, 2023, we are subleasing approximately 112,000 square feet in one of our facilities. Sublease income was $3.5 million and $2.0 million for the three months ended June 30, 2023 and 2022, respectively, and was $5.3 million and $4.0 million for the six months ended June 30, 2023 and 2022, respectively, which was netted against rent expense and is recorded as a component of general and administrative expenses in the consolidated statement of operations and comprehensive loss. Total sublease income to be earned, in aggregate, will be approximately $53.0 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 June 30, 2023. 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 June 30, 2023.

The maturity of our operating lease liabilities as of June 30, 2023 is as follows (in thousands):

Undiscounted Lease Payments	Amounts
2023 (remaining six months)	$ 3,260
2024	6,590
2025	6,711
2026	6,706
2027	6,484
Thereafter	12,421
Total undiscounted lease payments	42,172
Present value adjustment	(8,187)
Total net lease liability	$ 33,985
Net lease liability - current	$ 4,268
Net lease liability - non-current	29,717
Total net lease liability	$ 33,985

Rent expense recognized for operating leases was $2.3 million for both the three months ended June 30, 2023 and 2022, respectively, and was $4.7 million for both the six months ended June 30, 2023 and 2022. Variable lease payments, including non-lease components such as common area maintenance fees, recognized as rent expense for operating leases were $0.6 million and $0.8 million for the three months ended June 30, 2023 and 2022, respectively, and were $1.6 million for both the six months ended June 30, 2023 and 2022.

The following summarizes additional information related to our operating leases:

	June 30, 2023	December 31, 2022
Weighted-average remaining lease terms (in years)		
Operating leases	6.3	6.5
Weighted-average discount rate		
Operating leases	7.2%	7.4%

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

At-the-Market Sales Agreement

In April 2021, we entered into an "at-the-market" sales agreement (the "2021 Sales Agreement"), with Cantor Fitzgerald & Co. and SVB Securities LLC, previously known as SVB Leerink LLC, through which we may offer and sell shares of our common stock having an aggregate offering of up to $75.0 million through our sales agents, Cantor Fitzgerald & Co. and SVB Securities LLC. In November 2022, we amended the 2021 Sales Agreement to provide for offerings of up to $150.0 million. We will pay the sales agents a commission of up to 3% of the gross proceeds of sales made through the 2021 Sales Agreement. In the first quarter of 2023, we sold 0.9 million shares for $19.6 million in net proceeds under the 2021 Sales Agreement. As of June 30, 2023, we have $115.6 million remaining under the 2021 Sales Agreement, which is subject to the continued effectiveness of our automatic shelf registration statement on Form S-3 ASR (Registration No. 333-265168), or upon an effective replacement shelf registration statement.

14. Stock-Based Compensation

Equity Incentive Plans

In 2019, Private Chinook adopted the 2019 Equity Incentive Plan (the "2019 Plan"). In connection with the Aduro Merger, we assumed Aduro's two equity incentive plans, the Amended and Restated 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.

In 2022, our board of directors approved the 2022 Employment Inducement Incentive Award Plan (the "2022 Inducement Plan"). We reserved 1.5 million shares of our common stock for issuance pursuant to awards to be granted under the 2022 Inducement Plan. The terms of the 2022 Inducement Plan are substantially similar to the terms of the Plans with the exception that awards may only be made to an employee who has not previously been an employee or member of our board of directors if the award is in connection with commencement of employment. As of June 30, 2023 and December 31, 2022, there were 2.2 million and 2.1 million shares available for future grant, respectively, under the Plans and the 2022 Inducement Plan.

In connection with the Aduro Merger, we assumed Aduro's 2015 employee stock purchase plan ("2015 ESPP"). As of June 30, 2023 and December 31, 2022, there were 1.7 million and 1.1 million shares available for future issuance under the 2015 ESPP, respectively. As of June 30, 2023, there was $0.3 million of total unrecognized compensation expense related to ESPP that is expected to be recognized over a weighted-average period of 0.4 years.

Stock option activity under the Plans and the 2022 Inducement Plan 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, 2022	6,127	$ 12.49	8.2	$ 85,766
Granted	2,048	24.55		
Exercised	(264)	9.39		
Canceled or forfeited	(70)	19.40		
Balance—June 30, 2023	7,841	$ 15.68	8.2	$ 179,517
Options exercisable—June 30, 2023	3,146	$ 11.22	7.3	$ 86,835
Options vested and expected to vest—June 30, 2023	7,841	$ 15.68	8.2	$ 179,517

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 June 30, 2023. Options for 0.3 million and 0.4 million shares of our common stock were exercised during the six months ended June 30, 2023 and 2022, respectively, with an intrinsic value of $4.0 million and $2.7 million, respectively. As of June 30, 2023, there was $56.1 million of total unrecognized compensation expense related to stock options that is expected to be recognized over a weighted-average period of 2.7 years.

Restricted stock unit ("RSU") activity under the Plans and the 2022 Inducement Plan is set forth below:

	RSUs Outstanding	
	Number of RSUs (in thousands)	Weighted-Average Grant Date Fair Value Per Share
Balance—December 31, 2022	1,364	$ 15.33
Granted	701	24.46
Vested	(360)	14.35
Canceled or forfeited	(34)	19.39
Balance—June 30, 2023	1,671	$ 19.30

The total fair value of RSUs that vested in the six months ended June 30, 2023 and 2022 was $9.1 million and $2.2 million, respectively. As of June 30, 2023, there was $25.9 million of total unrecognized compensation expense related to RSUs that is expected to be recognized over a weighted-average period of 1.8 years.

Performance share unit ("PSU") activity under the Plans is set forth below:

	PSUs Outstanding	
	Number of PSUs (in thousands)	Weighted-Average Grant Date Fair Value Per Share
Balance—December 31, 2022	812	$ 22.00
Canceled or forfeited	(28)	21.75
Balance—June 30, 2023	784	$ 22.00

In 2022, we granted PSUs to our employees under the Plans. The vesting of these awards is subject to the achievement of specified regulatory performance targets. As of June 30, 2023, there was $17.3 million of total unrecognized compensation expense related to these PSUs with performance targets that are considered not probable of achievement.

Valuation Assumptions

The weighted-average assumptions used to estimate the fair value of stock options under the Plans and the 2022 Inducement Plan using the Black-Scholes option-pricing model and the resulting weighted-average grant date fair value were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Assumptions:				
Expected term (in years)	6.3	6.2	6.3	6.2
Volatility	74.7%	77.0%	75.3%	77.6%
Risk-free interest rate	3.5%	2.9%	3.6%	2.0%
Dividend yield	—	—	—	—

	Six Months Ended June 30,	
	2023	2022
Fair Value:		
Weighted-average grant date fair value per share	$ 16.98	$ 9.28

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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Assumptions:				
Expected term (in years)	0.5	0.5	0.5	0.5
Volatility	50.1%	57.1%	50.1%	57.1%
Risk-free interest rate	5.3%	0.0%	5.3%	0.0%
Dividend yield	—	—	—	—

	Six Months Ended June 30,	
	2023	2022
Fair Value:		
Weighted-average grant date fair value per share	$ 6.66	$ 4.29

Stock-Based Compensation Expense

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Research and development	$ 5,125	$ 2,355	$ 9,451	$ 4,540
General and administrative	4,067	2,405	7,651	4,489
Total stock-based compensation expense	$ 9,192	$ 4,760	$ 17,102	$ 9,029

15. Income Taxes

No income tax benefit or expense was recorded for the three and six months ended June 30, 2023 and 2022. 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.

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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Numerator:				
Net loss attributable to common stockholders	$ (66,944)	$ (37,648)	$ (127,121)	$ (69,332)
Denominator:				
Weighted-average shares outstanding	71,592	62,040	71,151	60,244
Less: weighted-average unvested restricted shares and shares subject to repurchase	—	(57)	(1)	(69)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	71,592	61,983	71,150	60,175
Net loss per share attributable to common stockholders, basic and diluted	$ (0.94)	$ (0.61)	(1.79)	(1.15)

As of June 30, 2023 and 2022, 4.6 million and 3.6 million pre-funded warrants to purchase common stock, respectively, issued in connection with the November 2021 and May 2022 public offerings, were included in the weighted-average shares outstanding used in the calculation of basic and diluted net loss per share. In the third quarter of 2023, 4.6 million pre-funded warrants were exercised.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Unvested RSUs	1,671	1,286	1,671	1,286
Unvested RSAs	—	46	—	46
Unvested PSUs	784	—	784	—
Options to purchase common stock	7,841	6,987	7,841	6,987
Total	10,296	8,319	10,296	8,319

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, 2022, included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or the SEC.

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. Our second product candidate, BION-1301, or zigakibart, is an anti-APRIL monoclonal antibody also in phase 3 development for patients with IgAN. Our third product candidate is CHK-336, an oral small molecule lactate dehydrogenase, or LDHA inhibitor for the treatment of primary and idiopathic hyperoxaluria that is currently in phase 1 development. In May 2023, we announced a collaboration with Ionis Pharmaceuticals, Inc, or Ionis, to develop an antisense oligonucleotide, or ASO, therapy for a rare, severe chronic kidney disease with significant unmet medical need. In addition, we are conducting research programs in several other rare, severe chronic kidney diseases. In November 2021, we established SanReno Therapeutics, or SanReno, a joint venture to develop, manufacture and commercialize kidney disease therapies in mainland China, Hong Kong, Macau, Taiwan and Singapore.

In June 2023, we entered into an Agreement and Plan of Merger, or the Merger Agreement, with Novartis AG, or Novartis, a company organized under the laws of Switzerland, and Cherry Merger Sub Inc., a Delaware corporation and an indirect wholly owned subsidiary of Novartis, or Merger Sub. The Merger Agreement provides that, among other things and on the terms and subject to the conditions set forth therein, (i) Merger Sub will be merged with and into Chinook, or the Merger, with Chinook surviving the Merger as a wholly owned subsidiary of Novartis, and (ii) at the effective time of the Merger, each outstanding share of Company common stock, par value $0.0001 per share, will automatically be converted into the right to receive (a) $40.00 in cash, without interest and less any applicable withholding taxes, and (b) one contractual contingent value right, or New CVR. At or prior to the effective time for the Merger, Novartis will also authorize, execute and deliver the contingent value rights agreement in connection with the New CVR pursuant to the Merger Agreement. On July 31, 2023, the waiting period under Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended expired. On August 2, 2023, our stockholders voted in favor of the adoption of the Merger Agreement. We expect to consummate the Merger on or about August 11, 2023. Following the consummation of the Merger, the Company will cease to be a public traded company.

Components of Operating Results

Collaboration and License Revenue

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

SanReno Therapeutics

In November 2021, we entered into a License Agreement with SanReno, or the China License Agreement. The China License Agreement includes the transfer of intellectual property rights in the form of a development and commercialization license in the

Territory; manufacturing and supply services; and participation in opt-in global studies with the collaboration party. The terms of the China License Agreement also include potential payments to us for the following: progress-dependent milestone payment; royalties on the net sales of a licensed product and reimbursement for certain expenses incurred. As of June 30, 2023, 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 Aduro 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 unaudited 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 and the discovery and development of our product candidates. Research and development costs include employee-related costs; licensing costs; materials and supplies; contracted research and manufacturing; consulting arrangements; allocated costs, such as facility costs; and other expenses incurred to advance our research and development activities. Employee-related costs consist of salaries, bonuses, severance and benefits. We recognize all research and development costs as they are incurred. Clinical trial costs, contract manufacturing and other development costs incurred by third parties are expensed as the contracted work is performed.

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

Amortization of Intangible Assets

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

Investment and Other Income (Expense), Net

Investment and 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.

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 unaudited 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 June 30, 2023 and 2022

	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Change
		(In thousands)	
Collaboration and license revenue	$ 1,008	$ 418	$ 590
Operating expenses:			
Research and development	57,897	30,023	27,874
General and administrative	13,061	8,635	4,426
Change in fair value of contingent consideration and contingent value rights liabilities	2,243	(1,984)	4,227
Amortization of intangible assets	433	429	4
Total operating expenses	73,634	37,103	36,531
Loss from operations	(72,626)	(36,685)	(35,941)
Investment and other income, net	3,670	767	2,903
Loss before income taxes and equity method investment gain (loss)	(68,956)	(35,918)	(33,038)
Equity method investment gain (loss)	2,012	(1,730)	3,742
Net loss	$ (66,944)	$ (37,648)	$ (29,296)

Collaboration and License Revenue

Total revenue was $1.0 million for the three months ended June 30, 2023, an increase of $0.6 million compared to $0.4 million for the three months ended June 30, 2022. The increase was primarily due to higher revenue recognized in the second quarter of 2023 related to 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 June 30, 2023 and 2022:

	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Change
	(In thousands)		
Product Candidates			
Atrasentan	$ 15,000	$ 13,188	$ 1,812
Zigakibart (BION-1301)	15,538	4,121	11,417
CHK-336	1,528	1,779	(251)
Other discovery, research and development programs	2,992	3,292	(300)
Subtotal	35,058	22,380	12,678
Stock-based compensation expense	5,125	2,355	2,770
Facility and depreciation costs	2,571	1,569	1,002
Other general research and development expenses	15,143	3,719	11,424
Total research and development expenses	$ 57,897	$ 30,023	$ 27,874

	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Change
		(In thousands)	
Licensing and contract research and manufacturing	$ 28,747	$ 12,244	$ 16,503
Employee-related costs	14,882	9,778	5,104
Supplies used in research and development	648	481	167
Stock-based compensation expense	5,125	2,355	2,770
Facility and depreciation costs	2,571	1,569	1,002
Consulting and outside services	4,343	2,734	1,609
Other	1,581	862	719
Total research and development expenses	$ 57,897	$ 30,023	$ 27,874

Research and development expenses were $57.9 million for the three months ended June 30, 2023, an increase of $27.9 million compared to $30.0 million for the three months ended June 30, 2022. The increase in research and development expenses was primarily due to higher licensing, contract research and manufacturing costs, which included a $10.0 million one-time payment in 2023 associated with a collaboration for a pre-clinical research program; employee-related costs, including stock-based compensation expense; and spending for consulting, outside services, and other costs. These higher costs also primarily resulted from startup activities for additional clinical trials and an increase in hiring to support our clinical programs.

General and Administrative Expenses

The following table summarizes our general and administrative expenses incurred during the three months ended June 30, 2023 and 2022:

	Three Months Ended June 30, 2023	2022	Change
		(In thousands)	
Consulting and outside services	$ 3,465	$ 2,796	$ 669
Employee-related costs	4,371	2,422	1,949
Stock-based compensation expense	4,067	2,405	1,662
Facility and depreciation costs	69	460	(391)
Other	1,089	552	537
Total general and administrative expenses	$ 13,061	$ 8,635	$ 4,426

General and administrative expenses were $13.1 million for the three months ended June 30, 2023, an increase of $4.4 million compared to $8.6 million for the three months ended June 30, 2022. The increase in general and administrative expenses was primarily due to higher employee-related costs, including stock-based compensation expense, which primarily resulted from increased headcount to continue to support our operations, higher consulting and outside services, and other costs. These increases were offset by a decrease in facilities costs, which are allocable from general and administrative to research and development expenses based on headcount.

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 $2.2 million for the three months ended June 30, 2023, an increase of $4.2 million compared to a benefit of $2.0 million for the three months ended June 30, 2022. The increase primarily resulted from remeasuring the value of our preferred shares in Sairopa at estimated fair value mainly as a result of Sairopa executing a license agreement for its SIRPa inhibitor ADU-1805 with Exelixis, Inc. in November 2022.

Amortization of intangible assets

Amortization of intangible assets expense was $0.4 million for both the three months ended June 30, 2023 and 2022 and was related to normal amortization of finite-lived intangible assets acquired in the Aduro Merger.

Equity method investment loss

Equity method investment loss decreased by $3.7 million for the three months ended June 30, 2023 compared to the three months ended June 30, 2022, resulting from our share of net loss of the Sairopa investment, net of any taxes.

Comparison of the Six Months Ended June 30, 2023 and 2022

	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022	Change
	(In thousands)		
Collaboration and license revenue	$ 2,836	$ 3,115	$ (279)
Operating expenses:			
Research and development	108,780	56,275	52,505
General and administrative	24,465	16,503	7,962
Change in fair value of contingent consideration and contingent value rights liabilities	2,769	(3,022)	5,791
Amortization of intangible assets	866	858	8
Total operating expenses	136,880	70,614	66,266
Loss from operations	(134,044)	(67,499)	(66,545)
Investment and other income, net	6,772	672	6,100
Loss before income taxes and equity method investment gain (loss)	(127,272)	(66,827)	(60,445)
Equity method investment gain (loss)	151	(2,505)	2,656
Net loss	$ (127,121)	$ (69,332)	$ (57,789)

Collaboration and License Revenue

Total revenue was $2.8 million for the six months ended June 30, 2023, a decrease of $0.3 million compared to $3.1 million for the six months ended June 30, 2022. The decrease was due to lower revenue recognized in the six months ended June 30, 2023 related to 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 six months ended June 30, 2023 and 2022:

	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022	Change
	(In thousands)		
Product Candidates			
Atrasentan	$ 34,041	$ 23,789	$ 10,252
Zigakibart (BION-1301)	30,019	8,925	21,094
CHK-336	4,387	4,109	278
Other discovery, research and development programs	6,072	6,333	(261)
Subtotal	74,519	43,156	31,363
Stock-based compensation expense	9,451	4,540	4,911
Facility and depreciation costs	4,429	3,016	1,413
Other general research and development expenses	20,381	5,563	14,818
Total research and development expenses	$ 108,780	$ 56,275	$ 52,505

	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022	Change
	(In thousands)		
Licensing and contract research and manufacturing	$ 52,467	$ 22,451	$ 30,016
Employee-related costs	29,471	19,041	10,430
Supplies used in research and development	1,186	905	281
Stock-based compensation expense	9,451	4,540	4,911
Facility and depreciation costs	4,429	3,016	1,413
Consulting and outside services	8,593	4,790	3,803
Other	3,183	1,532	1,651
Total research and development	$ 108,780	$ 56,275	$ 52,505

Research and development expenses were $108.8 million for the six months ended June 30, 2023, an increase of $52.5 million compared to $56.3 million for the six months ended June 30, 2022. The increase in research and development expenses was primarily due to higher licensing, contract research and manufacturing costs, which included a $10.0 million one-time payment in 2023 associated with a collaboration for a pre-clinical research program; employee-related costs, including stock-based compensation expense; and spending for consulting, outside services, and facilities and other costs. These higher costs also primarily resulted from completing enrollment of the phase 3 ALIGN trial, startup activities for additional clinical trials, and an increase in hiring to support our clinical programs.

General and Administrative Expenses

The following table summarizes our general and administrative expenses incurred during the six months ended June 30, 2023 and 2022:

	Six Months Ended June 30,		
	2023	2022	Change
	(In thousands)		
Consulting and outside services	$ 6,303	$ 5,128	$ 1,175
Employee-related costs	8,638	5,038	3,600
Stock-based compensation expense	7,651	4,489	3,162
Facility and depreciation costs	(84)	811	(895)
Other	1,957	1,037	920
Total general and administrative expenses	$ 24,465	$ 16,503	$ 7,962

General and administrative expenses were $24.5 million for the six months ended June 30, 2023, an increase of $8.0 million compared to $16.5 million for the six months ended June 30, 2022. The increase in general and administrative expenses was primarily due to higher employee-related costs, including stock-based compensation expense, which resulted from increased headcount to continue to support our operations, higher consulting and outside services, and other costs. These increases were offset by a decrease in facilities costs, which are allocable from general and administrative to research and development expenses based on headcount.

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 $2.8 million for the six months ended June 30, 2023, an increase of $5.8 million compared to a benefit of $3.0 million for the six months ended June 30, 2022. The increase primarily resulted from remeasuring the value of our preferred shares in Sairopa at estimated fair value mainly as a result of Sairopa executing a license agreement for its SIRPa inhibitor ADU-1805 with Exelixis, Inc. in November 2022.

Amortization of intangible assets

Amortization of intangible assets expense was $0.9 million for both the six months ended June 30, 2023 and 2022 and was related to normal amortization of finite-lived intangible assets acquired in the Aduro Merger.

Equity method investment loss

Equity method investment loss decreased by $2.7 million for the six months ended June 30, 2023 compared to the six months ended June 30, 2022, resulting from our share of net loss of the Sairopa investment, net of any taxes.

Liquidity and Capital Resources

Overview

As of June 30, 2023, we had $299.1 million in cash, cash equivalents and marketable securities.

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

Sources of Liquidity

In May 2022, we completed an underwritten public offering of 7.6 million shares of our common stock at a price to the public of $14.00 per share, which included the exercise in full of the underwriters' option to purchase an additional 1.1 million shares of our common stock in June 2022. As part of this offering, we also sold to certain investors pre-funded warrants, or 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 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, or the 2021 Sales Agreement, with Cantor Fitzgerald & Co. and SVB Securities LLC, previously known as SVB Leerink LLC, through which we may offer and sell shares of our common stock having an aggregate offering of up to $75.0 million through our sales agents, Cantor Fitzgerald & Co. and SVB Securities LLC. In November 2022, we amended the 2021 Sales Agreement to provide for offerings of up to $150.0 million. We will pay the sales agents a commission of up to 3% of the gross proceeds of sales made through the 2021 Sales Agreement. In the first quarter of 2023, we sold 0.9 million shares for $19.6 million in net proceeds under the 2021 Sales Agreement. As of June 30, 2023, we have $115.6 million remaining under the 2021 Sales Agreement.

Funding Requirements

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

- our ability to complete the Merger
- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates;
- the clinical development plans we establish for these product candidates;
- the timelines of our clinical trials and the overall costs to conduct and complete the clinical trials;
- the number and characteristics of product candidates that we develop;
- the cost of manufacturing our product candidates for clinical development and any potential products we successfully commercialize;
- the timing of, and the costs involved in, obtaining regulatory approvals for any product candidates we develop;
- the cost of commercialization activities, if any, of any product candidates we develop independently that are approved for sale, including marketing, sales and distribution costs;
- the timing and amount of any sales of our product candidates, if any, or royalties thereon;
- our ability to establish new collaborations, licensing or other arrangements, if any, and the financial terms of such arrangements;
- opportunities to in-license or otherwise acquire new technologies and therapeutic candidates;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patents, including any litigation costs and the outcomes of any such litigation; and
- the effect of competing technological and market developments.

As of June 30, 2023, our short and long-term material cash requirements from known contractual and other obligations primarily relate to our contractual obligations related to our operating leases. For additional information on our operating lease commitments, refer to Note 12 “Commitments and Contingencies” in our condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report on Form 10-Q.

We do not intend to pursue further funding and, instead, are seeking to complete the Merger with Novartis, who would fund further development and commercialization of our product candidates.

If we are unable to complete the Merger, 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:

	Six Months Ended June 30,	
	2023	2022
	(In thousands)	
Net cash provided by (used in):		
Operating activities	$ (111,863)	$ (55,340)
Investing activities	100,440	(89,335)
Financing activities	23,278	108,904
Effect of exchange rate changes	(144)	(26)
Net change in cash, cash equivalents, and restricted cash	$ 11,711	$ (35,797)

Operating Activities

Net cash used in operating activities was $111.9 million for the six months ended June 30, 2023, an increase of $56.5 million compared to $55.3 million for the six months ended June 30, 2022. The increase was primarily due to an increased operating loss, primarily resulting from research and development and general and administrative spending, as well as changes in net working capital usage.

Investing Activities

Net cash provided by investing activities was $100.4 million for the six months ended June 30, 2023, an increase of $189.8 million compared to net cash used in investing activities of $89.3 million for the six months ended June 30, 2022. The increase was primarily due to net proceeds from maturities of marketable securities, offset in part by purchases of property and equipment.

Financing Activities

Net cash provided by financing activities was $23.3 million for the six months ended June 30, 2023, a decrease of $85.6 million compared to $108.9 million for the six months ended June 30, 2022. The decrease was primarily due to net proceeds of $113.5 million received from the sale of common stock in the May 2022 underwritten public offering, offset in part by net proceeds of $19.6 million received from the sale of common stock under the 2021 Sales Agreement during the six months ended June 30, 2023.

Critical Accounting Policies and Significant Judgments and Estimates

Our unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes in our critical accounting policies during the six months ended June 30, 2023, as compared to those disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates" in our Annual Report on Form 10-K for the year ended December 31, 2022.

Recently Adopted Pronouncements

For information with respect to recently issued accounting standards and the impact of these standards on our unaudited condensed consolidated financial statements, refer to Note 2 "Summary of Significant Accounting Policies" in our unaudited 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

Interest Rate Risk

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. The primary objective of our investment portfolio is to preserve principal and at the same time maximize the income we receive from our investments without significantly increasing risk. As of June 30, 2023 and December 31, 2022, we had total cash, cash equivalents and short- and long-term investments of $299.1 million and $385.3 million, respectively, which consisted of cash, money market funds, U.S. government and agency securities, corporate debt securities, and commercial paper.

Foreign Exchange Risk

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

Item 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 effective at a reasonable assurance level as of June 30, 2023.

Changes in internal control over financial reporting.

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2023 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.

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

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

We are party to legal proceedings that arose in connection with our Preliminary Proxy Statement on Schedule 14A (the “Preliminary Proxy Statement”) filed with SEC on June 27, 2023 and our Definitive Proxy Statement on Schedule 14A (the “Definitive Proxy Statement”) filed with the SEC, on July 10, 2023. On July 6, 2023 a purported individual stockholder of Chinook filed a complaint in the United States District Court for the Southern District of New York, captioned *O’Dell v. Chinook Therapeutics, Inc., et al.*, 1:23-cv-05784, naming as defendants the Company and each member of our board of directors as of the date of the Merger Agreement (*O’Dell*). On July 11, 2023, an additional case was filed by a purported individual stockholder of Chinook in the United States District Court for the Southern District of New York, captioned *Wang v. Chinook Therapeutics, Inc., et al.*, 1:23-cv-05945 (*Wang*). On July 12, 2023, an additional case was filed by a purported individual stockholder of Chinook in the United States District Court for the Southern District of New York, captioned *Casey v. Chinook Therapeutics, Inc., et al.*, 1:23-cv-05986 (*Casey*). On July 13, 2023, an additional case was filed by a purported individual stockholder of Chinook in the United States District Court for the District of Delaware, captioned *Johnson v. Chinook Therapeutics, Inc., et al.*, 1:23-cv-00764-UNA (*Johnson*). The *O’Dell*, *Wang*, *Casey* and *Johnson* cases, and any similar subsequently filed cases involving us, our board of directors or any committee thereof and/or any of our directors or officers relating directly or indirectly to the Merger Agreement, the Merger or any related transaction, are referred to as the “Merger Litigations.”

The Merger Litigations filed to date generally allege that the Preliminary Proxy Statement or the Definitive Proxy Statement is materially incomplete and misleading by allegedly failing to disclose certain purportedly material information. The Merger Litigations assert violations of Section 14(a) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) and Rule 14a-9 promulgated thereunder against us and our board of directors and violations of Section 20(a) of the Exchange Act against our board of directors. The Merger Litigations seek, among other things: an injunction enjoining consummation of the Merger; rescission of the Merger Agreement, rescission of the Merger if consummated; an accounting of all damages suffered; costs of the action, including attorneys’ fees and experts’ fees and expenses; an order directing the filing of a proxy statement that does not contain any untrue statements of material fact; a declaratory order that the defendants violated Section 14(a) and/or Section 20(a) of the Exchange Act; and any other relief the court may deem just and proper.

We cannot predict the outcome of each Merger Litigation, nor can we predict the amount of time and expense that will be required to resolve each Merger Litigation. We believe that the *O’Dell*, *Wang*, *Casey* and *Johnson* cases are without merit and that no supplemental disclosures are required under applicable law. We and our directors intend to vigorously defend against each Merger Litigation and any subsequently filed similar actions. It is possible that additional similar complaints could be filed in connection with the Merger. We cannot estimate the possible loss or range of loss from the Merger Litigations. If any additional complaints are filed, absent new or significantly different allegations, we will not necessarily disclose such additional filings.

In addition, twelve purported stockholders of Chinook sent demand letters regarding the Preliminary Proxy Statement and Definitive Proxy Statement (the “Demand Letters”). Based on the same core allegations as the Merger Litigations, the Demand Letters request that the Company disseminate corrective disclosures in an amendment or supplement to the Preliminary Proxy Statement or Definitive Proxy Statement.

While we believe that the disclosures set forth in the Preliminary Proxy Statement and Definitive Proxy Statement comply fully with all applicable law and denies the allegations in the Merger Litigations and the Demand Letters, in order to moot these disclosure claims, avoid nuisance and possible expense and business delays, and provide additional information to our stockholders, we voluntarily supplemented certain disclosures in the Definitive Proxy Statement related to the aforementioned claims with the supplemental disclosures set forth in our definitive additional materials filed with the SEC on July 26, 2023. Nothing in the definitive additional materials shall be deemed an admission of the legal merit, necessity or materiality under applicable laws of any of the disclosures set forth herein. To the contrary, we specifically deny all allegations in the Merger Litigations and the Demand Letters that any additional disclosure was or is required or material.

We are not party to any other 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:

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

Risks Related to the Merger

The Merger is subject to a number of conditions beyond our control. Failure to complete the Merger within the expected time frame, or at all, could have a material adverse effect on our business, operating results, financial condition and our share price.

On June 11, 2023, we entered into the Merger Agreement, pursuant to which, and on the terms and subject to the conditions set forth therein, (i) Merger Sub will be merged with and into Chinook, or the Merger, with Chinook surviving the Merger and (ii) at the effective time of the Merger, each outstanding share of Company common stock, par value $0.0001 per share, will automatically be converted into the right to receive (A) $40.00 in cash, without interest and less any applicable withholding taxes, and (B) one New CVR.

Consummation of the Merger is subject to certain conditions, including approval by the Company's stockholders, the absence of any legal restraints restraining, enjoining, preventing, prohibiting or otherwise making illegal the consummation of the Merger, or the Governmental Entity Condition, expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, with such waiting period having expired on July 31, 2023 and any other specified required regulatory approvals that may be required will have been obtained, and each party's performance of its obligations in all material respects under the Merger Agreement.

On August 2, 2023, our stockholders voted in favor of the Merger. However, we cannot predict whether and when the other conditions to the Merger will be satisfied. If one or more of these conditions are not satisfied, and as a result, we do not complete the Merger, we would remain liable for significant transaction costs, and the focus of our management would have been diverted from seeking other potential strategic opportunities, in each case without realizing any benefits of the Merger. Certain costs associated with the Merger have already been incurred or may be payable even if the Merger is not consummated. Finally, any disruptions to our business resulting from the announcement and pendency of the Merger, including any adverse changes in our relationships with our partners, suppliers and employees, could continue or accelerate in the event that we fail to consummate the Merger.

Our share price may also fluctuate significantly based on announcements by Novartis, other third parties, or us regarding the Merger or based on market perceptions of the likelihood of the satisfaction of the conditions to the consummation of the Merger. Such announcements may lead to perceptions in the market that the Merger may not be completed, which could cause our share price to fluctuate or decline. Other factors outside of our control, such as a governmental entity enacting legislation that prohibits the Merger, could cause us not to satisfy the governmental entity condition and thus the Merger would not be consummated.

If we do not consummate the Merger, the price of our common stock may decline significantly from the current market price, which may reflect a market assumption that the Merger will be consummated. Any of these events could have a material adverse effect on our business, operating results and financial condition and could cause a decline in the price of our common stock.

Our stockholders may not receive any payment on the New CVRs and the New CVRs may otherwise expire valueless.

If the Merger is completed, the holders of our common stock will be entitled to receive one New CVR per share of common stock, representing the right to receive, subject to the terms and conditions of the New CVR Agreement, up to $4.00 in contingent cash payments from Novartis upon the achievement by specified dates of certain milestones set forth in the New CVR Agreement. The New CVRs will not be transferable, except in the limited circumstances specified in the New CVR Agreement, will not have any voting or dividend rights, and interest will not accrue on any amounts potentially payable on the New CVRs. Accordingly, the right of any of our stockholders to receive any future payment on or derive any value from the New CVRs will be contingent solely upon the achievement of the milestones set forth in the New CVR Agreement, and if these milestones are not achieved for any reason within the time periods specified in the New CVR Agreement, no payments will be made under the New CVRs, and the New CVRs will expire valueless.

Stockholder litigation could prevent or delay the consummation of the Merger or otherwise negatively impact our business, operating results and financial condition.

We may incur additional costs in connection with the defense or settlement of existing and any future stockholder litigation in connection with the Merger. These lawsuits or other future litigation may adversely affect our ability to complete the Merger. We could incur significant costs in connection with any such litigation, including costs associated with the indemnification of our directors and officers. Furthermore, one of the conditions to the consummation of the Merger is the absence of any governmental order or law preventing the consummation of the Merger or making the consummation of the Merger illegal. Consequently, if a plaintiff were to secure injunctive or other relief prohibiting, delaying or otherwise adversely affecting our ability to complete the consummation of the

Offer and Merger, then such injunctive or other relief may prevent the Merger from becoming effective within the expected time frame or at all.

Our executive officers and directors may have interests in the Merger that are different from, or in addition to, those of our stockholders generally.

Our executive officers and directors may have interests in the Merger that are different from, or are in addition to, those of our stockholders generally. These interests include direct or indirect ownership of our common stock and equity awards, the acceleration of equity awards upon consummation of the transactions and other interests. Such interests of our directors and executive officers are set forth in further detail in our definitive proxy statement on Schedule 14A filed by the Company with the SEC on July 10, 2023.

While the Merger is pending, we are subject to business uncertainties and contractual restrictions that could disrupt our business, and the Merger may impair our ability to attract and retain qualified employees or retain and maintain relationships with our suppliers and other business partners.

Whether or not the Merger is consummated, the Merger may disrupt our current plans and operations, which could have an adverse effect on our business and financial results. The pendency of the Merger may also divert management's attention and our resources from ongoing business and operations and our employees and other key personnel may have uncertainties about the effect of the Merger, and the uncertainties may impact our ability to retain, recruit and hire key personnel while the Merger is pending or if it fails to close. Furthermore, if key personnel depart, e.g., because of such uncertainties, our business and results of operations may be adversely affected. In addition, we cannot predict how our suppliers and other business partners will view or react to the Merger upon consummation. If we are unable to reassure our suppliers and other business partners to continue transacting business with us, our financial condition and results of operations may be adversely affected.

In addition, the Merger Agreement generally requires us to operate in the ordinary course of business consistent with past practice, pending consummation of the Merger, and restricts us from taking certain actions with respect to our business and financial affairs without the consent of Novartis. Such restrictions will be in place until either the Merger is consummated or the Merger Agreement is terminated. These restrictions could restrict our ability to, or prevent us from, pursuing attractive business opportunities (if any) that arise prior to the consummation of the Merger. For these and other reasons, the pendency of the Merger could adversely affect our business, operating results and financial condition.

We have incurred, and will continue to incur, direct and indirect costs as a result of the Merger.

We have incurred, and will continue to incur, significant costs and expenses, including fees for professional services and other transaction costs, in connection with the Merger, including costs that we may not currently expect. We must pay substantially all of these costs and expenses whether or not the transaction is completed. If the Merger Agreement is terminated under specified circumstances, we would be required to pay to Novartis a termination fee equal to $112.0 million. There are a number of factors beyond our control that could affect the total amount or the timing of these costs and expenses.

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, Novartis will 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.

The following risk factors do not take into account the proposed Merger and assume that we remain a stand-alone company except as otherwise noted.

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 the industry is volatile and involves a substantial degree of risk. 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 deteriorating macroeconomic factors could materially and adversely affect our stock price and ability to raise additional capital. 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 $127.1 million for the six months ended June 30, 2023. As June 30, 2023, we had an accumulated deficit of $546.8 million. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses over the next several years and for the foreseeable future as we intend to continue to conduct research and development, clinical testing, regulatory compliance activities, manufacturing activities, and, if any of our product candidates are approved, sales and marketing activities that, together with anticipated general and administrative expenses, will likely result in us incurring significant losses for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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

We will require substantial future capital in order to complete planned and future preclinical and clinical development for atrasentan and other product candidates and potentially commercialize these product candidates. Based upon our current operating plan, we believe that our existing cash, cash equivalents, and marketable securities held as of June 30, 2023 will enable us to fund our operating expenses and capital expenditure requirements into 2025. We expect our spending levels to increase in connection with our preclinical studies and clinical trials of our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant expenses related to commercial launch, product sales, medical affairs, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations before any commercial revenue may occur.

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

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

- the costs associated with the scope, progress and results of discovery, preclinical development, laboratory testing and clinical trials for our product candidates;
- the costs associated with the manufacturing of our product candidates;
- the costs related to the extent to which we enter into partnerships or other arrangements with third parties to further develop our product candidates;

- the costs and fees associated with the discovery, acquisition or in-license of product candidates or technologies;
- our ability to establish collaborations on favorable terms, if at all;
- the costs of future commercialization activities, if any, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval; and
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

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

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

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

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 zigakibart, 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 zigakibart, we are currently conducting a phase 1/2 clinical trial for the treatment of IgAN, and we initiated a global phase 3 trial in July 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 DKD, referred to as the SONAR trial. While patients receiving atrasentan in the SONAR trial had a lower rate of primary composite renal events than patients receiving placebo, the trial accrued measurable primary endpoints at a slower rate than expected, and AbbVie decided to close the study early for corporate strategic reasons. We believe the results of the SONAR trial support further evaluation of atrasentan in IgAN. Although the SONAR trial was not terminated due to safety concerns, further safety issues could be discovered in our phase 2 and phase 3 trials. Based on the data from the SONAR trial, we believe that atrasentan, combined with current standard of care, may have benefits compared to treatment with current standard of care. However, we cannot assure that any potential advantages that we believe atrasentan may have for treatment of patients with proteinuric glomerular diseases will be substantiated by our planned clinical trials or included in the product’s labeling should we obtain approval. Without head-to-head data, we will not be able to make comparative claims with respect to any other treatments. In addition, the patient populations under investigation with atrasentan have many co-morbidities that may cause severe illness or death, which may be attributed to atrasentan in a manner that negatively affects its safety profile. If the results of our clinical trials for atrasentan are inconclusive with respect to efficacy, if we do not meet our clinical endpoints with statistical significance, or if there are unanticipated safety concerns or adverse events that emerge during clinical trials, we may have to conduct further preclinical studies and/or clinical trials before obtaining marketing approval, or we may be prevented from or delayed in obtaining marketing approval.

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

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

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

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

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

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate, to the satisfaction of the FDA or comparable foreign regulatory authorities, that our product candidates are safe and effective for any of their proposed indications;
- the populations studied in clinical trials may not be sufficiently broad or representative to assure efficacy and safety in the populations for which we seek approval;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;

- we may be unable to demonstrate our product candidates' clinical and other benefits outweigh their safety risks;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA, BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the facilities of third-party manufacturers with which we contract or procure certain service or raw materials, may not be adequate to support approval of our product candidates; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

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

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

- regulatory authorities may suspend or withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings in the labeling;

- we may be required to change the way a product candidate is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- restrictions on such product candidates, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of any approved product from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of product candidates;

- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our product candidates;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

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

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

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

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

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

Risks Related to Commercialization and Manufacturing

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

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

- the efficacy, durability of treatment effect and safety of such product candidates as demonstrated in clinical trials;
- the potential and perceived advantages of product candidates over alternative treatments;
- the cost of treatment relative to alternative treatments;
- the clinical indications for which the product candidate is approved by the FDA, the HPFB or the European Commission;
- the willingness of providers to prescribe new therapies;

- the willingness of the target patient population to try new therapies;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA, the HPFB, EMA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- the quality of our relationships with patient advocacy groups;
- publicity concerning our product candidates or competing products and treatments; and
- sufficient third-party payor coverage and adequate reimbursement.

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

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

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

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

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

In addition to government and private payors, professional organizations such as the American Medical Association, or the AMA, can influence decisions about coverage and reimbursement for new products by determining standards for care. In addition, many private payors contract with commercial vendors who sell software that provide guidelines that attempt to limit utilization of, and therefore reimbursement for, certain products deemed to provide limited benefit to existing alternatives. Such organizations may set guidelines that limit reimbursement or utilization of our product candidates. Even if favorable coverage and reimbursement status is attained for one or more product candidates for which our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

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

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

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

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

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

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

The Biologics Price Competition and Innovation Act, or BPCIA, was enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the ACA, to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. The law is complex and is still being interpreted and implemented by the

FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement the BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our product candidates.

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

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

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

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

Many of our potential competitors, alone or with their strategic partners, may have substantially greater financial, technical and other resources than we do, such as larger research and development, clinical, marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors. Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any product candidates that we may develop. Competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our products, which could result in our competitors establishing a strong market position before we are able to enter the market, if ever. Additionally, new or advanced technologies developed by our competitors may render our current or future product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors.

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

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

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

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

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

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

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

We currently do not have an organization for the sales, marketing and distribution of atrasentan, zigakibart, 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 zigakibart 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 such as our research collaboration and option license agreement with Ionis Pharmaceuticals, Inc. that we entered into in May 2023. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator’s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator’s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

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

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

Risks Related to Government Regulation

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

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

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

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

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

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

In addition, the FDA may terminate the accelerated approval program or change the standards under which accelerated approvals are considered and granted in response to public pressure or other concerns regarding the accelerated approval program. Changes to or termination of the accelerated approval program could prevent or limit our ability to obtain accelerated approval of any of our clinical development programs. Recently, the accelerated approval pathway has come under scrutiny within the FDA and by Congress. The FDA has put increased focus on ensuring that confirmatory studies are conducted with diligence and, ultimately, that such studies confirm the benefit. Congress has also considered various proposals to potentially make changes to the accelerated approval pathway, including proposals to increase the likelihood of withdrawal of approval in such circumstances. The Food and Drug Omnibus Reform Act, or FDORA, was recently enacted, which included provisions related to the accelerated approval pathway. Pursuant to FDORA, the FDA is authorized to require a post-approval study to be underway prior to approval or within a specified time period following approval. FDORA also requires the FDA to specify conditions of any required post-approval study and requires sponsors to submit progress reports for required post-approval studies. FDORA enables the FDA to initiate criminal prosecutions for the failure to conduct with due diligence a required post-approval study, including a failure to meet any required conditions specified by the FDA or to submit timely reports.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- infringement and other intellectual property claims that, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages plus the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third-party licenses its product rights or proprietary technology to us, which it is not required to do, on commercially reasonable terms or at all;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our product candidates;
- the requirement that we redesign our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time; and
- there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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

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

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

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

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

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

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

To the extent our taxable income exceeds any current year operating losses, we plan to use our net operating loss carryforwards to offset income that would otherwise be taxable. Under Section 382 of the Code, changes in a company's ownership may limit the amount of net operating loss carryforwards and tax credit carryforwards that could be utilized annually to offset its future taxable income, if any. This limitation generally applies in the event of a cumulative change in ownership of more than 50 percent within a three-year period. Aduro experienced and Private Chinook likely experienced an ownership change under Section 382 as a result of the Aduro 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 Aduro CVRs

Our outstanding CVRs may expire valueless.

The right of the holders of our contingent value rights issued prior to the closing of the Aduro Merger, or the Aduro CVRs, will be contingent solely upon the occurrence of certain events described in the CVR Agreement and the consideration received being greater than the amounts that could be deducted by us under the CVR Agreement. In 2022, we paid $7.5 million to Aduro 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 Aduro CVR holders, provided such liquidity event occurs during the 10-year Aduro CVR period. If no additional events described within the CVR Agreement occur within the 10-year Aduro 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 Aduro 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 Aduro CVRs are unsecured obligations of us and all payments under the Aduro CVRs, all other obligations under the CVR Agreement and the Aduro 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 Aduro CVRs is unclear.

The U.S. federal income tax treatment of the Aduro 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 Aduro 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 Aduro CVRs.

For example, Aduro did not report the issuance of the Aduro CVRs as a current distribution of property with respect to its common stock, but it is possible that the IRS could assert that Aduro CVR recipients are treated as having received a distribution of property equal to the fair market value of the Aduro 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 Aduro CVRs (and/or any payments thereon) and the reverse stock split constitute a single "recapitalization" for U.S. federal income tax purposes with the Aduro CVRs constituting taxable "boot" received in such recapitalization exchange. In such case, the tax consequences of the Aduro CVRs and the reverse stock split would differ from those described in the Aduro Merger proxy statement, including with respect to the timing and character of income.

Risks Related to our Common Stock

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

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

- results of clinical trials, including our ALIGN trial for atrasentan, and preclinical studies of our product candidates, or those of our competitors or our existing or future collaborators;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about the combined business, or if they issue adverse or misleading opinions regarding our business and common stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions or market conditions in the pharmaceutical and biotechnology sectors, including rising interest rates and inflation;
- sales of securities by us or our security holders 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 Aduro Merger, some of whom have not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise related to public company reporting requirements and compliance with applicable laws and regulations to ensure that we comply with all of these requirements. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on the board of directors or on board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

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

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

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

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

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- a prohibition on stockholder action by written consent, which means that all stockholder action must be taken at an annual or special meeting of the stockholders;

- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the Chief Executive Officer or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to the board of directors;
- a requirement that no member of the board of directors may be removed from office by stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of voting stock to amend any bylaws by stockholder action or to amend specific provisions of the certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

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

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

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

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

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

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

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

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

General Risk Factors

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

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

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

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

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

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

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

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

Occurrences of epidemics or pandemics, depending on their scale, may cause different degrees of damage to the national and local economies within our geographic focus. Global economic conditions may be disrupted by widespread outbreaks of infectious or contagious diseases, and such disruption may adversely affect clinical development plans. For example, pandemics, such as 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 a pandemic, similar to that experienced during the outbreak of COVID-19, 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 any such future pandemic on our business. Further, the extent and duration of the current economic slowdown or other adverse effects potentially attributable to natural disasters or future pandemics 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 laws and government requirements include obligations of companies to notify regulators and/or individuals, in certain circumstances, of security breaches involving personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Even though we may have contractual protections with such vendors, contractors, or other organizations, notifications and follow-up actions related to a security breach could impact our reputation and cause us to incur significant costs. Any failure to prevent or mitigate security breaches or improper access to, use, disclosure or other misappropriation of our data or consumers' personal data could result in significant contractual and legal liability, such as under state breach notification laws, federal law (including HIPAA/Health Information Technology for Economic and Clinical Health Act, or HITECH), and international law (e.g., GDPR). Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous, expensive and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules and possible government oversight. Our failure to comply with such laws or to adequately secure the information we hold could result in significant liability and/or reputational harm and, in turn, a material adverse effect on our future client base, member base and revenue.

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

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

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

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

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

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

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

Further, the GDPR provides that countries in the EEA may establish their own laws and regulations further restricting the processing of certain personal data, including genetic data, biometric data, and health data.

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

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

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

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

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

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

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

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

Item 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.

(c) Insider Trading Arrangements and Policies

Termination of Written Stock Selling Plan

On June 6, 2023, Michelle Griffin, a director on the Company's board of directors, terminated a pre-arranged written stock sale plan previously adopted on March 8, 2023 in accordance with Rule 10b5-1, or the Griffin Rule 10b5-1 Plan, under the Exchange Act for the sale of up to 40% of net vested common shares from an RSU vesting as May 26, 2023. The Griffin Rule 10b5-1 Plan was entered into during an open trading window in accordance with our insider trading policy and was intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act.

On June 5, 2023, Eric Bjerkholt, our Chief Financial Officer, terminated a pre-arranged written stock sale plan previously adopted on January 4, 2023 in accordance with Rule 10b5-1, or the Bjerkholt Rule 10b5-1 Plan, under the Exchange Act for the sale of up to 10,000 shares of our common stock. The Bjerkholt Rule 10b5-1 Plan was entered into during an open trading window in accordance with our insider trading policy and was intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act.

On June 5, 2023, Andrew King, our Chief Scientific Officer, terminated a pre-arranged written stock sale plan previously adopted on December 2, 2022 in accordance with Rule 10b5-1, or the King Rule 10b5-1 Plan, under the Exchange Act for the sale of up to 25,000 shares of our common stock. The King Rule 10b5-1 Plan was entered into during an open trading window in accordance with our insider trading policy and was intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act.

Item 6. Exhibits.

EXHIBIT INDEX

		Incorporated by Reference				
Exhibit No	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Filed Herewith
2.1*	Agreement and Plan of Merger, dated as of June 11, 2023, by and among Chonook Therapeutics, Inc., Novartis AG and Cherry Merger Sub Inc.	8-K	001-37345	2.1	6/12/2023	
3.1	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Registrant, dated June 14, 2023					X
10.1	Amended and Restated 2015 Equity Incentive Plan					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.INS)					X

* Certain schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company will furnish to the SEC copies of any such schedules upon request.

** The certifications attached as Exhibit 32.1 accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed “filed” by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

SIGNATURES

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

		Chinook Therapeutics, Inc.
Date: August 7, 2023	By:	/s/ Eric L. Dobmeier
		Eric L. Dobmeier
		President and Chief Executive Officer
		(principal executive officer)
		Chinook Therapeutics, Inc.
Date: August 7, 2023	By:	/s/ Eric H. Bjerkholt
		Eric H. Bjerkholt
		Chief Financial Officer
		(principal financial and accounting officer)

CERTIFICATE OF AMENDMENT
TO THE
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
CHINOOK THERAPEUTICS, INC.

Chinook Therapeutics, Inc. (hereinafter called the "**Company**"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the "**DGCL**"), does hereby certify as follows:

1. That the name of this Company is Chinook Therapeutics, Inc., and that this Company was originally incorporated pursuant to the DGCL on May 5, 2011, under the name Aduro Biotech, Inc. The Amended and Restated Certificate of Incorporation of the Company was filed with the Secretary of State of the State of Delaware on April 20, 2015, as amended (the "**Amended and Restated Charter**").

2. Amendment to Article VI.

(a) Article VI of the Amended and Restated Charter is hereby amended and restated in its entirety as follows:

"**VI.**

A. LIMITATION OF LIABILITY. To the fullest extent permitted by law, neither a director of the Company nor an officer of the Company shall be personally liable to the Company or its stockholders for monetary damages for breach of fiduciary duty as a director or officer, as applicable. Without limiting the effect of the preceding sentence, if the DGCL is hereafter amended to authorize the further elimination or limitation of the liability of a director or officer, then the liability of a director or officer of the Company shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

B. INDEMNIFICATION. To the fullest extent permitted by applicable law, the Company is authorized to provide indemnification of (and advancement of expenses to) directors, officers and agents of the Company (and any other persons to which applicable law permits the Company to provide indemnification) through Bylaw provisions, agreements with such agents or other persons, vote of stockholders or disinterested directors or otherwise in excess of the indemnification and advancement otherwise permitted by such applicable law. If applicable law is amended after approval by the stockholders of this Article VI to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director to the company shall be eliminated or limited to the fullest extent permitted by applicable law as so amended.

C. CHANGE IN RIGHTS. Neither any amendment nor repeal of this Article VI, nor the adoption of any provision of this Amended and Restated Certificate of Incorporation inconsistent with this Article VI, shall eliminate, reduce or otherwise adversely affect any limitation on the personal liability of a director or officer of the Company existing at the time of such amendment, repeal or adoption of such an inconsistent provision."

3. That the foregoing amendment was duly adopted by the Board of Directors of the Company in accordance with Sections 141 and 242 of the DGCL and was approved by the holders of the requisite number of shares of capital stock of the Company.

IN WITNESS WHEREOF, the undersigned has executed this Certificate of Amendment on this 14th day of June, 2023.

By: /s/ Eric Dobmeier
Name: Eric Dobmeier
Title: Chief Executive Officer

Exhibit 10.1

CHINOOK THERAPEUTICS, INC.

AMENDED AND RESTATED 2015 EQUITY INCENTIVE PLAN

ADOPTED BY THE BOARD OF DIRECTORS: MARCH 30, 2015
APPROVED BY THE STOCKHOLDERS: APRIL 1, 2015
IPO DATE/EFFECTIVE DATE: APRIL 15, 2015
AS AMENDED AND RESTATED ON JUNE 9, 2023

1. GENERAL.

(a) Successor to and Continuation of Prior Plan.

(i) The Plan is the successor to and continuation of the Aduro Biotech 2009 Stock Incentive Plan, as amended (the "***Prior Plan***"). From and after 12:01 a.m. Pacific time on the Effective Date, no additional stock awards will be granted under the Prior Plan. All stock awards granted under the Prior Plan remain subject to the terms of the Prior Plan. All Awards granted on or after 12:01 a.m. Pacific Time on the Effective Date will be granted under the Plan.

(ii) Any shares that would otherwise remain available for future grants under the Prior Plan as of 12:01 a.m. Pacific Time on the Effective Date ceased to be available under the Prior Plan at such time. Instead, that number of shares of Common Stock equal to the number of shares of Common Stock of the Company then available for future grants under the Prior Plan (the "***Prior Plan's Available Reserve***") was added to the Share Reserve (as further described in Section 3(a) below) and became immediately available for grants and issuance pursuant to Stock Awards under the Plan, up to the maximum number set forth in Section 3(a) below.

(iii) From and after 12:01 a.m. Pacific time on the Effective Date, a number of shares of Common Stock equal to the total number of shares of Common Stock subject, at such time, to outstanding stock options granted under the Prior Plan that: (A) expire or terminate for any reason prior to exercise or settlement; (B) are forfeited or reacquired because of the failure to meet a contingency or condition required to vest such shares or are repurchased at the original issuance price; or (C) are otherwise reacquired or withheld (or not issued) to satisfy a tax withholding obligation in connection with an award (the "***Returning Shares***") will immediately be added to the Share Reserve (as further described in Section 3(a) below) as and when such shares become Returning Shares (up to the maximum number set forth in Section 3(a)), and become available for issuance pursuant to Stock Awards granted hereunder.

(b) Eligible Award Recipients. Employees, Directors and Consultants are eligible to receive Awards.

(c) Available Awards. The Plan provides for the grant of the following Awards: (i) Incentive Stock Options, (ii) Nonstatutory Stock Options, (iii) Stock Appreciation Rights (iv) Restricted Stock Awards, (v) Restricted Stock Unit Awards, (vi) Performance Stock Awards, (vii) Performance Cash Awards, and (viii) Other Stock Awards.

(d) Purpose. The Plan, through the granting of Awards, is intended to help the Company secure and retain the services of eligible award recipients, provide incentives for such persons to exert maximum efforts for the success of the Company and any Affiliate, and provide a means by which the eligible recipients may benefit from increases in value of the Common Stock.

2. ADMINISTRATION.

(a) Administration by Board. The Board will administer the Plan. The Board may delegate administration of the Plan to a Committee or Committees, as provided in Section 2(c).

(b) Powers of Board. The Board will have the power, subject to, and within the limitations of, the express provisions of the Plan:

(i) To determine: (A) who will be granted Awards; (B) when and how each Award will be granted; (C) what type of Award will be granted; (D) the provisions of each Award (which need not be identical), including when a person will be permitted to exercise or otherwise receive cash or Common Stock under the Award; (E) the number of shares of Common Stock subject to, or the cash value of, an Award; and (F) the Fair Market Value applicable to a Stock Award.

(ii) To construe and interpret the Plan and Awards granted under it, and to establish, amend and revoke rules and regulations for administration of the Plan and Awards. The Board, in the exercise of these powers, may correct any defect, omission or inconsistency in the Plan or in any Award Agreement or in the written terms of a Performance Cash Award, in a manner and to the extent it will deem necessary or expedient to make the Plan or Award fully effective.

(iii) To settle all controversies regarding the Plan and Awards granted under it.

(iv) To accelerate, in whole or in part, the time at which an Award may be exercised or vest (or at which cash or shares of Common Stock may be issued).

(v) To suspend or terminate the Plan at any time. Except as otherwise provided in the Plan or an Award Agreement, suspension or termination of the Plan will not materially impair a Participant's rights under his or her then-outstanding Award without his or her written consent, except as provided in subsection (viii) below.

(vi) To amend the Plan in any respect the Board deems necessary or advisable, including, without limitation, by adopting amendments relating to Incentive Stock Options and certain nonqualified deferred compensation under Section 409A of the Code and/or to bring the Plan or Awards granted under the Plan into compliance therewith, subject to the limitations, if any, of applicable law. If required by applicable law or listing requirements, and except as provided in Section 9(a) relating to Capitalization Adjustments, the Company will seek stockholder approval of any amendment of the Plan that (A) materially increases the number of shares of Common Stock available for issuance under the Plan, (B) materially expands the class of individuals eligible to receive Awards under the Plan, (C) materially increases the benefits accruing to Participants under the Plan, (D) materially extends the term of the Plan, or (E) materially expands the types of Awards available for issuance under the Plan. Except as otherwise provided in the Plan or an Award Agreement, no amendment of the Plan will materially impair that Participant's rights under an outstanding Award without his or her written consent.

(vii) To submit any amendment to the Plan for stockholder approval, including, but not limited to, amendments to the Plan intended to satisfy the requirements of (A) Section 162(m) of the Code regarding the exclusion of performance-based compensation from the limit on corporate deductibility of compensation paid to Covered Employees, (B) Section 422 of the Code regarding "incentive stock options" or (C) Rule 16b-3.

(viii) To approve forms of Award Agreements for use under the Plan and to amend the terms of any one or more outstanding Awards. Except with respect to amendments that disqualify or impair the status of an Incentive Stock Option or as otherwise provided in the Plan or an Award Agreement, no amendment of an outstanding Award will materially impair that Participant's rights under his or her outstanding Award without his or her written consent. To be clear, unless prohibited by applicable law, the Board may amend the terms of an Award without the affected Participant's consent if necessary (A) to maintain the qualified status of the Award as an Incentive Stock Option, (B) to clarify the manner of exemption from, or to bring the Award into compliance with, Section 409A of the Code, or (C) to comply with other applicable laws or listing requirements.

(ix) Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of the Plan or Awards.

(x) To adopt such procedures and sub-plans as are necessary or appropriate to permit or facilitate participation in the Plan by Employees, Directors or Consultants who are foreign nationals or employed outside the United States or allow Awards to qualify for special tax treatment in a foreign jurisdiction; *provided*, that Board approval will not be necessary for immaterial modifications to the Plan or any Award Agreement that are required for compliance with the laws of the relevant foreign jurisdiction.

(c) Delegation to Committee.

(i) General. The Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration of the Plan is delegated to a Committee, the Committee will have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to a subcommittee of the Committee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board will thereafter be to the Committee or subcommittee, as applicable). Any delegation of administrative powers will be reflected in resolutions, not inconsistent with the provisions of the Plan, adopted from time to time by the Board or Committee (as applicable). The Committee may, at any time, abolish the subcommittee and/or revest in the Committee any powers delegated to the subcommittee. The Board may retain the authority to concurrently administer the Plan with the Committee and may, at any time, revest in the Board some or all of the powers previously delegated.

(ii) Section 162(m) and Rule 16b-3 Compliance. The Committee may consist solely of two or more Outside Directors, in accordance with Section 162(m) of the Code, or solely of two or more Non-Employee Directors, in accordance with Rule 16b-3.

(d) Delegation to an Officer. The Board may delegate to one or more Officers the authority to do one or both of the following (i) designate Employees who are not Officers to be recipients of Options and SARs (and, to the extent permitted by applicable law, other Stock Awards) and, to the extent permitted by applicable law, the terms of such rights and options, and (ii) determine the number of shares of Common Stock to be subject to such Stock Awards granted to such Employees; *provided*, *however*, that the Board resolutions regarding such delegation will specify the total number of shares of Common Stock that may be subject to the Stock Awards granted by such Officer and that such Officer may not grant a Stock Award to himself or herself. Any such Stock Awards will be granted on the form of Stock Award Agreement most recently approved for use by the Committee or the Board, unless otherwise provided in the resolutions approving the delegation authority. The Board may not delegate authority to an Officer who is acting solely in the capacity of an Officer (and not also as a Director) to determine the Fair Market Value (as defined below).

(e) Effect of Board's Decision. All determinations, interpretations and constructions made by the Board in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons.

3. SHARES SUBJECT TO THE PLAN.

(a) Share Reserve.

(i) Subject to Section 9(a) relating to Capitalization Adjustments and the "evergreen" provision in Section 3(a)(ii), the aggregate number of shares of Common Stock that may be issued pursuant to Stock Awards from and after the A&R Effective Date (as defined below) will not exceed the sum of (A) 6,134,292 shares (the "Share Reserve") plus (B) the number of shares of Common Stock added thereto prior to or following the A&R Effective Date pursuant to the "evergreen" provision of Section 3(a)(ii), which number will be increased by the number of shares that are Returning Shares, as such shares become available from time to time, in an amount not to exceed 8,995,064 shares.

(ii) In addition, the Share Reserve will automatically increase on January 1st of each year, for the period commencing on (and including) January 1, 2024 and ending on (and including) January 1, 2030, in an amount equal to 5% of the total number of shares of Capital Stock outstanding on December 31st of the preceding calendar year. Notwithstanding the foregoing, the Board may act prior to January 1st of a given year to provide that there will be no January 1st increase in the Share Reserve for such year or that the increase in the Share Reserve for such year will be a lesser number of shares of Common Stock than would otherwise occur pursuant to the preceding sentence.

(iii) For clarity, the Share Reserve is a limitation on the number of shares of Common Stock that may be issued under the Plan. As a single share may be subject to grant more than once (e.g., if a share subject to a Stock Award is forfeited, it may be made subject to grant again as provided in Section 3(b) below), the Share Reserve is not a limit on the number of Stock Awards that can be granted.

(iv) Shares may be issued in connection with a merger or acquisition as permitted by NASDAQ Listing Rule 5635(c) or, if applicable, NYSE Listed Company Manual Section 303A.08, AMEX Company Guide Section 711 or other applicable rule, and such issuance will not reduce the number of shares available for issuance under the Plan.

(b) Reversion of Shares to the Share Reserve. If a Stock Award or any portion of a Stock Award (including, for the avoidance of doubt, Awards granted prior to the A&R Effective Date) (i) expires or otherwise terminates without all of the shares covered by such Stock Award having been issued or (ii) is settled in cash (*i.e.*, the Participant receives cash rather than stock), such expiration, termination or settlement will not reduce (or otherwise offset) the number of shares of Common Stock that may be available for issuance under the Plan. If any shares of Common Stock issued pursuant to a Stock Award are forfeited back to or repurchased by the Company because of the failure to meet a contingency or condition required to vest such shares in the Participant, then the shares that are forfeited or repurchased will revert to and again become available for issuance under the Plan. Any shares reacquired by the Company in satisfaction of tax withholding obligations on a Stock Award or as consideration for the exercise or purchase price of a Stock Award will again become available for issuance under the Plan.

(c) Incentive Stock Option Limit. Subject to the provisions of Section 9(a) relating to Capitalization Adjustments, the aggregate maximum number of shares of Common Stock that may be issued pursuant to the exercise of Incentive Stock Options will be 30,671,460 shares of Common Stock.

(d) Non-Employee Director Limit. Subject to the provisions of Section 9(a) relating to Capitalization Adjustments, No Non-Employee Director may receive Awards under the Plan with an aggregate grant date fair value that, when combined with cash compensation received for service as a Non-Employee Director, exceeds $750,000 in a calendar year, increased to $1,500,000 in the calendar year of his or her initial services as a non-employee director. Awards granted to an individual while he or she was serving in the capacity as an Employee or while he or she was a Consultant but not a Non-Employee Director will not count for purposes of the limitations set forth in this Section 3.

(e) Section 162(m) Limitations. Subject to the provisions of Section 9(a) relating to Capitalization Adjustments, at such time as the Company may be subject to the applicable provisions of Section 162(m) of the Code: (i) a maximum of 2,000,000 shares of Common Stock subject to Options, SARs and Other Stock Awards whose value is determined by reference to an increase over an exercise or strike price of at least 100% of the Fair Market Value on the date the Stock Award is granted may be granted to any one Participant during any one calendar year, (ii) a maximum of 2,00,000 shares of Common Stock subject to Performance Stock Awards may be granted to any one Participant during any one calendar year (whether the grant, vesting or exercise is contingent upon the attainment during the Performance Period of the Performance Goals) and (iii) a maximum of $5,000,000 may be granted as a Performance Cash Award to any one Participant during any one calendar year. If a Performance Stock Award is in the form of an Option, it will count only against the Performance Stock Award limit. If a Performance Stock Award could (but is not required to) be paid out in cash, it will count only against the Performance Stock Award limit.

(f) Source of Shares. The stock issuable under the Plan will be shares of authorized but unissued or reacquired Common Stock, including shares repurchased by the Company on the open market or otherwise.

4. ELIGIBILITY.

(a) Eligibility for Specific Stock Awards. Incentive Stock Options may be granted only to employees of the Company or a "parent corporation" or "subsidiary corporation" thereof (as such terms are defined in Sections 424(e) and 424(f) of the Code). Stock Awards other than Incentive Stock Options may be granted to Employees, Directors and Consultants; *provided, however*, that Stock Awards may not be granted to Employees, Directors and Consultants who are providing Continuous Service only to any "parent" of the Company, as such term is defined in Rule 405 of the Securities Act, unless (i) the stock underlying such Stock Awards is treated as "service recipient stock" under Section 409A of the Code (for example, because the Stock Awards are granted pursuant to a corporate transaction such as a spin off transaction), (ii) the Company, in consultation with its legal counsel, has determined that such Stock Awards are otherwise exempt from Section 409A of the Code, or (iii) the Company, in consultation with its legal counsel, has determined that such Stock Awards comply with the distribution requirements of Section 409A of the Code.

(b) Ten Percent Stockholders. A Ten Percent Stockholder will not be granted an Incentive Stock Option unless the exercise price of such Option is at least 110% of the Fair Market Value on the date of grant and the Option is not exercisable after the expiration of five years from the date of grant.

5. PROVISIONS RELATING TO OPTIONS AND STOCK APPRECIATION RIGHTS.

Each Option or SAR will be in such form and will contain such terms and conditions as the Board deems appropriate. All Options will be separately designated Incentive Stock Options or Nonstatutory Stock Options at the time of grant, and, if certificates are issued, a separate certificate or certificates will be issued for shares of Common Stock purchased on exercise of each type of Option. If an Option is not specifically designated as an Incentive Stock Option, or if an Option is designated as an Incentive Stock Option but some portion or all of the Option fails to qualify as an Incentive Stock Option under the applicable rules, then the Option (or portion thereof) will be a Nonstatutory Stock Option. The provisions of separate Options or SARs need not be identical; *provided*, *however*, that each Award Agreement will conform to (through incorporation of provisions hereof by reference in the applicable Award Agreement or otherwise) the substance of each of the following provisions:

(a) Term. Subject to the provisions of Section 4(b) regarding Ten Percent Stockholders, no Option or SAR will be exercisable after the expiration of ten years from the date of its grant or such shorter period specified in the Award Agreement.

(b) Exercise Price. Subject to the provisions of Section 4(b) regarding Ten Percent Stockholders, the exercise or strike price of each Option or SAR will be not less than 100% of the Fair Market Value of the Common Stock subject to the Option or SAR on the date the Award is granted. Notwithstanding the foregoing, an Option or SAR may be granted with an exercise or strike price lower than 100% of the Fair Market Value of the Common Stock subject to the Award if such Award is granted pursuant to an assumption of or substitution for another option or stock appreciation right pursuant to a Corporate Transaction and in a manner consistent with the provisions of Section 409A of the Code and, if applicable, Section 424(a) of the Code. Each SAR will be denominated in shares of Common Stock equivalents.

(c) Purchase Price for Options. The purchase price of Common Stock acquired pursuant to the exercise of an Option may be paid, to the extent permitted by applicable law and as determined by the Board in its sole discretion, by any combination of the methods of payment set forth below. The Board will have the authority to grant Options that do not permit all of the following methods of payment (or otherwise restrict the ability to use certain methods) and to grant Options that require the consent of the Company to use a particular method of payment. The permitted methods of payment are as follows:

(i) by cash, check, bank draft or money order payable to the Company;

(ii) pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of the stock subject to the Option, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds;

(iii) by delivery to the Company (either by actual delivery or attestation) of shares of Common Stock;

(iv) if an Option is a Nonstatutory Stock Option, by a “net exercise” arrangement pursuant to which the Company will reduce the number of shares of Common Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; *provided*, *however*, that the Company will accept a cash or other payment from the Participant to the extent of any remaining balance of the aggregate exercise price not satisfied by such reduction in the number of whole shares to be issued. Shares of Common Stock will no longer be subject to an Option and will not be exercisable thereafter to the extent that (A) shares issuable upon exercise are reduced to pay the exercise price pursuant to the “net exercise,” (B) shares are delivered to the Participant as a result of such exercise, and (C) shares are withheld to satisfy tax withholding obligations; or

(v) in any other form of legal consideration that may be acceptable to the Board and specified in the applicable Award Agreement.

(d) Exercise and Payment of a SAR. To exercise any outstanding SAR, the Participant must provide written notice of exercise to the Company in compliance with the provisions of the Stock Appreciation Right Agreement evidencing such SAR. The appreciation distribution payable on the exercise of a SAR will be not greater than an amount equal to the excess of (A) the aggregate Fair Market Value (on the date of the exercise of the SAR) of a number of shares of Common Stock equal to the number of Common Stock equivalents in which the Participant is vested under such SAR, and with respect to which the Participant is exercising the SAR on such date, over (B) the aggregate strike price of the number of Common Stock equivalents with respect to which the Participant is exercising the SAR on such date. The appreciation distribution may be paid in Common Stock, in cash, in any combination of the two or in any other form of consideration, as determined by the Board and contained in the Award Agreement evidencing such SAR.

(e) Transferability of Options and SARs. The Board may, in its sole discretion, impose such limitations on the transferability of Options and SARs as the Board will determine. In the absence of such a determination by the Board to the contrary, the following restrictions on the transferability of Options and SARs will apply:

(i) Restrictions on Transfer. An Option or SAR will not be transferable except by will or by the laws of descent and distribution (or pursuant to subsections (ii) and (iii) below), and will be exercisable during the lifetime of the Participant only by the Participant. The Board may permit transfer of the Option or SAR in a manner that is not prohibited by applicable tax and securities laws. Except as explicitly provided in the Plan, neither an Option nor a SAR may be transferred for consideration.

(ii) Domestic Relations Orders. Subject to the approval of the Board or a duly authorized Officer, an Option or SAR may be transferred pursuant to the terms of a domestic relations order or official marital settlement agreement or other divorce or separation instrument as permitted by Treasury Regulations Section 1.421-1(b)(2). If an Option is an Incentive Stock Option, such Option may be deemed to be a Nonstatutory Stock Option as a result of such transfer.

(iii) Beneficiary Designation. Subject to the approval of the Board or a duly authorized Officer, a Participant may, by delivering written notice to the Company, in a form approved by the Company (or the designated broker), designate a third party who, on the death of the Participant, will thereafter be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise. In the absence of such a designation, the executor or administrator of the Participant's estate will be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise. However, the Company may prohibit designation of a beneficiary at any time, including due to any conclusion by the Company that such designation would be inconsistent with the provisions of applicable laws.

(f) Vesting Generally. The total number of shares of Common Stock subject to an Option or SAR may vest and therefore become exercisable in periodic installments that may or may not be equal. The Option or SAR may be subject to such other terms and conditions on the time or times when it may or may not be exercised (which may be based on the satisfaction of Performance Goals or other criteria) as the Board may deem appropriate. The vesting provisions of individual Options or SARs may vary. The provisions of this Section 5(f) are subject to any Option or SAR provisions governing the minimum number of shares of Common Stock as to which an Option or SAR may be exercised.

(g) Termination of Continuous Service. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if a Participant's Continuous Service terminates (other than for Cause and other than upon the Participant's death or Disability), the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Award as of the date of termination of Continuous Service) within the period of time ending on the earlier of (i) the date which occurs three months following the termination of the Participant's Continuous Service (or such longer or shorter period specified in the applicable Award Agreement) and (ii) the expiration of the term of the Option or SAR as set forth in the Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the applicable time frame, the Option or SAR will terminate.

(h) Extension of Termination Date. Except as otherwise provided in the applicable Award Agreement, if the exercise of an Option or SAR following the termination of the Participant's Continuous Service (other than for Cause and other than upon the Participant's death or Disability) would be prohibited at any time solely because the issuance of shares of Common Stock would violate the registration requirements under the Securities Act, then the Option or SAR will terminate on the earlier of (i) the expiration of a total period of three months (that need not be consecutive) equal to the applicable post-termination exercise period after the termination of the Participant's Continuous Service during which the exercise of the Option or SAR would not be in violation of such registration requirements, and (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Agreement. In addition, unless otherwise provided in a Participant's Award Agreement, if the sale of any Common

Stock received upon exercise of an Option or SAR following the termination of the Participant's Continuous Service (other than for Cause) would violate the Company's insider trading policy, then the Option or SAR will terminate on the earlier of (i) the expiration of a period of days or months (that need not be consecutive) equal to the applicable post-termination exercise period after the termination of the Participant's Continuous Service during which the sale of the Common Stock received upon exercise of the Option or SAR would not be in violation of the Company's insider trading policy, or (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Agreement.

(i) Disability of Participant. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if a Participant's Continuous Service terminates as a result of the Participant's Disability, the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Option or SAR as of the date of termination of Continuous Service), but only within such period of time ending on the earlier of (i) the date which occurs 12 months following such termination of Continuous Service (or such longer or shorter period specified in the Award Agreement), and (ii) the expiration of the term of the Option or SAR as set forth in the Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the applicable time frame, the Option or SAR (as applicable) will terminate.

(j) Death of Participant. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if (i) a Participant's Continuous Service terminates as a result of the Participant's death, or (ii) the Participant dies within the period (if any) specified in the Award Agreement for exercisability after the termination of the Participant's Continuous Service for a reason other than death, then the Option or SAR may be exercised (to the extent the Participant was entitled to exercise such Option or SAR as of the date of death) by the Participant's estate, by a person who acquired the right to exercise the Option or SAR by bequest or inheritance or by a person designated to exercise the Option or SAR upon the Participant's death, but only within the period ending on the earlier of (i) the date which occurs 18 months following the date of death (or such longer or shorter period specified in the Award Agreement), and (ii) the expiration of the term of such Option or SAR as set forth in the Award Agreement. If, after the Participant's death, the Option or SAR is not exercised within the applicable time frame, the Option or SAR will terminate.

(k) Termination for Cause. Except as explicitly provided otherwise in a Participant's Award Agreement or other individual written agreement between the Company or any Affiliate and the Participant, if a Participant's Continuous Service is terminated for Cause, the Option or SAR will terminate immediately upon the date on which the event giving rise to the termination for Cause first occurred, and the Participant will be prohibited from exercising his or her Option or SAR from and after the date on which the event giving rise to the termination for Cause first occurred (or, if required by law, the date of termination of Continuous Service). If a Participant's Continuous Service is suspended pending an investigation of the existence of Cause, all of the Participant's rights under the Option or SAR will also be suspended during the investigation period.

(l) Non-Exempt Employees. If an Option or SAR is granted to an Employee who is a non-exempt employee for purposes of the Fair Labor Standards Act of 1938, as amended, the Option or SAR will not be first exercisable for any shares of Common Stock until at least six (6) months following the date of grant of the Option or SAR (although the Award may vest prior to such date). Consistent with the provisions of the Worker Economic Opportunity Act, (i) if such non-exempt Employee dies or suffers a Disability, (ii) upon a Corporate Transaction in which such Option or SAR is not assumed, continued, or substituted, (iii) upon a Change in Control, or (iv) upon the Participant's retirement (as such term may be defined in the Participant's Award Agreement in another agreement between the Participant and the Company, or, if no such definition, in accordance with the Company's then current employment policies and guidelines), the vested portion of any Options and SARs may be exercised earlier than six (6) months following the date of grant. The foregoing provision is intended to operate so that any income derived by a non-exempt employee in connection with the exercise or vesting of an Option or SAR will be exempt from his or her regular rate of pay. To the extent permitted and/or required for compliance with the Worker Economic Opportunity Act to ensure that any income derived by a non-exempt employee in connection with the exercise, vesting or issuance of any shares under any other Stock Award will be exempt from the employee's regular rate of pay, the provisions of this Section 5(l) will apply to all Stock Awards and are hereby incorporated by reference into such Stock Award Agreements.

6. PROVISIONS OF STOCK AWARDS OTHER THAN OPTIONS AND SARS.

(a) Restricted Stock Awards. Each Restricted Stock Award Agreement will be in such form and will contain such terms and conditions as the Board will deem appropriate. To the extent consistent with the Company's bylaws, at the Board's election, shares of Common Stock may be (x) held in book entry form subject to the Company's instructions until any restrictions relating to the Restricted Stock Award lapse; or (y) evidenced by a certificate, which certificate will be held in such form and manner as determined by the Board. The terms and conditions of Restricted Stock Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Award Agreements need not be identical. Each Restricted Stock Award Agreement will conform to (through incorporation of the provisions hereof by reference in the agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. A Restricted Stock Award may be awarded in consideration for (A) cash, check, bank draft or money order payable to the Company, (B) past services to the Company or an Affiliate, or (C) any other form of legal consideration (including future services) that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

(ii) Vesting. Shares of Common Stock awarded under the Restricted Stock Award Agreement may be subject to forfeiture to the Company in accordance with a vesting schedule to be determined by the Board.

(iii) Termination of Participant's Continuous Service. If a Participant's Continuous Service terminates, the Company may receive through a forfeiture condition or a repurchase right any or all of the shares of Common Stock held by the Participant that have not vested as of the date of termination of Continuous Service under the terms of the Restricted Stock Award Agreement.

(iv) Transferability. Rights to acquire shares of Common Stock under the Restricted Stock Award Agreement will be transferable by the Participant only upon such terms and conditions as are set forth in the Restricted Stock Award Agreement, as the Board will determine in its sole discretion, so long as Common Stock awarded under the Restricted Stock Award Agreement remains subject to the terms of the Restricted Stock Award Agreement.

(v) Dividends. A Restricted Stock Award Agreement may provide that any dividends paid on Restricted Stock will be subject to the same vesting and forfeiture restrictions as apply to the shares subject to the Restricted Stock Award to which they relate.

(b) Restricted Stock Unit Awards. Each Restricted Stock Unit Award Agreement will be in such form and will contain such terms and conditions as the Board will deem appropriate. The terms and conditions of Restricted Stock Unit Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Unit Award Agreements need not be identical. Each Restricted Stock Unit Award Agreement will conform to (through incorporation of the provisions hereof by reference in the Agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. At the time of grant of a Restricted Stock Unit Award, the Board will determine the consideration, if any, to be paid by the Participant upon delivery of each share of Common Stock subject to the Restricted Stock Unit Award. The consideration to be paid (if any) by the Participant for each share of Common Stock subject to a Restricted Stock Unit Award may be paid in any form of legal consideration that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

(ii) Vesting. At the time of the grant of a Restricted Stock Unit Award, the Board may impose such restrictions on or conditions to the vesting of the Restricted Stock Unit Award as it, in its sole discretion, deems appropriate.

(iii) Payment. A Restricted Stock Unit Award may be settled by the delivery of shares of Common Stock, their cash equivalent, any combination thereof or in any other form of consideration, as determined by the Board and contained in the Restricted Stock Unit Award Agreement.

(iv) Additional Restrictions. At the time of the grant of a Restricted Stock Unit Award, the Board, as it deems appropriate, may impose such restrictions or conditions that delay the delivery of the shares of Common Stock (or their cash equivalent) subject to a Restricted Stock Unit Award to a time after the vesting of such Restricted Stock Unit Award.

(v) Dividend Equivalents. Dividend equivalents may be credited in respect of shares of Common Stock covered by a Restricted Stock Unit Award, as determined by the Board and contained in the Restricted Stock Unit Award Agreement. At the sole discretion of the Board, such dividend equivalents may be converted into additional shares of Common Stock covered by the Restricted Stock Unit Award in such manner as determined by the Board. Any additional shares covered by the Restricted Stock Unit Award credited by reason of such dividend equivalents will be subject to all of the same terms and conditions of the underlying Restricted Stock Unit Award Agreement to which they relate.

(vi) Termination of Participant's Continuous Service. Except as otherwise provided in the applicable Restricted Stock Unit Award Agreement, such portion of the Restricted Stock Unit Award that has not vested will be forfeited upon the Participant's termination of Continuous Service.

(c) Performance Awards.

(i) Performance Stock Awards. A Performance Stock Award is a Stock Award (covering a number of shares not in excess of that set forth in Section 3(d) above) that is payable or that may be granted, may vest or may be exercised, contingent upon the attainment during a Performance Period of certain Performance Goals. A Performance Stock Award may, but need not, require the completion of a specified period of Continuous Service. The length of any Performance Period, the Performance Goals to be achieved during the Performance Period, and the measure of whether and to what degree such Performance Goals have been attained will be conclusively determined by the Committee (or, if not required for compliance with Section 162(m) of the Code, the Board), in its sole discretion. In addition, to the extent permitted by applicable law and the applicable Award Agreement, the Board may determine that cash may be used in payment of Performance Stock Awards.

(ii) Performance Cash Awards. A Performance Cash Award is a cash award (for a dollar value not in excess of that set forth in Section 3(d) above) that is payable contingent upon the attainment during a Performance Period of certain Performance Goals. A Performance Cash Award may also require the completion of a specified period of Continuous Service. At the time of grant of a Performance Cash Award, the length of any Performance Period, the Performance Goals to be achieved during the Performance Period, and the measure of whether and to what degree such Performance Goals have been attained will be conclusively determined by the Committee (or, if not required for compliance with Section 162(m) of the Code, the Board), in its sole discretion. The Board may specify the form of payment of Performance Cash Awards, which may be cash or other property, or may provide for a Participant to have the option for his or her Performance Cash Award, or such portion thereof as the Board may specify, to be paid in whole or in part in cash or other property.

(iii) Section 162(m) Compliance. Unless otherwise permitted in compliance with the requirements of Section 162(m) of the Code with respect to an Award intended to qualify as "performance-based compensation" thereunder, the Committee will establish the Performance Goals applicable to, and the formula for calculating the amount payable under, the Award no later than the earlier of (a) the date 90 days after the commencement of the applicable Performance Period, and (b) the date on which 25% of the Performance Period has elapsed, and in any event at a time when the achievement of the applicable Performance Goals remains substantially uncertain. Prior to the payment of any compensation under an Award intended to qualify as "performance-based compensation" under Section 162(m) of the Code, the Committee will certify the extent to which any Performance Goals and any other material terms under such Award have been satisfied (other than in cases where such relate solely to the increase in the value of the Common Stock). Notwithstanding satisfaction of any completion of any Performance Goals, the number of shares of Common Stock, Options, cash or other benefits granted, issued, retainable and/or vested under an Award on account of satisfaction of such Performance Goals may be reduced by the Committee on the basis of such further considerations as the Committee, in its sole discretion, will determine.

(d) Other Stock Awards. Other forms of Stock Awards valued in whole or in part by reference to, or otherwise based on, Common Stock, including the appreciation in value thereof, may be granted either alone or in addition to Stock Awards provided for under Section 5 and the preceding provisions of this Section 6. Subject to the provisions of the Plan, the Board will have sole and complete authority to determine the persons to whom and the time or times at which such Other Stock Awards will be granted, the number of shares of Common Stock (or the cash equivalent thereof) to be granted pursuant to such Other Stock Awards and all other terms and conditions of such Other Stock Awards.

7. COVENANTS OF THE COMPANY.

(a) Availability of Shares. The Company will keep available at all times the number of shares of Common Stock reasonably required to satisfy then-outstanding Awards.

(b) Securities Law Compliance. The Company will seek to obtain from each regulatory commission or agency having jurisdiction over the Plan such authority as may be required to grant Stock Awards and to issue and sell shares of Common Stock upon exercise of the Stock Awards; *provided*, *however*, that this undertaking will not require the Company to register under the Securities Act the Plan, any Stock Award or any Common Stock issued or issuable pursuant to any such Stock Award. If, after reasonable efforts and at a reasonable cost, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary for the lawful issuance and sale of Common Stock under the Plan, the Company will be relieved from any liability for failure to issue and sell Common Stock upon exercise of such Stock Awards unless and until such authority is obtained. A Participant will not be eligible for the grant of an Award or the subsequent issuance of cash or Common Stock pursuant to the Award if such grant or issuance would be in violation of any applicable securities law.

(c) No Obligation to Notify or Minimize Taxes. The Company will have no duty or obligation to any Participant to advise such holder as to the time or manner of exercising such Stock Award. Furthermore, the Company will have no duty or obligation to warn or otherwise advise such holder of a pending termination or expiration of an Award or a possible period in which the Award may not be exercised. The Company has no duty or obligation to minimize the tax consequences of an Award to the holder of such Award.

8. MISCELLANEOUS.

(a) Use of Proceeds from Sales of Common Stock. Proceeds from the sale of shares of Common Stock pursuant to Awards will constitute general funds of the Company.

(b) Corporate Action Constituting Grant of Awards. Corporate action constituting a grant by the Company of an Award to any Participant will be deemed completed as of the date of such corporate action, unless otherwise determined by the Board, regardless of when the instrument, certificate, or letter evidencing the Award is communicated to, or actually received or accepted by, the Participant. In the event that the corporate records (e.g., Board consents, resolutions or minutes) documenting the corporate action constituting the grant contain terms (e.g., exercise price, vesting schedule or number of shares) that are inconsistent with those in the Award Agreement or related grant documents as a result of a clerical error in the papering of the Award Agreement or related grant documents, the corporate records will control and the Participant will have no legally binding right to the incorrect term in the Award Agreement or related grant documents.

(c) Stockholder Rights. No Participant will be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to an Award unless and until (i) such Participant has satisfied all requirements for exercise of, or the issuance of shares of Common Stock under, the Award pursuant to its terms, and (ii) the issuance of the Common Stock subject to such Award has been entered into the books and records of the Company.

(d) No Employment or Other Service Rights. Nothing in the Plan, any Award Agreement or any other instrument executed thereunder or in connection with any Award granted pursuant thereto will confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Award was granted or will affect the right of the Company or an Affiliate to terminate (i) the employment of an Employee with or without notice and with or without Cause, (ii) the service of a Consultant pursuant to the terms of such Consultant's agreement with the Company or an Affiliate, or (iii) the service of a Director pursuant to the bylaws of the Company or an Affiliate, and any applicable provisions of the corporate law of the state in which the Company or the Affiliate is incorporated, as the case may be.

(e) Change in Time Commitment. In the event a Participant's regular level of time commitment in the performance of his or her services for the Company and any Affiliates is reduced (for example, and without limitation, if the Participant is an Employee of the Company and the Employee has a change in status from a full-time Employee to a part-time Employee or takes an extended leave of absence) after the date of grant of any Award to the Participant, the Board has the right in its sole discretion to (x) make a corresponding reduction in the number of shares or cash amount subject to any portion of such Award that is scheduled to vest or become payable after the date of such change in time commitment, and (y) in lieu of or in combination with such a reduction, extend the vesting or payment schedule applicable to such Award. In the event of any such reduction, the Participant will have no right with respect to any portion of the Award that is so reduced or extended.

(f) Incentive Stock Option Limitations. To the extent that the aggregate Fair Market Value (determined at the time of grant) of Common Stock with respect to which Incentive Stock Options are exercisable for the first time by any Optionholder during any calendar year (under all plans of the Company and any Affiliates) exceeds $100,000 (or such other limit established in the Code) or otherwise does not comply with the rules governing Incentive Stock Options, the Options or portions thereof that exceed such limit (according to the order in which they were granted) or otherwise do not comply with the rules will be treated as Nonstatutory Stock Options, notwithstanding any contrary provision of the applicable Option Agreement(s).

(g) Investment Assurances. The Company may require a Participant, as a condition of exercising or acquiring Common Stock under any Award, (i) to give written assurances satisfactory to the Company as to the Participant's knowledge and experience in financial and business matters and/or to employ a purchaser representative reasonably satisfactory to the Company who is knowledgeable and experienced in financial and business matters and that he or she is capable of evaluating, alone or together with the purchaser representative, the merits and risks of exercising the Award; and (ii) to give written assurances satisfactory to the Company stating that the Participant is acquiring Common Stock subject to the Award for the Participant's own account and not with any present intention of selling or otherwise distributing the Common Stock. The foregoing requirements, and any assurances given pursuant to such requirements, will be inoperative if (A) the issuance of the shares upon the exercise or acquisition of Common Stock under the Award has been registered under a then currently effective registration statement under the Securities Act, or (B) as to any particular requirement, a determination is made by counsel for the Company that such requirement need not be met in the circumstances under the then applicable securities laws. The Company may, upon advice of counsel to the Company, place legends on stock certificates issued under the Plan as such counsel deems necessary or appropriate in order to comply with applicable securities laws, including, but not limited to, legends restricting the transfer of the Common Stock.

(h) Withholding Obligations. Unless prohibited by the terms of an Award Agreement, the Company may, in its sole discretion, satisfy any federal, state or local tax withholding obligation relating to an Award by any of the following means or by a combination of such means: (i) causing the Participant to tender a cash payment; (ii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to the Participant in connection with the Award; *provided, however,* that no shares of Common Stock are withheld with a value exceeding the minimum amount of tax required to be withheld by law (or such lesser amount as may be necessary to avoid classification of the Stock Award as a liability for financial accounting purposes); (iii) withholding cash from an Award settled in cash; (iv) withholding payment from any amounts otherwise payable to the Participant, including proceeds from the sale of shares of Common Stock issued pursuant to a Stock Award; or (v) by such other method as may be set forth in the Award Agreement.

(i) Electronic Delivery. Any reference herein to a "written" agreement or document will include any agreement or document delivered electronically, filed publicly at www.sec.gov (or any successor website thereto) or posted on the Company's intranet (or other shared electronic medium controlled by the Company to which the Participant has access).

(j) Deferrals. To the extent permitted by applicable law, the Board, in its sole discretion, may determine that the delivery of Common Stock or the payment of cash, upon the exercise, vesting or settlement of all or a portion of any Award may be deferred and may establish programs and procedures for deferral elections to be made by Participants. Deferrals by Participants will be made in accordance with Section 409A of the Code (to the extent applicable to a Participant). Consistent with Section 409A of the Code, the Board may provide for distributions while a Participant is still an employee or otherwise providing services to the Company. The Board is authorized to make deferrals of Awards and determine when, and in what annual percentages, Participants may receive payments, including lump sum payments, following the Participant's termination of Continuous Service, and implement such other terms and conditions consistent with the provisions of the Plan and in accordance with applicable law.

(k) Compliance with Section 409A. Unless otherwise expressly provided for in an Award Agreement, the Plan and Award Agreements will be interpreted to the greatest extent possible in a manner that makes the Plan and the Awards granted hereunder exempt from Section 409A of the Code, and, to the extent not so exempt, in compliance with Section 409A of the Code. If the Board determines that any Award granted hereunder is not exempt from and is therefore subject to Section 409A of the Code, the Award Agreement evidencing such Award will incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code, and to the extent an Award Agreement is silent on terms necessary for compliance, such terms are hereby incorporated by reference into the Award Agreement. Notwithstanding anything to the contrary in this Plan (and unless the Award Agreement specifically provides otherwise), if the shares of Common Stock are publicly traded, and if a Participant holding an Award that constitutes "deferred compensation" under Section 409A of the Code is a "specified employee" for purposes of Section 409A of the Code, no distribution or payment of any amount that is due because of a "separation from service" (as defined in Section 409A of the Code without regard to alternative definitions thereunder) will be issued or paid before the date that is six (6) months following the date of such Participant's "separation from service" or, if earlier, the date of the Participant's death, unless such distribution or payment can be made in a manner that complies with Section 409A of the Code, and any amounts so deferred will be paid in a lump sum on the day after such six (6) month period elapses, with the balance paid thereafter on the original schedule.

(l) Clawback/Recovery. All Awards granted under the Plan will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. In addition, the Board may impose such other clawback, recovery or recoupment provisions in an Award Agreement as the Board determines necessary or appropriate, including but not limited to a reacquisition right in respect of previously acquired shares of Common Stock or other cash or property upon the occurrence of an event constituting Cause. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for "good reason" or "constructive termination" (or similar term) under any agreement with the Company or an Affiliate.

9. ADJUSTMENTS UPON CHANGES IN COMMON STOCK; OTHER CORPORATE EVENTS.

(a) Capitalization Adjustments. In the event of a Capitalization Adjustment, the Board will appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the Plan pursuant to Section 3(a), (ii) the class(es) and maximum number of securities that may be issued pursuant to the exercise of Incentive Stock Options pursuant to Section 3(c), (iii) the class(es) and maximum number of securities that may be awarded to any person pursuant to Sections 3(d), and (iv) the class(es) and number of securities and price per share of stock subject to outstanding Stock Awards. The Board will make such adjustments, and its determination will be final, binding and conclusive.

(b) Dissolution or Liquidation. Except as otherwise provided in the Stock Award Agreement, in the event of a dissolution or liquidation of the Company, all outstanding Stock Awards (other than Stock Awards consisting of vested and outstanding shares of Common Stock not subject to a forfeiture condition or the Company's right of repurchase) will terminate immediately prior to the completion of such dissolution or liquidation, and the shares of Common Stock subject to the Company's repurchase rights or subject to a forfeiture condition may be repurchased or reacquired by the Company notwithstanding the fact that the holder of such Stock Award is providing Continuous Service; *provided*, *however*, that the Board may, in its sole discretion, cause some or all Stock Awards to become fully vested, exercisable and/or no longer subject to repurchase or forfeiture (to the extent such Stock Awards have not previously expired or terminated) before the dissolution or liquidation is completed but contingent on its completion.

(c) Corporate Transaction. The following provisions will apply to Stock Awards in the event of a Corporate Transaction unless otherwise provided in the instrument evidencing the Stock Award or any other written agreement between the Company or any Affiliate and the Participant or unless otherwise expressly provided by the Board at the time of grant of a Stock Award. In the event of a Corporate Transaction, then, notwithstanding any other provision of the Plan, the Board will take one or more of the following actions with respect to Stock Awards, contingent upon the closing or completion of the Corporate Transaction:

(i) arrange for the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) to assume or continue the Stock Award or to substitute a similar stock award for the Stock Award (including, but not limited to, an award to acquire the same consideration paid to the stockholders of the Company pursuant to the Corporate Transaction);

(ii) arrange for the assignment of any reacquisition or repurchase rights held by the Company in respect of Common Stock issued pursuant to the Stock Award to the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company);

(iii) accelerate the vesting, in whole or in part, of the Stock Award (and, if applicable, the time at which the Stock Award may be exercised) to a date prior to the effective time of such Corporate Transaction as the Board determines (or, if the Board does not determine such a date, to the date that is five (5) days prior to the effective date of the Corporate Transaction), with such Stock Award terminating if not exercised (if applicable) at or prior to the effective time of the Corporate Transaction;

(iv) arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by the Company with respect to the Stock Award;

(v) cancel or arrange for the cancellation of the Stock Award, to the extent not vested or not exercised prior to the effective time of the Corporate Transaction, in exchange for such cash consideration, if any, as the Board, in its sole discretion, may consider appropriate; and

(vi) cancel or arrange for the cancellation of the Stock Award, to the extent not vested or not exercised prior to the effective time of the Corporate Transaction, in exchange for a payment, in such form as may be determined by the Board, equal to the excess, if any, of (A) the value of the property the Participant would have received upon the exercise of the Stock Award immediately prior to the effective time of the Corporate Transaction, over (B) any exercise price payable by such holder in connection with such exercise.

(vii) The Board need not take the same action or actions with respect to all Stock Awards or portions thereof or with respect to all Participants. The Board may take different actions with respect to the vested and unvested portions of a Stock Award.

(d) Change in Control. A Stock Award may be subject to additional acceleration of vesting and exercisability upon or after a Change in Control as may be provided in the Stock Award Agreement for such Stock Award or as may be provided in any other written agreement between the Company or any Affiliate and the Participant, but in the absence of such provision, no such acceleration will occur.

10. TERMINATION OR SUSPENSION OF THE PLAN.

(a) The Board may suspend or terminate the Plan at any time. No Incentive Stock Options may be granted after the tenth anniversary of the earlier of (i) the date the Plan is adopted by the Board (the "***Adoption Date***"), and (ii) the date the Plan is approved by the stockholders of the Company. No Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

11. EXISTENCE OF THE PLAN; TIMING OF FIRST GRANT OR EXERCISE.

The Plan originally became effective on the Effective Date. The amendment and restatement of this Plan as approved by the board of directors on March 3, 2023 will become effective on the date it is approved by the Company's stockholders (the "***A&R Effective Date***").

12. CHOICE OF LAW.

The law of the State of Delaware will govern all questions concerning the construction, validity and interpretation of this Plan, without regard to that state's conflict of laws rules.

13. DEFINITIONS. As used in the Plan, the following definitions will apply to the capitalized terms indicated below:

(a) "***Affiliate***" means, at the time of determination, any "parent" or "subsidiary" of the Company as such terms are defined in Rule 405 of the Securities Act. The Board will have the authority to determine the time or times at which "parent" or "subsidiary" status is determined within the foregoing definition.

(b) "***Award***" means a Stock Award or a Performance Cash Award.

(c) "***Award Agreement***" means a written agreement between the Company and a Participant evidencing the terms and conditions of an Award.

(d) "***Board***" means the Board of Directors of the Company.

(e) "***Capitalization Adjustment***" means any change that is made in, or other events that occur with respect to, the Common Stock subject to the Plan or subject to any Stock Award after the Adoption Date without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large non-recurring cash dividend, stock split, reverse stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or any similar equity restructuring transaction, as that term is used in Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or any successor thereto). Notwithstanding the foregoing, the conversion of any convertible securities of the Company will not be treated as a Capitalization Adjustment.

(f) "*Capital Stock*" means each and every class of common stock of the Company, regardless of the number of votes per share and including shares of common stock underlying outstanding Pre-Funded Warrants.

(g) "***Cause***" will have the meaning ascribed to such term in any written agreement between the Participant and the Company defining such term and, in the absence of such agreement, such term will mean, with respect to a Participant, the occurrence of any one or more of the following events: (i) Participant's conviction of, or plea of nolo contendere to, any felony or to any crime or offense causing substantial harm to the Company or its Affiliates or involving acts of theft fraud, embezzlement, moral turpitude or similar conduct; (ii) Participant's repeated intoxication by alcohol or drugs during the performance of Participant's duties in a manner that materially and adversely affects Participant's performance of such duties; (iii) malfeasance in the conduct of Participant's duties, including, but not limited to (A) willful and intentional misuse or diversion of funds of the Company or its Affiliates, (B) embezzlement, (C) fraudulent or willful and material misrepresentations or concealments on any written reports submitted to the Company or its Affiliates, or (D) any unauthorized use or disclosure of any confidential information or trade secrets of the Company or any Affiliate; (iv) Participant's material violation of any provision of an agreement between Participant and the Company; or (v) Participant's material failure to perform the duties of Participant's employment or engagement or material failure to follow or comply with the reasonable and lawful written directives of the Board or CEO of the Company or with the written employment policies of the Company. Cause shall be determined by the Administrator in its sole discretion.

(h) "***Change in Control***" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control will not be deemed to occur (A) on account of the acquisition of securities of the Company directly from the Company; (B) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Exchange Act Person that acquires the Company's securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities; or (C) solely because the level of Ownership held by any Exchange Act Person (the "***Subject Person***") exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned by the Subject Person over the designated percentage threshold, then a Change in Control will be deemed to occur;

(ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representing more than 50% of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction or (B) more than 50% of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction;

(iii) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; or

(iv) individuals who, on the date the Plan is adopted by the Board, are members of the Board (the "***Incumbent Board***") cease for any reason to constitute at least a majority of the members of the Board; *provided*, *however*, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member will, for purposes of this Plan, be considered as a member of the Incumbent Board.

For purposes of determining voting power under the term Change in Control, voting power shall be calculated by assuming the conversion of all equity securities convertible (immediately or at some future time) into shares entitled to vote, but not assuming the exercise of any warrant or right to subscribe to or purchase those shares. In addition, (A) the term Change in Control will not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company, (B) the term Change in Control will not include a change in the voting power of any one or more stockholders as a result of the conversion of any class of the Company's securities into another class of the Company's securities having a different number of votes per share pursuant to the conversion provisions set forth in the Company's Amended and Restated Certificate of Incorporation, and (C) the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Participant will supersede the foregoing definition with respect to Awards subject to such agreement; *provided*, *however*, that if no definition of Change in Control or any analogous term is set forth in such an individual written agreement, the foregoing definition will apply. If required for compliance with Section 409A of the Code, in no event will a Change in Control be deemed to have occurred if such transaction is not also a "change in the ownership or effective control of" the Company or "a change in the ownership of a substantial portion of the assets of" the Company as determined under Treasury Regulation Section 1.409A-3(i)(5) (without regard to any alternative definition thereunder). The Board may, in its sole discretion and without a Participant's consent, amend the definition of "Change in Control" to conform to the definition of "Change in Control" under Section 409A of the Code, and the regulations thereunder.

(i) "***Code***" means the Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(j) "***Committee***" means a committee of one or more Directors to whom authority has been delegated by the Board in accordance with Section 2(c).

(k) "***Common Stock***" means the common stock of the Company, having one vote per share.

(l) "***Company***" means Chinook Therapeutics, Inc., a Delaware corporation.

(m) “***Consultant***” means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of an Affiliate and is compensated for such services. However, service solely as a Director, or payment of a fee for such service, will not cause a Director to be considered a “Consultant” for purposes of the Plan. Notwithstanding the foregoing, a person is treated as a Consultant under this Plan only if a Form S-8 Registration Statement under the Securities Act is available to register either the offer or the sale of the Company’s securities to such person.

(n) “***Continuous Service***” means that the Participant’s service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Consultant or Director or a change in the entity for which the Participant renders such service, provided that there is no interruption or termination of the Participant’s service with the Company or an Affiliate, will not terminate a Participant’s Continuous Service; *provided*, *however*, that if the Entity for which a Participant is rendering services ceases to qualify as an Affiliate, as determined by the Board, in its sole discretion, such Participant’s Continuous Service will be considered to have terminated on the date such Entity ceases to qualify as an Affiliate. To the extent permitted by law, the Board or the chief executive officer of the Company, in that party’s sole discretion, may determine whether Continuous Service will be considered interrupted in the case of (i) any leave of absence approved by the Board or chief executive officer, including sick leave, military leave or any other personal leave, or (ii) transfers between the Company, an Affiliate, or their successors. Notwithstanding the foregoing, a leave of absence will be treated as Continuous Service for purposes of vesting in an Award only to such extent as may be provided in the Company’s leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Participant, or as otherwise required by law. In addition, to the extent required for exemption from or compliance with Section 409A of the Code, the determination of whether there has been a termination of Continuous Service will be made, and such term will be construed, in a manner that is consistent with the definition of “separation from service” as defined under Treasury Regulation Section 1.409A-1(h) (without regard to any alternative definition thereunder).

(o) “***Corporate Transaction***” means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) the consummation of a sale or other disposition of all or substantially all, as determined by the Board, in its sole discretion, of the consolidated assets of the Company and its Subsidiaries;

(ii) the consummation of a sale or other disposition of at least 90% of the outstanding securities of the Company;

(iii) the consummation of a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

(iv) the consummation of a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

To the extent required for compliance with Section 409A of the Code, in no event will an event be deemed a Corporate Transaction if such transaction is not also a “change in the ownership or effective control of” the Company or “a change in the ownership of a substantial portion of the assets of” the Company as determined under Treasury Regulation Section 1.409A-3(i)(5) (without regard to any alternative definition thereunder).

(p) “***Covered Employee***” will have the meaning provided in Section 162(m)(3) of the Code.

(q) “***Director***” means a member of the Board.

(r) “***Disability***” means, with respect to a Participant, the inability of such Participant to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or that has lasted or can be expected to last for a continuous period of not less than 12 months, as provided in Sections 22(e)(3) and 409A(a)(2)(c)(i) of the Code, and will be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances.

(s) “***Effective Date***” means April 14, 2015, the IPO Date.

(t) “***Employee***” means any person employed by the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, will not cause a Director to be considered an “Employee” for purposes of the Plan.

(u) “***Entity***” means a corporation, partnership, limited liability company or other entity.

(v) “***Exchange Act***” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

(w) “***Exchange Act Person***” means any natural person, Entity or “group” (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that “Exchange Act Person” will not include (i) the Company or any Subsidiary of the Company, (ii) any employee benefit plan of the Company or any Subsidiary of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, (iii) an underwriter temporarily holding securities pursuant to a registered public offering of such securities, (iv) an Entity Owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their Ownership of stock of the Company; or (v) any natural person, Entity or “group” (within the meaning of Section 13(d) or 14(d) of the Exchange Act) that, as of the Effective Date, is the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company’s then outstanding securities.

(x) “***Fair Market Value***” means, as of any date, the value of the Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on any established market, the Fair Market Value of a share of Common Stock will be, unless otherwise determined by the Board, the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the date of determination, as reported in a source the Board deems reliable.

(ii) Unless otherwise provided by the Board, if there is no closing sales price for the Common Stock on the date of determination, then the Fair Market Value will be the closing selling price on the last preceding date for which such quotation exists.

(iii) In the absence of such markets for the Common Stock, the Fair Market Value will be determined by the Board in good faith and in a manner that complies with Sections 409A and 422 of the Code.

(y) “***Incentive Stock Option***” means an option granted pursuant to Section 5 of the Plan that is intended to be, and qualifies as, an “incentive stock option” within the meaning of Section 422 of the Code.

(z) “***IPO Date***” means the date of the underwriting agreement between the Company and the underwriter(s) managing the initial public offering of the Common Stock, pursuant to which the Common Stock is priced for the initial public offering.

(aa) “***Non-Employee Director***” means a Director who either (i) is not a current employee or officer of the Company or an Affiliate, does not receive compensation, either directly or indirectly, from the Company or an Affiliate for services rendered as a consultant or in any capacity other than as a Director (except for an amount as to which disclosure would not be required under Item 404(a) of Regulation S-K promulgated pursuant to the Securities Act (“***Regulation S-K***”)), does not possess an interest in any other transaction for which disclosure would be required under Item 404(a) of Regulation S-K, and is not engaged in a business relationship for which disclosure would be required pursuant to Item 404(b) of Regulation S-K; or (ii) is otherwise considered a “non-employee director” for purposes of Rule 16b-3.

(bb) "***Nonstatutory Stock Option***" means any option granted pursuant to Section 5 of the Plan that does not qualify as an Incentive Stock Option.

(cc) "***Officer***" means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act.

(dd) "***Option***" means an Incentive Stock Option or a Nonstatutory Stock Option to purchase shares of Common Stock granted pursuant to the Plan.

(ee) "***Option Agreement***" means a written agreement between the Company and an Optionholder evidencing the terms and conditions of an Option grant. Each Option Agreement will be subject to the terms and conditions of the Plan.

(ff) "***Optionholder***" means a person to whom an Option is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Option.

(gg) "***Other Stock Award***" means an award based in whole or in part by reference to the Common Stock which is granted pursuant to the terms and conditions of Section 6(d).

(hh) "***Other Stock Award Agreement***" means a written agreement between the Company and a holder of an Other Stock Award evidencing the terms and conditions of an Other Stock Award grant. Each Other Stock Award Agreement will be subject to the terms and conditions of the Plan.

(ii) "***Outside Director***" means a Director who either (i) is not a current employee of the Company or an "affiliated corporation" (within the meaning of Treasury Regulations promulgated under Section 162(m) of the Code), is not a former employee of the Company or an "affiliated corporation" who receives compensation for prior services (other than benefits under a tax-qualified retirement plan) during the taxable year, has not been an officer of the Company or an "affiliated corporation," and does not receive remuneration from the Company or an "affiliated corporation," either directly or indirectly, in any capacity other than as a Director, or (ii) is otherwise considered an "outside director" for purposes of Section 162(m) of the Code.

(jj) "***Own,***" "***Owned,***" "***Owner,***" "***Ownership***" A person or Entity will be deemed to "Own," to have "Owned," to be the "Owner" of, or to have acquired "Ownership" of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

(kk) "***Parent***" means any corporation (other than the Company) in an unbroken chain of corporations ending with the Company, if each of the corporations other than the Company owns stock possessing 50% or more of the total combined voting power of all classes of stock in one of the other corporations in such chain. A corporation that attains the status of a Parent on a date after the adoption of the Plan shall be considered a Parent commencing as of such date.

(ll) "***Participant***" means a person to whom an Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Stock Award.

(mm) "***Performance Cash Award***" means an award of cash granted pursuant to the terms and conditions of Section 6(c)(ii).

(nn) "***Performance Criteria***" means the one or more criteria that the Committee (which to the extent that an Award is intended to comply with Section 162(m) of the Code shall consist solely of two or more Outside Directors in accordance with Section 162(m) of the Code) will select for purposes of establishing the Performance Goals for a Performance Period. The Performance Criteria that will be used to establish such Performance Goals may be based on any one of, or combination of, the following as determined by the Committee (which to the extent that an Award is intended to comply with Section 162(m) of the Code shall consist solely of two or more Outside Directors in accordance with Section 162(m) of the Code): (i) earnings (including earnings per share and net earnings); (ii) earnings before interest, taxes and depreciation; (iii) earnings before interest, taxes, depreciation and amortization; (iv) earnings before interest, taxes, depreciation, amortization and legal settlements; (v) earnings before interest, taxes, depreciation, amortization, legal settlements and other income (expense); (vi) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense) and stock-based compensation; (vii) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense), stock-based compensation and changes in deferred revenue; (viii) total stockholder return; (ix) return on equity or average stockholder's equity; (x) return on assets, investment, or capital employed; (xi) stock price; (xii) margin (including gross margin); (xiii) income (before or after taxes); (xiv) operating income; (xv) operating income after taxes; (xvi) pre-tax profit; (xvii) operating cash flow; (xviii) sales or revenue targets; (xix) increases in revenue or product revenue; (xx) expenses and cost reduction goals; (xxi) improvement in or attainment of working capital levels; (xxii) economic value added (or an equivalent metric); (xxiii) market share; (xxiv) cash flow; (xxv) cash flow per share; (xxvi) share price performance; (xxvii) debt reduction; (xxviii) implementation or completion of projects or processes; (xxix) employee retention; (xxx) stockholders' equity; (xxxi) capital expenditures; (xxxii) debt levels; (xxxiii) operating profit or net operating profit; (xxxiv) workforce diversity; (xxxv) growth of net income or operating income; (xxxvi) billings; (xxxvii) bookings; (xxxviii) initiation or completion of phases of clinical trials and/or studies by specified dates; (xxxix) patient enrollment rates, (xxxx) budget management; (xxxxi) regulatory body approval with respect to products, studies and/or trials; (xxxxii) commercial launch of products; and (xxxxiii) to the extent that an Award is not intended to comply with Section 162(m) of the Code, other measures of performance selected by the Board.

(oo) "***Performance Goals***" means, for a Performance Period, the one or more goals established by the Board for the Performance Period based upon the Performance Criteria. Performance Goals may be based on a Company-wide basis, with respect to one or more business units, divisions, Affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise by the Board (i) in the Award Agreement at the time the Award is granted or (ii) in such other document setting forth the Performance Goals at the time the Performance Goals are established, the Board will appropriately make adjustments in the method of calculating the attainment of Performance Goals for a Performance Period as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of any "extraordinary items" as determined under generally accepted accounting principles; (6) to exclude the dilutive effects of acquisitions or joint ventures; (7) to assume that any business divested by the Company achieved performance objectives at targeted levels during the balance of a Performance Period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of common stock of the Company by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock based compensation and the award of bonuses under the Company's bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to expensed under generally accepted accounting principles; (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles; (12) to exclude the effect of any other unusual, non-recurring gain or loss or other extraordinary item; (13) to exclude the effects of the timing of acceptance for review and/or approval of submissions to the Food and Drug Administration or any other regulatory body and (14) to exclude the effects of entering into or achieving milestones involved in licensing joint ventures. In addition, the Board retains the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of Performance Goals and to define the manner of calculating the Performance Criteria it selects to use for such Performance Period. Partial achievement of the specified criteria may result in the payment or vesting corresponding to the degree of achievement as specified in the Stock Award Agreement or the written terms of a Performance Cash Award.

(pp) "***Performance Period***" means the period of time selected by the Board over which the attainment of one or more Performance Goals will be measured for the purpose of determining a Participant's right to and the payment of a Stock Award or a Performance Cash Award. Performance Periods may be of varying and overlapping duration, at the sole discretion of the Board.

(qq) "***Performance Stock Award***" means a Stock Award granted under the terms and conditions of Section 6(c)(i).

(rr) "***Plan***" means this Amended and Restated Chinook Therapeutics, Inc. 2015 Equity Incentive Plan.

(**ss**) "***Pre-Funded Warrant***" mean any warrant to acquire shares of Common Stock for a nominal exercise price.

(tt) "***Restricted Stock Award***" means an award of shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(a).

(uu) "***Restricted Stock Award Agreement***" means a written agreement between the Company and a holder of a Restricted Stock Award evidencing the terms and conditions of a Restricted Stock Award grant. Each Restricted Stock Award Agreement will be subject to the terms and conditions of the Plan.

(vv) "***Restricted Stock Unit Award***" means a right to receive shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(b).

(ww) "***Restricted Stock Unit Award Agreement***" means a written agreement between the Company and a holder of a Restricted Stock Unit Award evidencing the terms and conditions of a Restricted Stock Unit Award grant. Each Restricted Stock Unit Award Agreement will be subject to the terms and conditions of the Plan.

(xx) "***Rule 16b-3***" means Rule 16b-3 promulgated under the Exchange Act or any successor to Rule 16b-3, as in effect from time to time.

(yy) "***Securities Act***" means the Securities Act of 1933, as amended.

(zz) "***Stock Appreciation Right***" or "***SAR***" means a right to receive the appreciation on Common Stock that is granted pursuant to the terms and conditions of Section 5.

(aaa) "***Stock Appreciation Right Agreement***" means a written agreement between the Company and a holder of a Stock Appreciation Right evidencing the terms and conditions of a Stock Appreciation Right grant. Each Stock Appreciation Right Agreement will be subject to the terms and conditions of the Plan.

(bbb) "***Stock Award***" means any right to receive Common Stock granted under the Plan, including an Incentive Stock Option, a Nonstatutory Stock Option, a Restricted Stock Award, a Restricted Stock Unit Award, a Stock Appreciation Right, a Performance Stock Award or any Other Stock Award.

(ccc) "***Stock Award Agreement***" means a written agreement between the Company and a Participant evidencing the terms and conditions of a Stock Award grant. Each Stock Award Agreement will be subject to the terms and conditions of the Plan.

(ddd) "***Subsidiary***" means, with respect to the Company, (i) any corporation of which more than 50% of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation will have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and

(ii) any partnership, limited liability company or other entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than 50%.

(eee) "***Ten Percent Stockholder***" means a person who Owns (or is deemed to Own pursuant to Section 424(d) of the Code) stock possessing more than ten percent of the total combined voting power of all classes of stock of the Company or any Affiliate.

Exhibit 31.1

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

I, Eric Dobmeier, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Chinook Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 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(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 7, 2023

/s/ Eric L. Dobmeier

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

Exhibit 31.2

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

I, Eric H. Bjerkholt, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Chinook Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 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(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 7, 2023

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

Exhibit 32.1

Certification Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Chinook Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2023 (the "Report"), Eric L. Dobmeier, President, Chief Executive Officer and Director of the Company, and Eric H. Bjerkholt, Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: August 7, 2023

/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.