UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 March 31, 2024

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: 001-39351

Nuvation Bio Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**85-0862255**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1500 Broadway , Suite 1401	
New York , New York	**10036**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (332) 208-6102

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**

Class A Common Stock, $0.0001 par value per share	NUVB	The New York Stock Exchange
Redeemable Warrants, each whole warrant exercisable for one share of Common Stock at an exercise price of $11.50 per share	NUVB.WS	The New York Stock Exchange

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 ☒

As of April 30, 2024, the registrant had

247,170,648
shares of common stock, $0.0001 par value per share, outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by terms such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “objective,” “ongoing,” “plan,” “potential,” “predict,” “project,” “should,” “will” and “would,” or the negative of these terms or other similar expressions intended to identify statements about the future. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements include, without limitation, statements about:

- our ability to recognize the anticipated benefits of the Merger (as defined below), which may be affected by, among other things, competition and our ability to grow and manage growth profitably;
- our plans to develop and commercialize our product candidates;
- the initiation, timing, progress and results of our current and future preclinical studies and clinical trials, as well as our research and development programs;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to successfully acquire or in-license additional product candidates on reasonable terms;
- our ability to maintain and establish collaborations or obtain additional funding;
- our ability to obtain regulatory approval of our current and future product candidates;
- our expectations regarding the potential market size and the rate and degree of market acceptance of such product candidates;
- our continued reliance on third parties to conduct clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials;
- our ability to fund our working capital requirements and expectations regarding the sufficiency of our capital resources;
- the implementation of our business model and strategic plans for our business and product candidates;
- our intellectual property position and the duration of our patent rights;
- developments or disputes concerning our intellectual property or other proprietary rights;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to compete in the markets we serve;
- the impact of government laws and regulations and liabilities thereunder;
- our need to hire additional personnel and our ability to attract and retain such personnel;
- our ability to raise additional funding in the future; and
- the anticipated use of our cash and cash equivalents.

The foregoing list of forward-looking statements is not exhaustive. These statements speak only as of the date of this report and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. The section of Part II of this report titled “Section 1A. Risk Factors” identifies important factors that could harm our business and financial performance and cause our actual results to differ materially from those expressed or implied by our forward-looking statements. We qualify all of our forward-looking statements by these cautionary statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise, except as required by law.

Table of Contents

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

NUVATION BIO INC. and Subsidiaries

Consolidated Balance Sheets
(In thousands, except share and per share data)

	March 31, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 34,510	$ 42,649
Prepaid expenses and other current assets	6,796	1,519
Marketable securities	562,466	568,564
Interest receivable on marketable securities	4,283	3,702
Total current assets	608,055	616,434
Property and equipment, net	686	717
Lease security deposit	141	141
Operating lease right-of-use assets	3,168	3,605
Other non-current assets	1,075	587
Total assets	$ 613,125	$ 621,484
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,436	$ 2,209
Current operating lease liabilities	2,023	1,972
Accrued expenses	11,303	9,793
Total current liabilities	15,762	13,974
Warrant liability	1,812	353
Non-current operating lease liabilities	1,509	2,035

Total liabilities	19,083	16,362
Commitments and contingencies (Note 9)		
Stockholders' equity		
Class A and Class B common stock and additional paid in capital, $ 0.0001 par value per share; 1,060,000,000 (Class A 1,000,000,000, Class B 60,000,000) shares authorized as of March 31, 2024 and December 31, 2023. 219,083,219 (Class A 218,083,219, Class B 1,000,000) and 219,046,219 (Class A 218,046,219, Class B 1,000,000) shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	952,807	947,745
Accumulated deficit	(357,596)	(342,804)
Accumulated other comprehensive loss	(1,169)	181
Total stockholders' equity	594,042	605,122
Total liabilities and stockholders' equity	$ 613,125	$ 621,484

See accompanying notes to the unaudited consolidated financial statements.

NUVATION BIO INC. and Subsidiaries

Consolidated Statements of Operations and Comprehensive Loss
(Unaudited, In thousands, except per share data)

	For the Three Months Ended March 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 12,842	$ 18,787
General and administrative	7,357	7,734
Total operating expenses	20,199	26,521
Loss from operations	(20,199)	(26,521)
Other income (expense):		
Interest income	7,130	4,979
Investment advisory fees	(265)	(230)
Change in fair value of warrant liability	(1,459)	142
Net gain (loss) on marketable securities	1	(96)
Total other income (expense), net	5,407	4,795
Loss before income taxes	(14,792)	(21,726)
Provision for income taxes	—	—
Net loss	$ (14,792)	$ (21,726)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.07)	$ (0.10)
Weighted average common shares outstanding, basic and diluted	219,048	218,741
Comprehensive loss:		
Net loss	$ (14,792)	$ (21,726)
Other comprehensive loss, net of taxes:		
Unrealized (loss) gain on available-for-sale securities, net	(1,350)	2,588

Comprehensive loss	(	(
	16,142	19,138
	$)	$)

See accompanying notes to the unaudited consolidated financial statements.

NUVATION BIO INC. and Subsidiaries

Consolidated Statements of Stockholders' Equity
(Unaudited, In thousands, except share data)

For the Three Months Ended March 31, 2024 and 2023

	Common Stock and Additional Paid-in Capital				Accumulated Other Comprehensive	Total Stockholders'
	Class A Shares	Class B Shares	Amount	Accumulated Deficit	Income (Loss)	Equity
Balance, December 31, 2023	218,046,219	1,000,000	$ 947,745	$ (342,804)	$ 181	$ 605,122
Exercise of stock options	37,000	—	21	—	—	21
Stock-based compensation	—	—	5,041	—	—	5,041
Net loss	—	—	—	(14,792)	—	(14,792)
Other comprehensive loss	—	—	—	—	(1,350)	(1,350)
Balance, March 31, 2024	218,083,219	1,000,000	$ 952,807	$ (357,596)	$ (1,169)	$ 594,042

	Common Stock and Additional Paid-in Capital				Accumulated Other Comprehensive	Total Stockholders'
	Class A Shares	Class B Shares	Amount	Accumulated Deficit	Loss	Equity
Balance, December 31, 2022	217,632,699	1,000,000	$ 927,604	$ (267,002)	$ (5,526)	$ 655,076
Exercise of stock options	171,023	—	298	—	—	298
Stock-based compensation	—	—	4,837	—	—	4,837
Net loss	—	—	—	(21,726)	—	(21,726)
Other comprehensive income	—	—	—	—	2,588	2,588
Balance, March 31, 2023	217,803,722	1,000,000	$ 932,739	$ (288,728)	$ (2,938)	$ 641,073

See accompanying notes to the unaudited consolidated financial statements.

NUVATION BIO INC. and Subsidiaries

Consolidated Statements of Cash Flows
(Unaudited, In thousands)

For the Three Months Ended March 31,	2024	2023
Cash flows from operating activities:		
Net loss	$ (14,792)	$ (21,726)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	5,041	4,837
Depreciation and amortization	58	56
Non-cash lease expense	(38)	(17)
Change in fair value of warrant liability	1,459	(142)
Net amortization on marketable securities	(2,820)	(2,147)
Net (gain) loss on marketable securities	(1)	96
Net loss on disposal of property and equipment	—	12
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(5,277)	137
Interest receivable on marketable securities	(581)	212
Other non-current assets	(488)	—
Accounts payable	227	806
Accrued expenses	1,510	(1,454)
Net cash used in operating activities	(15,702)	(19,330)
Cash flow from investing activities:		
Purchases of marketable securities	(128,409)	(236,967)
Proceeds from sale of marketable securities	135,978	184,983
Purchases of property and equipment	(27)	(12)

Net cash provided by (used in) investing activities	7,542	(51,996)
Cash flow from financing activities:		
Proceeds from exercises of options	21	298
Net cash provided by financing activities	21	298
Net decrease in cash and cash equivalents	(8,139)	(71,028)
Cash and cash equivalents, beginning of the period	42,649	101,099
Cash and cash equivalents, end of the period	$ 34,510	$ 30,071

See accompanying notes to the unaudited consolidated financial statements.

NUVATION BIO INC. and Subsidiaries

Notes to Consolidated Financial Statements

1. Nature of Operations

Nuvation Bio Inc. and subsidiaries ("Nuvation Bio"), a Delaware corporation, is a biopharmaceutical company tackling some of the greatest unmet needs in oncology by developing differentiated and novel therapeutic candidates. Nuvation Bio was incorporated on March 20, 2018 (inception date) and has offices in New York, San Francisco, Beijing, Guangzhou, Hangzhou, Shanghai and Yantai.

On February 10, 2021, (the "Closing Date"), Nuvation Bio Inc., a Delaware corporation ("Legacy Nuvation Bio"), Panacea Acquisition Corp. ("Panacea"), and Panacea Merger Subsidiary Corp, a Delaware corporation and a direct, wholly owned subsidiary of Panacea ("Merger Sub") consummated the transactions contemplated by an Agreement and Plan of Merger among them dated October 20, 2020 ("Merger Agreement").

Pursuant to the terms of the Merger Agreement, a business combination of Panacea and Legacy Nuvation Bio was effected through the merger of Merger Sub with and into Legacy Nuvation Bio, with Legacy Nuvation Bio surviving as a wholly owned subsidiary of Panacea (the "Merger") and, collectively with the other transactions described in the Merger Agreement. On the Closing Date, Legacy Nuvation Bio changed its name to Nuvation Bio Operating Company Inc. and Panacea changed its name to Nuvation Bio Inc. (the "Company" or "Nuvation Bio").

2. Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented.

Principles of Consolidation

The consolidated financial statements include the balances of the Company and its subsidiaries. All intercompany transactions and balances are eliminated in consolidation.

Unaudited Interim Financial Information

The accompanying unaudited condensed consolidated financial statements as of March 31, 2024 and for the three months ended March 31, 2024 and 2023, have been prepared in accordance with GAAP for interim financial statements and pursuant to Form 10-Q and Article 10 of Regulation S-X. In the opinion of management, all adjustments (consisting of normal recurring accruals) have been made that are considered necessary for a fair statement of the financial position of the Company as of March 31, 2024, the results of operations for the three months ended March 31, 2024 and 2023 and the cash flows for the three months ended March 31, 2024 and 2023. The condensed consolidated balance sheet as of December 31, 2023 has been derived from the Company's audited consolidated financial statements. Operating results for the three months ended March 31, 2024 are not necessarily indicative of the results that may be expected for the year ending December 31, 2024.

Certain information and disclosures normally included in the notes to annual financial statements prepared in accordance with GAAP have been omitted from these interim financial statements pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). Accordingly, these unaudited condensed consolidated financial statements should be read in conjunction with the financial statements for the fiscal year ended December 31, 2023, which are included in the Company's 10-K filed with the SEC on February 29, 2024.

Liquidity

As of March 31, 2024, the Company has an accumulated deficit of approximately $

357.6

million and net cash used in operating activities was approximately $

15.7

million for the three months ended March 31, 2024. Management expects to continue to incur operating losses and negative cash flows from operations for the foreseeable future.

As of March 31, 2024, the Company had cash, cash equivalents, and marketable securities of $

597.0

million. The Company believes that its existing cash, cash equivalents, and marketable securities will be sufficient to meet its cash commitments for at least the next 12 months after the date that these consolidated financial statements are issued. The Company's research and development activities can be costly, and the timing and outcomes are uncertain. The assumptions upon which the Company has based its estimates are routinely evaluated and may be subject to change. The actual amount of the Company's expenditures will vary depending upon a

number of factors including but not limited to the progress of the Company's research and development activities and the level of financial resources available.

Significant Risks and Uncertainties

The Company's operations are subject to a number of factors that can affect its operating results and financial condition. Such factors include, but are not limited to: the results of research and development, clinical testing and trial activities of the Company's products, the Company's ability to obtain regulatory approval to market its products, competition from products manufactured and sold or being developed by other companies, the price of, and demand for, Company's products, the Company's ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products, and the Company's ability to raise capital.

The Company currently has no commercially approved products and there can be no assurance that the Company's research and development will be successfully commercialized. Developing and commercializing a product requires significant time and capital and is subject to regulatory review and approval as well as competition from other biotechnology and pharmaceutical companies. The Company operates in an environment of rapid change and is dependent upon the continued services of its employees and vendors and obtaining and protecting intellectual property.

Use of Estimates

The preparation of financial statements in conformity with 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 and the reported amount of revenue and expenses during the year. Accordingly, actual results could differ from those estimates and those differences could be significant. Significant estimates and assumptions reflected in the accompanying consolidated financial statements include, but are not limited to, warrant liabilities, leases, stock options granted and depreciation expense.

Cash and Cash Equivalents

Cash equivalents include short-term, highly liquid instruments, consisting of money market accounts, a money market mutual fund and short-term investments with maturities from the date of purchase of 90 days or less. The majority of cash and cash equivalents are maintained with major financial institutions in North America. Deposits with these financial institutions may exceed the amount of insurance provided on such deposits. These deposits may be redeemed upon demand which reduces counterparty performance risk.

Marketable Securities

Debt securities have been classified as available-for-sale which may be sold before maturity or are not classified as held to maturity or trading. Marketable debt securities classified as available-for-sale are carried at fair value with unrealized gains or losses reported in other comprehensive income (loss). Exchange traded funds are equity securities, which are reported as marketable securities with readily determinable fair values, are also carried at fair value with unrealized gains and losses included in other (expense) income, net. Realized gains and losses on both debt and equity securities are included in other (expense) income, net.

For securities in an unrealized loss position, management considers the extent and duration of the unrealized loss, and the financial condition and near-term prospects of the issuer. Management also assesses whether it intends to sell, or it is more likely than not that it will be required to sell, a security in an unrealized loss position before recovery of its amortized cost basis. If management determines there is any other than temporary impairment, the entire difference between amortized cost and fair value is recognized as impairment through earnings.

The Company is exposed to credit losses primarily through its available-for-sale investments. The Company assesses whether its available-for sale investments are impaired at each reporting period. Unrealized losses or impairments resulting from the amortized cost basis of any available-for-sale debt security exceeding its fair value are evaluated for identification of credit losses and non-credit related losses. Any credit losses are charged to earnings against the allowance for credit losses of the debt security, limited to the difference between the fair value and the amortized cost basis of the debt security. Any difference between the fair value of the debt security and the amortized cost basis, less the allowance for expected credit losses, are reported in other comprehensive income (loss). Expected cash inflows due to improvements in credit are recognized through a reversal of the allowance for expected credit losses subject to the total allowance previously recognized. The Company's expected loss allowance methodology for the debt securities includes reviewing the extent of the unrealized loss, the size, term, geographical location, and industry of the issuer, the issuers' credit ratings and any changes in those ratings, as well as reviewing current and future economic market conditions and the issuers' current status and financial condition. As of March 31, 2024, the Company has not recognized an allowance for expected credit losses related

to available-for-sale investments as the Company has not identified any unrealized losses for these investments attributable to credit factors.

Interest income includes amortization and accretion of purchase premium and discount. Premiums and discounts on debt securities are amortized on the effective-interest method. Gains and losses on sales are recorded on the settlement date and determined using the specific identification method.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash, cash equivalents and marketable securities. The Company maintains its cash and cash equivalent balances in the form of business checking accounts and money market accounts, the balances of which, at times, may exceed federally insured limits. Exposure to cash and cash equivalents credit risk is reduced by placing such deposits with major financial institutions and monitoring their credit ratings. Marketable securities consist primarily of government and corporate bonds, municipal securities and exchange traded funds with fixed interest rates. Exposure to credit risk of marketable securities is reduced by maintaining a diverse portfolio and monitoring their credit ratings.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the related assets of generally five years for computers and seven years for furniture and equipment. The cost of leasehold improvements is amortized on the straight-line method over the lesser of the estimated asset life or remaining term of the lease. Maintenance costs are expensed as incurred, while major betterments are capitalized.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable and an impairment assessment may be performed on the recoverability of the carrying amounts. If an impairment occurs, the loss is measured by comparing the fair value of the asset to its carrying amount.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC 815, Derivatives and Hedging ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own ordinary shares, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded as a liability at their fair value on the date of issuance and each balance sheet date thereafter. Changes in the estimated fair value of the warrants are recognized as a non-cash gain or loss on the statements of operations.

Following the Merger, there were

5,787,472
warrants to purchase common stock outstanding, consisting of

4,791,639
Public Warrants,

162,500
Private Placement Warrants and

833,333
Forward Purchase Warrants (as defined below). Each whole warrant entitles the registered holder to purchase one share of our Class A common stock at a price of $

11.50
per share. Pursuant to the warrant agreement, a warrant holder may exercise its warrants only for a whole number of shares of our Class A common stock.

The Company evaluated Public Warrants, Private Placement Warrants and Forward Purchase Warrants (the "Warrants") under ASC 815-40, Derivatives and Hedging—Contracts in Entity's Own Equity, and concluded that they do not meet the criteria to be classified in stockholders' equity. Specifically, the settlement value of the Warrants is dependent, in part, on the holder of the Warrants at the time of settlement. Because the holder of an instrument is not an input into the pricing of a fixed-for-fixed option on our common stock, the Warrants fail the indexation guidance in ASC 815-40, which would preclude classification in stockholders' equity. Additionally, the exercise of the Warrants may be settled in cash upon the occurrence of a tender offer or exchange that involves more than 50% of the outstanding shares of the Company's common stock. Because not all of the Company's stockholders need to participate in such tender offer or exchange to trigger the potential cash settlement and the Company does not control the occurrence of such an event, the Company concluded that the Warrants do not meet the conditions to be classified in equity. Since the Warrants meet the definition of a derivative under ASC 815, the Company recorded these Warrants as liabilities on the balance sheet at fair value upon the closing of the Merger, with subsequent changes in their respective fair values recognized in the consolidated statement of operations and comprehensive loss at each reporting date. The fair value of Public and Forward Purchase Warrants was determined using the

closing price of the warrants on the NYSE market. The fair value of the Private Warrants was estimated using a Black-Scholes option pricing model (see Note 3).

Leases

The Company determines if an arrangement contains a lease at inception. For arrangements where the Company is the lessee, operating leases are included in operating lease right-of-use, or ROU assets; current operating lease liabilities; and non-current operating lease liabilities on its balance sheets. The Company currently does not have any finance leases.

Operating lease ROU assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at the commencement date. ROU assets also include any initial direct costs incurred and any lease payments made on or before the lease commencement date, less lease incentives received. The Company uses its incremental borrowing rate based on the information available at the commencement date in determining the lease liabilities as the Company's leases generally do not provide an implicit rate. The incremental borrowing rate is reevaluated upon a lease modification. The operating lease ROU asset also includes any initial direct costs and prepaid lease payments made less any lease incentives. The Company considered information available at the adoption date of Topic 842 to determine the incremental borrowing rate for leases in existence as of this date. The incremental borrowing rate used was the weighted average rate between secured and unsecured lending arrangements. Lease terms may include options to extend or terminate the lease when the Company is reasonably certain that the option will be exercised. Variable payments included in the lease agreement are expensed as incurred. Lease expense is recognized on a straight-line basis over the lease term.

The Company elected to apply each of the practical expedients described in ASC Topic 842-10-65-1(f) which allow companies not to reassess: (i) whether any expired or existing agreements contain leases, (ii) the classification of any expired or existing leases, and (iii) the capitalization of initial direct costs for any existing leases. The Company also elected to apply the short-term lease measurement and recognition exemption in which ROU assets and lease liabilities are not recognized for short-term operating leases. A short-term operating lease is a lease that, at the commencement date, has a lease term of 12 months or less and does not include an option to purchase the underlying asset that the lessee is reasonably certain to exercise. The Company also elected not to separate non-lease components from lease components and instead to account for each separate lease component and the non-lease components associated with that lease component as a single lease component.

Segment Information

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's operations are focused on oncology development activities.

Research and Development Costs

Costs incurred in connection with research and development activities are expensed as incurred. These costs include fees paid to consultants, vendors and various entities that perform certain research and testing on behalf of the Company.

Stock-based Compensation

The Company recognizes compensation cost for grants of employee stock options using a fair-value measurement method, that is recognized in operating results as compensation expense based on fair value over the requisite service period of the awards. Forfeitures are recorded as they occur instead of estimating forfeitures that are expected to occur.

The Company determines the fair value of stock-based awards that are based only on a service condition using the Black-Scholes option-pricing model which uses both historical and current market data to estimate fair value. The method incorporates various assumptions such as the risk-free interest rate, volatility, dividend yield, and expected life of the options.

The Company determines the fair value of stock-based awards that are based on both a service condition and achievement of the first to occur of a market or performance condition using a Monte Carlo simulation.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. The difference between the financial statement and tax basis of assets and liabilities is determined annually. Deferred income tax assets and liabilities are computed for those differences that have future tax consequences using the currently enacted tax laws and rates that apply to the years in which they are expected to affect taxable income. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense.

The Company uses a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken, or expected to be taken, in a tax return. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate. The Company's policy is to record interest and penalties related to income taxes as part of the tax provision. Returns for tax years beginning with those filed for the period ended December 31, 2018 are open to federal and state tax examination.

Recent Accounting Pronouncements

In November 2023, the FASB issued Topic 280 "Improvements to Reportable Segment Disclosures" which expands annual and interim disclosure requirements for reportable segments, primarily through enhanced disclosures about significant segment expenses. This guidance is effective for our annual periods beginning January 1, 2024, and for interim periods beginning January 1, 2025, with early adoption permitted. We are currently evaluating the potential effect that the updated standard will have on our financial statement disclosures.

In December 2023, the FASB issued Topics 740 "Improvements to Income Tax Disclosures" to expand the disclosure requirements for income taxes, specifically related to the rate reconciliation and income taxes paid. This guidance is effective for our annual periods beginning January 1, 2025, with early adoption permitted. We are currently evaluating the potential effect that the updated standard will have on our financial statement disclosures.

3. Fair Value Measurements and Marketable Securities Available-for-Sale

The Company provides disclosure of financial assets and financial liabilities that are carried at fair value based on the price that would be received upon sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Fair value measurements may be classified based on the amount of subjectivity associated with the inputs to fair valuation of these assets and liabilities using the following three levels:

Level 1 — Inputs are unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2 — Inputs include quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (i.e., interest rates, yield curves, etc.) and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs).

Level 3 — Unobservable inputs that reflect the Company's estimates of the assumptions that market participants would use in pricing the asset or liability. The Company develops these inputs based on the best information available, including its own data.

The following table presents information about the Company's marketable securities as of March 31, 2024 and December 31, 2023 and the Warrant liability as of March 31, 2024 and December 31, 2023, measured at fair value on a recurring basis, and indicates the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value. The Company's Warrant liabilities are included within the Level 1 and Level 3 fair value hierarchy. The fair value of the Public and Forward Purchase Warrants is determined using the closing price of the warrants on the NYSE market. The fair value of the Private Placement Warrants is determined using the Black-Scholes option pricing formula. The primary unobservable input utilized in determining the fair value of the Private Warrants is the expected volatility. The expected volatility was estimated considering observable Nuvation public warrant pricing, Nuvation's own historical volatility and the volatility of guideline public companies. There have not been any transfers between the levels during the periods.

	March 31, 2024			
	Total	Level 1	Level 2	Level 3
	(In thousands)			
Financial assets:				
Cash equivalents:				
Money market funds	$ 14,575	$ 14,575	$ —	$ —
U.S. government and government agency securities	8,191	—	8,191	—
	22,766	14,575	8,191	—
Marketable securities:				
Certificate of deposits	17,097	—	17,097	—
Commercial paper	28,216	—	28,216	—
U.S. government and government agency securities	436,691	—	436,691	—
Corporate bonds	80,462	—	80,462	—
	562,466	—	562,466	—
Total financial assets:	$ 585,232	$ 14,575	$ 570,657	$ —
Financial liabilities:				
Warrants	$ 1,812	$ 1,701	$ —	$ 111

	December 31, 2023			
	Total	Level 1	Level 2	Level 3
	(In thousands)			
Financial assets:				
Cash equivalents:				
Money market funds	$ 20,574	$ 20,574	$ —	$ —
U.S. government and government agency securities	4,988	—	4,988	—

Corporate bonds				
	947	—	947	—
	26,509	20,574	5,935	—
Marketable securities:				
Certificate of deposits				
	10,176	—	10,176	—
Commercial paper				
	23,628	—	23,628	—
U.S. government and government agency securities				
	453,175	—	453,175	—
Corporate bonds				
	81,585	—	81,585	—
	568,564	—	568,564	—
Total financial assets:				
	$ 595,073	$ 20,574	$ 574,499	$ —
Financial liabilities:				
Warrants				
	$ 353	$ 338	$ —	$ 15

Marketable securities consist primarily of U.S. government and government agency, certificate of deposits, commercial paper, corporate bond and municipal securities ("Debt Securities"). Based on the Company's intentions regarding its marketable securities, all Debt Securities are classified as available-for-sale and are carried at fair value based on the price that would be received upon sale of the security. The following table provides the amortized cost, aggregate fair value, and unrealized gains (losses) of marketable securities as of March 31, 2024 and December 31, 2023:

	March 31, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
	(In thousands)			
Cash equivalents:				
Money market funds	$ 14,575	$ —	$ —	$ 14,575
U.S. government and government agency securities	8,191	—	—	8,191
	22,766	—	—	22,766
Marketable securities:				
Certificate of deposits	17,095	6	(4)	17,097
Commercial paper	28,238	5	(27)	28,216
U.S. government and government agency securities	437,674	160	(1,143)	436,691
Corporate bonds	80,628	45	(211)	80,462
	563,635	216	(1,385)	562,466
	$ 586,401	$ 216	$ (1,385)	$ 585,232

	December 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
	(In thousands)			
Cash equivalents:				
Money market funds	$ 20,574	$ —	$ —	$ 20,574
U.S. government and government agency securities	4,987	1	—	4,988
Corporate bonds	947	—	—	947
	26,508	1	—	26,509
Marketable securities:				

Certificate of deposits	10,171	7	(2)	10,176
Commercial paper	23,609	22	(3)	23,628
U.S. government and government agency securities	452,813	1,095	(733)	453,175
Corporate bonds	81,791	68	(274)	81,585
	568,384	1,192	(1,012)	568,564
	$ 594,892	$ 1,193	$ (1,012)	$ 595,073

For the three months ended March 31, 2024 and 2023, there was no unrealized gains or losses on equity securities. The activity related to the net gains (losses) on marketable securities included in other income (expense) on the consolidated statements of operations and comprehensive loss were as follows (in thousands):

	Three months ended March 31,	
	2024	2023
Net realized gains (losses) on available-for-sale securities were as follows:		
Realized gains from sales of available-for-sale securities	$ 1	$ —
Realized losses from sales of available-for-sale securities	—	(96)
Total losses on marketable securities	$ 1	$ (96)

The following tables provide marketable securities with continuous unrealized losses for less than 12 months and 12 months or greater and the related fair values as of March 31, 2024 and December 31, 2023 were as follows:

	March 31, 2024					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Total Unrealized Losses
	(In thousands)					
Certificate of deposits	$ 9,863	$ (4)	$ —	$ —	$ 9,863	$ (4)
Commercial paper	23,247	(27)	—	—	23,247	(27)
U.S. government and government agency securities	287,141	(1,097)	6,322	(46)	293,463	(1,143)
Corporate bonds	33,790	(51)	23,385	(160)	57,175	(211)
	$ 354,041	$ (1,179)	$ 29,707	$ (206)	$ 383,748	$ (1,385)

	December 31, 2023					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Total Unrealized Losses
	(In thousands)					
Certificate of deposits	$ 5,693	$ (2)	$ —	$ —	$ 5,693	$ (2)
Commercial paper	9,101	(3)	—	—	9,101	(3)
U.S. government and government agency securities	199,552	(694)	24,761	(38)	224,313	(732)
Corporate bonds	21,844	(28)	26,484	(246)	48,328	(274)
	$ 236,190	$ (727)	$ 51,245	$ (284)	$ 287,435	$ (1,011)

Unrealized losses from the marketable securities are primarily attributable to changes in interest rates. The Company does not believe the unrealized losses represent impairments because the unrealized losses on certain of the Company's marketable securities are due to general market factors. The Company has not recognized an allowance for expected credit losses related to available-for-sale investments as the Company has not identified any unrealized losses for these investments attributable to credit factors during the three months ended March 31, 2024. As of March 31, 2024, the Company does not intend to sell these securities nor does the Company believe that it will be required to sell these securities before the recovery of their amortized cost basis.

Maturity information based on fair value is as follows as of March 31, 2024:

	Within one year	After one year through five years	Total
		(In thousands)	

Certificate of deposits			
	16,472	625	17,097
	$	$	$
Commercial paper			
	28,216	—	28,216
U.S. government and government agency securities			
	258,059	178,632	436,691
Corporate bonds			
	56,196	24,266	80,462
	358,943	203,523	562,466
	$	$	$

4. Leases

Our principal executive office is located in New York, New York, where we lease approximately

7,900

square feet of office space under a lease that terminates in 2027 , with an option for the Company to extend the lease for an additional five years which is not reasonably assured of exercise. We also occupy approximately

25,139

square feet of office space in San Francisco, California, under a lease that terminates in 2025 and a total of approximately

1,582

square meters of office space in the People's Republic of China, in the cities of Beijing, Guangzhou, Hangzhou, Shanghai and Yantai, under leases that terminate in 2024 through 2026.

Operating lease expense was $

0.5

million and $

0.3

million for the three months ended March 31, 2024 and 2023, respectively. Expense related to variable leases was

no

t significant for the three months ended March 31, 2024 and 2023. Operating cash flows for the three months ended March 31, 2024 and 2023 included $

0.5

million and $

0.3

million for operating leases, respectively.

The following table presents the future minimum lease analysis of the Company's operating lease liabilities showing the aggregate lease payments as of March 31, 2024.

	March 31, 2024 (In thousands)
2024 (remaining 9 months)	$ 1,634
2025	1,416
2026	629
2027 and thereafter	81
Total undiscounted lease payments	3,760
Less: imputed interest	(228)
Total operating lease liabilities	$ 3,532

The weighted average incremental borrowing rate used to determine the operating lease liabilities was 6.85 %. The Company's weighted average remaining lease term was 2.0 years as of March 31, 2024.

5. Net Loss per Share

Basic loss per share is computed by dividing net loss by the weighted-average number of shares of Class A and Class B common stock outstanding. Diluted loss per share reflects the potential dilution that could occur if the stock options to issue common stock were exercised. The Company had a net loss in all periods presented thus the dilutive net loss per common share is the same as the basic net loss per common share as the effect of any options or conversions is anti-dilutive.

The earnings per share amounts are the same for the different classes of common stock because the holders of each class are legally entitled to equal per share distributions whether through dividends or liquidation.

The following securities outstanding at March 31, 2024 and 2023 have been excluded from the calculation of weighted average shares outstanding:

	Three Months Ended March 31, 2024	2023
Warrants	5,787,462	5,787,462
Class A common stock options	38,224,240	30,905,880

6. Accumulated Other Comprehensive Income (Loss)

The following table presents a rollforward of the changes in accumulated other comprehensive income (losses) for the three months ended March 31, 2024 and 2023, which is all attributable to unrealized gains (losses) on available-for-sale securities. All amounts are net of tax.

	2024	2023
Balance at beginning of period	$ 181	$ (5,526)
Unrealized (loss) gain	(1,349)	2,492
Amount reclassified for realized (gain) loss on marketable securities	(1)	96

Balance at end of period	(	(
	1,169	2,938
	$)	$)

7. Stock-Based Compensation

The 2021 Equity Incentive Plan

In March 2019, the Company adopted the 2019 Equity Incentive Plan or ("2019 Plan"), which provided for the grant of options, stock appreciation rights, restricted stock, and other stock awards. In January 2021, our board of directors adopted the 2021 Equity Incentive Plan (the "2021 Plan"). The 2021 Plan was approved by our stockholders in February 2021 and became effective immediately upon the Closing Date of the Merger. Shares available for future issuance under the 2019 Plan were canceled.

Awards. The 2021 Plan provides for the grant of incentive stock options ("ISOs"), within the meaning of Section 422 of the Code to employees, including employees of any parent or subsidiary, and for the grant of nonstatutory stock options ("NSOs"), stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to employees, directors and consultants, including employees and consultants of our affiliates.

Authorized Shares. The maximum number of shares of Class A common stock reserved for issuance upon adoption of the 2021 Plan was

50,684,047

shares of Class A common stock. The number of shares of Class A common stock reserved for issuance under the 2021 Plan will automatically increase on January 1 of each year, starting on January 1, 2022 through January 1, 2031, in an amount

equal to (1)

4.0
% of the total number of shares of Class A common stock and Class B common stock outstanding or issuable upon conversion or exercise of outstanding instruments on December 31 of the preceding year, or (2) a lesser number of shares of Class A common stock determined by our board of directors prior to the date of the increase. The maximum number of shares of Class A common stock that may be issued on the exercise of ISOs under the 2021 Plan is three times the number of shares available for issuance upon the 2021 Plan becoming effective or

152,052,141
shares.

The Employee Stock Purchase Plan

In January 2021, our board of directors adopted the 2021 Employee Stock Purchase Plan (the "ESPP"). The ESPP was approved by our stockholders in February 2021 and became effective immediately upon the Closing Date of the Merger.

Share Reserve. The maximum number of shares of Class A common stock reserved for issuance upon the adoption of the 2021 ESPP was

4,750,354
shares of Class A common stock. The number of shares of Class A common stock reserved for issuance under the 2021 ESPP will automatically increase on January 1st of each year, beginning on January 1, 2022 and continuing through and including January 1, 2031, by

1.0
% of the total number of shares of Class A common stock and Class B common stock outstanding or issuable upon conversion or exercise of outstanding instruments on December 31st of the preceding calendar year or such lesser number of shares of Class A common stock as determined by our board of directors. Shares subject to purchase rights granted under the 2021 ESPP that terminate without having been exercised in full will not reduce the number of shares available for issuance under the 2021 ESPP.

The stock-based compensation expense included in the Company's condensed statement of operations and comprehensive loss for the three months ended March 31, 2024 and 2023 is as follows (in thousands):

	Three Months Ended March 31,	
	2024	2023
Research and development	$ 2,292	$ 2,012
General and administrative	2,749	2,825
	$ 5,041	$ 4,837

The following table summarizes stock option activity under the 2019 Plan and the 2021 Plan for the three months ended March 31, 2024.

	Shares
Outstanding at December 31, 2023	30,649,239
Granted	8,736,679
Exercised	(37,000)
Forfeited	(1,124,678)
Outstanding at March 31, 2024	38,224,240
Exercisable at March 31, 2024	11,877,245

The weighted average exercise price of all outstanding options as of March 31, 2024 was $

3.38
per share.

8. Warrants

Following the Merger, there were

5,787,472
warrants to purchase common stock outstanding, consisting of

4,791,639
Public Warrants,

162,500
Private Placement Warrants and

833,333
Forward Purchase Warrants. Each whole warrant entitles the registered holder to purchase one share of our Class A common stock at a price of $

11.50
per share. Pursuant to the warrant agreement, a warrant holder may exercise its warrants only for a whole number of shares of our Class A common stock. At March 31, 2024, there were an aggregate of

5,787,462
warrants outstanding.

The Company concluded that the Public Warrants, Private Warrants and Forward Purchase Warrants do not meet the conditions to be classified in equity. The warrants were recorded at fair value with subsequent changes in fair value reflected in earnings (see Note 3). The change in fair value resulted in a loss of $

1.5
million during the three months ended March 31, 2024.

The fair value of Public and Forward Purchase Warrants is determined using the closing price of the warrants on the NYSE market and the related Warrant Liability is included in Level 1 fair value measurements. The Company utilizes the Black-Scholes option pricing formula to determine the fair value of the Private Warrants at each reporting period, with changes in fair value recognized in the statement of operations. The estimated fair value of the warrant liability for the Private Warrants is determined using Level 3 inputs. Inherent in a binomial options pricing model are assumptions related to expected share-price volatility, expected life, risk-free interest rate and dividend yield. The annualized volatility of the Warrant was based on a calibration to the publicly traded warrant price as of the valuation date. The risk-free interest rate was estimated using linear interpolation assuming a term consistent with the time until the warrants expire, and yield information was based on U.S. Treasury Constant Maturities. The expected life of the warrants is assumed

to be equivalent to their remaining contractual term. The dividend rate is based on the historical rate, which the Company anticipates remaining at zero.

The aforementioned warrant liabilities are not subject to qualified hedge accounting.

There were no transfers between Levels 1, 2 or 3 during the period ended March 31, 2024.

The following table provides quantitative assumptions regarding Level 3 fair value measurements:

	March 31, 2024	December 31, 2023
Stock price	$ 3.64	$ 1.51
Strike price	$ 11.50	$ 11.50
Term (in years)	1.9	2.1
Volatility	87.6 %	82.7 %
Risk-free rate	4.5 %	4.1 %
Dividend yield	0.0 %	0.0 %

The Company determined the following fair values for the outstanding warrants (in thousands):

	March 31, 2024
Public Warrants	$ 1,449
Private Placement Warrants	111
Forward Purchase Warrants	252
Total	$ 1,812

The following presents changes in liabilities classified in Level 3 of the fair value hierarchy for the three months ended March 31, 2024 (in thousands):

	Three Months Ended March 31, 2024
Beginning balance	$ 15
Change in fair value of Private Warrants liability recognized in earnings	96
Ending balance	$ 111

9. Commitments and Contingencies

Commitments

The Company leases its office space under non-cancellable operating lease agreements. These leases also require the Company to pay real estate taxes and other operational expenses associated with the leased locations and are included in rent expense. The effect of graduating rents, net of the rent credits, is being amortized over the life of the leases so as to result in equal monthly rent expense over the lease term. Deferred rent liability reported in the accompanying consolidated balance sheets represents the cumulative excess of straight-line rental costs over the actual rental payments.

The Company has standby letters of credit with banks in the aggregate amount of $

0.6

million which serve as security for the New York and San Francisco spaces operating leases. The standby letters of credit automatically renew annually .

Contingencies

From time to time, the Company is involved in routine litigation that arises in the ordinary course of business. There are no pending significant legal proceedings to which the Company is a party, for which management believes the ultimate outcome would have a material adverse effect on the Company's financial position.

10. Subsequent Event

On April 9, 2024, the Company completed its previously announced acquisition (the "Acquisition") of AnHeart Therapeutics Ltd ., an exempted company incorporated under the laws of the Cayman Islands ("AnHeart"), pursuant to that certain Agreement and Plan of Merger (the "AnHeart Merger Agreement"), by and among the Company, AnHeart, Artemis Merger Sub I, Ltd., an exempted company incorporated under the laws of the Cayman Islands and a wholly owned subsidiary of the Company, and Artemis Merger Sub II, Ltd., an exempted company incorporated under the laws of the Cayman Islands and a wholly owned subsidiary of the Company.

Pursuant to the terms of the AnHeart Merger Agreement, at the effective time of the First Merger (as defined in the AnHeart Merger Agreement) (the “First Effective Time”), the Company issued to AnHeart securityholders (i) approximately

27,646,255
shares of Class A Common Stock of the Company, par value $

0.0001
per share (the “Class A Common Stock”), (ii)

851,202
shares of Series A Non-Voting Convertible Preferred Stock of the Company, par value $

0.0001
per share (the “Convertible Preferred Stock”), and (iii) warrants collectively exercisable for approximately

2,893,731
shares of Class A Common Stock at an exercise price of $

11.50
per share (the “Consideration Warrants”). The Company also reserved an aggregate of approximately

15,943,933
shares of Class A Common Stock for issuance upon exercise of Assumed Options or settlement of Assumed RSUs (as such terms are defined below). The shares of Convertible Preferred Stock are automatically convertible into an aggregate of approximately

85,120,200
shares of Class A Common Stock upon the approval of such conversion by the Company’s stockholders in accordance with the rules of the New York Stock Exchange. The Consideration Warrants are restricted with respect to the exercise and transfer thereof until receipt of such stockholder approval and otherwise have terms identical to those of the Company’s outstanding publicly traded warrants.

The Acquisition adds taletrectinib, a next-generation, potentially best-in-class ROS1 inhibitor with Breakthrough Therapy Designations currently completing two pivotal studies for the treatment of patients with ROS1-positive non-small cell lung cancer. The Acquisition also adds safusidenib, a potentially best-in-class mutant IDH1 inhibitor currently being evaluated in a global Phase 2 study of patients with grades 2 and 3 IDH1-mutant glioma.

The transaction is anticipated to be accounted for as an asset acquisition.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis provide information which our management believes is relevant to an assessment and understanding of our consolidated results of operations and financial condition. You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and notes thereto included elsewhere in this report. In addition to historical financial information, this discussion contains forward-looking statements based upon our current expectations that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the section titled "Item 1A. Risk Factors."

Overview

We are a late-stage, global biopharmaceutical company tackling some of the greatest unmet needs in oncology by developing differentiated and novel therapeutic candidates. We were founded in 2018 by our chief executive officer, David Hung, M.D., who founded Medivation, Inc. and led its successful development of oncology drugs Xtandi® and talazoparib (now marketed as Talzenna®), leading to its $14.3 billion sale to Pfizer Inc. ("Pfizer") in 2016. We leverage our team's extensive expertise in medicinal chemistry, preclinical development, drug development, and business development to pursue oncology targets validated by strong clinical or preclinical data and develop novel small molecules that improve the activity and overcome the liabilities of currently marketed drugs.

As a result of our April 2024 acquisition of AnHeart Therapeutics Ltd. ("AnHeart"), our most advanced clinical stage product candidate, taletrectinib, is an oral, potent, central nervous system-active, selective, next-generation ROS1 inhibitor specifically designed for the treatment of patients with advanced ROS1-positive non-small cell lung cancer ("NSCLC"). Taletrectinib is being evaluated for the treatment of patients with advanced ROS1-positive NSCLC in two Phase 2 single-arm pivotal studies: TRUST-I in China, and TRUST-II, a global study. Taletrectinib has been granted Breakthrough Therapy Designations by both the U.S. Food and Drug Administration ("FDA") and China's National Medical Products Administration ("NMPA") for the treatment of patients with advanced or metastatic ROS1-positive NSCLC. Based on results of the TRUST-I clinical study, China's NMPA has accepted and granted Priority Review Designations to New Drug Applications for taletrectinib for the treatment of adult patients with locally advanced or metastatic ROS1-positive NSCLC who either have or have not previously been treated with ROS1 tyrosine kinase inhibitors ("TKIs"). Worldwide development and commercial rights to taletrectinib have been in-licensed from Daiichi Sankyo. Commercial rights to taletrectinib have been out-licensed in China, Japan, and Korea.

In addition to taletrectinib, our pipeline includes differentiated, novel oncology therapeutic candidates that have been generated from our proprietary drug discovery and development programs or acquired through business development activities:

- Safusidenib, a novel, oral, potent, targeted inhibitor of mutant IDH1, ("mIDH1"), which is being evaluated in a global Phase 2 study for the treatment of patients with grades 2 and 3 IDH1-mutant glioma
- NUV-868, a BD2-selective, oral, small molecule bromodomain and extra-terminal ("BET") inhibitor that inhibits BRD4, which is being evaluated in a Phase 1b dose escalation study in combination with olaparib for the treatment of patients with ovarian cancer, pancreatic cancer, metastatic castration-resistant prostate cancer ("mCRPC"), triple negative breast cancer, and other solid tumors, and in combination with enzalutamide for the treatment of patients with mCRPC
- NUV-1511, our first clinical-stage drug-drug conjugate ("DDC"), which is being evaluated in a Phase 1/2 study for the treatment of patients with advanced solid tumors who previously received and progressed on or after treatment with Enhertu® and/or Trodelvy® per approved U.S. FDA labeling, human epidermal growth factor receptor 2-negative ("HER2-") metastatic breast cancer, mCRPC, advanced pancreatic cancer, and platinum-resistant ovarian cancer ("PROC")

Recent Developments

In January 2024, we announced that the FDA cleared an Investigational New Drug ("IND") application for NUV-1511, the first clinical candidate from our DDC platform.

On April 9, 2024, we completed the previously announced acquisition of AnHeart.

Financial Overview

Since our inception in 2018, we have focused substantially all of our resources on conducting research and development activities, including drug discovery, preclinical studies, clinical trials, establishing and maintaining our intellectual property portfolio, developing our manufacturing network and managing the manufacture of clinical and research material, hiring personnel, raising capital and providing general and administrative support for these operations. We have not recorded revenue from product sales or collaboration activities, or any other source. We have funded our operations to date primarily from the issuance and sale of our common and preferred stock, including through the Merger and a Private Investment in Public Equity ("PIPE") financing in connection with the Merger.

We have incurred net losses in each year since inception. As of March 31, 2024, we had an accumulated deficit of $361.2 million. Substantially all of our net 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 increasing operating losses over at least the next several years. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- advance product candidates through clinical trials;
- pursue regulatory approval of product candidates;
- operate as a public company;
- continue our preclinical programs and clinical development efforts;
- continue research activities for the discovery of new product candidates; and
- manufacture supplies for our preclinical studies and clinical trials.

In addition, we expect to incur additional costs associated with operating as a public company, including significant legal, audit, accounting, regulatory, tax-related, director and officer insurance, investor relations and other expenses that we did not incur as a private company. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the public or private sale of equity, government or private party grants, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. If we are unable to obtain additional funding, we could be forced to delay, reduce or eliminate some or all of our research and development programs, product portfolio expansion or any commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations. If we raise funds through strategic collaborations or other similar arrangements with third parties, we may have to relinquish valuable rights to our platform technology, future revenue streams, research programs or product candidates or may have to grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide. Because of the numerous risks and uncertainties associated with product development, we cannot predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability.

Components of Results of Operations

Research and Development Expenses

Research and development expenses include:

- expenses incurred under agreements with third-party contract organizations, and consultants;
- costs related to production of drug substance, including fees paid to contract manufacturers;
- laboratory and vendor expenses related to the execution of preclinical trials; and
- employee-related expenses, which include salaries, benefits and stock-based compensation.

We expense all research and development costs in the periods in which they are incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks and estimates of services performed using information and data provided to us by our vendors and third-party service providers. Nonrefundable advance payments for goods or services to be received in future periods for use in research and development activities are deferred and capitalized. The capitalized amounts are then expensed as the related goods are delivered and as services are performed. We expense in-process research and development projects acquired as part of asset acquisitions that have no alternative future use.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, as our product candidates advance into later stages of development, and as we begin to conduct clinical trials. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist of personnel-related costs, facilities costs, depreciation and amortization expenses and professional services expenses, including legal, human resources, audit and accounting services. Personnel-related costs consist of salaries, benefits and stock-based compensation. Facilities costs consist of rent and maintenance of facilities. We expect our general and administrative expenses to increase for the foreseeable future due to anticipated increases in headcount to advance our product candidates

and as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC, NYSE, additional insurance expenses, investor relations activities and other administrative and professional services.

Other Income (Expense), Net

Other income (expense) consists of change in fair value of warrant liabilities, interest earned on our cash equivalents and investments, advisory expense related to our investments and realized gains and losses on marketable securities.

Results of Operations

Three Months Ended March 31, 2024 and 2023

	Three Months Ended March 31, 2024	2023	Increase / (Decrease)
	(In thousands)		
Operating expenses:			
Research and development	$ 12,842	$ 18,787	$ (5,945)
General and administrative	7,357	7,734	(377)
Total operating expenses	20,199	26,521	(6,322)
Loss from operations	(20,199)	(26,521)	6,322
Other income (expense), net	5,407	4,795	612
Net loss	$ (14,792)	$ (21,726)	$ 6,934

Research and Development Expenses

Research and development expenses decreased by $6.0 million for the three months ended March 31, 2024 compared to 2023. The decrease was primarily due to a $6.7 million decrease in third-party costs related to research services and drug manufacturing as a result of completing the Phase 1 monotherapy study of NUV-868 offset by $0.7 increase in personnel-related costs driven by stock-based compensation and other benefits.

General and Administrative Expenses

General and administrative expenses decreased by $0.4 million for the three months ended March 31, 2024, compared to 2023. The decrease was due to a $0.5 million decrease in professional fees, $0.4 million decrease in insurance and a $0.2 million decrease in personnel-related costs offset by a $0.4 million increase in legal fees, $0.2 million increase in occupancy expense and a $0.1 million increase in miscellaneous expense.

Other Income (Expense), Net

Other income (expense), net increased by $0.6 million for the three months ended March 31, 2024 compared to 2023 primarily related to interest income from investments increase of $2.1 million in 2024 primarily because of higher treasury yield in 2024 compared to 2023 and a decrease of net loss of $0.1 million was primarily due to sale of U.S. Treasuries at losses in 2023 offset by a $1.6 million increase in the change of fair value of warrant compared to prior year.

Liquidity, Capital Resources and Plan of Operations

From inception through March 31, 2024, our operations have been financed primarily by the sale and issuance of Series A preferred stock and common stock. As of March 31, 2024, we had $597.0 million in cash, cash equivalents and marketable securities and an accumulated deficit of $357.6 million.

Our primary use of cash is to fund operating expenses, which consist of research and development expenses related to our clinical stage product candidates, NUV-868 and NUV-1511, and preclinical programs, and to a lesser extent, general and administrative expenses. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

Based upon our current operating plan, we believe that our existing cash, cash equivalents and marketable securities as of March 31, 2024, will enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months.

We expect to incur substantial expenses in the foreseeable future for the development and potential commercialization of our product candidates and ongoing internal research and development programs. At this time, we cannot reasonably estimate the nature, timing or aggregate amount of costs for our development, potential commercialization, and internal research and development programs. However, in order to complete our current and future preclinical studies and clinical trials, and to complete the process of obtaining

regulatory approval for our product candidates, as well as to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our product candidates, if approved, we may require substantial additional funding in the future.

Cash Flows

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

	Three Months Ended March 31,	
	2024	2023
	(In thousands)	
Cash used in operating activities	$ (15,702)	$ (19,330)
Cash provided by (used in) investing activities	7,542	(51,996)
Cash provided by financing activities	21	298
Net decrease in cash and cash equivalents	(8,139)	(71,028)

Operating Activities

In 2024, cash used in operating activities of $15.7 million was attributable to a net loss of $14.8 million, a net change of $4.6 million in our net operating assets and liabilities offset by non-cash charges of $3.7 million. The change in operating assets and liabilities was primarily due to a $5.3 million increase in prepaid expenses and other current assets, $0.6 million increase in interest receivable on marketable securities, $0.5 million increase in other non-current assets offset by $1.5 increase in accrued expenses and $0.3 million increase in accounts payable. The non-cash charges consisted primarily of stock-based compensation of $5.0 million and changes in fair value of warrant liability of $1.5 million offset by amortization of premium on marketable securities of $2.8 million.

In 2023, cash used in operating activities of $19.3 million was attributable to a net loss of $21.7 million, a net change of $0.3 million in our net operating assets and liabilities offset by non-cash charges of $2.7 million. The change in operating assets and liabilities was primarily due to a $1.4 million decrease in accrued expenses offset by $0.8 million increase in accounts payable, $0.2 million decrease in interest receivable on marketable securities and $0.1 million decrease in prepaid expenses. The non-cash charges consisted primarily of stock-based compensation of $4.8 million and loss on marketable securities of $0.1 million offset by amortization of premium on marketable securities of $2.1 million and changes in fair value of warrant liability of $0.1 million.

Investing Activities

In 2024, cash provided by investing activities of $7.5 million was related to the purchase of marketable securities of $128.5 million offset by $136.0 million of proceeds from the sale of marketable securities.

In 2023, cash used in for investing activities of $52.0 million was related to the purchase of marketable securities of $237.0 million offset by $185.0 million of proceeds from the sale of marketable securities.

Financing Activities

In 2024, cash provided by financing activities of $21 thousand was related to the proceeds from exercise of options.

In 2023, cash provided by financing activities of $0.3 million was related to the proceeds from exercise of options.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an on-going basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable in the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions.

While our significant accounting policies are described in the notes to our consolidated financial statements, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

Research and Development Expenses

We expense all research and development costs in the periods in which they are incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks and estimates of services performed using information and data provided to us by our vendors and third-party service providers. Nonrefundable advance payments for goods or services to be received in future periods for use in research and development activities are deferred and capitalized. The capitalized

amounts are then expensed as the related goods are delivered and as services are performed. We expense in-process research and development projects acquired as part of asset acquisitions that have no alternative future use.

Warrant Liability

We account for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC 815, Derivatives and Hedging ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the company's own ordinary shares, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded as a liability at their fair value on the date of issuance and each balance sheet date thereafter. Changes in the estimated fair value of the warrants are recognized as a non-cash gain or loss on the statements of operations. The fair value of Public and Forward Purchase Warrants was determined using the closing price of the warrants on the NYSE market. The fair value of the Private Warrants was estimated using the Black-Scholes option pricing formula (see Note 3).

Stock-Based Compensation Expense

We estimate the fair value of our stock-based awards to employees and non-employees that are based on a service condition only using the Black-Scholes option-pricing model, which is impacted by our common stock price as well as other variables including, but not limited to, expected term that options will remain outstanding, expected common stock price volatility over the term of the option awards, risk-free interest rates and expected dividends.

We determine the fair value of stock-based awards that are based on both a service condition and achievement of the first to occur of a market or performance condition using a Monte Carlo simulation.

The fair value of a stock-based award is recognized over the period during which a recipient is required to provide services in exchange for the award, known as the requisite service period (usually the vesting period) on a straight-line basis. Stock-based compensation expense is recognized based on the fair value determined on the date of grant and is reduced for forfeitures as they occur.

Estimating the fair value of stock-based awards as of the grant date using valuation models, such as the Black-Scholes option pricing model, is affected by assumptions regarding a number of variables. Changes in the assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized. These inputs are subjective and generally require significant analysis and judgment to develop.

Expected Term—We have opted to use the "simplified method" for estimating the expected term of options whose vesting is based on service condition only, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option (generally 10 years).

Expected Volatility—Due to our limited operating history and a lack of company specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded.

Risk-Free Interest Rate—The risk-free rate assumption is based on the U.S. Treasury instruments with maturities similar to the expected term of our stock options at the time of the grant.

Expected Dividend—We have not issued any dividends in our history and do not expect to issue dividends over the life of the options and therefore have estimated the dividend yield to be zero.

We will continue to use judgment in evaluating the expected volatility, and interest rates utilized for our stock-based compensation expense calculations on a prospective basis.

Recent Accounting Pronouncements

For information about recent accounting pronouncements, see the sections titled "Significant Accounting Policies—Recent Accounting Pronouncements" in Note 2 to our consolidated financial statements for the three months ended March 31, 2024 appearing elsewhere in this report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

We had cash and investments of $597.0 million as of March 31, 2024, consisting of cash, money market funds, government securities, and corporate bonds. To date, fluctuations in interest income have not been significant.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. We have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates.

Foreign Currency Risk

Our expenses are generally denominated in U.S. dollars. A 10% increase or decrease in current exchange rates would not have a material effect on our financial results.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Principal Financial and Accounting Officer, as appropriate, to allow timely decisions regarding required disclosure. Our management, with the participation of our Chief Executive Officer and Principal Financial and Accounting Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rule 13a–15(e) and 15d-15(e)) as of March 31, 2023. Based on that evaluation, the Chief Executive Officer and Principal Financial and Accounting Officer concluded that the Company's disclosure controls and procedures were effective as of March 31, 2024.

Changes in Internal Control Over Financial Reporting

There have not been any changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter to which this report relates that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

None.

Item 1A. Risk Factors.

Summary of Risk Factors

Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found in the section below. The below summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. You should consider carefully the risks and uncertainties described below as part of your evaluation of an investment in our securities:

- We have a limited operating history and have incurred significant losses since inception and anticipate that we may continue to incur losses for the foreseeable future, and may never achieve or maintain profitability.
- We will need substantial funding to pursue our business objectives. If we are unable to raise capital when needed or on favorable terms, we could be forced to delay, reduce or terminate our product development, other operations or commercialization efforts. Additionally, raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish proprietary rights.
- Following our recent acquisition of AnHeart, we may have difficulty integrating AnHeart's business, operations and employees, including those based in China. This may cause disruption to ongoing business, divert the attention of management, and the process of combining the companies may cost more and take longer than originally anticipated.
- If we do not obtain regulatory approval for and successfully commercialize our product candidates in one or more indications or we experience significant delays in doing so, we may never generate any revenue or become profitable.
- Our approach to the discovery and development of product candidates based on our Drug-Drug Conjugate platform is unproven and is based on novel technology, and we do not know whether we will be able to develop any products of commercial value, or if competing technological approaches will limit the commercial value of our product candidates or render our platform obsolete.
- Clinical trials are very expensive, time-consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.
- We may encounter substantial delays in our preclinical studies or clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.
- If any of our product candidates receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the drug could be compromised.
- We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.
- We have never commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any of our products that receive regulatory approval on our own or together with collaborators.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- Even if we obtain regulatory approval for our product candidates, they will remain subject to ongoing regulatory oversight.
- We rely on third parties to perform the chemistry work associated with our drug discovery and preclinical activities and to conduct our preclinical studies and future clinical trials, and our business could be substantially harmed if these third parties cease performing services or perform in an unsatisfactory manner.
- We do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of taletrectinib, safusidenib, NUV-868, NUV-1511 and our other current and future product candidates.

• If we are not able to maintain existing collaborations or establish new collaborations, we may have to alter some of our future development and commercialization plans.

• Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors and customers will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, health information privacy and security laws and other healthcare laws and regulations including equivalent foreign laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

• If we are unable to obtain, maintain, protect and enforce sufficient patent and other intellectual property rights for our product candidates and technology, or if the scope of patent and other intellectual property rights obtained is not sufficiently broad, we may not be able to compete effectively in our market.

• Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

• We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful, and issued patents covering our technology and product candidates could be found invalid or unenforceable if challenged.

• Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could negatively impact the success of our business.

• Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

• Our business, operations and clinical development plans and timelines and supply chain could be adversely affected by the effects of health epidemics, on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our contract manufacturing organizations ("CMOs"), contract research organizations ("CROs"), shippers and others.

• Our future success depends on our ability to retain Dr. Hung and our other key employees, consultants and advisors and to attract, retain and motivate qualified personnel.

• The dual-class structure of our common stock has the effect of concentrating voting power with our Chief Executive Officer, which limits other stockholders' ability to influence the outcome of important transactions, including a change in control.

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history and have incurred significant losses since inception and anticipate that we may continue to incur losses for the foreseeable future, and may never achieve or maintain profitability.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are an oncology company with a limited operating history upon which you can evaluate our business and prospects. We commenced operations in 2018, and to date, we have focused primarily on organizing and staffing our company, business planning, raising capital, identifying product candidates, establishing our intellectual property portfolio and conducting research, preclinical studies and clinical trials. Our approach to the discovery and development of product candidates is unproven, and we do not know whether we will be able to develop any product candidates that succeed in clinical development or products of commercial value. As an organization, we have not yet completed any clinical trials, obtained regulatory approvals, manufactured a commercial-scale product (or arranged for a third party to do so on our behalf), or conducted sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products.

Since inception, we have not generated any product revenue and have incurred significant operating losses. Our net losses were $104.2 million and $75.8 million in 2022 and 2023, respectively. As of March 31, 2024, we had an accumulated deficit of $357.6 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Since inception, we have devoted substantially all of our efforts to research and preclinical and clinical development of our product candidates, as well as to building our management team and infrastructure. It could be at least several years, if ever, before we have a commercialized drug. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we:

• continue to advance our research and preclinical and clinical development of our product candidates;

- expand and initiate further clinical trials for our product candidates;
- seek to identify additional product candidates;
- seek marketing approvals for our product candidates that successfully complete clinical trials, if any;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, expand, protect and enforce our intellectual property portfolio and obtain licenses to third-party intellectual property;
- attract, hire and retain additional administrative, clinical, regulatory and scientific personnel;
- enter into third-party relationships for clinical trials, manufacturing and supply; and
- incur additional legal, accounting and other expenses in operating our business, including the additional costs associated with operating as a public company.

In addition, because of the numerous risks and uncertainties associated with pharmaceutical products and development, we are unable to accurately predict the timing or amount of increased expenses and when, or if, we will be able to achieve profitability. Our expenses could increase and profitability could be further delayed if we decide to or are required by the FDA or other comparable foreign regulatory authorities such as the European Medicines Agency ("EMA"), the U.K. Medicines & Healthcare Products Regulatory Agency (the "MHRA"), or the National Medical Product Administration of China (the "NMPA"), to perform studies or trials in addition to those currently expected, or if there are any delays in the development or completion of any current or future preclinical studies or clinical trials of our current and future product candidates. Even if we complete the development and regulatory processes described above, we anticipate incurring significant costs associated with launching and commercializing our current and future product candidates.

Even 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 our value and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in value also could cause you to lose all or part of your investment.

We will need substantial funding to pursue our business objectives. If we are unable to raise capital when needed or on favorable terms, we could be forced to delay, reduce or terminate our product development, other operations or commercialization efforts.

Identifying and developing potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and begin selling any approved products. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our ongoing and planned preclinical studies and clinical trials, initiate additional clinical trials for our product candidates and seek regulatory approval for our current product candidates and any future product candidates we may develop. Our expenses could increase beyond our current expectations if the FDA, or comparable foreign regulatory authorities, require us to perform clinical trials and other studies in addition to those that we currently anticipate. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we will be forced to delay, reduce or terminate our research and development programs or future commercialization efforts.

As of March 31, 2024, we had $597.0 million in cash and investments, and an accumulated deficit of $357.6 million. Based upon our current operating plan, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operations for at least the next 12 months. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our development activities and changes in regulation. Our future capital requirements will depend on many factors, including:

- the scope, rate of progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our product candidates;
- the number and development requirements of product candidates that we may pursue, and other indications for our current product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- the scope and costs of manufacturing development and commercial manufacturing activities;
- the cost associated with commercializing any approved product candidates;

- the cost and timing of developing our ability to establish sales and marketing capabilities, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining, enforcing and protecting our intellectual property rights, defending intellectual property-related claims and obtaining licenses to third-party intellectual property;
- our ability to establish and maintain collaborations on favorable terms, if at all; and
- the extent to which we acquire or in-license other product candidates and technologies and associated intellectual property.

We may require additional capital to complete our planned clinical development programs for our clinical stage product candidates as well as our preclinical product candidates to obtain regulatory approval. Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future product candidates, if approved.

In addition, we cannot guarantee that future financing will be available on a timely basis, in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and our issuance of additional securities, whether equity or debt, or the market perception that such issuances are likely to occur, could cause the market price of our common stock to decline. If we are unable to obtain funding on a timely basis on acceptable terms, we may be required to delay, reduce or terminate one or more of our research and development programs or the commercialization of any product candidates that may be approved. This could harm our business and could potentially cause us to cease operations.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish proprietary rights.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. 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 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, reduce or terminate our product development or future commercialization efforts or grant rights to third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our earnings. Any new taxes could adversely affect our business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us, which could require us to pay additional taxes on a prospective or retroactive basis, as well as penalties, interest and other costs, including compliance costs. The Tax Cuts and Jobs Act enacted in 2017 (the “Tax Act”), the Coronavirus Aid, Relief, and Economic Security Act enacted in 2020 and the Inflation Reduction Act enacted in 2022 made many significant changes to the U.S. tax laws. For example, effective January 1, 2022, the Tax Act eliminated the option to deduct research and development expenses for tax purposes in the year incurred and instead requires taxpayers to capitalize and subsequently amortize such expenses over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. Although there have been legislative proposals to repeal or defer the capitalization requirement to later years, there can be no assurance that the provision will be repealed or otherwise modified. Future guidance from the Internal Revenue Service and other tax authorities with respect to any such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

In addition, our tax obligations and effective tax rate could increase, including as a result of the base erosion and profit shifting (“BEPS”) project that is being led by the Organization for Economic Co-operation and Development (“OECD”), and other initiatives led by the OECD. For example, the OECD is leading work on proposals, commonly referred to as “BEPS 2.0”, which, if and to the extent implemented, would make important changes to the international tax system. These proposals are based on two “pillars”, involving the reallocation of taxing rights in respect of certain multinational enterprises above a fixed profit margin to the jurisdictions in which they carry on business (referred to as “Pillar One”) and imposing a minimum effective corporate tax rate on certain

multinational enterprises (referred to as “Pillar Two”). A number of countries have enacted with effect from January 1, 2024, or are in the process of enacting, core elements of the Pillar Two rules. We are monitoring developments and evaluating the potential impacts of these new rules on our business.

Our ability to use our net operating loss carryforwards and certain other tax attributes to offset taxable income or taxes may be limited.

As of December 31, 2023, we had federal and state net operating loss (“NOL”) carryforwards of $95.2 million and $140.3 million, respectively. Under current law, federal NOLs incurred in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but such federal NOL carryforwards are permitted to be used in any taxable year to offset only up to 80% of taxable income in such year.

Separately, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which generally is defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change NOL carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income or taxes may be limited. The completion of the 2021 merger of Nuvation Bio Inc. and Panacea Acquisition Corp., together with private placements and other transactions that have occurred since our inception, may have triggered such an ownership change pursuant to Section 382. We have not completed a Section 382 analysis, and therefore, there can be no assurances that our NOLs are not already limited.

We also may experience ownership changes as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset U.S. federal taxable income may be subject to limitations, which potentially could result in increased future tax liability to us. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, this could harm our future operating results by effectively increasing our future tax obligations. In addition, due to changes in laws and regulations, including changes proposed or implemented by the current or a future U.S. presidential administration, such as alternative minimum taxes, or other unforeseen reasons, our existing net operating losses could become unavailable to reduce future income tax liabilities. Further, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Risks Related to the Development of our Product Candidates

If we do not obtain regulatory approval for and successfully commercialize our product candidates in one or more indications or we experience significant delays in doing so, we may never generate any revenue or become profitable.

We do not have any products that have received regulatory approval and may never be able to develop marketable product candidates. We have invested substantially all of our efforts in developing and identifying potential product candidates and conducting preclinical and clinical studies. As a result, our business currently depends heavily on the successful development, regulatory approval and, if approved, commercialization of taletrectinib, safusidenib, NUV-868 and NUV-1511. We cannot be certain that any of these or any other product candidates will receive regulatory approval or will be successfully commercialized even if we receive regulatory approval. The research, testing, manufacturing, safety, efficacy, labeling, approval, sale, marketing and distribution of product candidates is, and will remain, subject to comprehensive regulation by the FDA and similar foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through preclinical studies and clinical trials that the product candidate is safe and effective for use in each target indication. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our preclinical studies or clinical trials. For example, based on our preclinical or clinical experience since February 2022, we have discontinued or deprioritized three of the five programs, including the lead program, that we were pursuing at that time. Failure to obtain regulatory approval for our product candidates will prevent us from commercializing and marketing our product candidates. The success of our product candidates will depend on several additional factors, including:

- successful completion of preclinical studies;
- successful initiation of clinical trials;
- successful patient enrollment in, and completion, of clinical trials that demonstrate their safety and efficacy;
- receiving marketing approvals from applicable regulatory authorities;
- obtaining, maintaining, protecting and enforcing patent, trade secret and other intellectual property rights and regulatory exclusivity for our product candidates;
- completing any post-marketing studies required by applicable regulatory authorities;

• making and maintaining arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates;

• establishing sales, marketing and distribution capabilities and successfully launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;

• the prevalence and severity of adverse events experienced with our product candidates;

• acceptance of our product candidates by patients, the medical community and third-party payors;

• a continued acceptable safety profile following approval;

• obtaining and maintaining healthcare coverage and adequate reimbursement for our product candidates;

• competing effectively with other cancer therapies, including with respect to the sales and marketing of our product candidates, if approved; and

• obtaining licenses to any third-party intellectual property we deem necessary or desirable.

Many of these factors are beyond our control, including the time needed to adequately complete preclinical studies, clinical testing and the regulatory submission process, our ability to obtain and protect intellectual property rights and changes in the competitive landscape. It is possible that none of our product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully complete clinical trials, obtain regulatory approval or, if approved, commercialize our product candidates, which would materially harm our business, financial condition, results of operations and prospects.

In addition, the clinical trial requirements of the FDA, the European Commission, competent authorities of EU Member States, the MHRA, the NMPA and other comparable regulatory authorities and the criteria regulators may use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates can be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates.

Our approach to the discovery and development of product candidates based on our DDC platform is unproven, and we do not know whether we will be able to develop any products of commercial value, or if competing technological approaches will limit the commercial value of our product candidates or render our platform obsolete.

The success of our business depends in part upon our ability to identify, develop and commercialize products based on our proprietary Drug-Drug Conjugate ("DDC") platform, which leverages a novel and unproven therapeutic approach within the drug-conjugate class of anti-cancer therapies. While our first DDC clinical product candidate, NUV-1511, is in a Phase 1 dose escalation trial that began in the first quarter of 2024, we have not yet demonstrated safety or efficacy for NUV-1511 or any other DDC product candidate. Our research methodology and novel approach to oncology using our DDC platform may be unsuccessful in identifying additional product candidates, and any product candidates based on our technology may be shown to have harmful side effects or may have other characteristics that may necessitate additional clinical testing, or make the product candidates unmarketable or unlikely to receive marketing approval. In addition, adverse developments with respect to one of our DDC platform-based programs may have a significant adverse impact on the actual or perceived likelihood of success and value of similar programs.

In addition, the biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies. Our future success will depend in part on our ability to maintain a competitive position with our DDC platform. If we fail to stay at the forefront of technological change in utilizing our DDC platform to create and develop product candidates, we may be unable to compete effectively. Our competitors may render our DDC platform obsolete, or limit the commercial value of our product candidates, by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our drug discovery process that we believe we derive from our research approach and proprietary technologies. By contrast, adverse developments with respect to other companies that attempt to use a similar approach to our approach may adversely impact the actual or perceived value of our DDC platform and potential of our DDC platform-based product candidates. If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would harm our business.

Our DDC platform-based product candidates are based on a novel technology, which makes it difficult to predict the time and cost of product candidate development.

We have concentrated our product research and development efforts on our novel DDC platform, and our future success depends in part on the successful development of product candidates arising from our DDC platform. There can be no assurance that any development problems we may experience in the future related to our DDC platform will not cause significant delays or unanticipated costs, or that such development problems can be efficiently solved. We may also experience delays in developing a

sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all.

We may in the future develop product candidates in combination with other therapies and that may expose us to additional risks.

We may develop future product candidates for use in combination with one or more currently approved cancer therapies. Even if any product candidate we develop was to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate our product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or similar foreign regulatory authorities. We will not be able to market and sell our product candidates we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If the FDA or similar foreign regulatory authorities do not approve or revoke the approval of these other drugs, or if safety, efficacy, manufacturing or supply issues arise with the drugs we choose to evaluate in combination with our product candidates, we may be unable to obtain approval of or market our product candidates.

Clinical trials are very expensive, time-consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.

The risk of failure for our product candidates is high. It is impossible to predict when or if any of our product candidates will prove safe or effective in humans or will receive regulatory approval. To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans for use in each target indication. Preclinical investigation and clinical testing is expensive and can take many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the preclinical investigation or clinical trial process. For example, in August 2022, we announced the discontinuation of development of our former lead program, NUV-422, following the emergence of a safety signal, uveitis, which is a form of inflammation of the eye.

In addition, the results of preclinical studies and earlier clinical trials may not be predictive of the results of later-stage preclinical studies or clinical trials. The results generated to date in preclinical studies for our product candidates do not ensure that later preclinical studies or clinical trials will demonstrate similar results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and earlier stage clinical trials. In later-stage clinical trials, we will likely be subject to more rigorous statistical analyses than in completed earlier stage clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in later-stage clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other clinical trial protocols, and the rate of dropout among clinical trial participants. If we fail to produce positive results in our planned preclinical studies or clinical trials of any of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be materially and adversely affected.

Interim, "topline," and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial.

We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final

data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular drug candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

We may encounter substantial delays in our preclinical studies or clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate for its intended indications. Preclinical studies and clinical trials are expensive, time-consuming and uncertain as to outcome. We cannot guarantee that any preclinical studies or clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more preclinical studies or clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of preclinical or clinical development include:

- delays in conducting experiments or preclinical studies or unsatisfactory results from such experiments or studies;
- delays in reaching a consensus with regulatory authorities on trial design, dose optimization or dose selection;
- delays in reaching agreement or failing to agree on acceptable terms with prospective CROs and clinical trial sites;
- delays in opening sites and recruiting suitable patients to participate in our clinical trials;
- delays in enrollment due to travel or quarantine policies, or other factors, related to health epidemics, other pandemics or other events outside our control;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event, concerns with a class of product candidates or after an inspection of our clinical trial operations or trial sites;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

For instance, health epidemics and the measures taken in response by the governmental authorities could disrupt the supply chain and the manufacture or shipment of drug substances and finished drug products for our product candidates for use in our research and clinical trials, delay, limit or prevent our employees and CROs from continuing research and development activities, impede the ability of patients to enroll or continue in clinical trials, or impede testing, monitoring, data collection and analysis or other related activities, any of which could delay our clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations.

Any inability to timely and successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to achieve regulatory and commercialization milestones. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional testing to bridge our modified product candidate to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring comparable drugs to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects.

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our product candidates, we may:

- be delayed or unsuccessful in obtaining marketing approval;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, vary or suspend, their approval of the drug or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy, or REMS, or comparable foreign restrictions;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

Our drug development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all.

Further, we, the FDA or comparable foreign regulatory authorities, an Institutional Review Board, or an Ethics Committee may suspend our clinical trials at any time if it appears that we or our collaborators are failing to conduct a trial in accordance with applicable regulatory requirements, including the FDA's current Good Clinical Practice, ("GCP") and foreign equivalents, regulators find that we are exposing participants to unacceptable health risks or if the FDA or comparable foreign regulatory authorities find deficiencies in our INDs, clinical trial applications or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for commencement and completion of future clinical trials. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be negatively impacted, and our ability to generate revenues from our product candidates may be delayed or eliminated entirely.

If we encounter continued or new difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We have experienced and may in the future experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including challenges resulting from health epidemics, labor shortages, and global supply chain interruptions. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size and health of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial site. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies rather than enroll patients in any future clinical trial.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our current or planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

If we or third parties are unable to successfully develop companion diagnostics for taletrectinib, safusidenib, or any of our other product candidates that are targeted therapies, or if we experience significant delays in doing so, we may not achieve marketing approval or realize the full commercial potential of such product candidates.

A key part of our development strategy for taletrectinib, safusidenib, and any of our other product candidates that are targeted therapies, is to identify subsets of patients with specific types of tumors that express specific genetic markers. Identification of these patients may require the development and use of companion diagnostics. The FDA generally will require either approval or clearance of the diagnostic at the same time the FDA approves the therapeutic product, or as a post-marketing commitment at the time of the therapeutic product's approval. We do not have experience or capabilities in developing or commercializing diagnostics and plan to rely in large part on third parties to perform these functions.

Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and may require separate regulatory approval prior to commercialization of the associated product candidate. If we or third parties are unable to successfully develop companion diagnostics for our product candidates, or experience delays in doing so:

- the development of these product candidates may be delayed because it may be difficult to identify patients for enrollment in our clinical trials in a timely manner;
- these product candidates may not receive marketing approval if their safe and effective use depends on a companion diagnostic; and
- we may not realize the full commercial potential of these product candidates that receive marketing approval if, among other reasons, we are unable to appropriately identify patients or types of tumors with the specific genetic alterations targeted by these product candidates.

Even if our product candidates and any associated companion diagnostics are approved for marketing, the need for companion diagnostics may slow or limit adoption of our product candidates. Although we believe genetic testing is becoming more prevalent in the diagnosis and treatment of cancer, our product candidates may be perceived negatively compared to alternative treatments that do not require the use of companion diagnostics, due to either the additional cost of the companion diagnostic or the need to complete additional procedures to identify genetic markers prior to administering our product candidates.

If any of these events were to occur, our business and growth prospects would be harmed, possibly materially.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications, even those that we have begun investigating and that may have shown promise, that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial therapies or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. 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 to such product candidate.

If any of our product candidates receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the drug could be compromised.

Clinical trials of our product candidates are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If one or more of our product candidates receives regulatory approval, and we, or others, later discover that they are less effective than previously believed, or cause undesirable side effects, a number of potentially significant negative consequences could result, including:

- withdrawal, variation, suspension or limitation by regulatory authorities of approvals of such product;

• product candidate is approved under 21 CFR 314 (Subpart H, accelerated approval) or we receive a conditional marketing authorization but required confirmatory trials may fail to verify clinical benefit or we may fail to fulfill requirements of the conditional marketing authorization;

• seizure of the product by regulatory authorities;

• recall of the product;

• restrictions on the marketing of the product or the manufacturing process for any component thereof;

• requirement by regulatory authorities of additional warnings on the label, such as a “black box” warning or contraindication;

• requirements that we implement a REMS, or comparable foreign strategies, or create a medication guide outlining the risks of such side effects for distribution to patients;

• commitment to expensive additional safety studies prior to approval or post-marketing studies required by regulatory authorities of such product;

• adverse impact on the product’s competitiveness;

• initiation of regulatory investigations and government enforcement actions;

• initiation of legal action against us to hold us liable for harm caused to patients; and

• harm to our reputation and resulting harm to physician or patient acceptance of our products.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could harm our business, financial condition, results of operations and prospects.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. We currently have no products that have been approved for commercial sale. However, the current and future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients who use the product, healthcare providers, pharmaceutical companies or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend or settle, and could compromise the market acceptance of our product candidates or any prospects for commercialization of our product candidates, if approved. For more information regarding the risks associated with intellectual property-related litigation, see “Risk Factors—Risks Related to Our Intellectual Property.”

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen or rare side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates.

Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. As the expense of insurance coverage is increasing, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Even if we receive Fast Track designation or granting of other FDA expedited programs, or other comparable foreign expedited programs, for any of our product candidates, there is no guarantee that such product candidates will experience a faster regulatory review or obtain regulatory approval.

If a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track designation. The FDA has broad discretion whether or not to grant this designation, so 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. Even if we receive Fast Track designation for any of our product candidates, we may not experience a faster development process, review or approval compared to conventional FDA approval timelines, and the FDA may still decline to approve such product candidates. The FDA may rescind the Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program or for any other reason. Similarly,

the FDA's other expedited drug development programs (e.g., Breakthrough Therapy, Accelerated Approval, Priority Review) do not guarantee a product candidate's faster regulatory review or regulatory approval. Although taletrectinib has been granted Breakthrough Therapy Designations by both the FDA and China's NMPA for the treatment of advanced or metastatic ROS1-positive NSCLC, such designations may be rescinded and may not lead to faster regulatory review or regulatory approval. The EMA has a similar program called PRIME.

Even if we receive Orphan Drug designation for any of our product candidates, we may be unable to maintain the benefits associated with such designation, including the potential for market exclusivity.

Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs for 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 a drug intended to treat a rare disease or condition, which is generally 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 where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, Orphan Drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax credits for certain clinical trial costs and user-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 from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States.

Even if we receive Orphan Drug designation for any of our product candidates, there is no guarantee that we will obtain approval or Orphan Drug exclusivity for such product candidates. Even if we obtain Orphan Drug exclusivity for any of our product candidates, that exclusivity may not effectively protect the product candidates from competition because different therapies can be approved for the same condition and the same therapy could be approved for different conditions. Even after an Orphan Drug is approved, the FDA can subsequently approve 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, more effective or makes a major contribution to patient care. 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 the manufacturer is unable to assure sufficient quantity of the drug 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.

Risks Related to Commercialization of Our Product Candidates

We have never commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any of our products that receive regulatory approval on our own or together with collaborators.

We have never commercialized a product candidate. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, undertaking preclinical studies of our product candidates and enrolling patients in clinical trials for our clinical stage product candidates. We currently have no sales force, marketing, manufacturing or distribution capabilities. To achieve commercial success of our product candidates, if any are approved, we will have to develop our own sales, marketing and manufacturing capabilities or outsource these activities to a third party.

Factors that may affect our ability to commercialize our product candidates on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, persuading adequate numbers of physicians to prescribe our product candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization requires significant investment, is time-consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization in the U.S., the European Union or other key global markets. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may have difficulties generating revenue from them.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical, specialty pharmaceutical and biotechnology companies among others. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immunotherapies for the treatment of cancer. There are other companies working to develop immunotherapies for the treatment of cancer including divisions of large pharmaceutical and biotechnology companies of various sizes. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

We are developing our initial product candidates for the treatment of cancer, and currently none of these therapies are approved. There are already a variety of available drug therapies marketed for cancer and some of the currently approved drug therapies are branded and subject to patent protection, and others are available on a generic basis. Many of these approved drugs are well established therapies and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic products. This may make it difficult for us to achieve our business strategy of replacing existing therapies with our product candidates.

Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop. In addition, most of these companies have substantially greater sales, marketing and other experience and reserves than we do. Competition may further increase as a result of advances in the commercial applicability of technologies for drug discovery and development and greater availability of capital for investment in cancer therapies.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving FDA approval for or commercializing drugs before we do, which would have an adverse impact on our business and results of operations.

The availability of our competitors' products could limit the demand and the price we are able to charge for any product candidate we commercialize, if any. The inability to compete with existing or subsequently introduced drugs would harm our business, financial condition, results of operations and prospects.

Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If taletrectinib, safusidenib, NUV-868, NUV-1511 and our other current and future product candidates receive marketing approval, whether as a single agent or in combination with other therapies, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current approved immunotherapies, and other cancer treatments like chemotherapy and radiation therapy, are well established in the medical community, and doctors may continue to rely on these therapies. If any of our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may never become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the ability of our product candidates to treat cancer, as compared with other available drugs, treatments or therapies;
- the prevalence and severity of any adverse side effects associated with our product candidates;
- limitations or warnings contained in the labeling approved for our product candidates by the FDA or comparable foreign regulatory authorities;
- availability of alternative treatments;
- the size of the target patient population, and the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity for our product candidates and competing products and treatments;
- pricing and cost effectiveness;
- the effectiveness of our sales and marketing strategies; and
- our ability to obtain sufficient third-party coverage and adequate reimbursement.

The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels and pricing policies. 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 revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, comparable foreign healthcare programs, private health insurers and other third-party payors are essential for most patients to be able to afford products such as our product candidates, if approved. Our ability to achieve acceptable levels of coverage and

reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our product candidates and, if desired, attract collaboration partners to invest in the development of our product candidates. Coverage under certain government programs, such as Medicare, Medicaid, the 340B drug pricing program and TRICARE, or comparable foreign healthcare programs, may not be available for certain of our product candidates. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the U.S., the European Union or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates and other therapies as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing drugs may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the U.S., 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 and biologics will be covered. 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 and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Obtaining and maintaining reimbursement status is time-consuming and costly. No uniform policy for coverage and reimbursement for products exists among third-party payors in the U.S. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Moreover, increasing efforts by governmental and third-party payors in the U.S. and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products 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 health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care may adversely affect:

- the demand for any products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenues and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

In addition, in case a drug product needs companion diagnostics, then companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for the pharmaceutical or biological product. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

Even if we obtain regulatory approval for our product candidates, they will remain subject to ongoing regulatory oversight.

Even if we obtain regulatory approval for any of our product candidates, they will be subject to extensive and ongoing regulatory requirements for manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, sampling and record-keeping. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current Good Manufacturing Practice ("cGMP"), regulations and GCPs, for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize

such products. In addition, any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory authorities as reflected in the product's approved labeling. If we receive marketing approval for any future product candidates we may develop, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. However, if we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA or comparable foreign regulatory authorities may also require a REMS, or comparable foreign regulatory strategies as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

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. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. 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. Moreover, if there are changes in the application of legislation or regulatory policies, or if problems are discovered with a product or our manufacture of a product, or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include:

- issuing warning or untitled letters;
- seeking an injunction or imposing civil or criminal penalties or monetary fines;
- suspension or imposition of restrictions on operations, including product manufacturing;
- seizure or detention of products, refusal to permit the import or export of products or request that we initiate a product recall;
- suspension, variation or withdrawal of our marketing authorizations;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to applications submitted by us; or
- requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization.

If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could harm our business, financial condition, results of operations and prospects.

If any of our product candidates are approved for marketing and commercialization and we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we will be unable to successfully commercialize our product candidates if and when they are approved.

We have no sales, marketing or distribution capabilities or experience. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization, which would be expensive and time consuming, or outsource these functions to other third parties. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the benefits of prescribing any future product candidates;

• the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

• unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. In entering into third-party marketing or distribution arrangements, any revenue we receive will depend upon the efforts of the third parties and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or devote the necessary resources and attention to sell and market our product candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Risks Related to Our Dependence on Third Parties

We rely on third parties to perform the chemistry work associated with our drug discovery and preclinical activities and to conduct our preclinical studies and future clinical trials, and our business could be substantially harmed if these third parties cease performing services or perform in an unsatisfactory manner.

We do not have any laboratory facilities and have relied on CROs to perform most of the medicinal chemistry work associated with our drug discovery activities.

We also do not currently have the ability to independently conduct preclinical studies or clinical trials without outside assistance. We have relied on CROs to conduct all of our preclinical studies to date and intends to conduct our future clinical trials by leveraging expertise and assistance from CROs as appropriate. We plan to rely upon medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct or assist us in conducting GCP-compliant clinical trials on our product candidates properly and on time, and may not currently have all of the necessary contractual relationships in place to do so. Once we have established contractual relationships with such third-party CROs, we will have only limited control over their actual performance of these activities.

We and our CROs and other vendors are required to comply with cGMP, GCP, and good laboratory practice ("GLP"), which are regulations and guidelines enforced by the FDA, the competent authorities of EU Member States and any comparable foreign regulatory authorities for all of our product candidates in preclinical and clinical development. Regulatory authorities enforce these regulations through periodic inspections of trial sponsors, principal investigators, clinical trial sites and other contractors. Although we will rely on CROs to conduct any current or planned GLP-compliant preclinical studies and GCP-compliant clinical trials and has limited influence over their actual performance, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with our investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities. If we or any of our CROs or vendors fail to comply with applicable regulations, the data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA, European Commission, MHRA, NMPA or any other comparable foreign regulatory authority may require us to perform additional preclinical studies and 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 all of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced under cGMP requirements. We, our contract manufacturers, any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA, the competent authorities of EU Member States, the MHRA, the NMPA or other comparable foreign regulatory authorities, to monitor and ensure compliance with cGMP. Despite our efforts to audit and verify regulatory compliance, one or more of our third-party manufacturing vendors may be found on regulatory inspection by the FDA, the competent authorities of EU Member States, the MHRA, the NMPA or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations. This may result in shutdown of the third-party vendor or invalidation of drug product lots or processes. In some cases, a product recall may be warranted or required, which would materially affect our ability to supply and market our drug products. Our failure to comply with these requirements may require us to repeat clinical trials, which would delay the regulatory approval process.

While we or our CROs have or will have agreements governing their activities, we will not be able to control whether or not they devote sufficient time and resources to our future chemistry work and preclinical and clinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other chemistry or drug discovery or development activities. We face the risk of potential unauthorized disclosure, infringement, misappropriation or other violation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors, and other third parties, to access and exploit our proprietary technology. CROs also may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property-related proceedings that could jeopardize or invalidate our proprietary information and intellectual property. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to

the failure to adhere to our clinical protocols or regulatory requirements or for any other reason, our clinical trials or other drug discovery or development activities may be extended, delayed or terminated, the clinical data generated in our clinical trials may be deemed unreliable, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If our relationships with our CROs were to terminate, we might not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus, and could delay the discovery, development and commercialization of our product candidates. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a negative impact on our business and financial condition.

We do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of taletrectinib, safusidenib, NUV-868, NUV-1511 and our other current and future product candidates.

We have limited experience in drug formulation and manufacturing and do not own or operate, and we do not expect to own or operate, facilities for drug manufacturing, storage, distribution or testing. To date, we have obtained active pharmaceutical ingredients ("APIs") and drug product for our investigational products mostly from single-source third-party CMOs. We are in the process of developing our supply chain for each of our investigational products and intend to put in place framework agreements under which CMOs will generally provide us with necessary quantities of API and drug product on a project-by-project basis based on our development needs. We seek to use a different CMO for each investigational product and will consider further diversification of drug product and supply organizations as circumstances warrant.

Third-party CMOs may be unable or unwilling to supply us with sufficient clinical and commercial grade quantities of our clinical materials due to production shortages or other supply interruptions resulting from health epidemics, because they are purchased by one of our competitors or another company that decides not to continue supplying us with these materials, or for other reasons. If one or more of these events occur and we are unable to timely establish an alternate supply from one or more third-party CMOs, we could experience delays in our development efforts as we locate and qualify new manufacturers. Under such circumstances, we may be required to receive drug substance for use on a purchase order basis, and as such, there can be no assurance that we actually receive sufficient quantities. See also the risk factor titled "—Our business, operations and clinical development plans and timelines and supply chain could be adversely affected by the effects of health epidemics, on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our CMOs, CROs, shippers and others."

Further, our reliance on third-party manufacturers exposes us to risks beyond our control, including the risk of:

- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and quality issues, including related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for additional scale-up;
- failure of the manufacturer to comply with cGMP and similar foreign standards;
- inability to negotiate manufacturing agreements with third parties on commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on a limited number of sources, and in some cases, single sources for components, such that if we are unable to secure a sufficient supply of these drug components, we will be unable to manufacture and sell our product candidates in a timely fashion, in sufficient quantities or under acceptable terms;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or the issuance of a FDA Form 483 notice, warning letter, or cease and desist order;
- carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our products under specified storage conditions and in a timely manner.

Some of these events could be the basis for FDA or comparable foreign regulatory authority action, including injunction, recall, seizure or total or partial suspension of production. In addition, our third-party manufacturers and suppliers are subject to FDA inspection and may be subject to inspections from comparable foreign regulatory authorities from time to time. Failure by our third-party manufacturers and suppliers to pass such inspections and otherwise satisfactorily complete the FDA approval regimen, or comparable foreign regulatory authorities' approval regimen, with respect to our product candidate may result in regulatory actions such as the issuance of FDA Form 483 notices of observations, warning letters or injunctions or the loss of operating licenses. In addition, our third-party manufacturers and suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of waste products, and failure to comply with such laws and regulations could result in significant costs associated with civil or criminal fines and penalties for such third parties. Based on the severity of the regulatory action, our clinical or commercial supply of drug and packaging and other services could be interrupted or limited, which could harm our business.

In addition, our CMOs are or may be engaged with other companies to supply and manufacture materials or products for such companies, which also exposes our suppliers and manufacturers to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a contract supplier's or manufacturer's facility. If the FDA or a comparable foreign regulatory authority finds these facilities unsatisfactory in compliance with applicable regulations, does not approve these facilities for the supply or manufacture of our product candidates, or if it withdraws its approval in the future, we may need to find alternative supply or manufacturing facilities, which would negatively impact our ability to develop, obtain regulatory approval of or market our product candidates, if approved.

As we prepare for later-stage clinical trials and potential commercialization, we will need to take steps to increase the scale of production of our product candidates, which may include transferring production to new third-party suppliers or manufacturers. In order to conduct larger or late-stage clinical trials for our product candidates and supply sufficient commercial quantities of the resulting drug product and our components, if that product candidate is approved for sale, our CMOs and suppliers will need to produce our product candidates in larger quantities, more cost effectively and, in certain cases, at higher yields than they currently achieve. These third-party contractors may not be able to successfully increase the manufacturing capacity for any such product candidates in a timely or cost-effective manner or at all. Significant scale up of manufacturing may require additional processes, technologies and validation studies, which are costly, may not be successful and which the FDA and comparable foreign regulatory authorities must review and approve. In addition, quality issues may arise during those scale-up activities because of the inherent properties of a product candidate itself or of a product candidate in combination with other components added during the manufacturing and packaging process, or during shipping and storage of the APIs or the finished product. If our third-party CMOs are unable to successfully scale up the manufacture of any of our product candidates in sufficient quality and quantity and at commercially reasonable prices, and we are unable to find one or more replacement suppliers or manufacturers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and we are unable to successfully transfer the processes on a timely basis, the development of that product candidate and regulatory approval or commercial launch for any resulting products may be delayed, or there may be a shortage in supply, either of which could significantly harm our business, financial condition, results of operations and prospects.

Failure to maintain the License Agreement between Daiichi Sankyo Company, Limited and AnHeart Therapeutics Inc., dated December 7, 2018, as amended (the "Taletrectinib In-License Agreement") and the License Agreement between Daiichi Sankyo Company, Limited and AnHeart Therapeutics Inc., dated September 7, 2020 (the "Safusidenib In-License Agreement") could negatively impact our business.

Pursuant to the terms of the Taletrectinib In-License Agreement and the Safusidenib In-License Agreement, we received certain exclusive licenses to develop, manufacture and commercialize taletrectinib and safusidenib, respectively. Consequently, our ability to develop and commercialize talectretinib and safusidenib depends on our ability to maintain these agreements with Daiichi Sankyo. We are subject to a number of other risks associated with our dependence on the Taletrectinib In-License Agreement and the Safusidenib In-License Agreement, including:

- Our obligations to make certain milestone and royalty payments;
- Our obligation to use commercially reasonable efforts to perform certain develop and commercialization activities and to achieve certain milestones;
- Certain obligations not to develop or commercialize products that compete with taletrectinib or safusidenib; and
- Potential disputes between us and Daiichi Sankyo, including disagreements regarding the Taletrectinib In-License Agreement and the Safusidenib In-License Agreement.

If either the Taletrectinib In-License Agreement or the Safusidenib In-License Agreement is terminated early, we may be unable to pursue continued development, manufacture and commercialization of taletrectinib or safusidenib.

If we are not able to establish and maintain collaborations, we may have to alter some of our future development and commercialization plans.

Our product development programs and the potential commercialization of our product candidates will require substantial additional capital to fund expenses. The commercial rights to taletrectinib have been out-licensed in China, Japan, and Korea, and we may enter into other collaboration agreements with pharmaceutical and biotechnology companies for the future development and potential commercialization of our product candidates. We will likely have limited control over the amount and timing of resources that our current and future collaborators dedicate to the development or commercialization of any product candidates we may seek to develop and commercialize with them. We cannot predict the success of any current or future collaboration that we may enter into.

We face significant competition in seeking appropriate collaborators, and a number of more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization experience and capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. 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, European Commission, MHRA, NMPA or other similar foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, competing products, 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. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. 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 collaboration agreements on a timely basis, on acceptable terms, or at all. Even if we are able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the same rights and compete with us. Our collaboration partners, if any, may not prioritize our product candidates or otherwise not effectively pursue the development of our product candidates which may delay, reduce or terminate the development of such product candidate, reduce or delay its development program or delay its potential commercialization. Further if we are unable to successfully obtain rights to required third-party intellectual property rights or maintain and protect the existing intellectual property rights we have, we may have to delay, reduce or terminate the development of our product candidates, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. Doing so will likely harm our ability to execute our business plans. If we elect to increase our expenditures to fund development or commercialization activities on our own, 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.

Risks Related to Regulatory Compliance

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

The U.S. and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "Affordable Care Act"), includes measures that have significantly changed the way healthcare is financed by both governmental and private insurers. There have been judicial, executive and congressional challenges to certain aspects of the Affordable Care Act. In 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. In addition, there have been a number of health reform initiatives by the Biden administration that have impacted the Affordable Care Act. For example, the Inflation Reduction Act of 2022 ("IRA") , among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business. We continue to evaluate the effect that the Affordable Care Act and its possible repeal and replacement has on our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year until 2032 unless Congress takes additional action. Additionally, the American Rescue Plan Act of 2021 eliminates the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, effective January 1, 2024.

Recently, there has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. presidential executive orders, congressional inquiries and legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. For example, at the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. In 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, later in 2021, the Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions take effect progressively starting in fiscal year 2023. In 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration's 2022 executive order, in 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, in 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. Also in 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

At the state level, legislatures have increasingly passed legislation and implemented 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. For example, in January 2024, the FDA approved Florida's Section 804 Importation Program ("SIP") proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs.

We are unable to predict the future course of federal or state healthcare legislation in the U.S. directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. These and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations.

We expect that the healthcare reform measures that have been adopted and 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 and could seriously harm our future revenues. 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 products.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors and customers will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, health information privacy and security laws and other healthcare laws and regulations, including comparable foreign healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Although we do not currently have any products on the market, our current and future operations may be, directly or indirectly through our prescribers, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations. Healthcare providers and others play a primary role in the recommendation and prescription of any products for which we obtain

marketing approval. These laws may impact, among other things, our current business operations, including our clinical research activities, and proposed sales, marketing and education programs and constrain the business of financial arrangements and relationships with healthcare providers and other parties through which we may market, sell and distribute our products for which we obtain marketing approval. The laws that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. 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 U.S. federal false claims, including the False Claims Act, which can be enforced through whistleblower actions, and Civil Monetary Penalties Laws, which, among other things, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996, (“HIPAA”), which 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 knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. 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;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, (“HITECH”), and its implementing regulations, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by “covered entities”, i.e. health plans, healthcare clearinghouses and certain healthcare providers, as well as their “business associates” and covered subcontractors that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;

- the U.S. Federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- the U.S. federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the Affordable Care Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children’s Health Insurance Program to report annually to the Centers for Medicare & Medicaid Services ("CMS") information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;

- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and

- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices

do not comply with current or future statutes, regulations, agency guidance 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 the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the delay, reduction, termination or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business information, trade secrets, intellectual property, information we collect about trial participants in connection with clinical trials, and sensitive third-party information (collectively, sensitive data).

Our processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable protected health information. Additionally, in the past few years, numerous U.S. states – including California, Virginia, Colorado, Connecticut, and Utah – have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, or CCPA, applies to personal data of California residents and requires businesses subject to the CCPA to provide specific disclosures in privacy notices and respond to requests of such individuals to exercise certain privacy rights. Although there are minimum revenue thresholds for entities to be subject to these laws and there are limited exemptions for clinical trial data under the CCPA and similar US state comprehensive privacy laws, such laws may impact (possibly significantly) our business activities depending on how they are interpreted, should we become subject to the CCPA or other such state comprehensive privacy laws in the future. Similar laws are being considered in other states, as well as at the federal and local levels, and we expect more laws related to personal data to become effective in the future. These developments may further complicate compliance efforts and increase our legal risk and compliance costs.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR, the United Kingdom's GDPR, or UK GDPR, Australia's Privacy Act, and China's Personal Information Protection Law, or PIPL, impose strict requirements for processing personal data.

For example, under GDPR, companies may face private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests, temporary or definitive prohibitions on data processing and other corrective actions, or fines of up to the greater of 20 million Euros under the EU GDPR / 17.5 million pounds under the UK GDPR, or 4% of their worldwide annual revenue, whichever is higher.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area, or EEA, and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA's standard contractual clauses, the UK's

International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the EU GDPR's cross-border data transfer limitations.

We may also publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials, or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Obligations related to data privacy and security (and individuals' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties with whom we work (such as contract research organizations and clinical trial sites) may fail (or be perceived to have failed) to comply with such obligations, which could negatively impact our business operations. If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans or restrictions on processing personal data (including clinical trial data); orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process sensitive data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Risks Related to Our Intellectual Property

If we are unable to obtain, maintain, protect and enforce sufficient patent and other intellectual property rights for our product candidates and technology, or if the scope of patent and other intellectual property rights obtained is not sufficiently broad, we may not be able to compete effectively in our market.

Our success depends in significant part on our ability and the ability of any licensors and collaborators to obtain, maintain, protect and enforce patents and other intellectual property rights with respect to our product candidates and technology and to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others.

The patent prosecution process is uncertain, expensive and time-consuming. We and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our future licensors will fail to identify patentable aspects of our research and development output in time to obtain patent protection or fail to file patent applications covering inventions made in the course of development and commercialization activities before a competitor or another third party files a patent application covering, or publishes information disclosing, a same or similar, independently-developed invention. Such competitor's or other third party's patent application or published information may pose obstacles to or prohibit our ability to obtain patent protection or limit the scope of the patent protection we may obtain. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection in certain jurisdictions. In addition, publications of discoveries in the scientific literature often lag behind actual discoveries, and patent applications in the U.S. and other jurisdictions are

typically not published until approximately 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our future licensors were the first to conceive the inventions claimed in our owned or licensed patents or pending patent applications, or were the first to file for patent protection of such inventions.

The patent position of biotechnology and pharmaceutical companies generally is uncertain, involves complex legal and factual questions and is the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors' patent rights are uncertain. Our and our licensors' pending and future patent applications may not mature into patents or result in issued patents that protect our technology or product candidates, in whole or in part, or effectively exclude others from commercializing competitive technologies and product candidates. The patent examination process may require us or our licensors to narrow the scope of the claims of our pending and future patent applications, and therefore, even if such patent applications 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. Our and our licensors' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover such technology. Any patents that we hold or in-license may be challenged or, circumvented by third parties or narrowed, invalidated or held unenforceable in litigation or post-grant proceedings. Consequently, we do not know whether any of our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

The patent protection we obtain for our product candidates and technology may be challenged or not sufficient to provide us with any competitive advantage.

Even if our owned or licensed patent applications issue as patents, the issuance of any such patents is not conclusive as to their inventorship, scope, validity or enforceability, and such patents may be challenged, invalidated, narrowed or held to be unenforceable, including in the courts or patent offices in the U.S. and abroad, or circumvented. We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office (the "USPTO"), a federal court or equivalent foreign bodies, or become involved in opposition, derivation, revocation, re-examination, post-grant and inter partes review or interference proceedings, or other similar proceedings, challenging our patent rights or the patent rights of others. An adverse determination as a result of any such submission, proceeding or litigation could reduce the scope of, invalidate, or render unenforceable, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we, or one of our licensors, may have to participate in interference or derivation proceedings declared by the USPTO to determine priority or ownership of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such proceedings and any other patent challenges may result in loss of patent rights, loss of exclusivity, loss of priority 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. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Moreover, there could be public announcements of the results of hearings, motions or other developments related to any of the foregoing proceedings. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline. Any of the foregoing could harm our business, financial condition, results of operations and prospects.

Moreover, some of our owned or in-licensed patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such 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, who could market competing products and technology. In addition, we may need the cooperation of any such co-owners in order to enforce such patents against third parties, and such cooperation may not be provided to us.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to discover, develop and manufacture our product candidates, we must, at times, share certain of our trade secrets with them. We seek to protect our proprietary technology in part by entering into agreements containing confidentiality provisions, including if applicable, confidentiality agreements, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite these agreements with third parties, sharing trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part,

on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could impair our competitive position and may harm our business.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets could impair our competitive position and have an adverse impact on our business.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful, and issued patents covering our technology and product candidates could be found invalid or unenforceable if challenged.

Competitors and other third parties may infringe, misappropriate or otherwise violate our issued patents or other intellectual property or the patents or other intellectual property of our licensors. In addition, our patents or the patents of our licensors may become involved in inventorship or priority disputes. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. To counter infringement or other unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or that our patents are invalid and/or unenforceable. In a patent infringement proceeding, a court may decide that a patent of ours is invalid and/or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology. An adverse result in any litigation proceeding could put one or more of our owned or licensed patents at risk of being invalidated and/or held unenforceable, interpreted narrowly or interpreted in a manner that would not prevent competitors from entering the market. Further, we may find it impractical or undesirable to enforce our intellectual property against some third parties.

In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including, e.g., lack of novelty, obviousness, non-enablement or insufficient written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO or an equivalent foreign body, even outside the context of litigation. Potential proceedings include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our technology or any product candidates that we may develop. The outcome 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 and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on the applicable product candidates or technology covered by the patent rendered invalid and/or unenforceable. Such a loss of patent protection could materially harm our business, financial condition, results of operations and prospects.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the ownership or priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Such licenses may not be available on commercially reasonable terms, or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of one or more of the product candidates we may develop. In addition, if we or our licensors are unsuccessful in any inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights, such as exclusive ownership of, or the exclusive right to use, our owned or in-licensed patents. The loss of exclusivity or the narrowing of scope of our owned and/or licensed patents could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations or prospects. Even if we are successful in any of the foregoing disputes, it could result in substantial costs and be a distraction to management and other employees. 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 or proceeding.

Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, more likely to be able to sustain the costs of complex patent litigation or proceedings than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or otherwise violating our intellectual property. Even if

resolved in our favor, litigation or other legal proceedings relating to intellectual property claims could result in substantial costs and diversion of management resources, which could harm our business. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs or in-license needed technology or other product candidates. There could also be public announcements of the results of the hearing, motions or other interim proceedings or developments. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline. Any of the foregoing events could harm our business, financial condition, results of operations and prospects.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, maintaining, defending and enforcing patents and other intellectual property rights on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. As such, we may choose not to seek to protect our intellectual property in certain jurisdictions, which could leave us without recourse to prevent competitive products from being manufactured or commercialized in such jurisdictions. 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 U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries or from selling or importing products made using our inventions in all jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection or other intellectual property rights to develop their own products and may export otherwise infringing, misappropriating or violating products to territories where we have patent or other intellectual property protection, but enforcement rights are not as strong as those in the U.S. These products may compete with our product candidates, and our patents 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 some countries do not favor the enforcement of patents and other intellectual property rights, which could make it difficult for us to stop the infringement, misappropriation or other violation of our intellectual property rights generally. Proceedings to enforce our intellectual property 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.

Many countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. 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, which could adversely affect our business, financial condition, results of operations and prospects.

We may not identify relevant third-party patents or pending patent applications or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop and market our product candidates.

We are developing certain product candidates in highly competitive areas and cannot guarantee that any patent searches or analyses that we may conduct, including the identification of relevant patents or pending patent applications, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending patent application in the U.S. and abroad that is or may be relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the U.S. remain confidential until patents issue. Patent applications in the U.S. and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patents or pending patent applications covering our product candidates could have been or may be filed in the future by third parties without our knowledge. Additionally, patents and pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the manufacturing or use of our product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or pending patent application or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the U.S. or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents or pending patent applications may negatively impact our ability to develop and market our product candidates.

If we fail to identify or correctly interpret relevant patents or pending patent applications or if we are unable to obtain licenses to relevant patents or pending patent applications, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, potentially including in the form of future royalties, which may be significant, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could adversely affect our business, financial condition, results of operations and prospects.

If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, our business could be harmed.

It may be necessary for us to use the patented or other proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license or ownership from these third parties. The licensing or acquisition of third-party intellectual property rights is a competitive area, and more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources or 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. If we are unable to license or acquire such intellectual property or technology, or if we are forced to in-license such intellectual property or technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, or the cost of development, manufacture or commercialization may be materially increased, which could materially harm our business, and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

If we fail to comply with our obligations under any future license agreements, such counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or commercialize, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, or impede, delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements. If we were to lose our rights to licensed intellectual property, we may not be able to continue developing or commercializing our product candidates, if approved. If we breach any of the agreements under which we license the use, development and commercialization rights to our product candidates or technology from third parties or, in certain cases, we fail to meet certain development deadlines, we could lose license rights that are important to our business.

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 U.S., 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, and a given patent may be subject to other term adjustments, 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 for a product candidate, we may be open to competition from competitive products, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, 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, referred to as the Hatch-Waxman Amendments, and one or more of our foreign patents may be eligible for patent term extension under similar legislation, for example, in the European Union. In the U.S., the Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process provided other requirements are met. However, there are no assurances that the FDA, USPTO or any comparable foreign regulatory authority or national patent office will grant such extensions, in whole or in part and the length of any available extension may vary based on a number of factors. For example, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during

which we can enforce our patent rights for the applicable product candidate will be shortened, and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations and prospects could be adversely affected.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Obtaining and enforcing patents in the pharmaceutical industry is inherently uncertain, due in part to ongoing changes in the patent laws. Depending on decisions by Congress, the federal courts, and the USPTO and equivalent institutions in other jurisdictions, the laws and regulations governing patents, and interpretation thereof, could change in unpredictable ways that could weaken our and our licensors' or collaborators' ability to obtain new patents or to enforce existing or future patents. For example, in recent years the U.S. Supreme Court has ruled on several patent cases that have been interpreted to have either narrowed the scope of patent protection or weakened the rights of patent owners in certain situations. Therefore, there is increased uncertainty with regard to our and our licensors' or collaborators' ability to obtain patents in the future, as well as uncertainty with respect to the value of patents once obtained.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents. Assuming that other requirements for patentability are met, prior to March 16, 2013, in the U.S., the first to invent the claimed invention was entitled to the patent, while outside the U.S., the first to file a patent application was entitled to the patent. On March 16, 2013, under the Leahy-Smith America Invents Act enacted in September 2011 (the "Leahy-Smith Act"), the U.S. transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications are prosecuted and may also affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, particularly the first inventor-to-file provisions. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents, all of which could harm our business, financial condition, results of operations and prospects.

Obtaining and maintaining 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 if we fail to comply with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on any issued patents and certain pending patent applications are required to be paid to the USPTO or foreign patent agencies in several stages over the lifetime of a patent. In certain circumstances, we may rely on our licensors to pay these fees. The USPTO and various foreign patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar requirements during the patent application and prosecution process. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official communications within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. 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 rules, there are situations in which non-compliance can result in irrevocable abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we or our licensors or collaborators fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market with similar or identical products or technology, which would harm our business, financial condition, results of operations and prospects.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could negatively impact the success of our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including re-examination, interference, post-grant review, inter partes review or derivation proceedings, or other similar proceedings, before the USPTO, a federal court or an equivalent foreign body. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. In the event that any of these patents were asserted against us, we believe that we would have defenses against any such action, including that such patents are invalid and/or unenforceable, that our product candidates

do not infringe such patents, or that we would be able to replace such technology with alternative, non-infringing technology. However, if any such patents were to be asserted against us and our defenses to such assertion were unsuccessful and such alternative technology was not available or technologically or commercially practical, unless we obtain a license to such patents, we could be liable for damages, which could be significant and include treble damages and attorneys' fees if we are found to willfully infringe such patents, and we could be precluded from commercializing any product candidates that were ultimately held to infringe such patents. Any potential future legal proceedings relating to these patents could cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. If we are unsuccessful in our challenges to these patents and become subject to litigation or are unable to obtain a license on commercially reasonable terms with respect to these patents, it could harm our business, financial condition, results of operations and prospects.

Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that third-party patents asserted against us are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any product candidates we may develop and any other product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, and we are unsuccessful in demonstrating that such rights are invalid or unenforceable, we could be required to obtain a license from such a third party in order to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease commercializing the infringing technology or product candidates. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties and other fees, redesign our infringing drug or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

We may be subject to claims by third parties asserting that we or our employees have infringed upon, misappropriated or otherwise violated their intellectual property rights, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at other biotechnology or pharmaceutical companies. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of others, such as any such individual's former employer. Litigation may be necessary to defend against these claims.

In addition, we or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives, develops or reduces to practice intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in litigating such claims, litigation could result in substantial costs, delay development of our product candidates and be a distraction to management. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, 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, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities

or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development collaborations that would help us commercialize our product candidates, if approved. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

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

We rely on trade secrets and agreements containing confidentiality obligations to protect our unpatented know-how, technology and other proprietary information and to maintain our competitive position. With respect to our research and development programs, we consider trade secrets and know-how to be one of our important sources of intellectual property, including our extensive knowledge of certain drug delivery techniques and drug conjugation. Trade secrets and know-how can be difficult to protect. We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. 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. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U.S. are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

We may not be able to protect and enforce our trademarks and trade names, or build name recognition in our markets of interest thereby harming our competitive position.

We intend to rely on both registered and common law rights for our trademarks. We have applied to register certain of our trademarks with the USPTO and trademark authorities in certain other countries and may in the future seek to register additional trademarks in the U.S. or other countries. Our current and future trademark applications may not mature to registration in a timely fashion or at all, and our registered trademarks may not be maintained or enforced. In the U.S. and some foreign jurisdictions, our ability to obtain and maintain trademark registrations and acquire enforceable trademark rights depends on making use of our marks in commerce, meaning we must make a certain amount of progress, depending on the jurisdiction, in our clinical studies or in the commercialization of our products. If we fail to satisfy these requirements or any other requirements of applicable regulatory authorities, we may not have enforceable trademark rights or registrations in such jurisdictions. We have yet to obtain trademark registrations for the NUVATION or NUVATION BIO trademarks in the U.S., and we have yet to apply to register any brand name for any product candidate in the U.S. or any other jurisdiction.

In addition, the registered or unregistered trademarks or trade names that we own may be challenged, infringed, circumvented, declared generic, lapsed or determined to be infringing on or dilutive of other marks. We may be unable to develop any enforceable trademark rights in relevant countries, or to protect the rights that we do develop. We may be forced to stop using our trademarks or trade names, which we need for name recognition by potential partners and customers in our markets of interest, and spend time and money rebranding. In addition, third parties have filed, and may in the future file, for registration of trademarks similar or identical to our trademarks, thereby impeding our ability to build brand identity and possibly leading to market confusion. If they succeed in registering or developing common law rights in such trademarks, and if we are not successful in enforcing our rights, we may not be able to use these trademarks to develop brand recognition of our company, technologies, products or services. In addition, there could be potential trade name or trademark infringement litigation brought against us by owners of other trademarks that incorporate variations of our registered or unregistered trademarks or trade names.

During the trademark registration process, we may receive office actions from the USPTO or from comparable agencies in foreign jurisdictions refusing to register our trademarks. Although we would be given an opportunity to respond to those refusals, we may be unable to overcome them. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may in the future be filed against our trademark applications or registrations, and our trademark applications or registrations may not survive such proceedings. In addition, third parties may file first for our trademarks or similar variations thereof in certain countries. If they succeed in registering such trademarks, and if we are not successful in challenging such third-party rights, we may not be able to use these trademarks to market our products in those countries. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would. If we are unable to establish name

recognition based on our trademarks and trade names, we may be unable to compete effectively, which could have an adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we own or license now or in the future;
- we, or our current or future licensors, might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or license now or in the future;
- we, or our current or future licensors, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending owned or licensed patent applications or those that we may own or license in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by other persons;
- our competitors might conduct research and development activities in the U.S. under FDA-related safe harbor patent infringement exemptions and/or in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents or pending patent applications of others may harm our business; and
- we may choose not to file for patent protection in order to maintain certain trade secrets or know-how, and a third party may subsequently file for and obtain a patent covering such intellectual property.

Should any of these events occur, they could harm our business, financial condition, results of operations and prospects.

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

AnHeart could be difficult to integrate, divert the attention of management, and disrupt our business, and the anticipated synergies and other benefits of the AnHeart acquisition may not be realized in the amounts anticipated, or may not be realized within the anticipated timeframe, or at all.

It is possible that there could be a loss of our existing or AnHeart's key employees and customers, disruption of either company's or both companies' ongoing businesses or unexpected issues, higher than expected costs and an overall post-completion process that takes longer than originally anticipated. Specifically, the following issues, among others, must be addressed in combining AnHeart's operations with ours in order to realize the anticipated benefits of the AnHeart acquisition so the combined company performs as the parties hope:

- combining the companies' corporate functions;
- combining their business with our business in a manner that permits us to achieve the synergies anticipated to result from the acquisition, the failure of which would result in the anticipated benefits of the acquisition not being realized in the time frame currently anticipated or at all;
- maintaining existing and new agreements with customers, service providers, and vendors;
- determining whether and how to address possible differences in corporate cultures, management philosophies and strategies relating to channels, resellers, and partners;
- integrating the companies' administrative and information technology infrastructure;
- developing products and technology that allow value to be unlocked in the future; and
- evaluating and forecasting the financial impact of the acquisition transaction, including accounting impacts.

Failure to address any of the above-listed issues could have a material adverse effect on our business, results of operations and financial position. In addition, at times the attention of certain members of our management and resources may be focused on integration planning of the businesses of the two companies and diverted from day-to-day business operations, which may disrupt our ongoing business and the business of the combined company.

The failure to meet the challenges involved in combining the two companies could, among other things, cause an interruption of, or a loss of momentum in, our activities and could adversely affect our results of operations. The overall combination of the two companies may also result in, among other things, material unanticipated problems, expenses, liabilities, competitive responses and loss of customer and other business relationships. The difficulties of combining our operations include, among others:

- diversion of management and employee attention to integration matters;
- difficulties in integrating operations and systems, including, but not limited to, communications systems, administrative and information technology infrastructure, financial reporting and internal control systems;
- challenges in conforming standards, controls, procedures and accounting and other policies, business cultures and compensation structures between the two companies;
- difficulties in integrating employees and teams of the respective businesses and attracting and retaining key personnel;
- challenges in retaining and obtaining customers, suppliers and other commercial relationships;
- difficulties in managing the expanded operations of a larger and more complex company; and
- potential unknown liabilities, adverse consequences and unforeseen increased expenses associated with the integration.

Many of these factors are outside of our control and any of them could result in lower revenues, higher costs and diversion of management time and energy, which could materially impact our business, financial condition and results of operations. In addition, even if the operations of the companies are integrated successfully, the full benefits of the AnHeart acquisition may not be realized, including, among others, the synergies, cost savings or sales or growth opportunities that are expected. These benefits may not be achieved within the anticipated time frame or at all. As a result, it cannot be assured that the integration will result in the realization of the full benefits expected from the AnHeart acquisition within the anticipated time frames, or at all.

Our business, operations and clinical development plans and timelines and supply chain could be adversely affected by the effects of health epidemics on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our CMOs, CROs, shippers and others.

Our business could be adversely affected by health epidemics wherever we have clinical trial sites or other business operations. In addition, health epidemics could cause significant disruption in the operations of CMOs, CROs and other third parties upon whom we rely. For example, the COVID-19 pandemic presented a substantial public health and economic challenge around the world and affected employees, patients, communities and business operations, as well as the U.S. economy and financial markets. Geographic regions imposed “shelter-in-place” orders, quarantines or similar orders or restrictions to control the spread of epidemic disease. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

We are dependent on a worldwide supply chain for products to be used in our clinical trials and, if approved by the regulatory authorities, for commercialization. Quarantines, shelter-in-place and similar government orders, or the expectation that such orders, shutdowns or other restrictions could occur may impact personnel at third-party manufacturing facilities in the U.S. and other countries, or the availability or cost of materials or supplies, which could disrupt our supply chain or our ability to enroll patients in or perform testing for our clinical trials. In addition, closures of transportation carriers and modal hubs could materially impact our clinical development and any future commercialization timelines.

If our relationships with our suppliers or other vendors are terminated or scaled back as a result of health epidemics, we may not be able to enter into arrangements with alternative suppliers or vendors or do so on commercially reasonable terms or in a timely manner. Switching or adding additional suppliers or vendors involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new supplier or vendor commences work. As a result, delays generally occur, which could adversely impact our ability to meet our desired clinical development and any future commercialization timelines. Although we carefully manage our relationships with our suppliers and vendors, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects. See “Risk Factors—Risks Related to Our Dependence on Third Parties.”

In addition, our clinical trials may be affected by health epidemics. In the future, clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward such health epidemics or concerns among patients about participating in clinical trials during a health epidemic and public health measures imposed by the respective national governments of countries in which the clinical sites are located. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our inability to successfully recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to epidemic disease or experience additional restrictions by their institutions, city or state governments could adversely impact our clinical trial operations.

Health epidemics may lead to disruption and volatility in the global capital markets, which increases the cost of, and adversely impacts access to, capital and increases economic uncertainty. Health epidemics may also result in volatile trading prices for the common stock of biopharmaceutical companies. To the extent health epidemics adversely affect our business, financial results and value of our common stock, it may also affect our ability to access capital, which could in the future negatively affect our liquidity.

Our future success depends on our ability to retain Dr. Hung and our other key employees, consultants and advisors and to attract, retain and motivate qualified personnel.

We are highly dependent on the management, research and development, clinical, financial and business development expertise of Dr. Hung and our executive officers, as well as the other members of our scientific and clinical teams. Although we have employment offer letters with each of our executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we are successful in obtaining marketing approval for our product candidates, sales and marketing personnel, is critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

In particular, in light of Dr. Hung’s central role in the discovery of all of our current product candidates, our ongoing discovery activities and development programs, the recruitment of our other executives and key employees and all other aspects of our strategy and operations, we believe our loss of Dr. Hung’s services for any reason would severely impair our business and prospects. Replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval for and commercialize our product candidates.

Competition to hire qualified personnel in our industry is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. Furthermore, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited, and could harm our business, financial condition, results of operations and prospects.

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

As of April 9, 2024, we had 159 employees. As our preclinical and clinical development progresses, we expect to experience growth in the number of our employees and the scope of our operations, particularly in the areas of research, clinical operations, regulatory affairs, general and administrative and, if any of our product candidates receives marketing approval, sales, marketing and distribution. 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. 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.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include

intentional, reckless or negligent conduct or unauthorized activities that violates (1) the laws, regulations and guidance of the FDA, the European Commission, the EMA, the MHRA, NMPA and other similar regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (2) manufacturing standards, (3) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the U.S. and abroad and (4) laws that require the true, complete and accurate reporting of financial information or data. 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. Misconduct by these parties could also involve the improper use of individually identifiable information, including information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product candidates, which could result in regulatory sanctions and serious harm to our reputation.

We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by employees and other third parties, 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 be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm and the delay, reduction, termination or restructuring of our operations.

If our information technology systems or those of third parties upon which we rely, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

In the ordinary course of business, we and the third parties with whom we work, process sensitive data, and, as a result, we and the third parties with whom we work face a variety of evolving threats that could cause security incidents. Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties upon with whom we work. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer “hackers,” threat actors, “hacktivists,” organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services.

We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by artificial intelligence (“AI”), telecommunications failures, earthquakes, fires, floods, and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our personnel utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit or in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities’ systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our reliance on third parties could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on various third parties and technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, personnel email, and other functions . We also rely on third parties to provide other products, services, parts, or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties with whom we work experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if such third parties fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

While we have implemented security measures designed to protect against security incidents , there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties upon which we rely) . We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties with whom we work. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our services.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, regulators, and investors, of security incidents, or to implement other requirements, such as providing credit monitoring. Such disclosures and compliance with such requirements are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage, if any, will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive data about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive data of the Company could be leaked, disclosed, or revealed as a result of or in connection with our personnel's or vendors' use of generative AI technologies.

Risks Related to Doing Business in China and Our International Operations

Changes in the political and economic policies or in relations between China and the United States may affect our business, financial condition, and results of operations.

Due to our operations in China, our business, results of operations, financial condition and prospects may be influenced to a certain degree by economic, political, legal and social conditions in China or changes in government relations between China and the United States or other governments. The Chinese government may intervene in or influence our operations, which could result in a change in our operations. Any economic downturn, whether actual or perceived, further decrease in economic growth rates or an otherwise uncertain economic outlook could affect our business, financial condition and results of operations. In addition, the global macroeconomic environment is facing challenges. It is unclear whether these challenges and uncertainties will be contained or resolved, and what effects they may have on the global political and economic conditions, and our business operations in the long term. There is

significant uncertainty about the future relationship between the United States and China with respect to trade policies, treaties, government regulations and tariffs. The Chinese government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall Chinese economy, but may have a negative effect on us. Due to our operations in China, any future Chinese, U.S. or other rules and regulations that place restrictions on capital raising or other activities by companies with operations in China could affect our business and results of operations. If the business environment in China deteriorates from the perspective of domestic or international investment, or if relations between China and the United States or other governments deteriorate and geopolitical tensions between China and the United States increase, our business in China and United States may also be affected.

Changes in U.S. and Chinese regulations may impact our business, our operating results, and our ability to raise capital.

The U.S. government, including the SEC, has made statements and taken certain actions that led to changes to United States and international relations, and will impact companies with connections to the United States or China, including imposing several rounds of tariffs affecting certain products manufactured in China, imposing certain sanctions and restrictions in relation to China and issuing statements indicating enhanced review of companies with certain operations based in China. It is unknown whether and to what extent new legislation, executive orders, tariffs, laws or regulations will be adopted, or the effect that any such actions would have on companies with significant connections to the United States or to China, our industry or on us. We conduct research activities and have business operations both in the United States and China. Any unfavorable government policies on cross-border relations and/or international trade, including increased scrutiny on companies with certain operations based in China, capital controls or tariffs, may affect the competitive position of our drug products, the hiring of scientists and other research and development personnel, the demand for our drug products, the import or export of raw materials in relation to drug development, our ability to raise capital, or prevent us from selling our drug products in certain countries. Furthermore, the SEC has issued statements primarily focused on companies with certain operations based in China, such as us. For example, in 2021, the Chairman of the SEC, issued a Statement on Investor Protection Related to Recent Developments in China, pursuant to which he stated that he has asked the SEC staff to engage in targeted additional reviews of filings for companies with certain operations based in China. The statement also addressed risks inherent in companies with variable interest entity ("VIE") structures. We do not have a VIE structure and are not in an industry that is subject to foreign ownership limitations by China. However, it is possible that our periodic reports and other filings with the SEC may be subject to enhanced review by the SEC and this additional scrutiny could affect our ability to effectively raise capital in the United States.

In response to the SEC's 2021 statement, the China Securities Regulatory Commission ("CSRC") announced in August 2021, that "it is our belief that Chinese and U.S. regulators shall continue to enhance communication with the principle of mutual respect and cooperation, and properly address the issues related to the supervision of China-based companies listed in the U.S. so as to form stable policy expectations and create benign rules framework for the market." While the CSRC will continue to collaborate "closely with different stakeholders including investors, companies, and relevant authorities to further promote transparency and certainty of policies and implementing measures," it emphasized that it "has always been open to companies' choices to list their securities on international or domestic markets in compliance with relevant laws and regulations."

If any new legislation, executive orders, tariffs, laws and/or regulations are implemented, if existing trade agreements are renegotiated or if the U.S. or Chinese governments take retaliatory actions due to the recent U.S.-China tension, such changes could have an adverse effect on our business, financial condition and results of operations.

Compliance with China's new Data Security Law, Cyber Security Law, Cybersecurity Review Measures, Personal Information Protection Law, regulations and guidelines relating to the multi-level protection scheme on cyber security and any other future laws and regulations may entail significant expenses and could affect our business.

China has implemented or will implement rules and is considering a number of additional proposals relating to data protection. China's new Data Security Law took effect in September 2021. The Data Security Law provides that the data processing activities must be conducted based on "data classification and hierarchical protection system" for the purpose of data protection and prohibits entities in China from transferring data stored in China to foreign law enforcement agencies or judicial authorities without prior approval by the Chinese government.

Additionally, China's Cyber Security Law, promulgated by the Standing Committee of the National People's Congress in 2016 and came into effect in 2017, and the Administrative Measures for the Hierarchical Protection of Information Security promulgated by the Ministry of Public Security, National Administration of State Secrets Protection, State Cryptography Administration and other government authority in 2007, requires companies to take certain organizational, technical and administrative measures and other necessary measures to ensure the security of their networks and data stored on their networks. Specifically, the Cyber Security Law provides that China adopt a multi-level protection scheme ("MLPS"), under which network operators are required to perform obligations of security protection to ensure that the network is free from interference, disruption or unauthorized access, and prevent network data from being disclosed, stolen or tampered. Under the MLPS, entities operating information systems must have a thorough assessment of the risks and the conditions of their information and network systems to determine the level of the entity's information and network systems. These levels range from the lowest Level 1 to the highest Level 5 pursuant to a series of national standards on the grading and

implementation of the classified protection of cyber security. The grading result will determine the set of security protection obligations that entities must comply with. Entities classified as Level 2 or above should report the grade to the relevant government authority for examination and approval.

In 2021, the Cyberspace Administration of China ("CAC") published a draft revision to the existing Cybersecurity Review Measures for public comment (the "Revised Draft CAC Measures"). In 2022, together with 12 other Chinese regulatory authorities, the CAC released the final version of the Revised Draft CAC Measures (the "Revised CAC Measures"), which came into effect in 2022. Pursuant to the Revised CAC Measures, critical information infrastructure operators procuring network products and services, and online platform operators (as opposed to "data processors" in the Revised Draft CAC Measures) carrying out data processing activities which affect or may affect national security, shall conduct a cybersecurity review pursuant to the provisions therein. In addition, online platform operators possessing personal information of more than one million users seeking to be listed on foreign stock markets must apply for a cybersecurity review. In 2021, the CAC further published the Regulations on Network Data Security Management (Draft for Comment) (the "Draft Management Regulations"), under which data processors refer to individuals and organizations who determine the data processing activities in terms of the purpose and methods at their discretion. The Draft Management Regulations reiterate that data processors shall be subject to cybersecurity review if (i) they process personal information of more than one million persons and they are aiming to list on foreign stock markets, or (ii) their data processing activities affect or may affect Chinese national security. The Draft Management Regulations also request data processors seeking to list on foreign stock markets to annually assess their data security by themselves or through data security service organizations, and submit the assessment reports to relevant competent authorities. As the Draft Management Regulations are released only for public comment, the final version and the effective date thereof is subject to change.

As of the date of this Report, we have not received any notice from any Chinese regulatory authority identifying us as a "critical information infrastructure operator," "online platform operator" or "data processor," or requiring us to go through the cybersecurity review procedures pursuant to the Revised CAC Measures and the Draft Management Regulations. Based on our understanding of the Revised CAC Measures, and the Draft Management Regulations if enacted as currently proposed, we do not expect to become subject to cybersecurity review by the CAC for issuing securities to foreign investors because: (i) the clinical and preclinical data we handle in our business operations, either by its nature or in scale, do not normally trigger significant concerns over PRC national security; and (ii) we have not processed, and do not anticipate to process in the foreseeable future, personal information for more than one million users or persons. However, there remains uncertainty as to how the Revised CAC Measures, and the Draft Management Regulations if enacted as currently proposed, will be interpreted or implemented; for example, neither the Revised CAC Measures nor the Draft Management Regulations provides further clarification or interpretation on the criteria for determining those activities that "affect or may affect national security" and relevant Chinese regulatory authorities may interpret it broadly. Furthermore, there remains uncertainty as to whether the Chinese regulatory authorities may adopt new laws, regulations, rules, or detailed implementation and interpretation in relation, or in addition, to the Revised CAC Measures and the Draft Management Regulations. While we intend to closely monitor the evolving laws and regulations in this area and take all reasonable measures to mitigate compliance risks, we cannot guarantee that our business and operations will not be adversely affected by the potential impact of the Revised CAC Measures, the Draft Management Regulations or other laws and regulations related to privacy, data protection and information security.

Also, the National People's Congress released the Personal Information Protection Law, which became effective in 2021. The Personal Information Protection Law provides a comprehensive set of data privacy and protection requirements that apply to the processing of personal information and expands data protection compliance obligations to cover the processing of personal information of persons by organizations and individuals in China, and the processing of personal information of persons in China outside of China if such processing is for purposes of providing products and services to, or analyzing and evaluating the behavior of, persons in China. The Personal Information Protection Law also provides that critical information infrastructure operators and personal information processing entities who process personal information meeting a volume threshold set by Chinese cyberspace regulators are also required to store in China personal information generated or collected in China, and to pass a security assessment administered by Chinese cyberspace regulators for any export of such personal information. Lastly, the Personal Information Protection Law contains proposals for significant fines for serious violations of up to RMB 50 million or 5% of annual revenues from the prior year and may also be ordered to suspend any related activity by competent authorities. We do not maintain, nor do we intend to maintain in the future, personally identifiable health information of patients in China.

In addition, certain industry-specific laws and regulations affect the collection and transfer of data in the PRC. The Regulations on the Administration of Human Genetic Resources of the PRC (the "HGR Regulation"), promulgated by the State Council, came into effect in 2019. It stipulates that foreign organizations, individuals, and the entities established or actually controlled by foreign organizations or individuals are forbidden to collect, preserve and export China's human genetic resources. Foreign organizations and the entities established or actually controlled by foreign organizations or individuals may only utilize and be provided with China's human genetic resources after satisfaction of all requirements under the HGR Regulation and other applicable laws, such as (i) China's human genetic resources being utilized only in international cooperation with Chinese scientific research institutions, universities, medical institutions, and enterprises for scientific research and clinical trials after completion of requisite approval or filing formalities with competent governmental authorities, and (ii) China's human genetic resources information being provided after required filing and information backup procedures have been gone through. In 2020, the SCNPC promulgated the Biosecurity Law of the PRC, which

reaffirms the regulatory requirements stipulated by the HGR Regulation while potentially increasing the administrative sanctions where China's human genetic resources are collected, preserved, exported or used in international cooperation in violation of applicable laws. The Ministry of Science and Technology published the Implementing Rules for the Regulations on the Administration of Human Genetic Resources (the "HGR Implementing Rules"), which came into effect in 2023. The HGR Implementing Rules have, among other things, further clarified the scope of China's human genetic resources information, improved the procedure rules for applicable approval, filing and security review, and refined the provisions with respect to the forbiddance on the collection, preservation and export of China's human genetic resources by foreign organizations, individuals, and the entities established or actually controlled by foreign organizations or individuals. There remain significant uncertainties as to how various provisions of the HGR Regulation and the related laws and regulations may be interpreted and implemented. Given such uncertainty, although we have made great efforts to comply with mandatory requirements of laws and government authorities in this regard, we cannot assure you that we will be deemed at all times in full compliance with the HGR Regulation, the Biosecurity Law of the PRC, the HGR Implementing Rules and other applicable laws in our utilizing of and dealing with China's human genetic resources. As a result, we may be exposed to compliance risks under the HGR Regulation, the Biosecurity Law of the PRC and the HGR Implementing Rules.

Interpretation, application and enforcement of these laws, rules and regulations evolve from time to time and their scope may continually change, through new legislation, amendments to existing legislation or changes in enforcement. Compliance with China's new Cyber Security Law and Data Security Law could significantly increase the cost to us of providing our service offerings, require significant changes to our operations or even prevent us from providing certain service offerings in jurisdictions in which we currently operate or in which we may operate in the future. Despite our efforts to comply with applicable laws, regulations and other obligations relating to privacy, data protection and information security, it is possible that our practices, offerings or platform could fail to meet all of the requirements imposed on us by the Cyber Security Law, the Data Security Law and/or related implementing regulations. Any failure on our part to comply with such law or regulations or any other obligations relating to privacy, data protection or information security, or any compromise of security that results in unauthorized access, use or release of personally identifiable information or other data, or the perception or allegation that any of the foregoing types of failure or compromise has occurred, could damage our reputation, discourage new and existing counterparties from contracting with us or result in investigations, fines, suspension or other penalties by Chinese government authorities and private claims or litigation, any of which could adversely affect our business, financial condition and results of operations. Even if our practices are not subject to legal challenge, the perception of privacy concerns, whether or not valid, may harm our reputation and brand and adversely affect our business, financial condition and results of operations. Moreover, the legal uncertainty created by the Data Security Law, the Revised CAC Measures and the recent Chinese government actions could adversely affect our ability, on favorable terms, to raise capital, including engaging in follow-on offerings of our securities in the U.S. market.

Pharmaceutical companies operating in China are required to comply with extensive regulations and hold a number of permits and licenses to carry on their business. Our ability to obtain and maintain these regulatory approvals is uncertain, and future government regulation may place additional burdens on our current and planned operations in China.

The pharmaceutical industry in China is subject to extensive government regulation and supervision. The regulatory framework addresses all aspects of operating in the pharmaceutical industry, including product development activities, clinical trials, registration, production, distribution, packaging, labeling, storage and shipment, advertising, licensing and post-approval pharmacovigilance certification requirements and procedures, periodic renewal and reassessment processes, data security and data privacy protection requirements and compliance and environmental protection. In particular, we are subject to many of these laws and regulations because our wholly-owned subsidiary, AnHeart Therapeutics (Hangzhou) Co., Ltd., through which we conduct research and development activities, operates primarily in China. Violation of applicable laws and regulations may materially and adversely affect our business. The regulatory framework governing the pharmaceutical industry in China is subject to change and amendment from time to time. Any such change or amendment could materially and adversely impact our business, financial condition and prospects. The Chinese government has introduced various reforms to the Chinese healthcare system in recent years and may continue to do so, with an overall objective to expand basic medical insurance coverage and improve the quality and reliability of healthcare services. The specific regulatory changes under the various reform initiatives remain uncertain. The implementing measures to be issued may not be sufficiently effective to achieve the stated goals, and as a result, we may not be able to benefit from such reform to the extent we expect, if at all. Moreover, the various reform initiatives could give rise to regulatory developments, such as more burdensome administrative procedures, which may have an adverse effect on our business and prospects.

As a company with operations and business relationships outside of the United States, our business is subject to economic, political, regulatory and other risks associated with international operations.

As a company with operations in China, our business is subject to risks associated with conducting business outside the United States. In addition to our research and development activities through AnHeart Therapeutics (Hangzhou) Co., Ltd. in China, some of our suppliers and clinical trial relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;

- differing and changing regulatory requirements for product approvals;
- differing jurisdictions could present different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates of the RMB;
- increasing geopolitical tensions between the U.S. and China and changes in a specific country's or region's political or economic environment especially with respect to a particular country's treatment of or stance towards other countries;
- trade protection measures, import or export licensing requirements or other restrictive actions by governments;
- differing reimbursement regimes and price controls in certain non-U.S. markets;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- variable tax treatment in different jurisdictions of options granted under our equity incentive plans;
- workforce uncertainty in countries where labor unrest is more common than in the United States; and
- business interruptions resulting from geo-political actions, including war and terrorism, health epidemics, or natural disasters including earthquakes, typhoons, floods and fires.

If we fail to comply with Chinese environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures, fire safety and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Despite our efforts to comply fully with environmental and safety regulations, any violation of these regulations may result in substantial fines, criminal sanctions, revocations of operating permits, the shutdown of our facilities and the incurrence of obligations to take corrective measures.

Although we maintain workers' compensation insurance to cover costs and expenses incurred due to on-the-job injuries to our employees and public liability insurance to cover costs and expenses that may be incurred if third parties are injured on our property, such insurance may not provide adequate coverage against potential liabilities. Furthermore, the Chinese government may take steps towards the adoption of more stringent environmental regulations, and, due to the possibility of unanticipated regulatory or other developments, the amount and timing of future environmental expenditures may vary substantially from those currently anticipated. If there is any unanticipated change in the environmental regulations, our third-party manufacturers and other service providers may incur substantial capital expenditures to install, replace, upgrade or supplement their manufacturing facilities and equipment or make operational changes to limit any adverse impact or potential adverse impact on the environment in order to comply with new environmental protection laws and regulations. If such costs become prohibitively expensive, we may be forced to cease certain aspects of our business operations and our business may be materially adversely affected.

Development in the Chinese legal system could materially and adversely affect us.

Chinese laws and regulations govern our operations in China and the PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions under the civil law system may be cited for reference but have limited precedential value. As the laws and regulations are relatively new and the PRC legal system continues to evolve, there may be room for discretion in the implementation of these laws and regulations. And as these laws and regulations are evolving in response to changing economic and other conditions, factors related to the application and implementation of these laws and regulations may affect our business and results of operations.

We may be exposed to liabilities under the U.S. Foreign Corrupt Practices Act (the "FCPA"), and similar anti-corruption and anti-bribery laws of China and other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and any determination that we have violated these laws could have a material adverse effect on our business or our reputation.

Our operations are subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of China and other countries in which we operate. The FCPA and these other laws generally prohibit us, our officers, and our employees and intermediaries from, directly or indirectly, offering, authorizing or making improper payments to non-U.S. government officials for the purpose of obtaining or retaining business or other advantage. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. As our business expands, the applicability of the FCPA and other anti-bribery laws to our operations will increase. If our procedures and controls to monitor anti-bribery compliance fail to protect us from reckless or criminal acts committed by our employees or agents or if we, or our employees, agents, contractors or other collaborators, fail to comply with applicable anti-bribery laws, our reputation could be harmed and we could incur criminal or civil penalties, other sanctions and/or significant expenses, which could have a material adverse effect on our business, including our financial condition, results of operations, cash flows and prospects.

In addition, our products may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international or domestic sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to, existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business.

Regulatory Requirements on currency exchange may limit our ability to receive and use effectively financing in foreign currencies.

Our Chinese subsidiaries' ability to obtain currency exchange is subject to certain foreign exchange regulations and, in the case of transactions under the capital account, requires the approval of and/or registration with Chinese government authorities, including the State Administration of Foreign Exchange ("SAFE"). In particular, if we finance our Chinese subsidiaries by means of foreign debt from us or other foreign lenders, the amount is not allowed to, among other things, exceed the statutory limits and such loans must be registered with the local branch of SAFE. If we finance our Chinese subsidiaries by means of additional capital contributions, these capital contributions are subject to registration with the State Administration for Market Regulation or its local branch, reporting of foreign investment information with the Ministry of Commerce of the People's Republic of China ("MOFCOM"), or its local branch or registration with other governmental authorities in China.

In light of the various requirements imposed by Chinese regulations on loans to, and direct investment in, China-based entities by offshore holding companies, we cannot assure you that we will be able to complete the necessary government requirements or obtain the necessary government approvals on a timely basis, if at all, with respect to future loans or capital contributions by us to our Chinese subsidiaries. If we fail to adhere to such requirements or obtain such approval, our ability to fund our Chinese operations, including research and development activities through AnHeart Therapeutics (Hangzhou) Co., Ltd., may be negatively affected, which could materially and adversely affect our ability to fund and expand our business.

Chinese regulations relating to the establishment of offshore special purpose companies by residents in China may subject our China resident beneficial owners or our wholly foreign-owned subsidiaries in China to liability or penalties, limit our ability to inject capital into these subsidiaries, limit these subsidiaries' ability to increase their registered capital or distribute profits to us, or may otherwise adversely affect us.

In 2014, SAFE promulgated the SAFE Circular 37, which requires residents of China to register with local branches of SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with such residents' legally owned assets or equity interests in domestic enterprises or offshore assets or interests, referred to in SAFE Circular 37 as a "special purpose vehicle." The term "control" under SAFE Circular 37 is broadly defined as the operation rights, beneficiary rights or decision-making rights acquired by residents of China in the offshore special purpose vehicles or Chinese companies by such means as acquisition, trust, proxy, voting rights, repurchase, convertible bonds or other arrangements. SAFE Circular 37 further requires amendment to the registration in the event of any changes with respect to the basic information of or any significant changes with respect to the special purpose vehicle, such as an increase or decrease of capital contributed by China residents, share transfer or exchange, merger, division or other material events. If the shareholders of the offshore holding company who are residents of China do not complete their registration with the local SAFE branches, the Chinese subsidiaries may be prohibited from making distributions of profits and proceeds from any reduction in capital, share transfer or liquidation to the offshore parent company and from carrying out subsequent cross-border foreign exchange activities, and the offshore parent company may be restricted in its ability to

contribute additional capital into its Chinese subsidiaries. Moreover, failure to comply with the SAFE registration and amendment requirements described above could result in liability under Chinese law for evasion of applicable foreign exchange restrictions.

Certain residents of China may hold direct or indirect interests in our company, and we will request residents of China who we know hold direct or indirect interests in our company, if any, to make the necessary applications, filings and amendments as required under SAFE Circular 37 and other related rules. However, we may not at all times be fully aware or informed of the identities of our shareholders or beneficial owners that are required to make such registrations, and we cannot provide any assurance that these residents will comply with our requests to make or obtain any applicable registrations or comply with other requirements under SAFE Circular 37 or other related rules. The failure or inability of our China resident shareholders to comply with the registration procedures set forth in these regulations may subject us to fines or legal sanctions, restrictions on our cross-border investment activities or those of our China subsidiaries and limitations on the ability of our wholly foreign-owned subsidiaries in China to distribute dividends or the proceeds from any reduction in capital, share transfer or liquidation to us, and we may also be prohibited from injecting additional capital into these subsidiaries. Moreover, failure to comply with the various foreign exchange registration requirements described above could result in liability under Chinese law for circumventing applicable foreign exchange restrictions. As a result, our business operations and our ability to make distributions to you could be materially and adversely affected.

We and our shareholders face uncertainties in China with respect to indirect transfers of equity interests in China resident enterprises.

The indirect transfer of equity interests in China resident enterprises by a non-China resident enterprise ("Indirect Transfer"), is potentially subject to income tax in China at a rate of 10% on the gain if such transfer is considered as not having a commercial purpose and is carried out for tax avoidance. The SAT has issued several rules and notices to tighten the scrutiny over acquisition transactions in recent years. The Announcement of the State Administration of Taxation on Several Issues Concerning the Enterprise Income Tax on Indirect Property Transfer by Non-Resident Enterprises ("SAT Circular 7"), sets out the scope of Indirect Transfers, which includes any changes in the shareholder's ownership of a foreign enterprise holding Chinese assets directly or indirectly in the course of a group's overseas restructuring, and the factors to be considered in determining whether an Indirect Transfer has a commercial purpose. An Indirect Transfer satisfying all the following criteria will be deemed to lack a bona fide commercial purpose and be taxable under Chinese laws: (i) 75% or more of the equity value of the intermediary enterprise being transferred is derived directly or indirectly from the Chinese taxable assets; (ii) at any time during the one-year period before the indirect transfer, 90% or more of the asset value of the intermediary enterprise (excluding cash) is comprised directly or indirectly of investments in China, or 90% or more of its income is derived directly or indirectly from China; (iii) the functions performed and risks assumed by the intermediary enterprise and any of its subsidiaries that directly or indirectly hold the Chinese taxable assets are limited and are insufficient to prove their economic substance; and (iv) the non-Chinese tax payable on the gain derived from the indirect transfer of the Chinese taxable assets is lower than the potential Chinese income tax on the direct transfer of such assets. A transaction that does not satisfy all four tests in the immediately preceding sentence may nevertheless be deemed to lack a bona fide commercial purpose if the taxpayer cannot justify such purpose from a totality approach, taking into account the transferred group's value, income, asset composition, the history and substance in the structure, the non-Chinese tax implications, any tax treaty benefit and the availability of alternative transactions. Nevertheless, a non-resident enterprise's buying and selling shares of the same listed foreign enterprise on the public market will fall under the safe harbor available under SAT Circular 7 if the shares were purchased on the public market as well and will not be subject to Chinese tax pursuant to SAT Circular 7.

We face uncertainties regarding the reporting required for and impact on future private equity financing transactions, share exchanges or other transactions involving the transfer of shares in our company by investors that are non-Chinese resident enterprises, or the sale or purchase of shares in other non-Chinese resident companies or other taxable assets by us. For example, the Chinese tax authorities may consider that a future securities offering involves an indirect change of shareholding in our Chinese subsidiaries and therefore it may be regarded as an Indirect Transfer under SAT Circular 7. Even if we believe no SAT Circular 7 reporting is required on the basis that such an offering has commercial purposes and is not conducted for tax avoidance, Chinese tax authorities may pursue us to report under SAT Circular 7 and request that we and our Chinese subsidiaries assist in the filing. As a result, we and our subsidiaries may be required to expend significant resources to provide assistance and comply with SAT Circular 7, or establish that we or our non-resident enterprises should not be subject to tax under SAT Circular 7, for such an offering or other transactions, which may have an adverse effect on our and their financial condition and day-to-day operations.

Any failure to comply with Chinese regulations regarding the registration requirements for our employee equity incentive plans may subject us to fines and other legal or administrative sanctions, which could adversely affect our business, financial condition and results of operations.

In 2012, the SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies (the "Stock Option Rules"). In accordance with the Stock Option Rules and other relevant rules and regulations, Chinese citizens or non-Chinese citizens residing in China for a continuous period of not less than one year who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with SAFE through a domestic qualified agent, which could be a Chinese subsidiary of such

overseas listed company, and complete certain procedures. Our employees who are Chinese citizens or who reside in China for a continuous period of not less than one year and who participate in our stock incentive plans are subject to such regulation. We plan to assist our employees to register their equity awards. However, any failure of our Chinese individual beneficial owners and holders of equity awards to comply with the SAFE registration requirements may subject them to fines and legal sanctions and may limit the ability of our Chinese subsidiaries to distribute dividends to us. We also face regulatory uncertainties that could restrict our ability to adopt additional incentive plans for our employees under Chinese law.

Risks Related to Ownership of Our Securities

The market price of our securities may be volatile and fluctuate substantially, which could result in substantial losses for our investors and may subject us to securities litigation suits.

The market price of our securities may be volatile. The stock market in general and the market for pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their securities or above the price they paid. The market price for our securities may be influenced by many factors, including:

- adverse regulatory decisions;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- the impact of health epidemics;
- the commencement, enrollment or results of any future clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results from, delays in or termination of clinical trials;
- unanticipated serious safety concerns related to the use of our product candidates;
- lower than expected market acceptance of our product candidates following approval for commercialization;
- changes in financial estimates by us or by any securities analysts who might cover our securities;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the pharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our securities;
- currency exchange rate fluctuations;
- disputes or other developments relating to intellectual property rights, including patents, litigation matters and our ability to obtain, maintain, defend, protect and enforce patent and other intellectual property rights for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- proposed changes to healthcare laws in the U.S., China or other foreign jurisdictions, or speculation regarding such changes including changes in the structure of healthcare payment systems;

• general political and economic conditions; and

• other events or factors, many of which are beyond our control.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

The dual-class structure of our common stock has the effect of concentrating voting power with our Chief Executive Officer, which limits other stockholders' ability to influence the outcome of important transactions, including a change in control.

Dr. Hung holds all of the outstanding shares of our Class B common stock and approximately 24% of our Class A and Class B common stock outstanding. In addition to voting together with the Class A common stock (with one vote per share) on all matters, the holders of Class B common stock have (i) the right to elect and remove without cause three of our directors plus at least 50% of all directors in excess of seven and (ii) an approval right over any acquisition (whether by merger, sale of shares or sale of assets) or our liquidation. Accordingly, Dr. Hung has the ability to control or exert substantial influence over all matters submitted to our stockholders for approval, including the election of directors and amendments of our organizational documents, and an approval right over any acquisition or liquidation of our company. Dr. Hung may have interests that differ from those of the other stockholders and may vote in a way with which the other stockholders disagree and which may be adverse to their interests. This concentrated control may have the effect of delaying, preventing or deterring a change in control, could deprive our stockholders of an opportunity to receive a premium for their capital stock as part of a sale of our company, and might ultimately affect the market price of shares of our Class A common stock.

We cannot predict the impact our dual-class structure may have on the market price of our Class A common stock.

We cannot predict whether our dual-class structure, combined with the concentrated voting power of Dr. Hung by virtue of his ownership of 100% of the outstanding shares of our Class B common stock, will result in a lower or more volatile market price of our Class A common stock in the future, or in adverse publicity or other adverse consequences. Certain index providers have announced restrictions on including companies with multi-class share structures in certain of their indices. For example, in 2017, FTSE Russell and Standard & Poor's announced that they would cease to allow most newly public companies utilizing dual or multi-class capital structures to be included in their indices. Under the announced policies, our dual-class capital structure makes us ineligible for inclusion in any of these indices. Given the sustained flow of investment funds into passive strategies that seek to track certain indices, exclusion from stock indices would likely preclude investment by many of these funds and could make our securities less attractive to other investors. As a result, the market price of our Class A common stock could be adversely affected.

There can be no assurance that we will be able to comply with the continued listing standards of the NYSE.

Our Class A common stock and warrants are listed on the NYSE under the symbols "NUVB" and "NUVBW," respectively. Our continued eligibility for listing will depend on our compliance with the continued listing standards of the NYSE and may depend on the number of our shares that are redeemed. If the NYSE delists our securities from trading on its exchange for failure to meet the listing standards, we and our stockholders could face significant negative consequences including:

• limited availability of market quotations for our securities;

• a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for shares of our common stock;

• a limited amount of analyst coverage; and

• a decreased ability to issue additional securities or obtain additional financing in the future.

Future sales, or the perception of future sales, by us or our stockholders in the public market could cause the market price for our securities to decline.

The sale of our securities in the public market, or the perception that such sales could occur, could harm the prevailing market price of our securities. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

Immediately prior to our acquisition of AnHeart, we had a total of approximately 219,083,219 shares of common stock outstanding, consisting of approximately 218,083,219 shares of Class A common stock and 1,000,000 shares of Class B common stock. All of these shares are freely tradable without registration under the Securities Act, and without restriction by persons other than our "affiliates" (as defined under Rule 144 of the Securities Act, "Rule 144"), including our directors, executive officers and other affiliates.

In the AnHeart acquisition, we issued to AnHeart securityholders approximately (i) 27,646,255 shares of Class A Common Stock, (ii) shares of preferred stock convertible into an aggregate of approximately 85,120,200 shares of Class A Common Stock upon the approval of such conversion by our stockholders, and warrants exercisable for approximately 2,893,731 shares of Class A Common Stock at an exercise price of $11.50 per share. These securities were issued in a private placement and are subject to restrictions on resale under federal securities laws and, in most cases, lockup agreements restricting resale of more than 20% of such securities before December 31, 2024. We also reserved an aggregate of approximately 15,943,933 shares of Class A Common Stock for issuance under AnHeart's equity incentive plans. We intend to file with the SEC a registration statement with respect to the resale of the shares and warrants issued in the AnHeart acquisition.

In addition, the shares of Class A common stock reserved for future issuance under our equity incentive plans will become eligible for sale in the public market once those shares are issued, subject to provisions relating to various vesting agreements, lock-up agreements and, in some cases, limitations on volume and manner of sale applicable to affiliates under Rule 144, as applicable. Our compensation committee of our board of directors may determine the exact number of shares to be reserved for future issuance under our equity incentive plans at its discretion. We have filed and expect to file registration statements on Form S-8 under the Securities Act to register shares of Class A common stock or securities convertible into or exchangeable for shares of Class A common stock issued pursuant to our equity incentive plans. Any such Form S-8 registration statements will automatically become effective upon filing. Accordingly, shares registered under such registration statements will be available for sale in the open market.

In the future, we may also issue our securities in connection with investments or acquisitions. The amount of shares of Class A common stock issued in connection with an investment or acquisition could constitute a material portion of our then-outstanding shares of Class A common stock. Any issuance of additional securities in connection with investments or acquisitions may result in additional dilution to our stockholders.

Because we do not anticipate paying any cash dividends on our Class A common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.

We may retain future earnings, if any, for future operations, expansion and debt repayment and have no current plans to pay any cash dividends for the foreseeable future. Any decision to declare and pay dividends as a public company in the future will be made at the discretion of our board of directors and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions and other factors that our board of directors may deem relevant. In addition, our ability to pay dividends may be limited by covenants of any existing and future outstanding indebtedness we or our subsidiaries incur. As a result, you may not receive any return on an investment in our securities unless you sell your securities for a price greater than that which you paid for it.

There is no guarantee that our warrants will be in the money at the time they become exercisable, and they may expire worthless.

The exercise price for our outstanding warrants is $11.50 per share of Class A common stock. There is no guarantee that any of our warrants will be in the money following the time they become exercisable and prior to their expiration, and as such, the warrants may expire worthless.

We may issue additional securities without your approval, which would dilute your ownership interests and may depress the market price of our securities.

As of March 31, 2024, we have options outstanding to purchase approximately 38,224,240 shares of Class A common stock. Pursuant to the 2021 Equity Incentive Plan (the "2021 Plan") and the Employee Stock Purchase Plan (the "2021 ESPP"), we may issue under the 2021 Plan an aggregate of up to 57,590,961 shares of Class A common stock and Class B common stock, which amount will be subject to increase from time to time. In addition, in the AnHeart acquisition, we assumed the AnHeart equity incentive plans and reserved an aggregate of approximately 15,943,933 shares of Class A Common Stock for issuance upon exercise of outstanding options or settlement of outstanding restricted stock units issued under those plans. We may also issue additional shares of Class A common stock or other equity securities of equal or senior rank in the future in connection with, among other things, future acquisitions or repayment of outstanding indebtedness, without stockholder approval, in a number of circumstances.

The issuance of additional shares or other equity securities of equal or senior rank would have the following effects:

- existing stockholders' proportionate ownership interest in our company will decrease;
- the amount of cash available per share, including for payment of dividends in the future, may decrease;
- the relative voting strength of each previously outstanding common stock may be diminished; and
- the market price of our securities may decline.

Anti-takeover provisions in our amended and restated certificate of incorporation and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult, and may prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation contains provisions that may delay or prevent an acquisition of the company or change in our management in addition to the significant rights of Dr. Hung as the holder of 100% of the outstanding shares of our Class B common stock. These provisions may make it more difficult for stockholders to replace or remove members of our board of directors. Because the board of directors is responsible for appointing the members of the management team, these provisions could in turn frustrate or prevent any attempt by our stockholders to replace or remove our current management. In addition, these provisions could limit the price that investors might be willing to pay in the future for shares of our Class A common stock. Among other things, these provisions include:

- the limitation of the liability of, and the indemnification of, our directors and officers;
- a prohibition on actions by our stockholders except at an annual or special meeting of stockholders;
- a prohibition on actions by our stockholders by written consent; and
- the ability of the board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by the board of directors.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the "DGCL"), which prohibits a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired 15% or more of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. This could discourage, delay or prevent a third party from acquiring or merging with us, whether or not it is desired by, or beneficial to, our stockholders. This could also have the effect of discouraging others from making tender offers for our Class A common stock, including transactions that may be in our stockholders' best interests. Finally, these provisions establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings. These provisions would apply even if the offer may be considered beneficial by some stockholders.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising under the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine or otherwise related to our internal affairs.

To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation

to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could harm our business.

We are eligible to report as a "smaller reporting company," and as a result of the reduced reporting requirements applicable to "smaller reporting companies," our securities may be less attractive to investors.

We are eligible to report as a smaller reporting company. For as long as we continue to be eligible to report as a "smaller reporting company," we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "smaller reporting companies," including exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. If some investors find our securities less attractive because we rely on any of these exemptions, there may be a less active trading market for our securities and the price of our securities may be more volatile.

General Risk Factors

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the NYSE. Section 302 of the Sarbanes-Oxley Act requires, among other things, that public companies report on the effectiveness of our disclosure controls and procedures in our quarterly and annual reports and, beginning with this report, Section 404 of the Sarbanes-Oxley Act requires that we perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in our Annual Report on Form 10-K for that year. This has required us to incur substantial additional professional fees and internal costs to expand our accounting and finance functions and to expend significant management efforts.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the NYSE, the SEC or other regulatory authorities. In addition, our securities may not be able to remain listed on the NYSE or any other securities exchange.

We will incur costs and demands upon our management as a result of complying with the laws and regulations affecting public companies in the U.S., which may harm our business.

As a public company listed in the U.S., we incur on an ongoing basis significant legal, accounting and other expenses. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and the NYSE may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from regular business activities to compliance activities. If, notwithstanding our efforts, we fail to comply with new laws, regulations and standards, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

If securities or industry analysts cease publishing research or reports about us, our business or our market, or if they change their recommendations regarding our securities adversely, the price and trading volume of our securities could decline.

Equity research analysts may cease providing research coverage of our securities at any time, and such lack of research coverage may adversely affect the market price of our securities. In any event, we do not have any control over the analysts or the content and opinions included in their reports and the price of our 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 our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our securities' prices or trading volume to decline.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

(a) Issuer Purchases of Equity Securities

Period	Total number of shares (or units) purchased	Average price paid per share (or unit)	Total number of shares (or units) purchased as part of publicly announced plans or programs	Maximum number (or approximate dollar value) of shares (or units) that may yet be purchased under the plans or programs
January 2024	N/A	$ N/A	N/A	N/A
February 2024	N/A	$ N/A	N/A	N/A
March 2024	N/A	$ N/A	N/A	N/A
Total	—	$ N/A		

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information

2024 Annual Meeting of the Stockholders

The Company expects to hold the 2024 annual meeting of the stockholders (the "2024 Annual Meeting") on July 10, 2024. The time and meeting website information will be set forth in the Company's proxy statement for the 2024 Annual Meeting, which will be filed with the SEC in advance of the meeting. Because the scheduled date of the 2024 Annual Meeting represents a change of more than 30 days from the anniversary of the Company's 2023 annual meeting of stockholders, the deadlines for stockholders to propose actions for consideration or to nominate individuals to serve as directors at the 2024 Annual Meeting previously set forth in the Company's 2023 proxy statement are no longer applicable. Pursuant to Rule 14a-8, in order for a stockholder proposal or the nomination of a candidate for director to be included in the Company's definitive proxy statement for the 2024 Annual Meeting, it must be submitted in writing to our Secretary (Nuvation Bio Inc., Attn: Investor Relations, 1500 Broadway, Suite 1401, New York, New York, 10036) by May 24, 2024. The proposals and nominations must comply with all of the applicable requirements set forth in the rules and regulations of the SEC, under the Exchange Act, and our amended and restated bylaws.

Item 6. Exhibits.

The following exhibits are filed as part of this report:

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation previously filed with the SEC on February 12, 2021 as Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-39351), which is incorporated herein by reference.
3.2	Amended and Restated Bylaws previously filed with the SEC on February 12, 2021 as Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-39351), which is incorporated herein by reference.
10.1#*	Non-Employee Director Compensation Policy
10.2#†	Forms of Option Grant Notice and Option Agreement under the 2021 Equity Incentive Plan – Long-Term Incentive Program previously filed with the SEC on May 9, 2022 as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, which is incorporated herein by reference.
10.3*‡	License Agreement between Daiichi Sankyo Company, Limited and AnHeart Therapeutics Inc., dated December 7, 2018

10.4*‡	First Amendment to License Agreement between Daiichi Sankyo Company, Limited and AnHeart Therpaeutics Inc., dated August 17, 2020
10.5*‡	License Agreement between Daiichi Sankyo Company, Limited and AnHeart Therapeutics Inc., dated September 7, 2020
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

# Indicates management contract or compensatory plan or arrangement.

† Certain portions of this exhibit will be omitted because they are not material and would likely cause competitive harm to the registrant if disclosed.

‡ Confidential portions of this Exhibit were redacted pursuant to Item 601(b)(10) of Regulation S-K and the Company agrees to furnish supplementally to the Securities and Exchange Commission a copy of any omitted schedule and/or exhibit upon request.

* Filed herewith.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of New York, State of New York, on this 14th day of May, 2024.

NUVATION BIO INC.

Date: May 14, 2024

/s/ David Hung, M.D.
David Hung, M.D.
Founder, President and Chief Executive Officer

Date: May 14, 2024

/s/ Moses Makunje
Moses Makunje, VP, Finance
Principal Financial and Accounting Officer

Exhibit 10.1

Non-Employee Director Compensation Policy
of
Nuvation Bio Inc.

(Adopted April 20, 2023)

Non-Employee Directors of Nuvation Bio Inc. (the ***"Company"***) are compensated for service on the Board of Directors of the Company (the ***"Board"***) through a combination of cash retainer and equity awards. In addition, the Company reimburses Non-Employee Directors for reasonable expenses incurred in serving as a Non-Employee Director.

Cash Compensation

Annual retainers are paid in the following amounts to Non-Employee Directors:

Annual Retainer	$	40,000
Additional Annual Retainer for Board Chair	$	30,000
Additional Annual Retainer for Committee Chairs:		
Audit Committee	$	15,000
Compensation Committee	$	12,000
Nominating and Corporate Governance Committee	$	10,000
Additional Annual Retainer for Committee Members:		
Audit Committee	$	7,500
Compensation Committee	$	6,000
Nominating and Corporate Governance Committee	$	5,000

All annual retainers will be paid in cash quarterly in arrears promptly following the end of the applicable fiscal quarter.

Equity Compensation

Upon initial election or appointment to the Board, each Non-Employee Director shall be granted an option to purchase shares of the Company's Class A Common Stock with an aggregate value of $770,000 on the date on which the Non-Employee Director's service as a director begins. The initial option grant will be automatically granted, without further action, on the date on which the Non-Employee Director's service as a director begins and will vest as to 1/36 of the shares on the first monthly anniversary of the grant date, with the balance of the shares vesting in 35 equal monthly installments thereafter, subject to the Non-Employee Director's continued service through the vesting date.

On the date of each Annual Meeting of Stockholders ("Annual Meeting") held in or after 2023, each Non-Employee Director who was elected or appointed as a director prior to the beginning of the calendar year of the Annual Meeting and whose service as a director will continue after the Annual Meeting shall be granted an option to purchase shares of the Company's Class A Common Stock with an aggregate value of $385,000. The annual option grant will be automatically granted, without further action, on the date of the applicable Annual Meeting and will vest in full on the earlier to occur of (i) the first anniversary of the date of grant and (ii) the date immediately prior to the date of the Annual Meeting for the year following the year in which the grant is made, subject in each case to the Non-Employee Director's continued service through the vesting date.

The grant-date value of each option granted under this Policy shall be determined using substantially the same methodology utilized by the Company to determine the grant date values of stock options reported in its filings with the Securities and Exchange Commission (or such other methodology as the Board or its Compensation Committee may determine prior to the grant becoming effective).

Options granted under this Policy shall: (i) have an exercise price equal to the closing price of shares of the Company's Class A Common Stock on the New York Stock Exchange on the grant date; (ii) expire on the tenth anniversary of the grant date; and (iii) be subject to all applicable terms of the Company's 2021 Equity Incentive Plan and applicable equity award agreements thereunder.

Amendment, Modification and Termination

This Policy may be amended, modified or terminated by the Board in the future, upon the recommendation of its Compensation Committee.

Exhibit 10.3

In accordance with Item 601(b)(10) of Regulation S-K, certain portions of this exhibit have been omitted because the information (i) is not material and (ii) would likely cause competitive harm to Nuvation Bio if publicly disclosed. The omissions have been indicated by "[Redacted**]".**

LICENSE AGREEMENT
BETWEEN
DAIICHI SANKYO COMPANY, LIMITED AND
ANHEART THERAPEUTICS INC.

20181207 – AnHeart-DS Exclusive

TABLE OF CONTENTS

LICENSE AGREEMENT

This License Agreement (the "Agreement"), dated the 7th day of December, 2018 (the "Effective Date"), is between DAIICHI SANKYO COMPANY, LIMITED, a Japanese corporation having an office and principal place of business at 5-1, Nihonbashi-honcho 3- chome Chuo-ku, Tokyo 103-8426, Japan ("Daiichi Sankyo"), and ANHEART THERAPEUTICS INC., a Delaware corporation having an office and place of business at 5 Penn Plaza, 23rd floor, New York, NY 10001, USA ("AnHeart"). Daiichi Sankyo and AnHeart are each referred to herein by name, individually as a "Party", or collectively as "Parties".

RECITALS:

1.Daiichi Sankyo owns Patents (hereinafter defined), technology and Know-how (hereinafter defined) in existence as of the Effective Date relating to the Licensed Compound (hereinafter defined); and

2.AnHeart desires to research, develop and commercialize products containing the Licensed Compound for therapeutic uses in humans; and

3.Daiichi Sankyo desires to grant to AnHeart an exclusive license under its intellectual property relating to the Licensed Compound, on the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual agreements and covenants set forth herein, Daiichi Sankyo and AnHeart agree as follows:

1. Definitions.

As used in this Agreement, each capitalized term used herein shall have the meaning set forth below unless context clearly and unambiguously dictates otherwise.

1.1."Affiliate" means, with respect to a legal person or entity, any other legal person or entity that controls, is controlled by or is under common control with such legal person or entity, for so long as such control exists. For purposes of this definition only, "control" shall mean: (a) beneficial ownership (direct or indirect) of more than fifty percent (50%) of the shares of the person entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, in the election of the corresponding managing authority); or (b) the de facto ability to control or direct the management of such person or entity.

1.2. "AnBio" means, AnBio Inc., a Delaware corporation, which owns one hundred percent (100%) of the share capital of AnHeart as of the Effective Date.

1.3. "Business Day" means any day other than a Saturday, a Sunday or a day on which commercial banks located in the United States, China or Japan are authorized or required by law to remain closed.

1.4. "Commercially Reasonable Effort" means, with respect to a Party, those efforts and resources, as applicable, relating to a certain activity or activities, including, without limitation, the research, development and commercialization of a Product in accordance with such Party's business, legal, medical and scientific judgment, such reasonable efforts and diligence to be in accordance with the efforts and resources a reasonably comparable pharmaceutical company would use for a product owned by it, or to which it has rights, which is of similar market potential, at a similar stage in its product life, taking into account the establishment of the Product in the marketplace, the competitiveness of the marketplace, the proprietary position of the Product, the regulatory structure involved, the profitability of the Product and other relevant factors.

1.5. "Competing Molecules" means drug candidates other than Licensed Compounds which: (1) have been **[**Redacted**]** (2) **[**Redacted**]**; and (3) **[**Redacted**]**. For the avoidance of doubt, drug candidates that **[**Redacted**]** shall not be deemed to be Competing Molecules.

1.6. "Confidential Information" has the meaning provided in Section 7.1.

1.7. "Control", when used in reference to intellectual property, means possession of the ability (whether by license or ownership, or an Affiliate having possession by license or ownership) to grant a license or sublicense, of or within the scope set forth in this Agreement, without violating the terms of any written agreement with any Third Party.

1.8. "Cover", "Covering" or "Covered" means, with respect to a Patent, that, but for a license granted to a Party under a Valid Claim included in such Patent, the practice by such Party of an invention claimed in such Patent would infringe such Valid Claim (or in the case of a Patent that is a patent application, would infringe a Valid Claim in such patent application if it were to issue as a patent).

1.9. "Daiichi Sankyo Technology" means the Daiichi Sankyo Patents and Daiichi Sankyo Know-how.

1.9.1. "Daiichi Sankyo Know-how" means Know-how related to the Licensed Compounds that is owned or Controlled by Daiichi Sankyo as of the Effective Date.

1.9.2.“Daiichi Sankyo Patents” means Patents owned or Controlled by Daiichi Sankyo as of the Effective Date with a Valid Claim Covering the Licensed Compounds or a Product, or that are otherwise reasonably necessary or useful for researching, developing, manufacturing, using, selling or importing the Licensed Compounds or a Product, or that would otherwise Cover manufacturing, using, selling or importing a Product, in each case within the Field and in the Territory. The Daiichi Sankyo Patents are set forth in **Exhibit A**.

1.10. “DMF” means a Drug Master File as more fully defined in 21 C.F.R. §314.420 in the United States or similar documents filed with a Regulatory Authority in another jurisdiction.

1.11. “EMA” means the European Medicines Agency or any successor entity.

1.12.“FDA” means the United States Food and Drug Administration or any successor entity.

1.13.“Field” means all human therapeutic uses of the Licensed Compounds that derives therapeutic effect from ROS proto-oncogene 1 (ROS1) and/or the neurotrophic receptor tyrosine kinase (NTRK), and/or anaplastic lymphoma kinase (ALK) pathways for the diagnosis, prevention, or treatment of any indication.

1.14.“First Commercial Sale” means the date on which the Product is first shipped by AnHeart, its Affiliate, or its Sublicensee to Third Parties for commercial sale in any country in the Territory after all required Marketing Approvals have been granted, or such sale is otherwise permitted, by the Regulatory Authority in such country, excluding samples, compassionate use (including named patient programs) and the like.

1.15.“IND” means, in the United States, an effective Notice of a Claimed Investigational New Drug Application filed with the FDA as more fully defined in 21
C.F.R. §312.3, and, with respect to every other country in the Territory, the equivalent application (i.e., a filing that must be made prior to commencing clinical testing of Product in humans) for such country, filed with the applicable Regulatory Authority in such country.

1.16.“Invention” means any new or useful process, machine, manufacture, or composition of matter relating to or comprising a Licensed Compound or a Product, and any improvement, enhancement, modification or derivative work to any Daiichi Sankyo Technology, that is conceived or first reduced to practice or first demonstrated to have utility during the Term in connection with the Parties' activities to develop, manufacture and commercialize the Licensed Compound and Product(s) worldwide.

1.17. “Joint Technology” means the Joint Patents and Joint Know-how.

1.17.1."Joint Know-how" means Know-how, including any Invention, that is conceived of discovered, developed, made and/or reduced to practice jointly by or on behalf of employees, agents, or consultants of Daiichi Sankyo or its Affiliates or its or their Sublicensees, on the one hand, and employees, agents, or consultants of AnHeart, its Affiliates, or its Sublicensees, on the other hand.

1.17.2."Joint Patents" means Patents with a Valid Claim Covering an Invention, that is conceived of discovered, developed, made and/or reduced to practice jointly by or on behalf of employees, agents, or consultants of Daiichi Sankyo or its Affiliates or its or their Sublicensees, on the one hand, and employees, agents, or consultants of AnHeart, its Affiliates, or its Sublicensees, on the other hand.

1.18."Know-how" means confidential and proprietary information and tangible materials, whether patentable or unpatentable, that is necessary or useful to develop or commercialize a Licensed Compound or a Product and that exists as of the Effective Date or is discovered, developed or acquired during the Term, including, without limitation: (a) ideas, discoveries, Inventions, improvements or trade secrets; (b) tests, assays, techniques, methods, procedures, formulas, processes and data, including, but not limited to, clinical data (including patient report forms, preliminary and final investigators' reports, statistical analyses, expert opinions and reports, safety and other electronic databases, Regulatory Filings and communications, and the like), pharmacological, preclinical and toxicological data, as well as manufacturing information and descriptions, with respect to a Licensed Compound or a Product; and (c) pharmaceutical, chemical and biological materials, products and compositions of matter in each case that are reasonably necessary or useful to research, develop, manufacture and commercial a Licensed Compound or a Product in accordance with this Agreement. Know-How does not include any Patents.

1.19."Licensed Compounds" means the compounds claimed in Daiichi Sankyo Patents, including, but not limited to the compound which is identified by the internal Daiichi Sankyo compound code DS-6051b with the molecular structure set forth in **Exhibit A**, and any salts, hydrates, solvates, esters, and stereoisomers of any Licensed Compound.

1.20. "MAA" means a Marketing Authorization Application, filed with the EMA.

1.21."Major Markets" means the **[**Redacted**]**.

1.22. "Marketing Approval" means, with respect to a Product, all approvals, licenses, registrations or authorizations of any Regulatory Authority, necessary for the manufacturing, use, storage, import, transport and sale of such Product in a particular country, but excluding pricing or reimbursement approval where governmental approval is required for pricing, or for the Product to be reimbursed by national health insurance.

1.23. "NDA" means a New Drug Application, filed with the FDA.

1.24."Net Sales" means the gross amounts invoiced for Product sold by AnHeart, its Affiliates, or its Sublicensees (each a "Selling Party") in finished product form, packaged

and labeled for sale in arm's length transactions to Third Parties, less the following deductions from such gross amounts: (a) normal and customary trade, cash and other discounts and allowances actually allowed by the Selling Party and taken by the customer;

5

(b) credits, price adjustments or allowances actually granted to the customer for damaged goods, returns or rejections of a Product; (c) sales taxes or similar taxes, including duties or other governmental charges imposed on the sale of a Product (including value added taxes or other governmental charges, but excluding any income taxes), to the extent the Selling Party is not otherwise entitled to a credit or a refund for such taxes, duties or payments made; (d) chargeback payments, rebates, fees, and other adjustments, including those granted on
price adjustments, billing errors, reimbursements or similar payments granted or given to wholesalers or other distributors, buying groups, health insurance carriers or other institutions, including those paid in connection with such sales to any governmental entity; and (e) any invoiced freight, shipping, insurance and other transportation charges. Net Sales does not include samples or Product for compassionate use and the like. Net Sales, as set forth in this definition, will be calculated by applying the Selling Party's standard accounting practices, in accordance with generally accepted accounting principles used by the Selling Party, as consistently applied in its respective audited financial statements.

1.24.1. Sales between or among AnHeart, its Affiliates and its Sublicensees may be excluded from the computation of Net Sales if such sales are not intended for end use, but Net Sales will include the subsequent final sales to Third Parties by AnHeart, its Affiliates or its Sublicensees.

1.24.2. If AnHeart, its Affiliate, or its Sublicensee sells or transfers units of a Product in conjunction with any other product, and in so doing sells or transfers such units for an amount less than the sum of the weighted average selling price for such units of such Product sold separately, for the purposes of determining Net Sales from such sales or transfers, Net Sales shall be based upon the price of such Product sold to a similar size customer ordering a similar volume of units of the Product under similar terms and conditions, but sold separately.

1.25. "Patents" means any of the following: (a) any issued and unexpired patent, including without limitation, any inventor's certificate, substitution, extension, re-registration, confirmation, reissue, re-examination, re-validation, renewal or any similar governmental grant for protection of inventions (including, but not limited to, patent term extensions, pediatric exclusivity or supplementary protection certificate); (b) any patent application including, without limitation, any continuation, divisional, substitution, continuation-in-part, provisional applications and converted provisional applications; and (c) all foreign counterparts of any of the foregoing.

1.26. "Product(s)" means any pharmaceutical preparations containing a Licensed Compound as an active ingredient.

1.27. "Regulatory Authority" means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with

authority over the research, development, manufacture, commercialization or other use (including the granting of Marketing Approvals) of the Product(s) in any country in the Territory including, with respect to the United States, the FDA, and with respect to the European Union, the EMA.

1.28. "Regulatory Filings" means, collectively, all INDs for the Licensed Compounds, the DMF, any application for Marketing Approval, Marketing Approvals and other filings, such as annual reports, required by any Regulatory Authority in any country in the Territory.

1.29. "Sublicensee" means any Third Party that is approved by Daiichi Sankyo under Section 2.3 or otherwise permitted under Section 2.2, and receives a sublicense under Section
2.2 to the rights granted by Daiichi Sankyo, regardless of the number of intermediate sublicenses (tiers) granted between AnHeart and such Third Party.

1.30. "Term" has the meaning provided in Section 10.1

1.31. "Territory" means all countries worldwide.

1.32. "Third Party" means any legal person or entity other than a Party or an Affiliate of a Party.

1.33. "Valid Claim" means any claim of an **[**Redacted**]**

2. License Grants.

2.1. Scope of Grant.

2.1.1 In the Field. In consideration of and subject to the terms and conditions of this Agreement, Daiichi Sankyo grants to AnHeart a royalty-bearing, exclusive right and license in the Field in the Territory, with the right to grant one or more sublicenses in accordance with the terms of Section 2.2, under the Daiichi Sankyo Technology: (a) to develop the Licensed Compounds and Product(s); (b) to make, have made, use, import and export the Licensed Compounds for the purpose of making, having made, using, offering for sale, selling, marketing, distributing, importing and exporting Product(s); and (c) to make, have made, use, offer for sale, sell, market, distribute, import and export Product(s).

2.1.2 Outside of the Field. Daiichi Sankyo grants to AnHeart a royalty-free, non-exclusive right and license, without the right to grant sublicenses, to use the Licensed Compounds in pre-clinical research outside of the Field. If AnHeart decides to file an IND for the use of a Licensed Compound outside of the Field, it shall notify Daiichi Sankyo of such decision and the Parties will negotiate in good faith the terms and conditions of a license for additional rights to allow AnHeart to develop, and commercialize specific Licensed Compounds.

2.2. Sublicenses. AnHeart may grant sublicenses of the license granted under Section 2.1 to one or more Sublicensees. Such sublicenses may be granted with or without the right to grant further sublicenses through multiple tiers, provided that AnHeart notifies Daiichi Sankyo of the identity of each proposed Sublicensee, obtains approval from Daiichi Sankyo if necessary under Section 2.3, and gives Daiichi Sankyo a reasonable opportunity to review and comment on the terms of the proposed sublicense. Notwithstanding anything provided herein to the contrary (including without limitation Sections 2.2 and 2.3), if, as of the effective date of a sublicense, a joint venture company to be initially formed in China by AnBio and investment funds managed
by Decheng Capital LLC or the wholly-owned subsidiary of such funds (the "JV Company") owns one hundred percent (100%) of the share capital of AnHeart, Daiichi Sankyo hereby expressly approves the grant of such sublicense by AnHeart to the JV Company, with the right to grant further sublicenses only to Affiliates of the JV Company, of its rights in the Peoples Republic of China (for the avoidance of doubt, including the Hong Kong Special Administrative Region, the Macau Special Administrative Region and Taiwan), and hereby expressly approves the grant of sublicenses by AnHeart, without the right to grant further sublicenses, to any Affiliate of the JV Company, and no further approval by Daiichi Sankyo shall be necessary for the grant of such sublicenses to the JV Company and/or its Affiliates. If, as of the effective date of a sublicense, the JV Company does not own one hundred percent (100%) of the share capital of AnHeart, Daiichi Sankyo hereby expressly approves the grant of such sublicense by AnHeart to the JV Company of its rights under this Agreement, with the right to grant further sublicenses of its rights in the Peoples Republic of China (for the avoidance of doubt, including the Hong Kong Special Administrative Region, the Macau Special Administrative Region and Taiwan) to any subsidiary that is wholly-owned by the JV Company; provided that AnHeart shall inform or cause the JV Company to inform Daiichi Sankyo of the identity of such wholly-owned subsidiary of the JV Company and reasons for such further sublicense and consider Daiichi Sankyo's comments (if any) in good faith, and no further approval by Daiichi Sankyo shall be necessary for the grant of such sublicenses to the JV Company or such wholly-owned subsidiary of the JV Company. For clarity, except as expressly provided in this Section 2.2, AnHeart, and/or the JV Company shall be required to obtain approval of sublicenses to all Sublicensees as provided in Sections 2.2 and 2.3 of this Agreement. AnHeart will ensure that all Sublicensees are bound by the same obligations as those set forth hereunder, including, but not limited to the obligations of confidentiality and non-use of Confidential Information. AnHeart will be liable to Daiichi Sankyo for any material breach of the
terms of this Agreement by a Sublicensee without regard to whether Daiichi Sankyo approves such sublicensee or raises any objection or concerns about such sublicense at the time it is executed.

2.3.Approval of Sublicensees. Promptly after the Effective Date, and on the anniversary of the Effective Date each year of the Term thereafter, AnHeart shall provide Daiichi Sankyo a list of proposed Sublicensees for review and preapproval, which approval shall not be unreasonably withheld. Daiichi Sankyo shall review such list and inform AnHeart in writing of any potential Sublicensees on the list that are not approved. If Daiichi Sankyo does not notify AnHeart of its denial of approval of a proposed sublicensee within **[**Redacted**]** calendar days of receiving the list from AnHeart, such sublicensee shall be deemed approved. If AnHeart wishes to engage a sublicensee that is not on the then current list of approved Sublicensees, it may request approval of such sublicensee by submitting a written request to Daiichi Sankyo. Daiichi Sankyo shall review such list and inform AnHeart in writing if such proposed sublicensee is not approved. If Daiichi Sankyo does not notify AnHeart of its denial of approval of a sublicensee within **[**Redacted**]** calendar days of receiving the request from AnHeart, such sublicensee shall be deemed approved. Any denial of approval by Daiichi Sankyo shall be made in good faith based on reasonable concerns related to the particular sublicensee. If requested by AnHeart, Daiichi Sankyo shall discuss its reasons for denying approval of a sublicensee. For clarity, approval of a Sublicensee by Daiichi Sankyo does not change or limit AnHeart's obligations under Section 8.1.5.

2.4.No Other Rights. It is expressly understood that AnHeart is not granted any rights to the Daiichi Sankyo Technology, except as expressly provided in paragraph 2.1.

3. Development and Commercialization.

3.1. Development.

3.1.1Diligence. AnHeart shall have the sole responsibility to research and develop the Licensed Compounds and Product(s) throughout the Territory. AnHeart,
either directly or through one or more of its Affiliates or Sublicensees, will use Commercially Reasonable Efforts to develop one or more Products for use in the Field in each of **[**Redacted**]**, and at least **[**Redacted**]** of the Major Markets in Europe. For clarity, the results of multi-regional clinical trials that can be used to apply for Marketing Approval in each of the Major Markets can be used to satisfy such diligence requirement.

3.1.2 Ongoing Clinical Trials

(a)Daiichi Sankyo shall continue the Phase I clinical study of DS-6051b in Japan (i.e., Daiichi Sankyo's internal reference "J102") after the Effective Date until all subjects complete the study treatment, the clinical drug supplies in Daiichi Sankyo's possession as of the Effective Date are depleted or the expiration date of such clinical drug supplies has passed, whichever is the earliest. AnHeart shall reimburse Daiichi Sankyo within **[**Redacted**]** calendar days of receiving an itemized quarterly invoice from Daiichi Sankyo for customary and reasonable Third Party costs and expenses incurred for CRO services and data management after the Effective Date to continue the J102 clinical study, the cumulative total amount of which shall not exceed

[Redacted**]** for CRO services, and **[**Redacted**]** for data management fees, respectively.

(b)Daiichi Sankyo shall cause its subsidiary in the United States, Daiichi Sankyo Inc. ("DSI"), which is the sponsor of the Phase I clinical study of DS-6051b in the United States (i.e., Daiichi Sankyo's internal reference "U101"), (i) to transfer the IND sponsorship of the U101 study to AnHeart by sending Form 1571 or other sponsorship transfer request form or letter to FDA, and (ii) to provide all documents listed in **Exhibit D** including the Regulatory Filings, the trial protocols and other documents related to the U101 study to AnHeart, in both cases no later than **[**Redacted**]** calendar days after the Effective Date in accordance with Section 4.1.2. Daiichi Sankyo or DSI shall promptly take such actions and execute all instruments, assignments and documents as may be necessary to effect the transfer of rights under the Regulatory Filings relating to the U101 study to AnHeart or its designee. If applicable law prevents or delays the transfer of ownership of the Regulatory Filings, Daiichi Sankyo or DSI will grant AnHeart or its designee a permanent, exclusive and irrevocable right of access and reference to such Regulatory Filing for a Product and will fully cooperate to make the benefits of such Regulatory Filings available to AnHeart or its designee.

(c)Notwithstanding the transfer of the sponsorship of the U101 IND to AnHeart, Daiichi Sankyo will cause DSI to continue the operational work of the U101 study with the remaining human subjects until: (a) **[**Redacted**]** calendar days after the **[**Redacted**]**, or (b) **[**Redacted**]**, whichever is earlier. **[**Redacted**]** will use its best efforts to complete **[**Redacted**]** by **[**Redacted**]**. The Parties will discuss and agree upon a plan to transfer the operational work for the U101 study to AnHeart to ensure that AnHeart can continue the U101 study after the transfer from DSI under this Section 3.1.2(c). Such transition plan shall include the timelines for Daiichi Sankyo to assign the agreed upon contract research agreements for the U101 study and of Daiichi Sankyo to make arrangements to deliver its remaining clinical drug supplies, if any, to AnHeart or its designee. Any remaining clinical drug supplies for the U101 study will be delivered to AnHeart or its designee at no cost to AnHeart except the cost of shipping and related insurance. AnHeart shall reimburse Daiichi Sankyo within **[**Redacted**]** calendar days of receiving an itemized quarterly invoice from Daiichi Sankyo for customary and reasonable Third Party costs and expenses incurred by Daiichi Sankyo or DSI for CRO services after the Effective Date to continue the U101 clinical study, the cumulative total amount of which shall not exceed **[**Redacted**]**.

3.1.3Further Development. AnHeart shall be solely responsible for promptly initiating and conducting all development activities after the Effective Date related to the Licensed Compounds and all Products, including conducting all clinical trials and non-clinical studies that it deems appropriate to obtain Marketing Approval(s) within the Territory. On or before December 31st of each year after the Effective Date until the First Commercial Sale of each Product sold by AnHeart, its Affiliate or its Sublicensee,

AnHeart shall provide Daiichi Sankyo an annual development report describing: (a) the achievement of any development milestone event described in Section 5.2 of this Agreement;
(b) any other significant or material events in the development of the Licensed Compounds, and/or Product(s); and (c) a summary of development milestones expected to be achieved for the Licensed Compounds and/or each Product during the subsequent twelve (12) months. Until the First Commercial Sale of the first Product sold by AnHeart, its Affiliate, or its Sublicensee, such reports shall also include: (d) a good faith projection of the current development plan for each Product, including the source and amount of any financial commitments that will be necessary to undertake the described activities. In addition to such annual reports, AnHeart shall inform Daiichi Sankyo in writing of any material change to its development plan that is made between the annual reports.

3.2. Regulatory Submissions. AnHeart, either directly or through its Affiliates or Sublicensees, will use Commercially Reasonable Efforts to prepare and file with the applicable Regulatory Authorities those Regulatory Filings deemed necessary or desirable by AnHeart, its Affiliates, or its Sublicensees to undertake development activities, obtain Marketing Approvals and maintain the same in each of **[**Redacted**]**, and at least **[**Redacted**]** of the Major Markets in Europe.

3.3.Compliance. AnHeart and all of its Affiliates and Sublicensees will conduct all development and regulatory activities with respect to the Product(s) in compliance in all material respects with all applicable legal requirements and regulatory standards including, for the avoidance of doubt, GLP, GCP and GMP, where necessary. The Parties acknowledge that certain of these activities may not require that GLP, GCP or GMP standards be followed and therefore such activities need not be performed under such guidelines.

3.4. Commercialization. AnHeart shall have the sole responsibility to commercialize Products throughout the Territory. AnHeart, either directly or through its Affiliates, and/or its Sublicensees, shall use Commercially Reasonable Efforts to launch the Product(s) in the Field as soon as reasonably practicable after receipt of the Marketing Approval therefor in each of the countries within the Territory, and thereafter to market, promote and sell Product(s) in the Field in such countries.

3.5. Manufacturing.

3.5.1Existing Stock of Materials. Within **[**Redacted**]** calendar days after AnHeart notifies Daiichi Sankyo of the location where the materials will be delivered, but in no case less than **[**Redacted**]** calendar days after the Effective Date, Daiichi Sankyo will make arrangements to deliver to AnHeart or its designee the quantities of the Licensed Compounds, and materials that are useful in manufacturing the Licensed Compounds that are listed in **Exhibit B**. Such materials will be delivered to AnHeart or its designee at no cost to AnHeart except the cost of shipping and related insurance. Appropriate documentation will be provided for all materials transferred pursuant to this Section 3.5.1. All costs for shipping materials from Daiichi Sankyo to AnHeart or its designee, and related insurance, shall be paid by AnHeart. All materials provided under this Section 3.5.1 are provided “as-is” and subject

to Section 8.3 (Disclaimer of Warranties) and Section 8.4 (Limitation of Liability) of this Agreement.

3.5.2 Responsibility. AnHeart will be solely responsible for manufacturing of all of the Licensed Compounds and Product(s) that are necessary for further development and commercialization of such Licensed Compounds and Products(s) after the Effective Date. Manufacturing of the Licensed Compounds and Product(s) may be done by AnHeart directly, or through an Affiliate or Sublicensee, provided that Daiichi Sankyo is informed of any sublicensing of Daiichi Sankyo Technology to an Affiliate or Sublicensee as provided in Section 2.2, or AnHeart has obtained approval to grant a sublicense to the Sublicensee as provided in Section 2.3.

3.6. Competing Programs.

3.6.1 Competing Molecules. During the Term, AnHeart its Affiliates, and its Sublicensees shall not develop or commercialize any Competing Molecules.

3.6.2 Acquired Molecules. If during the Term, as a result of a merger or other transaction, AnHeart acquires, or is acquired by a Third Party that is developing and/or distributing, marketing or selling, either on its own or through an Affiliate or licensee, a product that contains Competing Molecules, the surviving entity shall discontinue development of, or license out its rights with respect to such Competing Molecules within **[**Redacted**]** calendar days after the acquisition transaction is completed.

3.6.3 Confidential Information. During and after the Term, AnHeart, its Affiliates, and its Sublicensees shall not use any Daiichi Sankyo Technology or any Confidential Information received form Daiichi Sankyo for any purpose, including to research, develop, manufacture, or commercialize any molecule other than the Licensed Compound, other than expressly allowed under the terms of this Agreement.

4. Technology Transfer.

4.1 Data Transfer.

4.1.1 Pre-Clinical Data. Within **[**Redacted**]** calendar days after the Effective Date, Daiichi Sankyo will transfer to AnHeart the pre-clinical data or study reports listed
in **Exhibit C**, that are necessary for AnHeart to submit an IND, MAA, NDA, or a similar application for approval to develop or market a Product in any jurisdiction. Such transfer of documents, reports, data, analytical reports, and any other information will be done through an electronic data room or other reasonable means, as determined by Daiichi Sankyo after consulting with AnHeart.

4.1.2 Data and Reports from Ongoing Clinical Trials.

(a) Clinical Trial Data. Promptly after the Effective Date, Daiichi Sankyo will transfer all documents and trial data listed in **Exhibit D** including, but not limited

to, the most recent clinical and PK data from the U101 study and the J102 study to AnHeart or its designee as soon as practical, but no later than **[**Redacted**]** calendar days after the Effective Date. Daiichi Sankyo and/or DSI will timely prepare and submit 2018 development safety update reports (DSUR) for the U101 study and the J102 clinical study, and will transfer to AnHeart or its designee a complete set of clinical data, including efficacy data, which was obtained from each of such clinical studies within **[**Redacted**]** calendar days after the date of data cuts. Upon a written request from AnHeart, Daiichi Sankyo will transfer interim trial data from such clinical trial(s) to AnHeart or its designee according to an agreement between the Parties regarding the data and information to be transferred, and the schedule for such transfer.

(b) Final Clinical Study Reports. AnHeart shall be responsible for preparing the final report for the U101 study on its own or by another vendor of its choice, and Daiichi Sankyo shall have no responsibility for preparing such final report. AnHeart shall not be required to reimburse Daiichi Sankyo for any fees incurred in connection with the preparation of such final report. The cost to prepare the final report for the J102 study has been included in the costs to be reimbursed by AnHeart, as provided in Section 3.1.2(a).

12

4.2Development and Manufacturing Technology. Within **[**Redacted**]** calendar days after the Effective Date, Daiichi Sankyo will transfer to AnHeart, the documents, reports, data, analytical reports, and other information listed in **Exhibit D** that are necessary to: (a) research and develop the Licensed Compounds and/or apply for Marketing Approval for a Product, and (b) manufacture the Licensed Compounds. Such transfer of documents, reports, data, analytical reports, and any other information will be done through an electronic data room or other reasonable means, as determined by Daiichi Sankyo after consulting with AnHeart.

4.3Further Assistance. Following the transfer of data and technology under this Article 4, appropriate personnel at Daiichi Sankyo will remain available to answer questions, and to provide other assistance reasonably requested by AnHeart regarding the transferred technology, for up to **[**Redacted**]** from the Effective Date. If AnHeart wishes Daiichi Sankyo and or DSI's participation in AnHeart's FDA Meeting, then AnHeart shall make a request to Daiichi Sankyo no later than **[**Redacted**]** calendar days before such meeting, accompanied by a summary of the expected roles of participants from Daiichi Sankyo and/or DSI (the "Notice Requirements"), unless Daiichi Sankyo waives such Notice Requirements. AnHeart will reimburse Daiichi Sankyo for reasonable out-of-pocket expenses, in accordance with AnHeart's expense reimbursement policies, and will pay Daiichi Sankyo a rate of **[**Redacted**]** per day for the time expended by Daiichi Sankyo personnel for travel requested by AnHeart. Reimbursement of any other costs or expenses associated with providing assistance to AnHeart under this Section 4.3 will be subject to the Parties reaching an agreement regarding reimbursement before such cost or expense is incurred.

5. Payments.

5.1. Upfront Payment. AnHeart will pay Daiichi Sankyo a non-refundable, non- creditable payment of **[**Redacted**]** within **[**Redacted**]** Business Days of the Effective Date.

5.2. Development Milestones. AnHeart will pay Daiichi Sankyo the following non- refundable, non-creditable milestone payments within **[**Redacted**]** Business Days of AnHeart, its Affiliate, or its Sublicensee achieving such milestone. If any development milestone event is achieved before one or more of the preceding development milestone events, as described in this Section 5.2, such preceding development milestone payment(s) shall become due at the same time as the subsequent development milestone payment. For clarity, AnHeart shall be required to pay each development milestone payment only once, regardless of the order in which the milestone events occur.

Milestone	Payment
[Redacted**]**	**[**Redacted**]**
[Redacted**]**	**[**Redacted**]**
[Redacted**]**	**[**Redacted**]**
[Redacted**]**	**[**Redacted**]**
[Redacted**]**	**[**Redacted**]**

5.3. Sales Milestone Payments. AnHeart will pay to Daiichi Sankyo the following payments upon the first achievement of the following levels of cumulative worldwide annual Net Sales of all Product(s) by AnHeart, its Affiliates, and its Sublicensees.

Worldwide Annual Net Sales	Payment Amount
[Redacted**]**	**[**Redacted**]**
[Redacted**]**	**[**Redacted**]**

5.4. Royalty Payments.

5.4.1. Royalty Rates. AnHeart will pay Daiichi Sankyo royalties of **[**Redacted**]** of Net Sales of all Product(s) sold by AnHeart, its Affiliates, and/or its Sublicensees.

5.4.2. Term of Royalty Payments. AnHeart's obligation to pay royalties under Section 5.4.1 above will expire on a country-by-country basis upon the later to occur of: (a) the expiration of the last Valid Claim in a Daiichi Sankyo Patent that Covers the Licensed Compounds and/or Product(s) in the country, if any, and (b) **[**Redacted**]** years from the First Commercial Sale of a Product containing a Licensed Compound in the country. After the expiration of the royalty term in a country under this Section 5.4.2, AnHeart will have a fully paid up license under the Daiichi Sankyo Technology to make use, sell, offer for sale, and import the Licensed Compounds and the Product(s) for use in the Field in such country.

5.4.3. Payments for Third Party Licenses. Daiichi Sankyo will remain responsible for all obligations arising from licenses from Third Parties executed prior to the Effective Date. AnHeart will be responsible, at its own expense, for obtaining any required licenses to intellectual property from a Third Party that, in the absence of such license, would be infringed by the manufacture, use, import, export or sale of a Licensed Compound or a Product in a particular country. AnHeart shall, in its sole discretion and at its sole expense, determine which Third Party licenses are necessary, and shall negotiate and execute all such licenses directly with the Third Party licensors.

5.5. Payments and Reports. All Sales Milestone and Royalty payments due to Daiichi Sankyo under this Agreement are due and payable within **[**Redacted**]** calendar days of the close of the calendar quarter during which the corresponding milestone event and/or Net Sales are recognized. Together with any such payment, AnHeart will deliver a report specifying in the aggregate and on a country-by-country basis: (a) total gross invoiced amount from sales of each Product by AnHeart, its Affiliates, and its Sublicensees; (b) amounts deducted by category (e.g., normal and customary trade, cash and other discounts, allowances and credits actually allowed and taken directly with respect to sales of the Product) from gross invoiced amounts to calculate Net Sales; (c) Net Sales; and (d) royalties payable; and (e) a forecast of Net Sales and royalties to be paid to Daiichi Sankyo for each of the next **[**Redacted**]** quarters. AnHeart shall send the first such report within **[**Redacted**]** calendar days of receiving the first Marketing Approval anywhere in the Territory, provided that such first report need only include a forecast (i.e. no royalty payment will be due) of Net Sales for the next **[**Redacted**]** quarters.

5.6. Payment Method. All payments due to Daiichi Sankyo under this Agreement will be made by bank wire transfer in immediately available funds to an account designated by Daiichi Sankyo. All payments hereunder shall be made in the legal currency of the United States, and all references to "$" or "Dollars" herein refer to U.S. Dollars. AnHeart shall be responsible for paying all transfer and other fees related to completing all bank wire transfers required under this Agreement, except for the transfer fee imposed by the bank designated by Daiichi Sankyo. Within **[**Redacted**]** calendar days after the Effective Date, Daiichi Sankyo will provide AnHeart all information necessary to make such bank wire transfers. Thereafter, any change to such bank wire transfer information will be transmitted to AnHeart by a notice in accordance with Section 12.11.

5.7. Currency Conversion. If any currency conversion is required in connection with the calculation of amounts payable hereunder, such conversion will be made using the average of the buying and selling exchange rate for conversion of the foreign currency and U.S. Dollars, quoted for current transactions reported in The Wall Street Journal (U.S., Eastern Edition) for the last business day of each month of the calendar quarter to which such payment pertains.

5.8. Late Payments. AnHeart shall pay interest to Daiichi Sankyo on the aggregate amount of any payments that are not paid on or before the date such payments are due under this Agreement at a rate per annum equal to the lesser of the London Interbank Offered Rate of interest plus **[**Redacted**]**, as reported by The Wall Street Journal for the applicable period, and the highest rate permitted by applicable law, calculated on the number of days such payment is delinquent. This Section 5.8 will in no way limit any other remedies available to Daiichi Sankyo.

5.9. Taxes.

5.9.1 Withholding Taxes. If AnHeart is required to withhold any tax to the tax or revenue authorities in any country in the Territory regarding any payment to Daiichi Sankyo, such amount may be deducted from the payment to be made by AnHeart, provided that AnHeart takes all reasonable and lawful actions to avoid or minimize such withholding and promptly notifies Daiichi Sankyo so that Daiichi Sankyo may also take lawful actions to avoid or minimize such withholding. AnHeart will promptly furnish Daiichi Sankyo with copies of any tax certificate or other documentation evidencing such withholding, as necessary to enable Daiichi Sankyo to support a claim, if permissible, for income tax credit in respect of any amount so withheld. Each Party agrees to cooperate with the other Party in claiming exemptions from such deductions or withholdings under any agreement or treaty in effect from time to time.

5.9.2 Value Added Taxes. All payments due to Daiichi Sankyo from AnHeart pursuant to this Agreement shall be paid exclusive of any value added tax, which will be paid by AnHeart upon receipt of a valid value added tax invoice. For clarity, the upfront, milestone and royalty payments under this Agreement are not subject to such value added tax as long as AnHeart's entity in Japan does not make the payment.

5.10 Records. AnHeart will keep, and will cause its Affiliates, and its Sublicensees to keep, complete, true and accurate books of accounts and records, in compliance with applicable laws and the terms and conditions of this Agreement, sufficient to determine and establish the

calculation of Net Sales and royalties payable under this Agreement for a period of **[**Redacted**]** after the year in which the sale of the Product(s) generating the same occurred.

5.11 Inspection of Records. At the request of Daiichi Sankyo, AnHeart, its Affiliates, and its Sublicensees will permit an independent certified public accountant appointed by Daiichi Sankyo, to inspect the books and records described in Section 5.10; provided that such inspection shall be at reasonable times and upon reasonable notice and not more often than **[**Redacted**]**. Any inspection conducted under this Section 5.11 will be at Daiichi Sankyo's expense, unless such inspection reveals any underpayment of **[**Redacted**]** or more of any amount due to Daiichi Sankyo during the audited period, in which case the full costs of such inspection will be paid by AnHeart. Any amount found to be due to Daiichi Sankyo, will be paid by AnHeart within **[**Redacted**]** Business Days with interest on the underpayment at the rate specified in Section 5.8 from the date such payment was originally due until paid.

6. Intellectual Property.

6.1 Ownership of Licensed Intellectual Property. Subject to the licenses granted in Article 2 of this Agreement, each Party will retain all right, title and interest in and to, and ownership of, all Patents and other intellectual property conceived, discovered, developed, reduced to practice, or otherwise made solely by or on behalf of such Party (or its Affiliates. or its or their Sublicensees). Subject to the licenses and other rights granted herein, as between the Parties, each Party will own an equal, undivided interest in any and all Joint Know-how and Joint Patents. Inventorship and ownership rights in Inventions and other Know-how created, developed, conceived and/or reduced to practice after the Effective Date under this Agreement will be determined under the intellectual property laws of the United States, irrespective of where such creation, development, conception, discovery, development or making occurs.

6.2 Filing, Prosecution and Maintenance.

6.2.1 Daiichi Sankyo Patents. Using counsel of its choice, AnHeart shall be responsible, at its sole expense, for preparing, filing, prosecuting, and maintaining the Daiichi Sankyo Patents that Cover the Licensed Compounds and/or Product(s), including preparing and filing requests for patent term extensions, supplemental protection certificates, pediatric exclusivity, or similar protections that extend the term of such Daiichi Sankyo Patents. AnHeart shall also be solely responsible for defending the Daiichi Sankyo Patents from any challenges to their validity or enforceability, including responding to patent office communications or office actions, oppositions, reissue or reexamination proceedings, or interferences, brought by any Third Party, whether before a patent authority or judicial body. Daiichi Sankyo shall, upon request, provide reasonable support to AnHeart in (i) preparing, filing, prosecuting, and maintaining the Daiichi Sankyo Patents and (ii) defending the Daiichi Sankyo Patents from any challenges to their validity or enforceability, including, but not limited to, providing and signing documents or making experts available for testimony as necessary for AnHeart to fulfill its obligations under this Section 6.2.1. AnHeart will reimburse Daiichi Sankyo for reasonable

out-of-pocket expenses, in accordance with AnHeart's expense reimbursement policies, and will pay Daiichi Sankyo a rate of **[**Redacted**]** per day for the time expended by Daiichi Sankyo personnel for travel requested by AnHeart. If AnHeart

19

decides that it will no longer prosecute or maintain a Daiichi Sankyo Patent, it will give Daiichi Sankyo reasonable notice of its decision, which will include sufficient time prior to the expiration or termination of all relevant deadlines for taking necessary actions to preserve the rights in such Daiichi Sankyo Patent, and will allow Daiichi Sankyo to assume control over and continue prosecuting and maintaining such Daiichi Sankyo Patent. If Daiichi Sankyo continues to prosecute and/or maintain a Daiichi Sankyo Patent after AnHeart returns responsibility to Daiichi Sankyo, such Daiichi Sankyo Patent shall **[**Redacted**]**.

6.2.2AnHeart Patents and Joint Patents. AnHeart will be responsible, at its sole expense, for preparing, filing, prosecuting, and maintaining Patents that Cover its own inventions, and Joint Patents that are useful to research, develop or commercialize the Licensed Compounds or Product(s). If AnHeart, in its sole discretion, decides that it will no longer prosecute or maintain a Joint Patent, it will give Daiichi Sankyo reasonable notice of its decision, which will include sufficient time prior to the expiration or termination of all relevant deadlines for taking necessary actions to preserve the rights in such Joint Patent, and will allow Daiichi Sankyo to assume control over and continue prosecuting and maintaining such Joint Patent. If requested by Daiichi Sankyo, AnHeart will **[**Redacted**]**.

6.2.3Regulatory Exclusivity. If AnHeart decides to seek regulatory and/or data exclusivity for a Product, AnHeart will be responsible, at its sole expense, for preparing and filing such requests with the applicable Regulatory Authority. Daiichi Sankyo will, upon request, provide reasonable support to AnHeart in preparing and filing such requests.

6.3 Defense of Infringement Claims by Third Parties.

6.3.1Liability. If a Third Party files or threatens to file an infringement claim against either Party or both Parties related to the manufacture, use, offer for sale, sale, importation or exportation of a Licensed Compound or Product in any country within the Territory, AnHeart will defend such suit at its own expense and will be solely responsible for all damages awarded to the Third Party plaintiff, whether as the result of a court order or an agreement to settle. AnHeart's liability under this Section 6.3.1 will be subject to AnHeart's right to indemnification under Section 9.1, if applicable. Daiichi Sankyo will assist and cooperate with AnHeart in defending such claim(s) upon reasonable requests and at AnHeart's expense.

6.3.2Control. AnHeart will solely control the defense of infringement claim(s) brought against either Party or both Parties by Third Parties, including the right to control settlement of such claim(s), provided that AnHeart may not agree to terms in the settlement that will adversely affect Daiichi Sankyo's rights or interests unless Daiichi Sankyo has given prior written consent, which will not be unreasonably withheld or delayed. Notwithstanding AnHeart's right to control the defense of claim(s) of infringement, if Daiichi Sankyo is named as a defendant, it will have the right to participate in such case, including by engaging separate counsel, at its sole expense. Without affecting or limiting AnHeart's right to

control the defense of infringement claims by Third Parties, if Daiichi Sankyo elects to engage separate counsel, the Parties shall cooperate in defending and/or settling such claims.

6.4 Enforcement Actions Against Third Parties.

6.4.1Notification. If either Party learns of any infringement, unauthorized use, misappropriation or ownership claim, or threatened infringement of any Daiichi Sankyo Technology by a Third Party with respect to the Licensed Compound or Product(s) anywhere within the Territory, such Party will promptly notify the other Party in writing and will promptly provide the other Party with available evidence of such infringement or other such claim.

6.4.2Control. AnHeart will have the first right, but not the obligation, to institute an infringement suit, initiate administrative proceedings, or take other appropriate action against a Third Party for any alleged infringement of any Daiichi Sankyo Technology anywhere within the Territory. If AnHeart does not secure actual cessation of the offending activities, or institute an infringement proceeding or other administrative proceeding against an offending Third Party, AnHeart will notify Daiichi Sankyo of such circumstances as soon as reasonably practicable, but in any case no later than **[**Redacted**]** days of learning of such infringement or threatened infringement. Upon receiving such notice, Daiichi Sankyo will have the right, but not the obligation, at its sole discretion, to take appropriate actions in the name of either Party or both Parties. Each Party will execute all necessary and proper documents, and take such actions as are necessary and appropriate to allow the other Party to institute and prosecute such infringement actions and will otherwise cooperate in instituting and prosecuting such actions (including, without limitation, consenting to being named as a nominal party thereto).

6.4.3Expenses. The costs and expenses of any such enforcement actions against Third Parties (including fees of attorneys and other professionals) will be paid by the Party instituting the action, or, if the Parties elect to cooperate in instituting and
maintaining such action, such costs and expenses will be borne by the Parties in such proportions as they may agree in writing. Any damages paid by Third Parties as a result of such an enforcement action (whether by way of settlement or otherwise) will be applied first to reimburse both Parties for all costs and expenses incurred. If such funds are not sufficient to reimburse all expenses of both Parties, all funds will be divided on a pro rata basis in the same proportion as the costs and expenses incurred. If any funds remain after all expenses of both Parties have been reimbursed, such excess funds will be **[**Redacted**]**.

6.5Trademarks. If a Product receives Regulatory Approval and will be marketed pursuant to the terms of this Agreement, AnHeart will have the right to select the trademark or trademarks under which the Product(s) will be marketed by AnHeart, its Affiliates, and/or its Sublicensees. AnHeart will own all trademarks used to market the Product(s).

7. Confidentiality.

7.1.Confidential Information. Except to the extent expressly authorized by this Section 7 or otherwise agreed in a writing signed by both Parties, each Party (the "Receiving

Party") shall, during and after the Term of this Agreement, keep confidential and not publish or otherwise disclose or use for any purpose other than as explicitly provided for in this Agreement any confidential and proprietary information or materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic, or otherwise) that are disclosed or provided to it by the other Party or an Affiliate of the other Party(each a "Disclosing Party") or otherwise received or accessed by a Receiving Party, its Affiliates, or its Sublicensees in the course of performing its obligations under this Agreement including, but not limited to, any trade secrets, Know-How, Product specifications, formulae, processes, techniques and information relating to the Disclosing Party's past, present and future marketing, financial, and research and development activities for any product of the Disclosing Party and the pricing thereof (collectively, "Confidential Information"). Confidential Information of each Party includes the terms and conditions of this Agreement.

22

7.2.Exceptions. Notwithstanding the foregoing, Confidential Information does not include information or materials to the extent that it can be established by the Receiving Party that such information or material:

7.2.1.is already lawfully known to the Receiving Party, other than under an obligation of confidentiality at the time of disclosure by the Disclosing Party as evidenced by written records kept in the ordinary course of business, or other documentary proof of actual use by the Receiving Party;

7.2.2.is generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

7.2.3.becomes generally available to the public or otherwise part of the public domain after its disclosure to the Receiving Party and other than through any act or omission of the Receiving Party, its Affiliates, or its Sublicensees in violation of this Agreement;

7.2.4.is independently developed by the Receiving Party as demonstrated by documented evidence prepared contemporaneously with such independent development; or

7.2.5.is lawfully disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation not to disclose such information to others.

7.3.Authorized Disclosure. Notwithstanding Section 7.1, the Receiving Party may disclose Confidential Information of the Disclosing Party:

7.3.1.to its respective employees, consultants and advisors, and to the employees, consultants and advisors of such Receiving Party's Affiliates, sublicensees or potential investors or sublicensees, who have a need to know such Confidential Information in connection with the activities or transactions contemplated in this Agreement and have an

obligation to treat such Confidential Information as confidential under terms no less restrictive than those set forth herein; or

7.3.2.in its publicly filed financial statements or other public statements pursuant to applicable laws, regulations, and stock exchange rules or otherwise disclosed pursuant to applicable law; provided, that: (a) the terms of this Agreement are redacted to the greatest extent possible; and (b) such Receiving Party provides the Disclosing Party with a copy of the proposed text of such statements or disclosure (including any exhibits containing this Agreement) sufficiently in advance of the scheduled release or publication thereof to afford the Disclosing Party a reasonable opportunity to review and comment on the proposed text (including redacted versions of this Agreement).

7.3.3.to governmental authorities to facilitate the issuance of Marketing Approvals for Product; provided that reasonable measures are taken to assure confidential treatment of such information;

7.3.4.to the extent such disclosure is reasonably necessary in filing or prosecuting patent, copyright and trademark applications, prosecuting or defending litigation, complying with applicable governmental regulations, conducting preclinical activities or clinical trials and marketing a Product;

7.3.5.to Third Parties in connection with a Receiving Party's efforts to secure financing or enter into strategic partnerships, provided such information is disclosed only on a need-to-know basis and under confidentiality provisions at least as stringent as those in this Agreement;

7.3.6.that is required to be disclosed in response to a valid order by a court or other governmental body and provided that the Receiving Party provides the Disclosing Party with prompt notice of such requirement so that the Disclosing Party may seek a protective order or other appropriate remedy, then the Receiving Party may furnish only that portion of the Confidential Information which the Receiving Party is legally compelled to disclose; or

7.3.7.that is required to be disclosed in connection with any legal or regulatory requirements or obligations, including SEC filings or Regulatory Filings, provided that the Receiving Party offers reasonable cooperation to the Disclosing Party in an attempt, as may be permitted and appropriate, to redact or seek confidential treatment of sensitive Confidential Information.

7.4.Publications. If AnHeart, its Affiliates, and/or its Sublicensees, but excluding its clinical investigators proposes a publication related to a Licensed Compound or a Product that includes Confidential Information of Daiichi Sankyo, AnHeart will first submit an early draft of such publication to Daiichi Sankyo, whether they are to be presented orally or in written form, at least **[**Redacted**]** days prior to submission for publication or presentation. Daiichi Sankyo may review such proposed publication/presentation in order to avoid unauthorized disclosure of its Confidential Information and to preserve the

patentability of

25

inventions and will, as soon as reasonably possible, but no more than **[**Redacted**]** days from receipt of the advance copy of the proposed publication, inform AnHeart if:

7.4.1.its proposed publication contains Confidential Information of Daiichi Sankyo, in which case AnHeart, its Affiliate, or its Sublicensee will delete such Confidential Information from its proposed publication; and/or

7.4.2.its proposed publication could be expected to have a material adverse effect on any Patent, Know-How, compound or product of Daiichi Sankyo, in which case AnHeart, its Affiliate, or its Sublicensee will delay such proposed publication for a reasonable period to permit the timely preparation and first filing of patent application(s) covering the information involved.

7.4.3. This Section 7.4 does not apply to any disclosures permitted pursuant to Section 7.2.

7.5.Press Releases. Neither Party may issue any press release relating to this Agreement without obtaining the other Party's prior written approval, which approval will not be unreasonably withheld or delayed, provided that such approval is not be required for a press release issued in connection with a disclosure made pursuant to Section 7.3.7.

7.6.Restrictions on Use. During and after the Term, the Receiving Party shall not use, and shall ensure that its Affiliates, and its Sublicensees do not use any Confidential Information disclosed to it by a Disclosing Party or otherwise received or accessed in the course of performing its obligations under this Agreement for any purpose other than as expressly provided herein. For clarity, this restriction will not apply to information that is covered by one or more of the exceptions described in Section 7.2 of this Agreement.

8. Representations, Warranties and Covenants.

8.1.Representations and Warranties of Both Parties. Each Party represents and warrants to the other, as of the Effective Date, that:

8.1.1.it is duly organized and validly existing under the laws of its jurisdiction of incorporation, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

8.1.2.it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder and that it has the right to grant to the other Party the licenses and sublicenses granted pursuant to this Agreement, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action;

8.1.3.this Agreement is legally binding upon it and, upon execution by the other Party, shall be enforceable in accordance with its terms except to the extent that enforceability may be limited by applicable bankruptcy, insolvency or other laws affecting

the enforcement of creditors' rights generally and subject to the general principles of equity (regardless of whether enforcement is sought in a court of law or equity);

8.1.4.the execution, delivery and performance of this Agreement by such Party does not knowingly conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any governmental agency or Regulatory Authority having jurisdiction over it;

8.1.5.it has not granted any right to any Third Party that would knowingly conflict with the rights granted to the other Party hereunder;

8.1.6.it has not been debarred under the Generic Drug Enforcement Act of 1992 (21 U.S.C. §301 et seq.), is not under investigation for debarment action, has not been disqualified as an investigator pursuant to 21 C.F.R. §312.70, does not have a disqualification hearing pending and is not currently employing any person or entity that has been so debarred or disqualified to perform any of its obligations under this Agreement. It shall promptly notify the other Party if it is so debarred or disqualified and shall terminate any so debarred or disqualified individual's or entity's participation in the performance of any of its obligations under this Agreement promptly upon its awareness of such debarment or disqualification; and

8.1.7.it is not aware of any action, suit or inquiry or investigation instituted by any person or governmental agency that questions or threatens the validity of this Agreement.

8.2.Additional Representations, Warranties and Covenants of Daiichi Sankyo. Daiichi Sankyo warrants, represents and covenants to AnHeart as follows:

8.2.1.As of the Effective Date, Daiichi Sankyo owns or Controls all of the Daiichi Sankyo Technology in existence on the Effective Date, and the exclusive right to grant licenses with respect thereto;

8.2.2.Unless specifically disclosed to be otherwise, the Daiichi Sankyo Patents: (a) that are issued as of the Effective Date are valid and in full force and effect, and
(b) are not the subject of any interference or opposition proceedings, and (c) Daiichi Sankyo is not aware of any pending or threatened action, suit proceeding or claim by a Third Party challenging the ownership rights in, or the validity or scope of the Daiichi Sankyo Patents;

8.2.3. As of the Effective Date, none of the Daiichi Sankyo's Know-How: (a) was obtained by Daiichi Sankyo in violation of any contractual or fiduciary obligation to which it or any of its employees or staff members are or were bound, or by the misappropriation of a trade secret of any Third Party, (b) there is no pending or threatened action, suit, proceeding or claim by a Third Party asserting that any of Daiichi Sankyo's Know-How infringes or otherwise is violating any patents, trade secret or other proprietary right of any Third Party, and (c) to the knowledge of Daiichi Sankyo, the use of Daiichi

Sankyo Technology licensed under this Agreement does not violate the patent, trade secret, or other proprietary rights of any Third Party.

8.3. Disclaimer of Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS SECTION 8, DAIICHI SANKYO DISCLAIMS ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND UNDER THIS AGREEMENT (INCLUDING WITH RESPECT TO ANY MATERIALS PROVIDED UNDER THIS AGREEMENT), EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, QUALITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT, OR VALIDITY OF PATENT CLAIMS, WHETHER ISSUED OR PENDING.

8.4. Limitation of Liability. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY OR ANY OTHER PERSON FOR INCIDENTAL, CONSEQUENTIAL, EXEMPLARY, PUNITIVE, MULTIPLE OR OTHER INDIRECT DAMAGES, OR FOR LOSS OF PROFITS, LOSS OF DATA OR LOSS OF USE DAMAGES, ARISING OUT OF THIS AGREEMENT, WHETHER BASED UPON WARRANTY, CONTRACT, TORT, STATUTE, STRICT LIABILITY OR OTHERWISE, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR LOSSES. THE FOREGOING LIMITATION OF LIABILITY, HOWEVER, SHALL NOT LIMIT THE OBLIGATIONS OF EITHER PARTY TO INDEMNIFY THE OTHER PARTY FROM AND AGAINST THIRD PARTY CLAIMS UNDER ARTICLE 9.

9. Indemnification.

9.1. Indemnification by Daiichi Sankyo. Daiichi Sankyo will defend, hold harmless and indemnify (collectively "Indemnify") AnHeart and its Affiliates, and their respective agents, directors, contractors, representatives, officers and employees (collectively "AnHeart Indemnitees") from and against any liability or expense, including without limitation reasonable legal expenses and attorneys' fees, (collectively "Losses") resulting from suits, claims, actions and demands, in each case brought by a Third Party (each, a "Third Party Claim") relating to or arising from a material breach of any of Daiichi Sankyo's representations, warranties or covenants under Sections 8.1 or 8.2 or other obligations pursuant to this Agreement, or any gross negligence or willful misconduct by Daiichi Sankyo or its officers, directors, employees in the exercise of any of Daiichi Sankyo's rights or the performance of any of Daiichi Sankyo's obligations under this Agreement. Daiichi Sankyo's obligation to Indemnify the AnHeart Indemnitees pursuant to this Section 9.1 will not apply to the extent that any such Losses arise from the gross negligence, willful misconduct or wrongful acts or omissions of any AnHeart Indemnitee; or are Losses for which AnHeart is obligated to Indemnify the Daiichi Sankyo Indemnitees pursuant to Section 9.2.

9.2. Indemnification. AnHeart will Indemnify Daiichi Sankyo and its Affiliates, and its and their agents, directors, contractors, representatives, officers and employees (collectively "Daiichi Sankyo Indemnitees") from and against any and all Losses resulting from Third Party Claims relating to or arising from a material breach of any of AnHeart's

representations, warranties or covenants under Section 8.1 or 8.3 or other obligations pursuant to this Agreement, any gross negligence or willful misconduct by AnHeart, its Affiliates, and/or its Sublicensees or their respective officers, directors, employees in the exercise of any of AnHeart's rights or the performance of any of AnHeart's obligations under this Agreement, or any tort claims of personal injury (including death) or property damage relating to or arising out of any sale, offer for sale or importation of any Product in the Territory by AnHeart, its Affiliates, and/or its Sublicensees, or any claims relating to or arising out of the marketing or sales activities of AnHeart, its Affiliates, and/or its Sublicensees in the Territory. AnHeart's obligation to Indemnify the Daiichi Sankyo Indemnitees pursuant to this Section 9.2 shall not apply to the extent that any such Losses arise from the gross negligence, willful misconduct or wrongful acts or omissions of any Daiichi Sankyo Indemnitee, or are Losses for which Daiichi Sankyo is obligated to Indemnify the AnHeart Indemnitees pursuant to Section 9.1.

9.3. Procedure. To be eligible to be indemnified hereunder, any AnHeart Indemnitee under Section 9.1, or Daiichi Sankyo Indemnitee under Section 9.2, as the case may be (an "Indemnitee") seeking indemnification, must provide the indemnifying Party with prompt notice of the Third Party Claim giving rise to the claimed indemnification obligation and must assign the exclusive ability to defend or settle any such claim to the indemnifying Party; provided, however, that the indemnifying Party may not enter into any settlement that admits fault, wrongdoing or damages on the part of the Indemnitee without such Indemnitee's written consent, such consent not to be unreasonably withheld or delayed. The Indemnitee will cooperate with reasonable requests from the indemnifying Party, at the indemnifying Party's expense, and will have the right to participate, at its own expense and with counsel of its choice, in the defense of any claim or suit that has been assumed by the indemnifying Party. Without affecting or limiting the indemnifying Party's right to control the defense of the Third Party Claim, if the Indemnitee elects to engage separate counsel, the Parties shall cooperate in defending and/or settling such claims.

9.4. Complete Indemnification. Indemnification under this Article 9 will include the reasonable costs and expenses of the Indemnitee relating to legal fees and expenses and damages awarded to the Indemnitee in connection with enforcement of Sections 9.1 and 9.2.

9.5. Allocation. If a claim is based in part on an indemnified claim, as described in Sections 9.1 and 9.2, and in part on a non-indemnified claim, or is based in part on a claim described in Section 9.1 and in part on a claim described in Section 9.2, any payments and reasonable attorney fees incurred in connection with such claims will be apportioned between the Parties in accordance with the degree of fault attributable to each Party.

9.6. Insurance. During the Term and for **[**Redacted**]** years thereafter, AnHeart will maintain a policy of insurance at levels sufficient to support its indemnification obligations, but in any case such insurance must provide adequate coverage for clinical trials liability, products liability, worker's compensation, employer's liability, and comprehensive general liability. Upon Daiichi Sankyo's request, AnHeart shall provide evidence of such insurance.

10. Term and Termination.

10.1.Term. This Agreement is effective as of the Effective Date and, unless earlier terminated pursuant to the other provisions of this Article 10, will continue in full force and effect until AnHeart and all of its Affiliates and sublicensees cease all commercial activity related to all Products throughout the Territory (the "Term").

30

10.2. Termination by Daiichi Sankyo.

10.2.1.Daiichi Sankyo may terminate this Agreement, without prejudice to any other remedies available to it at law or in equity, if AnHeart, its Affiliate, or its Sublicensee commits a material breach of this Agreement that, in the case of a material breach capable of remedy, has not have been remedied within **[**Redacted**]** days of receiving a notice from Daiichi Sankyo identifying the breach and requiring its remedy, or if such material breach cannot be cured within **[**Redacted**]** days, if AnHeart does not commence and diligently continue actions to cure such breach during such **[**Redacted**]** days. The Parties acknowledge that non-payment of sums due from AnHeart hereunder will be considered a material breach of this Agreement.

10.2.2.To the extent permitted by law, Daiichi Sankyo may terminate this Agreement immediately if: (a) AnHeart becomes insolvent, or makes or seeks to make or arrange an assignment for the benefit of creditors; (b) proceedings in voluntary bankruptcy are initiated by or on behalf of AnHeart or proceedings in involuntary bankruptcy are initiated against AnHeart (and, in the case of any such involuntary proceeding, not dismissed within **[**Redacted**]** days); or (c) a receiver or trustee of AnHeart's property is appointed and not discharged within **[**Redacted**]** days.

10.2.3.Daiichi Sankyo may terminate this Agreement immediately upon written notice if AnHeart, its Affiliate, or its Sublicensees initiates or joins any challenge, whether in a court of law or in an administrative proceeding, to the validity or enforceability of a Daiichi Sankyo Patent.

10.3. Termination by AnHeart.

10.3.1.AnHeart may terminate this Agreement, without prejudice to any other remedies available to it at law or in equity, if Daiichi Sankyo commits a material breach of this Agreement that, in the case of a material breach capable of remedy, has not been remedied within **[**Redacted**]** days of receiving a notice from AnHeart identifying the breach and requiring its remedy, or if such material breach cannot be cured within such **[**Redacted**]** day period, if Daiichi Sankyo does not commence and diligently continue actions to cure such breach during such **[**Redacted**]** days.

10.3.2.AnHeart may terminate its activities under this Agreement on a country-by-country basis or may terminate this Agreement in its entirety, at AnHeart's sole discretion, upon **[**Redacted**]** months prior written notice if: (i) it has bona fide material concerns regarding the lack of safety for human use and toxicity of the Licensed Compounds or the lack of efficacy of the Licensed Compounds, (ii) claim(s) Covering the Licensed Compound in the Product offered for sale are invalidated by a competent court in the relevant

jurisdiction in a final unappealed or unappealable decision, or (iii) the Licensed Compounds is determined by a competent court in the relevant jurisdiction in a final unappealed or unappealable decision to infringe one or more claims of a patent asserted by a Third Party. The notice under this Section 10.3.2 will specify in detail the basis for such termination, including a reasonable description of such concerns.

10.4. Accrued Obligations/Survival. Expiration or termination of this Agreement for any reason does not release either Party from any obligation or liability which, at the time of such expiration or termination, has already accrued to the other Party or which is attributable to a period prior to such expiration or termination. Section 3.6.3 (Confidential Information), Section 5.8 (Late Payments), Section 5.10 (Records), Section 5.11 (Inspection of Records), Article 7 (Confidentiality), Section 8.4 (Limitation of Liability), Article 9 (Indemnification.), this Section 10.4 (Accrued Obligations/Survival), Section 10.5 (Effects of Terminations), Section 12.9 (Governing Law) and Section 12.11 (Notices) shall survive expiration or termination of this Agreement for any reason.

10.5. Effects of Terminations.

10.5.1. If AnHeart terminates this Agreement in its entirety or terminates its activities in a particular country in the Territory (each affected country being a "Terminated Country") pursuant to Section 10.3 in each case, then:

(a) If there are any ongoing clinical trials in such Terminated Country being conducted by or on behalf of AnHeart, its Affiliate, or its Sublicensee, at the time the notice of termination is sent, AnHeart will, as of the actual termination date: (i) promptly transfer to Daiichi Sankyo or its designee some or all of such clinical trials and the activities related to or supporting such trials; or (ii) terminate such clinical trials; in each case upon request from Daiichi Sankyo and at Daiichi Sankyo's sole discretion. Notwithstanding the foregoing, if the clinical trials in the Terminated Country are required or useful for Regulatory Filings or permitted activities with respect to a Product outside of the Terminated Country, then AnHeart will, upon sending written notice of its decision to terminate its activities in the Terminated Country, have the option of completing such clinical trials.

(b) If requested by Daiichi Sankyo, AnHeart will: (i) promptly transfer to Daiichi Sankyo or its designee copies of all data, reports, records, materials that relate to the Product(s) in such Terminated Country, (ii) provide Daiichi Sankyo or its designee with all information necessary or desirable to cross-reference or assume responsibility for any Regulatory Filings, as the case may be, in AnHeart's name with respect to the Product(s), in such Terminated Country, and (iii) return to Daiichi Sankyo all relevant records and materials in AnHeart's possession or control containing Confidential Information of Daiichi Sankyo relating solely to the Product(s) in such Terminated Country, provided that AnHeart may keep one copy of such Confidential Information for archival purposes or as may be necessary or useful in connection with AnHeart's activities under this Agreement outside of the Terminated Country. If AnHeart elects to terminate this Agreement in its entirety, within **[**Redacted**]** calendar days of such termination, AnHeart will also provide Daiichi Sankyo with copies of all preclinical and clinical data (including

investigator reports, both preliminary and final, statistical analyses, expert opinions and reports, safety and other electronic databases).

(c)If requested by Daiichi Sankyo after receiving a notice of termination with regard to a Terminated Country under Section 10.3.2, AnHeart will engage in good faith negotiation regarding the commercial terms and consideration for an exclusive royalty-bearing license, with the right to sublicense, under any Patents and Know- how that are Controlled by AnHeart that are necessary or useful for Daiichi Sankyo to make, have made, use, sell, offer for sale, import and export the Licensed Compound or the
Product(s) in such Terminated Country. Upon termination of this entire Agreement, if requested by Daiichi Sankyo, AnHeart will engage in good faith negotiation regarding the commercial terms and consideration for a separate exclusive royalty-bearing license, with the right to sublicense, under any Patents and Know-how that are Controlled by AnHeart that are reasonably necessary or useful for Daiichi Sankyo to make, have made, use, sell, offer for sale, import and export the Licensed Compound or the Product(s).

(d)If requested by Daiichi Sankyo, AnHeart will grant and will cause to be granted to Daiichi Sankyo an exclusive royalty-bearing license, with the right to sublicense, to use any Trademarks specific to the Product in such Terminated Country. Upon termination of this Agreement, at the request of Daiichi Sankyo, AnHeart will engage in
good faith negotiation regarding the commercial terms and consideration for an exclusive royalty-bearing license, with the right to sublicense for Daiichi Sankyo or it designee to use any Trademarks specific to the Product(s). It is understood that such license will not include the AnHeart name or any trademark, trade name, or logo of AnHeart itself.

(e)The licenses granted to AnHeart under Section 2.1 will terminate in the Terminated Country or throughout the Territory if this Agreement is terminated in its entirety.

(f)If requested by Daiichi Sankyo, AnHeart will assign all sublicense agreements granted by AnHeart under this Agreement in the Terminated Country to Daiichi Sankyo or its designee to the extent permitted under those agreements and not adversely affecting AnHeart's activities outside of the Terminated Country. If Daiichi Sankyo does not request assignment of such sublicense agreements, then such sublicense agreements will terminate upon termination of AnHeart's rights with respect to the Licensed Compound or the Product(s).

(g)If AnHeart elects to terminate this Agreement in its entirety, AnHeart shall return all relevant records and materials in its possession or control containing Daiichi Sankyo's Confidential Information to Daiichi Sankyo, provided that AnHeart may keep one copy of such Confidential Information for archival purposes only.

10.5.2.If Daiichi Sankyo terminates this Agreement in its entirety pursuant to Section 10.2, then:

(a)If there are any ongoing clinical trials with respect to a Product being conducted by or on behalf of AnHeart, its Affiliates, or its Sublicensees at the time of

notice of termination, AnHeart will, as of the termination date, promptly transfer some or all of such clinical trials and the activities related to or supporting such trials to Daiichi Sankyo or its designee, or complete or terminate such clinical trials, in each case as requested by Daiichi Sankyo at Daiichi Sankyo's sole expense.

34

(b)If requested by Daiichi Sankyo, AnHeart will promptly assign and transfer to Daiichi Sankyo or its designee all Regulatory Filings for Product(s) that are held by AnHeart, its Affiliates or its Sublicensees, and shall take such actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights under the Regulatory Filings to Daiichi Sankyo or its designee. If applicable law prevents or delays the transfer of ownership of a Regulatory Filing, AnHeart will grant Daiichi Sankyo or its designee a permanent, exclusive and irrevocable right of access and reference to such Regulatory Filing for a Product, and will fully cooperate to make the benefits of such Regulatory Filings available to Daiichi Sankyo or its designee. At the request of Daiichi Sankyo, within **[**Redacted**]** calendar days of such termination, AnHeart will provide to Daiichi Sankyo or its designee copies of all such Regulatory Filings, and of all preclinical and clinical data (including investigator reports, both preliminary and final, statistical analyses, expert opinions and reports, safety and other electronic databases) and other Know-How controlled by AnHeart (other than marketing information).

(c)Notwithstanding other provisions in this Section 10.5.2, (i) if Daiichi Sankyo terminates this Agreement in its entirety pursuant to Section 10.2.1 or Section 10.2.3, upon Daiichi Sankyo's request, AnHeart will grant Daiichi Sankyo an exclusive, irrevocable, fully paid up license, with the right to sublicense, under any Patents and Know-how that are Controlled by AnHeart that are reasonably necessary or useful to make, have made, use, sell, offer for sale, import and export the Licensed Compounds or the Product(s); and (ii) if Daiichi Sankyo terminates this Agreement in its entirety pursuant to Section 10.2.2, upon Daiichi Sankyo's request, AnHeart will engage in good faith
negotiation regarding the commercial terms and consideration for a separate exclusive royalty-bearing license, with the right to sublicense, under any Patents and Know-how that are Controlled by AnHeart that are reasonably necessary or useful for Daiichi Sankyo to make, have made, use, sell, offer for sale, import and export the Licensed Compound or the Product(s).

(d)Notwithstanding other provisions in this Section 10.5.2, (i) if Daiichi Sankyo terminates this Agreement in its entirety pursuant to Section 10.2.1 or Section 10.2.3, upon Daiichi Sankyo's request, AnHeart will grant Daiichi Sankyo or its designee an exclusive, irrevocable, fully paid up license, with the right to sublicense, to use any Trademarks specific to the Product(s) in the Territory. It is understood that such assignment will not include the AnHeart name or any trademark, trade name, or logo of AnHeart itself; and (ii) if Daiichi Sankyo terminates this Agreement in its entirety pursuant to Section 10.2.2, upon Daiichi Sankyo's request, AnHeart will engage in good faith negotiation regarding the commercial terms and consideration for an exclusive royalty-bearing license, with

the right to sublicense for Daiichi Sankyo or it designee to use any Trademarks specific to the Product(s). It is understood that such license will not include the AnHeart name or any trademark, trade name, or logo of AnHeart itself.

(e)If requested by Daiichi Sankyo, AnHeart will assign any or all of the sublicense agreements granted by AnHeart under this Agreement to Daiichi Sankyo or its designee to the fullest extent permitted under those agreements. If Daiichi Sankyo does not request such assignment(s), then such sublicense agreements will terminate upon termination of AnHeart's rights with respect to the Licensed Compound and the Product(s).

(f)If requested by Daiichi Sankyo, AnHeart will fully cooperate with Daiichi Sankyo or its designee to facilitate a smooth, orderly and prompt transition of the development and commercialization of the Product(s) to Daiichi Sankyo or its designee upon termination. Without limiting the foregoing, and if applicable, AnHeart will promptly provide Daiichi Sankyo copies of customer lists, customer data and other customer information relating to the Product(s), which Daiichi Sankyo shall have the right to use and disclose for any purpose.

(g)If requested by Daiichi Sankyo, AnHeart shall complete, or shall cause its Affiliate, or its Sublicensee to complete, all work-in-process to manufacture finished Product(s) and will transfer any quantities of the Licensed Compounds and finished Product(s) (including work-in-process when finished) in its or its Affiliates' possession to Daiichi Sankyo or its designee, for which Daiichi Sankyo shall reimburse AnHeart one hundred percent (100%) of its (or its Affiliate's) cost of goods within **[**Redacted**]** days of such transfer. Daiichi Sankyo will pay all shipping, insurance and customs charges associates with such transfer.

(h)If AnHeart or its Affiliate is manufacturing the Product(s) at the time the termination becomes effective, then AnHeart or its Affiliate will continue to manufacture such Product(s) for Daiichi Sankyo, at one hundred percent (100%) of the cost of goods plus a reasonable profit, from the date of notice of such termination until such time as Daiichi Sankyo is able to secure an acceptable alternative commercial manufacturing source, which period shall not exceed **[**Redacted**]** months. If requested by Daiichi Sankyo, AnHeart will engage in good-faith negotiation regarding the commercial terms and consideration for, effective upon termination of this Agreement, a separate agreement to transfer the technology necessary to manufacture the Product(s) for sale in the Territory.

(i)Upon receiving instructions from Daiichi Sankyo, AnHeart shall return, and shall cause its Affiliates, and its Sublicensees, to Daiichi Sankyo or destroy all relevant records and materials in its possession or control containing Confidential Information of Daiichi Sankyo, provided that AnHeart may keep one copy of such Confidential Information for archival purposes only.

10.5.3.Each Party acknowledges that the other Party's obligations following any termination are subject to, and may be limited by, all applicable laws, rules, regulations, or contractual restrictions.

11. Dispute Resolution.

37

11.1Between the Parties. In the event of a dispute between the Parties arising out of or related to the terms of this Agreement, either Party may request that the Parties engage in good faith discussions to resolve such dispute. Within **[**Redacted**]** calendar days of such request, each Party will appoint an appropriate representative to engage discussions to resolve the dispute in a mutually acceptable manner. Such representative will have a reasonable level of expertise in the subject matter of the dispute and possess the requisite authority to resolve the dispute. If such representatives are unable to resolve the dispute within **[**Redacted**]** calendar days, either Party may provide a written request to submit the dispute for discussions between Executive Officers appointed by the respective Chief Executive Officers of each Party. If the Executive Officers are unable to resolve the dispute within **[**Redacted**]** calendar days after referral, either Party may provide a written request to refer the dispute for arbitration.

11.2Arbitration. Any dispute that is not resolved through good faith discussion between the Parties as provided in Section 11.1 will be referred to arbitration upon a request from either Party. Such disputes will be finally settled under the Rules of Arbitration of the International Chamber of Commerce. The venue for such arbitration proceedings will be New York City, New York and all arbitration proceedings will be conducted in English.

12. Miscellaneous Provisions.

12.1.Relationship of the Parties. AnHeart and Daiichi Sankyo agree that the relationship between them established by this Agreement is that of independent contractors. The Parties further agree that this Agreement does not, is not intended to, and should not be construed to establish an employment, agency, partnership, joint venture, or any other relationship between them. Except as may be specifically provided herein, neither Party has any right, power or authority, nor may they represent themselves as having any right, power or authority, to assume, create or incur any expense, liability or obligation, express or implied, on behalf of the other Party, or otherwise act as an agent for the other Party for any purpose.

12.2.No Third Party Beneficiaries. No person or entity other than AnHeart, Daiichi Sankyo and their respective Affiliates, permitted assignees and sublicensees may be deemed an intended beneficiary or have any right to enforce any obligation of this Agreement.

12.3.Assignments. Except in connection with the acquisition of all or substantially all of its assets, AnHeart may not assign this Agreement or any of its rights or obligations hereunder to any Third Party without the written consent of Daiichi Sankyo. No assignment or transfer of this Agreement is valid or effective unless and until the assignee/transferee agrees in writing to be bound by the provisions of this Agreement. The terms and conditions of this Agreement will be binding on and inure to the benefit of the successors and permitted assigns of the Parties. Any attempted assignment not in accordance with the terms of this Agreement will be void.

12.4.Performance by Affiliates. AnHeart may perform its obligations under this Agreement through one or more Affiliates without the need to obtain prior approval from Daiichi Sankyo. AnHeart will nonetheless remain solely responsible for the performance of

its

39

obligations under this Agreement by its Affiliate(s) and for any breach of the terms of this Agreement by its Affiliate(s).

12.5.No Implied Waivers; Rights Cumulative. The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement does not constitute a waiver of that right or excuse a similar subsequent failure to perform such term or condition. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver is effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. No waiver by any Party of any term or condition of this Agreement, in any one or more instances, may be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any future occasion. Except as expressly set forth in this Agreement, all rights and remedies available to a Party, whether under this Agreement or afforded by law or otherwise, are cumulative and not in the alternative to any other rights or remedies that may be available to such Party.

12.6.Severability. If any provision of this Agreement is held to be invalid, illegal or unenforceable under law in any jurisdiction, the Parties will negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions of this Agreement will remain in full force and effect in such jurisdiction and will be liberally construed in order to carry out the intentions of the Parties as nearly as may be possible. A holding of invalidity, illegality or unenforceability of a provision in one jurisdiction will not affect the validity, legality or enforceability of such provision in any other jurisdiction.

12.7.Entire Agreement; Amendments. This Agreement, together with all appendices, constitutes the entire agreement between the Parties with respect to the subject matter hereof, and supersedes all previous arrangements, whether written or oral, with respect to the subject matter contained herein. Any amendment or modification to this Agreement must be made in a writing signed by both Parties.

12.8.Force Majeure. Neither Party will be liable to the other Party for failure or delay in performing of any of its obligations under this Agreement for the time and to the extent such failure or delay is caused by; epidemic, earthquake, riot, civil commotion, rebellion; insurrection, invasion, fire, acts of God, war, terrorist acts, strike, storm, flood, or governmental acts or restriction, or other cause that is beyond the reasonable control of the affected Party. The Party affected by such force majeure must provide the other Party with full particulars thereof (including its best estimate of the likely extent and duration of the interference with its activities) as soon as it becomes aware of the same, but in no event more than **[**Redacted**]** calendar days after becoming aware of it. The affected Party will use Commercially Reasonable Efforts to overcome the difficulties created by the force majeure and to resume performance of its obligations as soon as practicable. In such event, the Parties will meet promptly to determine an equitable solution to minimize or accommodate the effects of any such event, including the possibility of terminating this Agreement.

12.9.Governing Law. This Agreement shall be governed by, and any disputes, claims or controversies in connection with this Agreement, including any question regarding its

formation, existence, validity, enforceability, performance, interpretation or termination, shall be resolved in accordance with, the laws of the State of New York without regard to its conflict of laws rules.

41

12.10.Submission to Jurisdiction. Each Party submits to the exclusive jurisdiction of the courts sitting in New York City, New York, with respect to actions or proceedings arising out of or relating to this Agreement brought by a Party. Each Party may serve on the other Party by sending or delivering a copy of the process to the Party to be served at the address and in the manner provided for giving notices, as provided in Section 12.11. Nothing in this Section 12.10, however, shall affect the right of any Party to serve legal process in any other manner permitted by law.

12.11.Notices. Any notice, request, delivery, approval or consent required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given if delivered in person, transmitted by email (receipt verified) or by express courier service or **[**Redacted**]** calendar days after it was sent by registered letter, return receipt requested (or its equivalent), provided that no postal strike or other disruption is then in effect or comes into effect within **[**Redacted**]** calendar days after such mailing, to the Party to which it is directed at its address or email shown below or such other address or email as such Party shall have last given by notice to the other Party. If such notice, request, delivery, approval or consent is transmitted by email, the sending Party shall also transmit an identical copy of such documentation to the receiving Party by express courier service at the address shown below or to such other addresses and emails as a Party may designate by written notice.

If to Daiichi Sankyo, addressed to:

Daiichi Sankyo Company,
Limited 5-1 Nihonbashi-honcho
3-Chome Chuo-ku, Tokyo 103-
8426 Japan

Attention: **[**Redacted**]**
Telephone: **[**Redacted**]**
Email: **[**Redacted**]**

If to AnHeart, addressed to:

AnHeart Therapeutics
Inc. 5 Penn Plaza, 23rd
floor New York, NY
10001, USA

Attention: **[**Redacted**]**
Telephone: **[**Redacted**]**

Email: **[**Redacted**]**

12.12.No Strict Construction. This Agreement has been prepared jointly by the Parties and should not be strictly construed against either Party.

12.13.Interpretation. The captions and headings in this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Sections or Appendix mean those particular Sections and Appendices to this Agreement and references to this Agreement include all attachments hereto. Unless context otherwise clearly requires, whenever used in this Agreement: (a) the words "include" or "including" shall be construed as incorporating, also, "but not limited to" or "without limitation;" (b) the word "day" or "year" means a calendar day or year unless otherwise specified; (c) the word "notice" means notice in writing (whether or not specifically stated); (d) the words "hereof," "herein," "hereby" and derivative or similar words refer to this Agreement (including any Exhibits); (e) the word "or" shall be construed as the inclusive meaning identified with the phrase "and/or;"; (f) words using the singular or plural number also include the plural or singular number, respectively; and (g) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement law, rule or regulation thereof.

12.14.Counterparts. This Agreement may be executed in any number of counterparts, each of which will be deemed an original, and all of which together, will constitute one and the same.

12.15.Use of Name. Except as otherwise provided herein, neither Party has any right, express or implied, to use the name or other designation of the other Party or any other trade name, trademark or logo of the other Party in any manner or for any purpose in connection with the performance of this Agreement, except for use in connection with notices or filings required by law, rule, or regulation.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

43

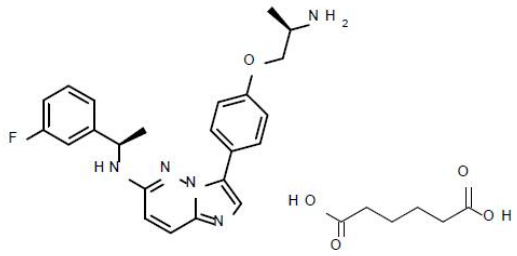
IN WITNESS WHEREOF, AnHeart and Daiichi Sankyo have caused this License Agreement to be executed by their duly authorized representatives as of the date first written above.

DAIICHI SANKYO COMPANY, LIMITED	**ANHEART THERAPEUTICS INC.**
Signature: /s/Sunao Manabe	Signature: /s/Junyuan Wang
Printed Name: Sunao Manabe	Printed Name: Junyuan Wang
Title: President and Chief Operating Officer	Title: Chief Executive Officer

Exhibit A
DAIICHI SANKYO PATENTS

[Redacted**]**

The molecular structure of DS-6051b



45

Exhibit B
EXISTING MATERIALS

[Redacted**]**

46

Exhibit C
PRECLINICAL DATA

[Redacted**]**
47

Exhibit D
DEVELOPMENT AND MANUFACTURING TECHNOLOGY

[Redacted**]**
48

Exhibit 10.4

In accordance with Item 601(b)(10) of Regulation S-K, certain portions of this exhibit have been omitted because the information (i) is not material and (ii) would likely cause competitive harm to Nuvation Bio if publicly disclosed. The omissions have been indicated by "[Redacted**]".**

FIRST AMENDMENT TO LICENSE AGREEMENT

This first amendment (the "**First Amendment**") to License Agreement (later defined) is made as of August 17, 2020 ("**First Amendment Effective Date**") by and between Daiichi Sankyo Company, Limited, a Japanese corporation having an office and principal place of business at 5-1, Nihonbashi-honcho 3-chome Chuo-ku, Tokyo 103-8426, Japan ("**Daiichi Sankyo**") and AnHeart Therapeutics Inc., a Delaware corporation having an office and place of business at 5 Penn Plaza 23rd floor, New York, NY 10001, USA ("**AnHeart**"). Daiichi Sankyo and AnHeart are each referred to herein individually as a "Party," or collectively as "Parties". As used in this First Amendment, capitalized terms, whether used in the singular or plural, shall have the respective meanings set forth in the License Agreement.

RECITALS:

A. Daiichi Sankyo and AnHeart have entered into the License Agreement dated December 7, 2018 (the **"License Agreement").**

B. Pursuant to Section 3.1.2 of the License Agreement, Daiichi Sankyo has been conducting Phase I clinical study of DS-6051b in Japan **("J102 Clinical Study").**

C. The Parties wish to amend certain terms and conditions of the License Agreement as well as to memorialize certain understanding with respect to the conduct of J102 Clinical Study.

NOW, THEREFORE, in consideration of the mutual covenants and conditions contained herein and intending to be legally bound, the Patties agree as follows:

1. Section 3.1.2 (a) of the License Agreement shall be amended and restated as follows:

3.1.2 Ongoing Clinical Trials

(a) Daiichi Sankyo shall continue the Phase I clinical study of DS-6051b in Japan (i.e., Daiichi Sankyo's internal reference "J102") after the Effective Date until all subjects complete the study treatment, the clinical drug supplies in Daiichi Sankyo's possession as of the Effective Date are depleted or the expiration date of such clinical drug supplies has passed, whichever is the earliest (such date, **"Study Completion Date").** AnHeart shall reimburse Daiichi Sankyo within

[Redacted**]** calendar days of receiving an itemized quarterly invoice from Daiichi Sankyo for customary and reasonable Third Party costs and expenses incurred for CRO services and data management after the Effective Date to continue the J102 clinical study, the cumulative total amount of which shall not exceed **[**Redacted**]**.

2. Both Parties agree and acknowledge that, after the Study Completion Date, Daiichi Sankyo will not have any responsibility for continuing the J102 Clinical Study.

3. Both Parties agree that, upon the Study Completion Date, AnHeart will make a decision on its own as to whether it will take over the patients of the J102 Clinical Study or discontinue treatment of the patients in the J102 Clinical Study.

4. AnHeart will be responsible for preparing Clinical Study Report **("CSR")** for the J102 Clinical Study (whether by itself or through use of CRO), upon completion of the J102 Clinical Study. Daiichi Sankyo will review a draft of CSR and provide reasonable support to AnHeart in CSR preparation upon request.

5. Except as expressly modified by this First Amendment, all of the terms and conditions of the License Agreement shall remain in full force and effect.

6. This First Amendment shall become effective as of the First Amendment Effective Date.

IN WITNESS WHEREOF, the Parties have caused this First Agreement to be executed by their duly authorized representatives as of the date of last signature below.

Daiichi Sankyo Company, Limited

By : /s/Tetsuya Iwabuchi
Name : Tetsuya Iwabuchi
Title : Vice President, Business Development & Licensing Department
Date : 08/17/2020

AnHeart Therapeutics Inc.

By : /s/Junyuan Wang
Name : Junyuan Wang
Title : Chief Executive Officer
Date : 8/27/2020

Exhibit 10.5

In accordance with Item 601(b)(10) of Regulation S-K, certain portions of this exhibit have been omitted because the information (i) is not material and (ii) would likely cause competitive harm to Nuvation Bio if publicly disclosed. The omissions have been indicated by "[Redacted**]".**

LICENSE AGREEMENT
BETWEEN
DAIICHI SANKYO COMPANY, LIMITED
AND
ANHEART THERAPEUTICS INC.

LICENSE AGREEMENT

This License Agreement (the "Agreement"), dated the 7th day of September, 2020 (the "Effective Date"), is between DAIICHI SANKYO COMPANY, LIMITED, a Japanese corporation having an office and principal place of business at 5-1, Nihonbashi-honcho 3-chome Chuo-ku, Tokyo 103-8426, Japan ("Daiichi Sankyo"), and, ANHEART THERAPEUTICS INC., a Delaware corporation having an office and place of business at 5 Penn Plaza, 23rd floor, New York, NY 10001, USA ("AnHeart"). Daiichi Sankyo and AnHeart are each referred to herein by name, individually as a "Party" or collectively as "Parties".

RECITALS:

1. Daiichi Sankyo owns Patents (hereinafter defined), and Know-How (hereinafter defined) in existence as of the Effective Date relating to the Licensed Compound (hereinafter defined); and

2. AnHeart desires to research, develop and commercialize products containing the Licensed Compound for therapeutic uses in humans; and

3. Daiichi Sankyo desires to grant to AnHeart an exclusive license under its Patents, and Know-How, on the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual agreements and covenants set forth herein, Daiichi Sankyo and AnHeart agree as follows:

1. Definitions.

As used in this Agreement, each capitalized term used herein shall have the meaning set forth below unless context clearly and unambiguously dictates otherwise.

1.1. "Affiliate" means, with respect to a Party, any person, firm, trust, corporation, company, partnership, or other entity or combination thereof that controls, is controlled by or is under common control with such Party, for so long as such control exists. For purposes of this definition only, "control" shall mean: (a) beneficial ownership (direct or indirect) of more than fifty percent (50%) of the shares of the person entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, in the election of the corresponding managing authority); or (b) the de facto ability to control or direct the management of such person or entity.

1.2. “Applicable Laws” means any federal, state, local, national, and supra-national laws, statutes, rules and/or regulations, including any rules, regulations, guidance, guidelines, or requirements of Regulatory Authorities, national securities exchanges, or securities listing organizations, that may be in effect from time to time during the Term (hereinafter defined) and apply to a particular activity hereunder and including laws, regulations, and guidelines governing the import, export, development, manufacture, transport, handling, storage, distribution, or commercialization of the Licensed Compound or Product(s) (hereinafter defined) in or for the Territory (hereinafter defined), including without limitation, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, the European Union Data Protection Directive, Anti-Corruption Laws, Transparency Laws and Privacy Laws.

1.2.1. “Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule” means the Standards for Privacy of Individually Identifiable Health Information found in 45 CFR Part 160 and Subparts A and E of Part 164.

1.2.2. “European Union Data Protection Directive” means Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

1.2.3. “Anti-Corruption Laws” means the UK Bribery Act 2010, as amended, the United States Foreign Corrupt Practices Act of 1977, as amended, 15 U.S.C. 78dd-1 et seq. and any other applicable anti-corruption laws and laws for the prevention of fraud, racketeering, money laundering or terrorism.

1.2.4. “Transparency Laws” means laws related to: (i) the collection and reporting of any payments or transfers of value to certain healthcare professionals and teaching hospitals, which include, without limitation, relevant provisions of the U.S. Physician Payments Sunshine Act (42 U.S.C. § 1320a-7h) and its implementing regulations along with similar laws and regulations in other countries; and (ii) the collection and reporting requirements, and the processing of any applicable rebate, chargeback or adjustment, under applicable rules and regulations relating to the Medicaid Drug Rebate Program (42 U.S.C. § 1396r-8) and any state supplemental rebate program, Medicare average sales price reporting (42 U.S.C. § 1395w-3a), the Public Health Service Act (42 U.S.C. § 256b), the VA Federal Supply Schedule (38 U.S.C. § 8126) or under any state pharmaceutical assistance program or U.S. Department of Veterans Affairs agreement, and any successor government programs, as well as any registration, notification and reporting requirements under any state drug pricing transparency laws, and its implementing regulations, respectively, along with similar laws and regulations in other countries.

1.2.5. “Privacy Laws” means the Health Insurance Portability and Accountability Act (“HIPAA”), the General Data Protection Regulation 2016/679 or any other similar law to be obtained in connection with safety information from any sources, permit the sharing of safety information.

1.3. “Business Days” means a day other than a Saturday, Sunday, a day on which commercial banks located in the United States, China or Japan are authorized or required by law to remain closed, or each Party’s Corporate Holiday (hereinafter defined).

1.4. “Calendar Quarter” means each three (3) month period during a Calendar Year starting on January 1st, April 1st, July 1st, or October 1st and ending on March 31st, June 30th, September 30th or December 31st, respectively.

1.5. “Calendar Year” means each twelve (12) month period starting on January 1st and ending on December 31st.

1.6. “Commercially Reasonable Effort” means, with respect to a Party, those efforts and resources, as applicable, relating to a certain activity or activities, including, without limitation, the research, development and commercialization of a Product (hereinafter defined) in accordance with such Party's business, legal, medical and scientific judgment, such reasonable efforts and diligence to be in accordance with the efforts and resources a reasonably comparable pharmaceutical company would use for a product owned by it, or to which it has rights, which is of similar market potential, at a similar stage in its product life, taking into account the establishment of the Product in the marketplace, the competitiveness of the marketplace, the patent or proprietary position of the Product, the regulatory structure involved, the profitability of the Product, the safety and efficacy of the Product, the stage of its development or product life, the clinical setting in which it is expected to be used, and other conditions then prevailing. **[**Redacted**]**. It is understood that a Party’s Commercially Reasonable Effort will not in any event require that Party to take any action that would be reasonably likely to result in a breach of any other provision of this Agreement, or that the Party in good faith believes may violate any Applicable Laws or any order, or direction of any court or governmental authority having appropriate jurisdiction over the Party and subject matter.

1.7. “Confidential Information” has the meaning provided in Section 7.1.

1.8. “Control” or “Controlled”, with respect to Patents or Know-How, means possession of the ability (whether by license or ownership, or an Affiliate having possession by license or ownership) to grant a license or sublicense, of or within the scope set forth in this Agreement, without violating the terms of any written agreement with any Third Party.

1.9. “Corporate Holiday” means, with respect to a Party, a day on which the office of such Party is closed, and such Party gave prior notice and got prior consent from the other Party.

1.10. “Cover”, “Covering” or “Covered” means, with respect to a Patent, that, but for a license granted to a Party under a claim included in such Patent, the practice by such Party of an invention claimed in such Patent would infringe such claim or in the case of a Patent that is a patent application, would infringe a claim in such patent application if it were to issue as a patent.

1.11. “Daiichi Sankyo Technology” means the Daiichi Sankyo Patents and Daiichi Sankyo Know-How.

1.11.1. “Daiichi Sankyo Know-How” means Know-How related to the Licensed Compound or Product(s) that is Controlled by Daiichi Sankyo as of the Effective Date that are reasonably necessary to research, develop and manufacture the Licensed Compound or Product(s).

1.11.2. “Daiichi Sankyo Patents” means Patents Controlled by Daiichi Sankyo which includes Daiichi Sankyo Partially Owned Patent and Daiichi Sankyo Fully Owned Patent (each as defined below). Daiichi Sankyo Patents as of the Effective Date are set forth in Exhibit B.

(a) “Daiichi Sankyo Partially Owned Patents” means Patents partially Controlled by Daiichi Sankyo and partially in-licensed from **[**Redacted**]**, as of the Effective Date Covering the Licensed Compound or Product specifically set forth in Exhibit B.

(b) “Daiichi Sankyo Fully Owned Patent” means Patents fully Controlled by Daiichi Sankyo as of the Effective Date Covering the Licensed Compound or Product specifically set forth in Exhibit B.

1.12. “DMF” means a Drug Master File as more fully defined in 21 C.F.R. §314.420 in the United States or similar documents filed with a Regulatory Authority (hereinafter defined) in another jurisdiction.

1.13. “EMA” means the European Medicines Agency or any successor entity.

1.14. “Existing Clinical Trials” means any on-going Phase 1 clinical trials conducted by Daiichi Sankyo or its Affiliates as of the Effective Date listed on Exhibit C.

1.15. “FDA” means the United States Food and Drug Administration or any successor entity.

1.16. “Field” means all human prophylactic or therapeutic uses of the Licensed Compound for the prevention, or treatment of any Indication.

1.17. “First Commercial Sale” means the date on which a Product is first shipped by AnHeart, its Affiliate, or its Sublicensee (hereinafter defined) in finished product form, packaged and labeled for sale in arm's length transactions to Third Parties (hereinafter defined) for commercial sale in any country in the Territory after Marketing Approvals (hereinafter defined) have been granted, or such sale is otherwise permitted, by the Regulatory Authority in such country, excluding the use of the Product for testing purposes and/or a sale for experimental, compassionate named patient, charitable or test market purposes.

1.18. “Foreground Technology” shall mean any Patent and Know-How that is conceived, discovered, developed, produced or reduced to practice (respectively called as “Foreground Patents” and “Foreground Know-How”) after the Effective Date by a Party or its Affiliate and Sublicensee in connection with the activities performed under this Agreement.

1.18.1. “Foreground Patent” means Patents with a Valid Claim to Inventions Covering the Licensed Compound or Product that are conceived of, discovered, developed, made and/or reduced to practice after the Effective Date under this Agreement, (i) by or on behalf of employees, agents, or consultants of Daiichi Sankyo or its Affiliates (“Foreground Daiichi Sankyo Patents”), (ii) by or on behalf of employees, agents, or consultants of AnHeart or its Affiliates (“Foreground AnHeart Patents”) and (iii) jointly by or on behalf of employees, agents, or consultants of Daiichi Sankyo or its Affiliates on the one hand, and employees, agents, or consultants of AnHeart, its Affiliates, or its Sublicensees, on the other hand. Foreground Joint Patents does not include Foreground Daiichi Sankyo Patents and Foreground AnHeart Patents (“Foreground Joint Patents”).

1.18.2. “Foreground Know-How” means Know-How specific to the Licensed Compound or Product(s) that is conceived, discovered, developed, produced or reduced to practice after the Effective Date under this Agreement (i) by or on behalf of employees, agents, or consultants of Daiichi Sankyo or its Affiliates (“Foreground Daiichi Sankyo Know-How”), (ii) by or on behalf of employees, agents, or consultants of AnHeart or its Affiliates (“Foreground AnHeart Know-How”), and (iii) jointly by or on behalf of employees, agents, or consultants of Daiichi Sankyo or its Affiliates on the one hand, and employees, agents, or consultants of AnHeart, its Affiliates, or its Sublicensees, on the other hand (“Foreground Joint Know-How”).

1.19. “IND” means, in the United States, an effective Notice of a Claimed Investigational New Drug Application filed with the FDA as more fully defined in 21 C.F.R. §312.3, and, with respect to every other country in the Territory, the equivalent application (i.e., a filing that must be made prior to commencing clinical testing of a Product in humans) for such country, filed with the applicable Regulatory Authority in such country.

1.20. “Indication” means, with respect to a Product, a prophylactic or therapeutic use for a particular disease or condition, with respect to which use at least one clinical trial is required to support the inclusion of such disease or condition in the indication statement of a package insert approved by a Regulatory Authority for such Product and for which an application for Marketing Approval (or a supplement, extension or amendment thereto) must be filed to obtain such approval by such Regulatory Authority.

1.21. “Invention” means any new or useful process, machine, manufacture, or composition of matter relating to or comprising the Licensed Compound or Product(s), and any improvement, enhancement, modification or derivative work to any Daiichi Sankyo Technology, that is conceived or first reduced to practice or first demonstrated to have utility during the Term in connection with the Parties' activities to develop, manufacture and commercialize the Licensed Compound and Product(s) anywhere in the world.

1.22. “Know-How” means confidential and proprietary information and tangible materials, whether patentable or unpatentable, including, without limitation: (a) ideas, discoveries, Inventions, improvements or trade secrets; (b) tests, assays, techniques, methods, procedures, formulas, processes and data, including, but not limited to, clinical data (including patient report forms, preliminary and final investigators' reports, statistical analyses, expert opinions and reports, safety and other electronic databases, Regulatory Filings and communications, and the like), pharmacological, preclinical and toxicological data, as well as manufacturing information and descriptions; and (c) pharmaceutical, chemical and biological

materials, products and compositions of matter, provided that Know-How does not include any Patents.

1.23. "Licensed Compound" means (i) the compound identified by the internal Daiichi Sankyo compound code DS-1001b with the molecular structure set forth in Exhibit A, and (ii) Other Compound (hereinafter defined) that is agreed by the Parties to be included as the Licensed Compound in writing pursuant to Section 2.5.

1.24. "Market Exclusivity" means exclusive right to sell a Product in a country or region as the result of applicable laws and/or regulations, including data exclusivity, pediatric exclusivity.

1.25. "Marketing Approval" means, with respect to a Product, all approvals including conditional approvals, licenses, registrations or authorizations of any Regulatory Authority, necessary for the manufacturing, use, storage, import, transport and sale of such Product in any country within the Territory but excluding pricing or reimbursement approval where governmental approval is required for pricing, or for the Product to be reimbursed by national health insurance.

1.26. "NDA" means a New Drug Application, filed with the FDA to obtain Marketing Approval for a Product in the United States, or its foreign equivalent (or a supplement, extension or amendment thereto), or any successor application having substantially the same function.

1.27. "Net Sales" means the gross amounts invoiced for a Product sold by AnHeart, its Affiliates, or its Sublicensees (each a "Selling Party") in finished product form, packaged and labeled for sale in arm's length transactions to Third Parties, less the following deductions from such gross amounts: (a) normal and customary trade, cash and other discounts and allowances actually allowed by the Selling Party and taken by the customer; (b) credits, price adjustments or allowances actually granted to the customer for damaged goods, returns or rejections of the Product; (c) sales taxes or similar taxes, including duties or other governmental charges imposed on the sale of the Product (including value added taxes or other governmental charges, but excluding any income taxes), to the extent the Selling Party is not otherwise entitled to a credit or a refund for such taxes, duties or payments made; (d) chargeback payments, rebates, fees, and other adjustments, including those granted on price adjustments, billing errors, reimbursements or similar payments granted or given to wholesalers or other distributors, buying groups, health insurance carriers or other institutions, including those paid in connection with such sales to any governmental entity; and (e) any invoiced freight, shipping, insurance and other transportation charges. Net Sales, as set forth in this definition, will be calculated by applying the Selling Party's standard accounting practices, in accordance with generally accepted accounting principles used by the Selling Party, as consistently applied in its respective audited financial statements.

1.27.1. Sales between or among AnHeart, its Affiliates and its Sublicensees may be excluded from the computation of Net Sales if such sales are not intended for end use, but Net Sales will include the subsequent final sales to Third Parties by AnHeart, its Affiliates or its Sublicensees. Additionally, the following will not be included in Net Sales: (i) samples of a Product used to promote additional Net Sales, in amounts consistent with normal business practices of AnHeart and (ii) disposal or use of a Product in clinical trials or under compassionate use, patient assistance, named patient use, or test marketing programs or other

similar programs or studies where the Product is supplied without charge or at the actual manufacturing cost thereof.

1.27.2. In the event that a Product is sold as part of a Combination Product, where “Combination Product” means any unified dose of pharmaceutical product which is comprised of the Product and other therapeutically active compound(s) and/or ingredients (collectively, the “Other Products”), Net Sales of Product, for the purposes of determining royalty payments and achievement of sales milestones, shall be determined by multiplying the Net Sales of the Combination Product by the fraction, A / (A+B) where A is the weighted average sale price of the Product when sold separately in finished form, and B is the weighted average sale price of the Other Products sold separately in finished form. In the event that no separate sales are made of either the Product or the Other Products, the reasonably estimated commercial value thereof will be used instead of the sale price. Each of “weighted average sale price” and “reasonably estimated commercial value” shall be determined, on a country-by-country basis, as set forth below:

“Weighted average sale price” and “reasonably estimated commercial value,” as the case may be, for the Product and the Other Products shall be calculated once at the commencement of each Calendar Year and such amount shall be used during all applicable royalty reporting periods for the entire following Calendar Year. When determining the weighted average sale price of the Product or the Other Products, the weighted average sale price shall be calculated by dividing the Net Sales (translated into U.S. dollars in accordance with Section 5.6 hereof) by the units of active ingredient sold during the twelve (12) months (or the number of months sold in a partial Calendar Year) of the preceding Calendar Year for the respective Product or Other Products. “Reasonably estimated commercial value” shall be determined by agreement of the Parties using criteria to be mutually agreed upon by the Parties. If the Parties do not agree, such dispute shall be first referred to the discussion between the Parties in accordance with Section 11.1, but if not resolved as set forth in Section 11.1, shall be resolved in accordance with Section 11.2 hereof. In the Calendar Year in which the First Commercial Sale occurs, a forecasted weighted average sale price will be used for the Product and the Other Products, if applicable. Any over or under payment due to a difference between forecasted and actual weighted average sale prices will be paid or credited in the first royalty payment of the following Calendar Year.

1.28. “Other Compound” means any compound that is any salt, hydrate, solvate, ester or stereoisomer of DS-1001b, other than the Licensed Compound, Covered in Daiichi Sankyo Patents.

1.29. “Patents” means any of the following: (a) any issued and unexpired patent, including without limitation, any inventor's certificate, substitution, extension, re-registration, confirmation, reissue, re-examination, re-validation, renewal or any similar governmental grant for protection of inventions (including, but not limited to, patent term extensions, pediatric exclusivity or supplementary protection certificate); (b) any patent application including, without limitation, any continuation, divisional, substitution, continuation-in-part, provisional applications and converted provisional applications; and (c) all foreign counterparts of any of the foregoing.

1.30. “PCT Application” means a patent application which is filed under The Patent Cooperation Treaty (PCT).

1.31. “Phase 2 Clinical Trial” means a human clinical trial of the Licensed Compound or a Product, the principal purpose of which is a determination of safety and efficacy in the target patient population, which is prospectively designed to generate sufficient data that may permit commencement of Pivotal Clinical Trials (hereinafter defined), or a similar clinical study prescribed by the Regulatory Authorities, from time to time, pursuant to law or otherwise, including the trials referred to in 21 C.F.R. §312.21(b), as amended, irrespective of whether it is nominally titled or referred to as a “Phase 2 clinical trial” or “Phase 2 clinical study”.

1.32. “Phase 3 Clinical Trial” means a human clinical trial of the Licensed Compound or a Product on a sufficient number of subjects in an indicated patient population that is designed to establish that the Licensed Compound or the Product is safe and efficacious for its intended use and to determine the benefit/risk relationship, warnings, precautions, and adverse reactions that are associated with such Licensed Compound or Product in the dosage range to be prescribed, which trial is intended to support Marketing Approval of such Licensed Compound or Product, including all tests and studies that are required by the Regulatory Authorities from time to time, pursuant to Applicable Laws or otherwise, including the trials referred to in 21 C.F.R. §312.21(c), as amended, irrespective of whether it is nominally titled or referred to as a “Phase 3 clinical trial” or“ Phase 3 clinical study”.

1.33. “Pivotal Clinical Trial” means a Phase 3 Clinical Trial or any other clinical trial that has been identified by Regulatory Authority as being sufficient to obtain Marketing Approval to market the Product in a given Indication.

1.34. “Product” means any pharmaceutical preparations in all dosage forms which contain the Licensed Compound as an active ingredient, whether alone or in combination with other active pharmaceutical ingredient(s).

1.35. “Regulatory Authority” means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the research, development, manufacture, commercialization or other use (including the granting of Marketing Approvals) of Product(s) in any country in the Territory including, with respect to the United States of America, the FDA, and with respect to the European Union, the EMA.

1.36. “Regulatory Filings” means, collectively, all INDs for the Licensed Compound, the DMF, any application for Marketing Approval, Marketing Approvals and other filings for Product(s), such as annual reports, required by any Regulatory Authority in any country in the Territory.

1.37. “Sublicensee” means any Third Party or Affiliate of AnHeart that is granted a sublicense of the rights granted in Section 2.1 by Daiichi Sankyo hereunder in accordance with the terms of Sections 2.2 and 2.3, regardless of the number of intermediate sublicenses (tiers) granted between AnHeart and such AnHeart’s Affiliate(s) or Third Party.

1.38. “Term” has the meaning provided in Section 10.1

1.39. “Territory” means all countries and territories of the world other than Japan.

1.40. “Third Party” means any entity other than a Party or an Affiliate of a Party.

1.41. “Valid Claim” means **[**Redacted**]**

2. License Grants.

2.1. Scope of Grant. In consideration of and subject to the terms and conditions of this Agreement, Daiichi Sankyo grants to AnHeart, a royalty-bearing, exclusive (even as to Daiichi Sankyo, except as otherwise expressly set forth herein) right and license in the Field in the Territory, with the right to grant one or more sublicenses in accordance with the terms of Sections 2.2 and 2.3, under the Daiichi Sankyo Technology: (a) to research and develop the Licensed Compound and Product(s); (b) to make, have made, use, import and export the Licensed Compound for the purpose of making, having made, using, offering for sale, selling, marketing, distributing, importing and exporting Product(s); and (c) to make, have made, use, offer for sale, sell, have sold, market, distribute, import and export Product(s). Notwithstanding anything in this Agreement to the contrary, Daiichi Sankyo retains the rights in the Field in the Territory under the Daiichi Sankyo Technology and the Daiichi Sankyo Foreground Technology to, and cause its Affiliate and contract manufacture organization to, (a) make, have made, use, import and export the Licensed Compound for the purpose of making, having made, using, offering for sale, selling, marketing, distributing, importing and exporting Product(s) in and to Japan; and (b) make, have made, use and import and export Product(s) for the same purpose as (a) above.

2.2. Sublicenses. AnHeart may grant sublicenses of the license granted under Section 2.1 to one or more sublicensees. Such sublicenses may be granted with or without the right to grant further sublicenses through multiple tiers, provided that AnHeart shall notify Daiichi Sankyo of the identity of each proposed sublicensee including contract manufacturing organization and obtain approval from Daiichi Sankyo in accordance with Section 2.3, and give Daiichi Sankyo a reasonable opportunity to review and comment on the terms of the proposed sublicense. AnHeart will ensure that all Sublicensees are bound by the same obligations as those set forth hereunder, including, but not limited to the obligations of confidentiality and non-use of Confidential Information. AnHeart will be liable to Daiichi Sankyo for the acts and omissions of its Sublicensees, and for any breach of the terms of this Agreement by a Sublicensee without regard to whether Daiichi Sankyo approved such Sublicensee or raised any objection or concerns about such sublicense at the time it was executed. On or before the anniversary of the Effective Date until the expiration or termination of the Term, AnHeart shall provide Daiichi Sankyo an annual sublicense report describing: (a) identity (name and address) of all current Sublicensees (including AnHeart’s Affiliate as of the Effective Date who is granted sublicense pursuant to Section 2.3), irrespective of tiers of sublicense and (b) the nature and scope of sublicense (subject activities, geographical location, etc.).

2.3. Approval of Proposed Sublicensees. Promptly after the Effective Date, and on the anniversary of the Effective Date in each year of the Term thereafter, AnHeart shall provide Daiichi Sankyo a list of proposed sublicensees for review and preapproval, which approval shall not be unreasonably withheld. Daiichi Sankyo shall review such list and inform AnHeart in writing of any potential sublicensee(s) on the list that are approved (such approval shall not be unreasonably withheld, delayed or conditioned), provided that such approval is not required if the sublicensee is an AnHeart’s existing Affiliate as of the Effective Date. If Daiichi Sankyo does not notify AnHeart of its approval of a proposed sublicensee within **[**Redacted**]** days of receiving the list from AnHeart, such sublicensee shall be deemed approved. If AnHeart wishes to engage a sublicensee that is not on the then current list of approved Sublicensees, it

may request approval of such sublicensee by submitting a written request to Daiichi Sankyo. Daiichi Sankyo shall review such request and inform AnHeart in writing if such proposed sublicensee is approved. If Daiichi Sankyo does not notify AnHeart of its approval of a sublicensee within **[**Redacted**]** days of receiving the request from AnHeart, such sublicensee shall be deemed approved. Any denial of approval by Daiichi Sankyo shall be made in good faith based on reasonable concerns related to the particular sublicensee. If requested by AnHeart, Daiichi Sankyo shall discuss its reasons for denying approval of a sublicensee. For clarity, approval of a sublicensee by Daiichi Sankyo does not change or limit AnHeart's obligations under this Agreement.

2.4. Foreground Technology.

2.4.1. Foreground Patents. During the Term, each Party shall disclose the Foreground Patents to the other Party before filing. (The Party which discloses such information is called "Disclosing Party", and the other Party is called "Receiving Party" in this Section.) The Receiving Party shall review such information and notify to the Disclosing Party whether the Receiving Party desires to obtain a license for such Disclosing Party's Foreground Patents within the **[**Redacted**]** months before the entering the national phase of PCT Application. In case that the Receiving Party notifies the Disclosing Party that it desires to obtain the license under such Disclosing Party's Foreground Patents, the Disclosing Party shall grant the other Party royalty-free, exclusive right and license, with the right to grant one or more sublicenses under its Foreground Patents within the scope of (a) researching and developing the Licensed Compound and Product(s); (b) making, having made, using, importing and exporting the Licensed Compound for the purpose of making, having made, using, offering for sale, selling, marketing, distributing, importing and exporting Product(s); and (c) making, having made, using, offering for sale, selling, having sold, marketing, distributing, importing and exporting Product(s), in the Field (i) in the Territory in case of AnHeart and (ii) in Japan in case of Daiichi Sankyo.

2.4.2. Foreground Know-How. During the Term, each Party shall disclose the Foreground Know-How to the other Party at the meeting of the Joint Operational Team (hereinafter defined) after such Foreground Know-How is obtained by such Party. (The Party which discloses such information is called "Disclosing Party", and the other Party is called "Receiving Party" in this Section.) In case that the Receiving Party notifies the Disclosing Party it that desires to obtain the license under such Foreground Know-How, the Disclosing Party shall grants to the other Party, royalty-free, exclusive right and license, with the right to grant one or more sublicenses under the Party's interests in Foreground Know-How in the Field in the Territory (when AnHeart is the licensee) and in Japan (when Daiichi Sankyo is the licensee): (a) to research and develop the Licensed Compound and Product(s); (b) to make, have made, use, import and export the Licensed Compound for the purpose of making, having made, using, offering for sale, selling, marketing, distributing, importing and exporting Product(s); and (c) to make, have made, use, offer for sale, sell, have sold, market, distribute, import and export Product(s).

2.5. Expansion of the definition of Licensed Compound. In the event that AnHeart wishes to develop or commercialize Other Compound, it shall request Daiichi Sankyo written approval thereof, and the Parties shall discuss in good faith expansion of the definition of Licensed Compound to include such Other Compound. Should the Parties so agree in writing, then such Other Compound shall, from such point forward, be the Licensed Compound.

2.6. No Other Rights. It is expressly understood that AnHeart is not granted any rights to the Daiichi Sankyo Technology and the Daiichi Sankyo's interest in Foreground Technology, except as expressly provided in Sections 2.1, 2.2 and 2.4.

3. Governance, Development and Commercialization.

3.1. Governance

3.1.1. Joint Operational Team. The Parties shall establish a joint operational team ("Joint Operational Team") and any other appropriate governing bodies to guide and monitor each Party's clinical development, manufacturing and commercialization of the Licensed Compound and Product and to share information regarding the Parties' respective activities to coordinate the clinical development and commercialization of the Product. The Joint Operational Team and any other governing bodies shall be composed of equal number of representatives from each Party. Meetings of the Joint Operational Team shall be scheduled from time to time by mutual agreement of the Parties or upon request of one Party but in no event less than (i) once every **[**Redacted**]** months. Without limiting the generality of the foregoing, its duties shall include (but not be limited to) as follows;

(a) disclosing and reviewing recent progress and future plans;

(b) disclosing and reviewing any information regarding Third Party Licenses set forth in the Section 3.7;

(c) disclosing and reviewing any information regarding clinical safety and pharmacovigilance:

(d) resolving any dispute regarding the development of the Licensed Compound between the Parties stipulated in Section 3.1.2; and

(e) disclosing and reviewing any Foreground Technology which is conceived, discovered, developed, produced or reduced to practice by a Party.

3.1.2. Report. Each Party shall deliver to the other Party the report including plans, status, and results in fulfilling their obligation set forth in the Section 3.2.2 in quarterly basis. In particular, Each Party shall provide the other Party with (i) key updates from the last time meeting, (ii) Party's annual goal, milestone, and progress, (iii) issues and risks of a Party's activity under this Agreement. Receiving Party shall review the report and if there is something that it may have adverse effect on the development of Licensed Compound by Receiving Party, Receiving Party shall notify Disclosing Party and the Parties shall discuss in good faith in the Joint Operational Team for **[**Redacted**]** Business Days to resolve. If the Parties may not reach an agreement in the Joint Operational Teams, the Head of R&D Division or another applicable representative who shall control such matter of Daiichi Sankyo and chief executive

officer of AnHeart shall discuss in good faith for **[**Redacted**]** Business Days. If the Parties may not reach an agreement by the discussion with each representative, each Party shall have the right to determine its activity in its territory (the Territory in case of AnHeart, Japan in case of Daiichi Sankyo).

3.1.3. Other communication. Notwithstanding anything in Section 3.1.1.and 3.1.2 to the contrary, either Party shall immediately inform the other Party of any matter which may have an effect on the development, commercialization, or any other activity by the other Party in order to consider whether a Party shall request to hold the meeting of Joint Operational Team pursuant to Section 3.1.1.

3.2. Research and Development

3.2.1. Responsibility. AnHeart will be solely responsible at its expense for research, development and registration of the Licensed Compound and Product(s) in the Field in the Territory after the Effective Date.

3.2.2. Diligence. AnHeart, either directly or through one or more of its Affiliates or Sublicensees, will use Commercially Reasonable Efforts to receive Marketing Approvals in the Territory in the Field and to maintain the same during the Term for **[**Redacted**]** glioma, **[**Redacted**]** **[**Redacted**]** and (c) anywhere in any country within the Territory **[**Redacted**]** for use in the Field; provided that, with respect to subsection (c) above, the requirement may be met by (i) Marketing Approvals for **[**Redacted**]** Indications in one country, (ii) Marketing Approvals for the same Indication in each of **[**Redacted**]** different countries or (iii) the combination of the foregoing.

3.2.3. Further Development. AnHeart shall conduct all clinical trials and non-clinical studies that it deems appropriate to obtain Marketing Approval(s) within the Territory. On or before December 31st of each year, AnHeart shall provide Daiichi Sankyo an annual development report describing: (a) the achievement of any development milestone event described in Section 5.3 of this Agreement; (b) any other significant or material events in the development of the Licensed Compound, and/or Product(s); and (c) a summary of development milestones specified in Section 5.2 expected to be achieved for the Licensed Compound and/or each Product during the subsequent Calendar Year. Until all the development milestone payments set forth in Section 5.2 are paid by AnHeart, such reports shall also include a good faith projection of the current development plan for each Product. In addition to such annual reports, AnHeart shall inform immediately Daiichi Sankyo in writing of any material change to its research and development plan.

3.2.4. Regulatory Submissions. AnHeart shall be responsible for the preparation, filing and maintenance of all Regulatory Filings and related submissions with respect to the Licensed Compound and Product(s) in the Territory and shall bear the cost of such preparation, filing and maintenance of Regulatory Filings. AnHeart shall be responsible for all regulatory interactions and responsibilities relating to obtaining any Marketing Approval in the Territory.

3.3. Commercialization.

3.3.1. Responsibility. AnHeart will be solely responsible at its own expense for commercialization of Product(s) in the Field in the Territory.

3.3.2. Diligence. AnHeart shall have the sole responsibility to commercialize Products throughout the Territory. AnHeart, either directly or through its Affiliates, and/or its Sublicensees, shall use Commercially Reasonable Efforts to launch Product(s) in the Territory in the Field as soon as reasonably practicable after receipt of the Marketing Approval in a country where such Marketing Approval was obtained, and thereafter to market, promote and sell Product(s) in the Territory in the Field in such country.

3.4. Manufacturing.

3.4.1. Responsibility. AnHeart will be solely responsible for manufacturing of all of the Licensed Compound and Product(s) that are necessary for further development and commercialization of such Licensed Compound and Product(s) in the Territory after the Effective Date. Manufacturing of the Licensed Compound and Product(s) in the Territory may be done by AnHeart directly, or through an Affiliate or Sublicensee, provided that Daiichi Sankyo is informed of any sublicensing of Daiichi Sankyo Technology to an Affiliate as provided in Section 2.2, or AnHeart has obtained approval to grant a sublicense to the Sublicensee as provided in Section 2.3.

3.4.2. Existing Stock of Materials. Within **[**Redacted**]** Business Days after AnHeart notifies Daiichi Sankyo of the location where the existing stock of materials will be delivered, Daiichi Sankyo will make arrangements to deliver to AnHeart or its designee the existing stock of the Licensed Compound and other materials that are listed in Exhibit D. Upon request, appropriate documentation will be provided for all materials transferred pursuant to this Section 3.4.2. Such stock of the Licensed Compound and other materials set forth in this Section 3.4.2 will be provided, free of charge, by Daiichi Sankyo to AnHeart; provided, however, that all related shipping costs and insurance shall be paid by AnHeart. All materials provided under this Section 3.4.2 are provided “as-is” and subject to Section 8.3 (Disclaimer of Warranties) and Section 8.4 (Limitation of Liability) of this Agreement.

3.5. Pharmacovigilance Agreement. In the case that either Party, its Affiliate, or Sublicensee obtains the information concerning pharmacovigilance data (e.g. safety information regarding case reports, a product labeling change, safety measures and others) for any Product(s), such Party shall notify the other Party (and, in respect of AnHeart, its Affiliate, or Sublicensee) of such information. The detail of this notification procedure shall be agreed separately from this Agreement by a pharmacovigilance agreement which shall be executed between the parties by the time when AnHeart, its Affiliate, or Sublicensee makes an application for the First IND.

3.6. Compliance. AnHeart and all of its Affiliates and Sublicensees will conduct all research, development, regulatory, manufacturing and commercialization activities with respect to the Licensed Compound and/or Product(s) in compliance with all material respects for all applicable legal requirements and regulatory standards including GLP, GCP and GMP, to the extent applicable, and in compliance with all other Applicable Laws.

3.7. Third Party Licenses. If AnHeart finds any Patent that is Controlled by a Third Party and which AnHeart believes is necessary to research, develop, register, manufacture and

commercialize the Licensed Compound and Product(s) in the Field in the Territory, AnHeart shall obtain a license from such Third Party under such Patent ("Third Party License"). AnHeart will be responsible for all obligations arising from such Third Party License executed on and after the Effective Date. In the event that AnHeart obtains Third Party License, **[**Redacted**]**. In advance of obtaining a Third Party License, AnHeart shall notify Daiichi Sankyo at the meeting of Joint Operational Team, and if Daiichi Sankyo desires to obtain such Third Party License in Japan, Daiichi Sankyo and AnHeart shall discuss in good faith regarding the terms and conditions of a license agreement for such Third Party License. Daiichi Sankyo will be responsible for all obligations arising from agreements with Third Parties executed before the Effective Date that are necessary to research, develop, register manufacture and commercialize Product(s) in the Territory including without limitation the **[**Redacted**]**.

3.8. Competing Programs.

3.8.1. Non-Compete. During the Term, AnHeart shall not, itself or through its Affiliates or Sublicensee, conduct, participate in, or advise, assist or enable any Third Party to conduct or participate in, any research, development, commercialization or manufacturing of any **[**Redacted**]** in the Territory. During the Term, Daiichi Sankyo shall not, itself or through its Affiliates, conduct, participate in, or advise, assist or enable any Third Party to conduct or participate in, any development or commercialization of any **[**Redacted**]** in the Territory.

3.8.2. Acquired Molecules. During the Term, if AnHeart or its Affiliate, as a result of a merger or other transaction, acquires or is acquired by a Third Party that is developing and/or distributing, marketing or selling, either on its own or through such Third Party's affiliate or licensee, a product that contains **[**Redacted**]**, the surviving entity in such transaction shall discontinue development or commercialization of, or divest such **[**Redacted**]** within **[**Redacted**]** calendar days after such transaction is completed.

3.8.3. Confidential Information. During and after the Term, AnHeart shall not and shall, cause its Affiliates, and its Sublicensees not to, use any Daiichi Sankyo Technology or any Confidential Information received from Daiichi Sankyo for any purpose, including to research, develop, register, manufacture, or commercialize any compound and product other than the Licensed Compound and Product(s), other than expressly allowed under this Agreement.

3.9. Retention of data. Each Party, its Affiliate and Sublicensee shall keep any document and material related to any clinical study conducted under this Agreement, provided that, it may destroy such document or material with prior consent by the other Party. If (i) a Regulatory Authority requests a Party to provide, or (ii) the Party reasonably consider that it shall provide to a Regulatory Authority, any data or other information for the purpose of any Regulatory Filing of any Product and the other Party retains such data or information, the other Party shall immediately provide it with the Party.

4. Technology Transfer.

4.1. Non-Clinical Data. Within **[**Redacted**]** Business Days after the Effective Date, Daiichi Sankyo will provide to AnHeart the non-clinical data and study reports listed in Exhibit E, that are necessary for AnHeart to submit Regulatory Filings to develop or

commercialize Licensed Compound and Product(s) in any country in the Territory. Such provision of data and study reports, and any other information will be done through an electronic data room or other reasonable means, as determined by Daiichi Sankyo after consulting with AnHeart. Daiichi Sankyo will provide such data and study reports in the original language and Daiichi Sankyo shall not be obligated to translate such documents.

4.2. Clinical Data. Within **[**Redacted**]** Business Days after the Effective Date, Daiichi Sankyo will provide to AnHeart the clinical data or study reports listed in Exhibit F, that are necessary for AnHeart to submit a Regulatory Filings or a similar application for approval to develop or commercialize Product(s) in any jurisdiction. Such provision of documents, reports, data, analytical reports, and any other information will be done through an electronic data room or other reasonable means, as determined by Daiichi Sankyo after consulting with AnHeart. Daiichi Sankyo will provide data and study reports in the original language and Daiichi Sankyo shall not be obligated to translate such documents.

4.3. Manufacturing Technology. Within **[**Redacted**]** Business Days after the Effective Date, Daiichi Sankyo will provide to AnHeart, the documents, reports, data, analytical reports, and other information listed in Exhibit G that are necessary to manufacture the Licensed Compound and Product(s). Such provision of documents, reports, data, analytical reports, and any other information will be done through an electronic data room or other reasonable means, as determined by Daiichi Sankyo after consulting with AnHeart. Daiichi Sankyo will provide data and study reports in the original language and Daiichi Sankyo shall not be obligated to translate such documents.

4.4. Assistance. Following the technology transfer under Sections 4.1, 4.2 and 4.3, upon the request of AnHeart, appropriate personnel at Daiichi Sankyo will remain reasonably available to answer questions and to provide other assistance including assistance to obtain notarized certificates of a contract research organization relating to preclinical or clinical studies that were conducted by Daiichi Sankyo that a Regulatory Authorities requires AnHeart to include in Regulatory Filings up to **[**Redacted**]** from the Effective Date, subject to reasonable conditions and consent with Daiichi Sankyo. AnHeart shall reimburse Daiichi Sankyo for reasonable out-of-pocket expenses that are required to provide assistance specified in this Section 4.4 to AnHeart, in accordance with AnHeart's expense reimbursement policies, and shall pay Daiichi Sankyo a rate of **[**Redacted**]** per day per person for the time expended by Daiichi Sankyo personnel for travel outside of Japan requested by AnHeart.

5. Payments.

5.1. Upfront Payment. In consideration of Daiichi Sankyo's grant of the rights and licenses to AnHeart hereunder, AnHeart shall pay Daiichi Sankyo a non-refundable, non-creditable payment of **[**Redacted**]** within **[**Redacted**]** Business Days of the Effective Date.

5.2. Development Milestones. As further consideration for Daiichi Sankyo's grant of the rights and licenses to AnHeart hereunder, AnHeart shall pay Daiichi Sankyo the following non-refundable, non-creditable milestone payments with respect to a Product to achieve the milestone events on an Indication-by-Indication described below. AnHeart shall promptly (and in any event within **[**Redacted**]** Business Days after achievement of such milestone event)

notify Daiichi Sankyo in writing of the achievement of any such milestone event. Daiichi Sankyo shall issue AnHeart an invoice for the amount of the corresponding milestone payment. AnHeart shall pay within **[**Redacted**]** Business Days after receipt of an invoice therefor from Daiichi Sankyo. If at the time any given milestone payment set forth in this Section 5.2 is due and one or more preceding milestone payments for antecedent level of milestone events for the same Indication in the same geographic category (i.e., the United States, People's Republic of China, or anywhere in the Territory other than United States and People's Republic of China) have not been paid, then such unpaid precedent milestone payments shall be paid at such time as well. In respect of the geographic category in this Section 5.2, Hong Kong is not included in People's Republic of China, but is included in anywhere in the Territory other than United States and People's Republic of China. For clarity, AnHeart shall be required to pay each development milestone payment only once, regardless of the order in which the milestone events occur.

5.2.1. Indication glioma

Milestone Event	Payment Amount
1) **[**Redacted**]**	**[**Redacted**]**
2) **[**Redacted**]**	**[**Redacted**]**
3) **[**Redacted**]**	**[**Redacted**]**
4) **[**Redacted**]**	**[**Redacted**]**
5) **[**Redacted**]**	**[**Redacted**]**
6) **[**Redacted**]**	**[**Redacted**]**
7) **[**Redacted**]**	**[**Redacted**]**
8) **[**Redacted**]**	**[**Redacted**]**

5.2.2. Indication **[**Redacted**]**

Milestone Event	Payment Amount
1) **[**Redacted**]**	**[**Redacted**]**
2) **[**Redacted**]**	**[**Redacted**]**
3) **[**Redacted**]**	**[**Redacted**]**

5.2.3. Indication other than glioma **[**Redacted**]**

Milestone Event	Payment Amount
1) **[**Redacted**]**	**[**Redacted**]**
2) **[**Redacted**]**	**[**Redacted**]**
3) **[**Redacted**]**	**[**Redacted**]**
4) **[**Redacted**]**	**[**Redacted**]**
5) **[**Redacted**]**	**[**Redacted**]**
6) **[**Redacted**]**	**[**Redacted**]**

7) **[**Redacted**]**	**[**Redacted**]**
8) **[**Redacted**]**	**[**Redacted**]**
9) **[**Redacted**]**	**[**Redacted**]**
10) **[**Redacted**]**	**[**Redacted**]**

5.3. Sales Milestone Payments. As further consideration for Daiichi Sankyo's grant of the rights and licenses to AnHeart hereunder, AnHeart shall pay to Daiichi Sankyo the following payments upon the first achievement of the following levels of aggregate annual Net Sales of all Products by AnHeart, its Affiliates, and its Sublicensees. If two or more sales milestone events are achieved in the same Calendar Quarter, then AnHeart shall pay to Daiichi Sankyo all of the applicable milestone payments achieved in such Calendar Quarter. AnHeart shall deliver written notice to Daiichi Sankyo within **[**Redacted**]** Business Days after the end of the Calendar Quarter in which a sales milestone threshold described in this Section 5.3 is achieved for the first time. Aggregate annual Net Sales of all Products shall be calculated based on Net Sales for each Calendar Year. Daiichi Sankyo shall issue AnHeart an invoice for the amount corresponding to the applicable sales milestones event. AnHeart shall pay Daiichi Sankyo within **[**Redacted**]** Business Days after receipt of an invoice therefor from Daiichi Sankyo.__

Milestone Event	Payment Amount
[Redacted**]**	**[**Redacted**]**
[Redacted**]**	**[**Redacted**]**

[Redacted**]** **[**Redacted**]**

5.4. Royalty Payments.

5.4.1. General. During the royalty term described in Section 5.4.3, AnHeart shall pay royalties to Daiichi Sankyo based on the aggregate annual Net Sales of all Products combined in the Territory by AnHeart, and its Affiliates and Sublicensees. Each aggregate annual Net Sales of all Products in the Territory shall be calculated based on Net Sales for such Products in each Calendar Year. The amount or royalties to be paid by AnHeart shall be calculated using the royalty rate set forth in Section 5.4.2.

5.4.2. Royalty Rates. During the royalty term pursuant to Section 5.4.3, AnHeart shall pay Daiichi Sankyo royalties of **[**Redacted**]** % of aggregate annual Net Sales of all Products sold by AnHeart, its Affiliates, and/or its Sublicensees.

5.4.3. Term of Royalty Payments. The duration of AnHeart's royalty obligation will be determined on a country-by-country basis until the later of: (i) the loss of all Market Exclusivity, (ii) the expiration of all of Valid Claims Covering Licensed Compound or Product of the Daiichi Sankyo Patents in such country, or (iii) **[**Redacted**]** years from the launch of the first Product that is sold by AnHeart, its Affiliate, or its Sublicensee in that country. Thereafter AnHeart will have a fully paid up exclusive license to the Licensed Compound and Product(s) in that country.

5.5. Payments and Reports. Within **[**Redacted**]** Business Days of the close of each Calendar Quarter during which Net Sales are recognized, AnHeart shall deliver a report specifying, on a country-by-country and monthly basis and in the aggregate: (a) total gross invoiced amount from sales of each Product by AnHeart, its Affiliates, and its Sublicensees; (b) amounts deducted by category (e.g., normal and customary trade, cash and other discounts, allowances and credits actually allowed and taken directly with respect to sales of Product(s)) from gross invoiced amounts to calculate Net Sales; (c) Net Sales; and (d) royalties payable and its calculation; and (e) whether any of the sales milestone event has been achieved. Daiichi Sankyo shall issue AnHeart an invoice for the amount of the corresponding royalty payments, which invoice AnHeart shall pay Daiichi Sankyo within **[**Redacted**]**Business Days of its receipt thereof. In addition, AnHeart shall deliver a flash report specifying in the aggregate and monthly basis, (a) total Net Sales and (b) royalties payable within **[**Redacted**]** Business Days of the close of the Calendar Quarter during which Net Sales are recognized.

5.6. Forecast Reports. Within **[**Redacted**]** Business Days of the close of each Calendar Year, AnHeart shall deliver a report specifying a good faith forecast of Net Sales, royalties and sales milestones to be paid to Daiichi Sankyo for each of the next **[**Redacted**]** Calendar Quarters. AnHeart shall send the first such report within **[**Redacted**]** Business Days of receiving the first Marketing Approval anywhere in the Territory, provided that such first report shall include a forecast of Net Sales for the next **[**Redacted**]** Calendar Quarters.

5.7. Payment Method. All payments due to Daiichi Sankyo under this Agreement will be made by bank wire transfer in immediately available funds to an account designated by Daiichi Sankyo. All payments hereunder shall be made in the legal currency of the United States, and all references to "$" or "Dollars" herein refer to U.S. Dollars. AnHeart shall be responsible for paying all transfer and other fees related to completing all bank wire transfers required under this Agreement, except for the transfer fee imposed by the bank designated by Daiichi Sankyo. Within **[**Redacted**]** Business Days after the Effective Date, Daiichi Sankyo will provide AnHeart all information necessary to make such bank wire transfers. Thereafter, any change to such bank wire transfer information will be transmitted to AnHeart by a notice in accordance with Section 12.11. In case a payment by AnHeart to Daiichi Sankyo cannot meet the timeline stipulated in this Agreement, subject to Daiichi Sankyo's prior written consent, AnHeart's Affiliate may make such payment on behalf of AnHeart, on the conditions that (i) Daiichi Sankyo will receive the same amount of payment as it would receive if AnHeart makes such payment, (ii) Daiichi Sankyo's tax liability arising out of such payment by AnHeart's Affiliate is not more than the tax liability that Daiichi Sankyo would have if AnHeart makes such payment and (iii) AnHeart shall be liable to Daiichi Sankyo for any failure by such AnHeart's Affiliate to make the payment. If AnHeart desires to cause its Affiliate to make any payment on behalf of AnHeart pursuant to the foregoing sentence, AnHeart shall notify Daiichi Sankyo accordingly and request for Daiichi Sankyo's written consent no later than **[**Redacted**]** Business Days prior to the due date of such payment, in which case Daiichi Sankyo shall respond in writing with its decision as to whether or not it consents to such request within **[**Redacted**]** Business Days after the receipt of such request from AnHeart.

5.8. Currency Conversion. If any currency conversion is required in connection with the calculation of amounts payable hereunder, such conversion will be made using the average of the buying and selling exchange rate for conversion of the foreign currency and U.S. Dollars, quoted for current transactions reported in The Wall Street Journal (U.S., Eastern Edition) for the last Business Day in the Calendar Quarter to which such payment pertains.

5.9. Late Payments. AnHeart shall pay interest to Daiichi Sankyo on the aggregate amount of any payments that are not paid on or before the date such payments are due under this Agreement at a rate per annum equal to the lesser of the London Interbank Offered Rate of interest plus **[**Redacted**]**, as reported by The Wall Street Journal for the applicable period, and the highest rate permitted by Applicable Laws, calculated on the number of days such payment is delinquent. This Section 5.9 will in no way limit any other remedies available to Daiichi Sankyo.

5.10. Taxes.

5.10.1. Withholding Taxes. If AnHeart is required to withhold any tax to the tax or revenue authorities in any country in the Territory regarding any payment to Daiichi Sankyo, such amount may be deducted from the payment to be made by AnHeart, provided that AnHeart takes all reasonable and lawful actions to avoid or minimize such withholding and promptly notifies Daiichi Sankyo so that Daiichi Sankyo may also take lawful actions to avoid or minimize such withholding. AnHeart will promptly furnish Daiichi Sankyo with copies of any tax certificate or other documentation evidencing such withholding, as necessary to enable Daiichi Sankyo to support a claim, if permissible, for income tax credit in respect of any amount so withheld. Each Party agrees to cooperate with the other Party in claiming exemptions from

or reductions of such deductions or withholdings under any agreement or treaty in effect from time to time.

5.10.2. Value Added Taxes. All payments due to Daiichi Sankyo from AnHeart pursuant to this Agreement shall be paid exclusive of any value added tax, which will be paid by AnHeart upon receipt of a valid value added tax invoice. For clarity, the upfront, milestone and royalty payments under this Agreement are not subject to such value added tax in Japan as long as AnHeart's entity in Japan does not make the payment.

5.11. Records. AnHeart will keep, and will cause its Affiliates and its Sublicensees to keep, complete, true and accurate books of accounts and records, in compliance with Applicable Laws and the terms and conditions of this Agreement, sufficient to determine and establish the calculation of Net Sales and royalties payable under this Agreement for a period of **[**Redacted**]** after the year in which the sale of Product(s) generating the same occurred.

5.12. Inspection of Records. At the request of Daiichi Sankyo, AnHeart, its Affiliates and its Sublicensees will permit an independent certified public accountant appointed by Daiichi Sankyo, to inspect the books and records described in Section 5.11; provided that such inspection shall be at reasonable times and upon reasonable notice and not more often than **[**Redacted**]**. Any inspection conducted under this Section 5.12 will be at Daiichi Sankyo's expense, unless such inspection reveals any underpayment of **[**Redacted**]** or more of any amount due to Daiichi Sankyo during the audited period, in which case the full costs of such inspection will be paid by AnHeart. Any amount found to be due to Daiichi Sankyo, will be paid by AnHeart within **[**Redacted**]** Business Days with interest on the underpayment at the rate specified in Section 5.9 from the date such payment was originally due until paid.

6. Intellectual Property.

6.1. Ownership of Intellectual Property. Subject to the licenses granted in Article 2 of this Agreement, each Party will retain all right, title and interest in and to, and ownership of, all Patents and other intellectual property conceived, discovered, developed, reduced to practice, or otherwise made solely by or on behalf of such Party (or its Affiliates or its or their Sublicensees). Subject to the licenses and other rights granted herein, as between the Parties, each Party will own an equal, undivided interest in any and all Joint Foreground Know-How and Joint Foreground Patents. Inventorship and ownership rights in Inventions and other Know-How created, developed, conceived and/or reduced to practice after the Effective Date under this Agreement will be determined under the intellectual property laws of the United States of America, irrespective of where such creation, development, conception, discovery, development or making occurs.

6.2. Filing, Prosecution and Maintenance.

6.2.1. Daiichi Sankyo Partially Owned Patent. Using counsel of its choice, Daiichi Sankyo will, at its own expense, be responsible for further prosecuting and paying issue fee of the Daiichi Sankyo Partially Owned Patent of all countries in Exhibit B, provided that Daiichi Sankyo shall provide AnHeart a reasonable opportunity to review material submissions and correspondence during the prosecution. AnHeart has the right to provide any comment to Daiichi Sankyo within **[**Redacted**]** days after the receipt of such material submissions and correspondences. After issuance of patents, AnHeart shall be responsible, at

its sole expense, for maintaining the Daiichi Sankyo Partially Owned Patent in the Territory, including preparing, filing requests for and prosecuting patent term extensions, supplemental protection certificates, pediatric exclusivity, or similar protections that extend the term of such Daiichi Sankyo Partially Owned Patents. AnHeart shall also be solely responsible, at its sole expense, for defending the Daiichi Sankyo Partially Owned Patents from any challenges to their validity or enforceability, including responding to patent office communications, or office actions, oppositions, reissue, reexamination proceedings or interference, brought by any Third Party, whether before a patent authority or judicial body in the Territory, **[**Redacted**]**. AnHeart shall keep Daiichi Sankyo reasonably informed regarding actions it takes in connection with maintaining and defending Daiichi Sankyo Partially Owned Patents. Daiichi Sankyo shall, upon request, provide reasonable support to AnHeart, including signing documents necessary for AnHeart to fulfill its obligations under this Section 6.1.2. at AnHeart's expense, **[**Redacted**]**. On a country by country basis, if AnHeart decides that it will no longer maintain Daiichi Sankyo Partially Owned Patent in certain country, it will give Daiichi Sankyo reasonable notice of its decision, which will include sufficient time prior to the expiration or termination of all relevant deadlines for taking necessary actions to preserve the rights in such Daiichi Sankyo Partially Owned Patent. Daiichi Sankyo will have the right, but not the obligation, to maintain, assume control over and continue maintaining Daiichi Sankyo Partially Owned Patent that AnHeart ceases to maintain ("Terminated Daiichi Sankyo Patent"). In this case, such Daiichi Sankyo Partially Owned Patent and a Know-How associated with such Terminated Daiichi Sankyo Patent shall **[**Redacted**]**.

6.2.2. Daiichi Sankyo Fully Owned Patent.

(a) In Japan. Using counsel of its choice, Daiichi Sankyo shall, at its own expense, be responsible for further filing PCT application and domestic applications claiming the priority based on the applications set forth in Exhibit B respectively, prosecuting and maintaining the basic domestic application in Japan that is described in the Daiichi Sankyo Fully Owned Patent. Daiichi Sankyo may also be solely responsible, at its sole expense, for defending such Daiichi Sankyo Fully Owned Patent from any challenges to their validity or enforceability, including responding to patent office communications or office actions, oppositions, reissue reexamination proceedings or interference, or interferences, brought by any Third Party in Japan, whether before a patent authority or judicial body. Daiichi Sankyo will provide AnHeart a reasonable opportunity to review material submissions and correspondence in Japanese regarding the prosecution, maintenance or defence of Daiichi Sankyo Fully Owned Patent in Japan. AnHeart has the right to provide any comment to Daiichi Sankyo within **[**Redacted**]** days after the receipt of such material submissions and correspondences.

In the Territory. Using counsel of its choice, AnHeart shall be responsible, at its sole expense, for preparing, filing, prosecuting, and maintaining the Daiichi Sankyo Fully Owned Patents in the Territory, including preparing and filing requests for patent term extensions, supplemental protection certificates, pediatric exclusivity, or similar protections that extend the term of such Daiichi Sankyo Fully Owned Patents. AnHeart shall also be solely responsible for defending the Daiichi Sankyo Fully Owned Patents from any challenges to their validity or enforceability, including responding to patent office communications or office actions, oppositions, reissue or reexamination proceedings, or interferences, brought by any Third Party, whether before a patent authority or judicial body in the Territory, **[**Redacted**]**. AnHeart shall keep Daiichi Sankyo reasonably informed regarding actions it takes in connection with preparing, filing, prosecuting, maintaining and defending Daiichi Sankyo Fully Owned Patents. Daiichi Sankyo

shall, upon request, provide reasonable support to AnHeart, including signing documents necessary for AnHeart to fulfill its obligations under this Section 6.2 at AnHeart's expense. **[**Redacted**]**. On a country by country basis, if AnHeart decides that it will no longer prosecute or maintain Daiichi Sankyo Fully Owned Patent in certain country, it will give Daiichi Sankyo reasonable notice of its decision, which will include sufficient time prior to the expiration or termination of all relevant deadlines for taking necessary actions to preserve the rights in such Daiichi Sankyo Fully Owned Patent. Daiichi Sankyo will have the right, but not the obligation, to prosecute, maintain, assume control over and continue prosecuting and maintaining Daiichi Sankyo Fully Owned Patent that AnHeart ceases to prosecute and maintain ("Terminated Daiichi Sankyo Patent"). In this case, such Daiichi Sankyo Fully Owned Patent and a Know-How associated with such Daiichi Sankyo Fully Owned Terminated Daiichi Sankyo Patent shall **[**Redacted**]**.

6.2.3. Foreground Daiichi Sankyo Patents.

(a) In Japan. Using counsel of its choice, Daiichi Sankyo shall, at its own expense, be responsible for filing basic domestic application, PCT application and domestic application claiming the priority based on the basic domestic application respectively, prosecuting and maintaining the domestic application in Japan that is described in the Foreground Daiichi Sankyo Patents. Daiichi Sankyo may also be solely responsible for defending such Foreground Daiichi Sankyo Patent from any challenges to their validity or enforceability, including responding to patent office communications or office actions, oppositions, reissue or reexamination proceedings, or interferences, brought by any Third Party in Japan, whether before a patent authority or judicial body. Daiichi Sankyo will provide AnHeart a reasonable opportunity to review material submissions and correspondence in Japanese regarding to the prosecution, maintaining or defending of Foreground Daiichi Sankyo Patent in Japan.

(b) In the Territory. In case that AnHeart notifies Daiichi Sankyo that it desires to obtain the license under Foreground Daiichi Sankyo Patents, using counsel of its choice, AnHeart shall be responsible, at its sole expense, for entering national phase in the Territory, prosecuting, and maintaining the PCT application of the Foreground Daiichi Sankyo Patents in the Territory, including preparing and filing requests for patent term extensions, supplemental protection certificates, pediatric exclusivity, or similar protections that extend the term of such Foreground Daiichi Sankyo Patents. AnHeart shall also be solely responsible, at its sole expense, for defending the Foreground Daiichi Sankyo Patents from any challenges to their validity or enforceability, including responding to patent office communications or office actions, oppositions, reissue or reexamination proceedings, brought by any Third Party, whether before a patent authority or judicial body in the Territory, provided that AnHeart shall provide Daiichi Sankyo a reasonable opportunity to review material submission and correspondence regarding such prosecution, maintenance, enforcement and defense. Daiichi Sankyo has the right to provide any comment to AnHeart within **[**Redacted**]** days after the receipt of such material submissions and correspondences. AnHeart shall keep Daiichi Sankyo reasonably informed regarding actions it takes in connection with prosecuting, maintaining and defending Foreground Daiichi Sankyo Patents. Daiichi Sankyo shall, upon request, provide reasonable support to AnHeart, including signing documents necessary for AnHeart to fulfill its obligations under this Section 6.2 at AnHeart's expense, **[**Redacted**]**. On a country by country basis, if AnHeart decides that it will not enter the national phase, no longer prosecute or maintain Foreground Daiichi Sankyo Patent in certain country, it will give Daiichi Sankyo reasonable

notice of its decision, which will include sufficient time prior to the expiration or termination of all relevant deadlines for taking necessary actions to preserve the rights in such Foreground Daiichi Sankyo Patent. In this case, such Foreground Daiichi Sankyo Patents and a Know-How associated with such Foreground Daiichi Sankyo Patents shall **[**Redacted**]**.

6.2.4. Foreground AnHeart Patents.

(a) In the Territory. Using counsel of its choice, AnHeart shall, at its own expense, be responsible for filing basic domestic application and PCT application claiming the priority based on the basic domestic application respectively, entering national phase in the Territory, prosecuting and maintaining the PCT application in the Territory that is described in the Foreground AnHeart Patents. AnHeart shall also be solely responsible for defending such Foreground AnHeart Patent from any challenges to their validity or enforceability, including responding to patent office communications or office actions, oppositions, reissue or reexamination proceedings, or interferences, brought by any Third Party in the Territory, whether before a patent authority or judicial body. AnHeart shall provide Daiichi Sankyo a reasonable opportunity to review material submissions and correspondence regarding to the prosecution, maintaining or defending of Foreground AnHeart Patent in the Territory.

(b) In Japan. In case that the Daiichi Sankyo notifies AnHeart that it desires to obtain the license under Foreground AnHeart Patents, using counsel of its choice, Daiichi Sankyo shall be responsible, at its sole expense, for entering national phase in Japan, prosecuting, and maintaining the PCT application of the Foreground AnHeart Patents in Japan, including preparing and filing requests for patent term extensions, supplemental protection certificates, pediatric exclusivity, or similar protections that extend the term of such Foreground AnHeart Patents. Daiichi Sankyo shall also be solely responsible for defending the Foreground AnHeart Patents from any challenges to their validity or enforceability, including responding to patent office communications or office actions, oppositions, reissue or reexamination proceedings, brought by any Third Party, whether before a patent authority or judicial body in the Territory, provided that Daiichi Sankyo shall provide AnHeart a reasonable opportunity to review material submission and correspondence regarding such prosecution, maintenance, enforcement and defence. AnHeart has the right to provide any comment to Daiichi Sankyo within **[**Redacted**]** days after the receipt of such material submissions and correspondences. Daiichi Sankyo shall keep reasonably AnHeart informed regarding actions it takes in connection with prosecuting, maintaining and defending Foreground AnHeart Patents. AnHeart shall, upon request, provide reasonable support to Daiichi Sankyo, including signing documents necessary for Daiichi Sankyo to fulfill its obligations under this Section 6.2.4.(b) at Daiichi Sankyo's expense, **[**Redacted**]**. If Daiichi Sankyo decides that it will not enter the national phase in Japan, no longer prosecute or maintain Foreground AnHeart Patent in Japan, it will give AnHeart reasonable notice of its decision, which will include sufficient time prior to the expiration or termination of all relevant deadlines for taking necessary actions to preserve the rights in such Foreground AnHeart Patent. AnHeart will have the right, but not the obligation, to prosecute maintain, assume control over and continue prosecuting and maintaining Foreground AnHeart Patent that Daiichi Sankyo ceases to enter the national phase in Japan, prosecute and maintain. In this case, such Foreground AnHeart Patents and a Know-How associated with such Foreground AnHeart Patents shall **[**Redacted**]**.

6.2.5. Foreground Joint Patents. The responsibility of preparing and filing, the share of its interest and the share of expense of Foreground Joint Patents shall be decided in the joint patent agreement.

(a) In Japan. Using counsel of its choice, Daiichi Sankyo may, at its own expense, be responsible for prosecuting and maintaining Foreground Joint Patent in Japan. Daiichi Sankyo may also be solely responsible for defending such Foreground Joint Patent from any challenges to their validity or enforceability, including responding to patent office communications or office actions, oppositions, reissue or reexamination proceedings, or interferences, brought by any Third Party in Japan, whether before a patent authority or judicial body.

(b) In the Territory. Using counsel of its choice, AnHeart shall, at its own expense, be responsible for prosecuting and maintaining Foreground Joint Patents in the Territory. AnHeart shall also be solely responsible for defending such Foreground Joint Patent from any challenges to their validity or enforceability, including responding to patent office communications or office actions, oppositions, reissue or reexamination proceedings, or interferences, brought by any Third Party in the Territory, whether before a patent authority or judicial body.

(c) Each Party shall provide the other Party a reasonable opportunity to review material submissions and correspondence regarding to the prosecution, maintenance or defense of Foreground Joint Patent in each territory. If one Party, in its sole discretion, decides that it will no longer prosecute or maintain a Foreground Joint Patent in own Territory, it will give other Party reasonable notice of its decision, which will include sufficient time prior to the expiration or termination of all relevant deadlines for taking necessary actions to preserve the rights in such Foreground Joint Patent, and will allow other Party to assume control over and continue prosecuting and maintaining such Foreground Joint Patent. (The Party which cease to prosecute or maintain the Foreground Joint Patent is called “Abandoning Party”, and the other Party is called “Maintaining Party” in this Section.) If requested by Maintaining Party, Abandoning Party will **[**Redacted**]**. In this case, such Foreground Joint Patents and a Know-How associated with such Foreground Joint Patents shall **[**Redacted**]**.

6.2.6. Regulatory Exclusivity. If AnHeart decides to seek regulatory and/or data exclusivity for a Product, AnHeart will be responsible, at its sole expense, for preparing and filing such requests with the applicable Regulatory Authority. Daiichi Sankyo will, upon request, provide reasonable support to AnHeart in preparing and filing such requests at AnHeart’s expense.

6.3. Defense of Infringement Claims by Third Parties.

6.3.1. Liability. If a Third Party files or threatens to file an infringement claim against either Party or both Parties related to the manufacture, use, offer for sale, sale, importation or exportation of the Licensed Compound or Product(s) in any country within the Territory, AnHeart will promptly notify Daiichi Sankyo thereof and AnHeart will defend such claim at its own expense and will be solely responsible for all damages awarded to the Third Party plaintiff, whether as a result of a court order or an agreement to settle. Daiichi Sankyo will assist and cooperate with AnHeart in defending such claim(s) upon reasonable requests and at AnHeart’s expense.

6.3.2. Control. AnHeart will solely control the defense of infringement claim(s) brought against the either Party or both Parties by Third Parties, including the right to control settlement of such claim(s), provided that AnHeart may not agree to terms in the settlement that will adversely affect Daiichi Sankyo's rights or interests unless Daiichi Sankyo has given prior written consent, which will not be unreasonably withheld or delayed. Notwithstanding AnHeart's right to control the defense of claim(s) of infringement, if Daiichi Sankyo is named as a defendant, it will have the right to participate in such case, including by engaging separate counsel, at its sole expense. Without affecting or limiting AnHeart's right to control the defense of infringement claims by Third Parties, if Daiichi Sankyo elects to engage separate counsel, the Parties shall cooperate in defending and/or settling such claims. AnHeart shall keep Daiichi Sankyo reasonably informed regarding actions it takes in connection with any such infringement claim.

6.4. Enforcement Actions Against Third Parties.

6.4.1. Notification. If either Party learns of any infringement, unauthorized use, misappropriation or ownership claim, or threatened infringement of any Daiichi Sankyo Patents and/or Foreground Patents by a Third Party with respect to the Licensed Compound or Product(s) anywhere within the Territory, such Party will promptly notify the other Party in writing and will promptly provide the other Party with available evidence of such infringement or other such claim.

6.4.2. Control. AnHeart will have the first right, but not the obligation, to institute an infringement suit, initiate administrative proceedings, or take other appropriate action against a Third Party for any alleged infringement of any Daiichi Sankyo Patents (except Terminated Daiichi Sankyo Patent) or Foreground Patents anywhere within the Territory, including a defense or counterclaim in connection with any Third Party infringement claim, at its sole cost and expense, using counsel of its own choice. AnHeart shall provide Daiichi Sankyo a reasonable opportunity to review and comment on material submissions and correspondence regarding to the infringement of Daiichi Sankyo Patents and Foreground Patents. **[**Redacted**]**. If AnHeart does not secure actual cessation of the offending activities, or institute an infringement proceeding or other administrative proceeding against an offending Third Party, AnHeart will notify Daiichi Sankyo of such circumstances as soon as reasonably practicable, but in any case no later than **[**Redacted**]** days of learning of such infringement or threatened infringement. Upon receiving such notice, Daiichi Sankyo will have the right, but not the obligation, at its sole discretion, to take appropriate actions in the name of either Party or both Parties. Each Party will execute all necessary and proper documents, and take such actions as are necessary and appropriate to allow the other Party to institute and prosecute such infringement actions and will otherwise cooperate in instituting and prosecuting such actions (including, without limitation, consenting to being named as a nominal party thereto).AnHeart shall not enter into any settlement admitting the invalidity of, or otherwise impairing the Daiichi Sankyo Patents, Foreground Daiichi Sankyo Patents or Foreground Joint Patents without the prior written consent of Daiichi Sankyo, which consent shall not be unreasonably withheld, conditioned, or delayed.

6.4.3. Expenses. The costs and expenses of any such enforcement actions against Third Parties (including fees of attorneys and other professionals) will be paid by the Party instituting the action, or, if the Parties elect to cooperate in instituting and maintaining such action, such costs and expenses will be borne by the Parties in such proportions as they

may agree in writing. Any damages paid by Third Parties as a result of such an enforcement action (whether by way of settlement or otherwise) will be applied first to reimburse both Parties for all costs and expenses incurred. If such funds are not sufficient to reimburse all expenses of both Parties, all funds will be divided on a pro rata basis in the same proportion as the costs and expenses incurred. If any funds remain after all expenses of both Parties have been reimbursed, such excess funds will be **[**Redacted**]**.

6.5. Trademarks. Provided that AnHeart consults with Daiichi Sankyo at Joint Operational Team or appropriate governing body, AnHeart will have the right and the responsibility, at its expense, to choose the brand(s) under which Product(s) will be marketed in the Territory. AnHeart will, at its expense, own all trademarks used in the marketing of Product(s) in the Territory.

7. Confidentiality.

7.1. Confidential Information. Except to the extent expressly authorized by this Section 7 or otherwise agreed in a writing signed by both Parties, each Party (the "Receiving Party") shall, during and after the Term of this Agreement, keep confidential and not publish or otherwise disclose or use for any purpose other than as explicitly provided for in this Agreement any confidential and proprietary information or materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic, or otherwise) that are disclosed or provided to it by the other Party or an Affiliate of the other Party (each a "Disclosing Party") or otherwise received or accessed by a Receiving Party, its Affiliates, or its Sublicensees in the course of performing its obligations under this Agreement including, but not limited to, any trade secrets, Know-How, Product specifications, formulae, processes, techniques and information relating to the Disclosing Party's past, present and future marketing, financial, and research and development activities for any product of the Disclosing Party and the pricing thereof (collectively, "Confidential Information"). Confidential Information of each Party includes the terms and conditions of this Agreement.

7.2. Exceptions. Notwithstanding the foregoing, Confidential Information does not include information or materials to the extent that it can be established by the Receiving Party that such information or material:

7.2.1. is already lawfully known to the Receiving Party, other than under an obligation of confidentiality at the time of disclosure by the Disclosing Party as evidenced by written records kept in the ordinary course of business, or other documentary proof of actual use by the Receiving Party;

7.2.2. is generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

7.2.3. becomes generally available to the public or otherwise part of the public domain after its disclosure to the Receiving Party and other than through any act or omission of the Receiving Party, its Affiliates, or its Sublicensees in violation of this Agreement;

7.2.4. is independently developed by the Receiving Party as demonstrated by documented evidence prepared contemporaneously with such independent development; or

7.2.5. is lawfully disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation not to disclose such information to others.

7.3. Authorized Disclosure. Notwithstanding Section 7.1, the Receiving Party may disclose Confidential Information of the Disclosing Party:

7.3.1. to its respective directors, officers, employees, consultants and advisors, and to the directors, officers, employees, consultants and advisors of such Receiving Party's Affiliates, Sublicensees, or potential investors or sublicensees, who have a need to know such Confidential Information in connection with the activities or transactions contemplated in this Agreement and have an obligation to treat such Confidential Information as confidential under terms no less restrictive than those set forth herein; or

7.3.2. in its publicly filed financial statements or other public statements pursuant to applicable laws, regulations, and stock exchange rules or otherwise disclosed pursuant to applicable law; provided, that: (a) the terms of this Agreement are redacted to the greatest extent possible; and (b) such Receiving Party provides the Disclosing Party with a copy of the proposed text of such statements or disclosure (including any exhibits containing this Agreement) sufficiently in advance of the scheduled release or publication thereof to afford the Disclosing Party a reasonable opportunity to review and comment on the proposed text (including redacted versions of this Agreement).

7.3.3. to governmental authorities to facilitate the issuance of Marketing Approvals for Product(s); provided that reasonable measures are taken to assure confidential treatment of such information;

7.3.4. to the extent such disclosure is reasonably necessary in filing or prosecuting patent, copyright and trademark applications, prosecuting or defending litigation, complying with applicable governmental regulations, conducting preclinical activities or clinical trials and marketing a Product;

7.3.5. to Third Parties in connection with a Receiving Party's efforts to secure financing or enter into strategic partnerships, provided such information is disclosed only on a need-to-know basis and under confidentiality provisions at least as stringent as those in this Agreement;

7.3.6. that is required to be disclosed in response to a valid order by a court or other governmental body and provided that the Receiving Party provides the Disclosing Party with prompt notice of such requirement so that the Disclosing Party may seek a protective order or other appropriate remedy, then the Receiving Party may furnish only that portion of the Confidential Information which the Receiving Party is legally compelled to disclose; or

7.4. Publications. If a Party, its Affiliates, and/or its Sublicensees, excluding its clinical investigators and the owner of Daiichi Sankyo Partially Owned Patent other than Daiichi Sankyo, proposes a publication related to its performance under this Agreement, such Party will first submit an draft of such publication to Joint Operational Team, whether they are to be presented orally or in written form, at least **[**Redacted**]** days prior to submission for publication or presentation. The Joint Operational Team will review such proposed

publication/presentation and, **[**Redacted**]**, such Party may make such publication or presentation.

7.5. Press Releases. Neither Party may issue any press release for the execution of this Agreement and any activities related to the Licensed Compound and all Products throughout the Territory and Japan without obtaining the other Party's prior written approval, which approval will not be unreasonably withheld or delayed.

7.6. Restrictions on Use. During and after the Term, the Receiving Party shall not use, and shall ensure that its Affiliates, and its Sublicensees do not use any Confidential Information disclosed to it by a Disclosing Party or otherwise received or accessed in the course of performing its obligations under this Agreement for any purpose other than as expressly provided herein. For clarity, this restriction will not apply to information that is covered by one or more of the exceptions described in Section 7.2 of this Agreement.

7.7. Use of Name. Except as otherwise provided herein, neither Party has any right, express or implied, to use the name or other designation of the other Party or any other trade name, trademark or logo of the other Party in any manner or for any purpose in connection with this Agreement without the prior written approval of the other Party, except for use in connection with notices or filings required by law, rule, or regulation.

8. Representations, Warranties and Covenants.

8.1. Representations and Warranties of Both Parties. Each Party represents and warrants to the other, as of the Effective Date, that:

8.1.1. it is duly organized and validly existing under the laws of its jurisdiction of incorporation, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

8.1.2. it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder and that it has the right to grant to the other Party the licenses and sublicenses granted pursuant to this Agreement, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action;

8.1.3. this Agreement is legally binding upon it and, upon execution by the other Party, shall be enforceable in accordance with its terms except to the extent that enforceability may be limited by applicable bankruptcy, insolvency or other laws affecting the enforcement of creditors' rights generally and subject to the general principles of equity (regardless of whether enforcement is sought in a court of law or equity);

8.1.4. the execution, delivery and performance of this Agreement by such Party does not knowingly conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any governmental agency or Regulatory Authority having jurisdiction over it;

8.1.5. it has not granted any right to any Third Party that would knowingly conflict with the rights granted to the other Party hereunder;

8.1.6. it has not been debarred under the Generic Drug Enforcement Act of 1992 (21 U.S.C. §301 et seq.), is not under investigation for debarment action, has not been disqualified as an investigator pursuant to 21 C.F.R. §312.70, does not have a disqualification hearing pending and is not currently employing any person or entity that has been so debarred or disqualified to perform any of its obligations under this Agreement. It shall promptly notify the other Party if it is so debarred or disqualified and shall terminate any so debarred or disqualified individual's or entity's participation in the performance of any of its obligations under this Agreement promptly upon its awareness of such debarment or disqualification; and

8.1.7. it is not aware of any action, suit or inquiry or investigation instituted by any person or governmental agency that questions or threatens the validity of this Agreement.

8.2. Additional Representations, Warranties and Covenants of Daiichi Sankyo. Daiichi Sankyo warrants, represents and covenants to AnHeart as follows:

8.2.1. As of the Effective Date, Daiichi Sankyo owns or Controls all of the Daiichi Sankyo Technology in existence on the Effective Date, and has the right to grant the licenses with respect thereto;

8.2.2. Unless specifically disclosed to be otherwise, as of the Effective Date, to the knowledge of Daiichi Sankyo, the Daiichi Sankyo Patents: (a) that are issued as of the Effective Date, are valid and in full force and effect, and (b) are not the subject of any interference or opposition proceedings;

8.2.3. As of the Effective Date, to the knowledge of Daiichi Sankyo, Daiichi Sankyo is not aware of any pending or threatened action, suit proceeding or claim by a Third Party challenging the ownership rights in, or the validity or scope of the Daiichi Sankyo Patents;

8.2.4. As of the Effective Date, to the knowledge of Daiichi Sankyo, none of the Daiichi Sankyo Know-How was obtained by Daiichi Sankyo in violation of any contractual or fiduciary obligation to which it or any of its employees or staff are or were bound, or by the misappropriation of a trade secret of any Third Party;

8.2.5. Unless specifically disclosed to be otherwise, as of the Effective Date, there is no pending or threatened action, suit, proceeding or claim that was brought to Daiichi Sankyo’s attention by a Third Party in writing asserting that the use or practice of any of Daiichi Sankyo’s Know-How infringes or otherwise is violating any patents, trade secret or other proprietary right of any Third Party; and

8.2.6. As of the Effective Date, Daiichi Sankyo is not engaged in the development of a Mutant-IDH1 inhibitor except for DS-1001b in the Territory.

8.3. Disclaimer of Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS ARTICLE 8, DAIICHI SANKYO DISCLAIMS ANY REPRESENTATIONS ANY WARRANTIES OF ANY KIND UNDER THIS AGREEMENT (INCLUDING WITH RESPECT TO ANY MATERIALS PROVIDED UNDER THIS AGREEMENT), EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, QUALITY, FITNESS FOR A PARTICULAR PURPOSE,

NONINFRINGEMENT, OR VALIDITY OF PATENT CLAIMS, WHETHER ISSUED OR PENDING.

8.4. Limitation of Liability. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY OR ANY OTHER PERSON FOR INCIDENTAL, CONSEQUENTIAL, EXEMPLARY, PUNITIVE, MULTIPLE OR OTHER INDIRECT DAMAGES, OR FOR LOSS OF PROFITS, LOSS OF DATA OR LOSS OF USE DAMAGES, ARISING OUT OF THIS AGREEMENT, WHETHER BASED UPON WARRANTY, CONTRACT, TORT, STATUTE, STRICT LIABILITY OR OTHERWISE, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR LOSSES. THE FOREGOING LIMITATION OF LIABILITY, HOWEVER, SHALL NOT LIMIT THE OBLIGATIONS OF EITHER PARTY TO INDEMNIFY THE OTHER PARTY FROM AND AGAINST THIRD PARTY CLAIMS UNDER ARTICLE 9.

9. Indemnification.

9.1. Indemnification by Daiichi Sankyo. Daiichi Sankyo will defend, hold harmless and indemnify (collectively, "Indemnify") AnHeart and its Affiliates, and their respective agents, directors, contractors, representatives, officers and employees (collectively, "AnHeart Indemnitees") from and against any liability or expense, including without limitation reasonable legal expenses and attorneys' fees, (collectively, "Losses") resulting from suits, claims, actions and demands, in each case brought by a Third Party (each, a "Third-Party Claim") relating to or arising from a material breach of any of Daiichi Sankyo's representations, warranties or covenants under Section 8.1 or 8.2 or other obligations pursuant to this Agreement, or any gross negligence or willful misconduct by Daiichi Sankyo or its officers, directors, employees in the exercise of any of Daiichi Sankyo's rights or the performance of any of Daiichi Sankyo's obligations under this Agreement. Daiichi Sankyo's obligation to Indemnify the AnHeart Indemnitees pursuant to this Section 9.1 will not apply to the extent that any such Losses arise from the gross negligence, willful misconduct or wrongful acts or omissions of any AnHeart Indemnitee; or are Losses for which AnHeart is obligated to Indemnify the Daiichi Sankyo Indemnitees pursuant to Section 9.2.

9.2. Indemnification by AnHeart. AnHeart will Indemnify Daiichi Sankyo and its Affiliates, and its and their agents, directors, contractors, representatives, officers and employees (collectively, "Daiichi Sankyo Indemnitees") from and against any and all Losses resulting from Third-Party Claims relating to or arising from a material breach of any of AnHeart's representations, warranties or covenants under Section 8.1 or other obligations pursuant to this Agreement, any violation of Applicable Laws, any gross negligence or willful misconduct by AnHeart, its Affiliates, and/or its Sublicensees or each of their respective officers, directors, employees in the exercise of any of AnHeart's rights or the performance of any of AnHeart's obligations under this Agreement, or any tort claims of personal injury (including death) or property damage relating to or arising out of any research, development, sale, offer for sale or importation of any Product in the Territory by AnHeart, its Affiliates, and/or its Sublicensees, or any claims relating to or arising out of the marketing or sales activities of AnHeart, its Affiliates, and/or its Sublicensees in the Territory. AnHeart's obligation to Indemnify the Daiichi Sankyo Indemnitees pursuant to this Section 9.2 shall not apply to the extent that any such Losses arise from the gross negligence, willful misconduct or wrongful acts or omissions of any Daiichi Sankyo Indemnitee, or are Losses for which Daiichi Sankyo is obligated to Indemnify the AnHeart Indemnitees pursuant to Section 9.1.

9.3. Procedure. To be eligible to be indemnified hereunder, any AnHeart Indemnitee under Section 9.1 or Daiichi Sankyo Indemnitee under Section 9.2, as the case may be (an "Indemnitee") seeking indemnification, must provide the indemnifying Party with prompt notice of the Third-Party Claim giving rise to the claimed indemnification obligation and must assign the exclusive ability to defend or settle any such claim to the indemnifying Party; provided, however, that the indemnifying Party may not enter into any settlement that admits fault, wrongdoing or damages on the part of the Indemnitee without such Indemnitee's written consent, such consent not to be unreasonably withheld or delayed. The Indemnitee will cooperate with reasonable requests from the indemnifying Party, at the indemnifying Party's expense, and will have the right to participate, at its own expense and with counsel of its choice, in the defense of any claim or suit that has been assumed by the indemnifying Party. Without affecting or limiting the indemnifying Party's right to control the defense of the Third Party Claim, if the Indemnitee elects to engage separate counsel, the Parties shall cooperate in defending and/or settling such claims.

9.4. Complete Indemnification. Indemnification under this Article 9 will include the reasonable costs and expenses of the Indemnitee relating to legal fees and expenses and damages awarded to the Indemnitee in connection with enforcement of Sections 9.1 and 9.2.

9.5. Allocation. If a claim is based in part on an indemnified claim, as described in Sections 9.1 and 9.2, and in part on a non-indemnified claim, or is based in part on a claim described in Section 9.1 and in part on a claim described in Section 9.2, any payments and reasonable attorney fees incurred in connection with such claims will be apportioned between the Parties in accordance with the degree of fault attributable to each Party.

9.6. Insurance. During the Term and for **[**Redacted**]** years thereafter, AnHeart will maintain a policy of insurance at levels sufficient to support its indemnification obligations, but in any case such insurance must provide adequate coverage for clinical trials liability, products liability, worker's compensation, employer's liability, and comprehensive general liability and consistent with the normal business practices of prudent pharmaceutical companies of similar size, scope, and territory. Upon Daiichi Sankyo's request, AnHeart shall provide evidence of such insurance. AnHeart shall notify Daiichi Sankyo of any cancellation, lapse or material change in the applicable insurance.

10. Term and Termination.

10.1. Term. This Agreement is effective as of the Effective Date and, unless earlier terminated pursuant to the other provisions of this Article 10, will continue in full force and effect until AnHeart and all of its Affiliates and Sublicensees cease all development and commercial activity related to all Licensed Compound and Products throughout the Territory (the "Term").

10.2. Termination by Daiichi Sankyo.

10.2.1. Daiichi Sankyo may terminate this Agreement, without prejudice to any other remedies available to it at law or in equity, if AnHeart, its Affiliate, or its Sublicensee commits a material breach of this Agreement that, in the case of a material breach capable of remedy, has not have been remedied within **[**Redacted**]** days of receiving a notice from Daiichi Sankyo identifying the breach and requiring its remedy, or if such material breach

cannot be cured within **[**Redacted**]** days, if AnHeart does not commence and diligently continue actions to cure such breach during such **[**Redacted**]** days. The Parties acknowledge that non-payment of sums due from AnHeart hereunder will be considered a material breach of this Agreement.

10.2.2. To the extent permitted by law, Daiichi Sankyo may terminate this Agreement immediately if: (a) AnHeart becomes insolvent, or makes or seeks to make or arrange an assignment for the benefit of creditors; (b) proceedings in voluntary bankruptcy are initiated by or on behalf of AnHeart or proceedings in involuntary bankruptcy are initiated against AnHeart (and, in the case of any such involuntary proceeding, not dismissed within **[**Redacted**]** days); or (c) a receiver or trustee of AnHeart's property is appointed and not discharged within **[**Redacted**]** days.

10.2.3. Daiichi Sankyo may terminate this Agreement immediately upon written notice if AnHeart, its Affiliate, or its Sublicensees initiates or joins any challenge, whether in a court of law or in an administrative proceeding, to the validity or enforceability of a Daiichi Sankyo Patent.

10.3. Termination by AnHeart.

10.3.1. AnHeart may terminate this Agreement, without prejudice to any other remedies available to it at law or in equity, if Daiichi Sankyo commits a material breach of this Agreement that, in the case of a material breach capable of remedy, has not been remedied within **[**Redacted**]** days of receiving a notice from AnHeart identifying the breach and requiring its remedy, or if such material breach cannot be cured within such **[**Redacted**]** day period, if Daiichi Sankyo does not commence and diligently continue actions to cure such breach during such **[**Redacted**]** days.

10.3.2. AnHeart may terminate its activities under this Agreement on a country-by-country basis (or region-by-region basis) or may terminate this Agreement in its entirety upon **[**Redacted**]** months prior written notice to Daiichi Sankyo if AnHeart has bona fide material concerns regarding the lack of safety for human use arising from toxicity of the Licensed Compound or Product(s) or the lack of efficacy of the Licensed Compound or Product(s). The notice under this Section 10.3.2 will specify in detail the basis for such termination, including a reasonable description of such material concern(s). Prior to the written notice of termination, AnHeart shall discuss in good faith such material concerns with Daiichi Sankyo for **[**Redacted**]** Business Days. Termination by AnHeart of its activities under this Agreement in all of the countries/regions within the Territory shall constitute termination of this Agreement in its entirety pursuant to this Section 10.3.2.

10.3.3. AnHeart may terminate its activities under this Agreement in a country or region within the Territory upon **[**Redacted**]** months prior written notice to Daiichi Sankyo if: (i) all claims of Daiichi Sankyo Patents in such country or region Covering the Licensed Compound in the Product offered for sale are invalidated by a competent court in the relevant jurisdiction in a final unappealed or unappealable decision or (ii) the Licensed Compound is determined by a competent court in the relevant jurisdiction in a final unappealed or unappealable decision to infringe one or more claims of a patent asserted by a Third Party in such country or region. The notice under this Section 10.3.3 will specify in detail the basis for such termination, including a reasonable description of the situation(s) that triggers the

conditions specified in (i) or (ii) of the foregoing sentence. Prior to the written notice of termination, AnHeart shall discuss in good faith such situation(s) with Daiichi Sankyo for **[**Redacted**]** Business Days. Termination by AnHeart of its activities under this Agreement in all of the countries/regions within the Territory shall constitute termination of this Agreement in its entirety pursuant to this Section 10.3.3.

10.4. Accrued Obligations/Survival. Expiration or termination of this Agreement for any reason does not release either Party from any obligation or liability which, at the time of such expiration or termination, has already accrued to the other Party or which is attributable to a period prior to such expiration or termination. Section 3.8.3 (Confidential Information), Section 5.9 (Late Payments), Section 5.11 (Records), Section 5.12 (Inspection of Records), Article 6 (Intellectual Property), Article 7 (Confidentiality), Section 8.4 (Limitation of Liability), Article 9 (Indemnification), this Section 10.4 (Accrued Obligations/Survival), Section 10.5 (Effects of Terminations), Article 11 (Dispute Resolution), Section 12.9 (Governing Law), Section 12.10 (Submission to Jurisdiction) and Section 12.11 (Notices) shall survive expiration or termination of this Agreement for any reason.

10.5. Effects of Terminations.

10.5.1. If AnHeart terminates this Agreement in its entirety or terminates its activities in a particular country in the Territory (each affected country being a "Terminated Country") pursuant to Section 10.3 in each case:

(a) If there are any ongoing clinical trials in such Terminated Country being conducted by or on behalf of AnHeart, its Affiliate, or its Sublicensee, at the time the notice of termination is sent, AnHeart will, as of the effective date of termination: (i) promptly transfer to Daiichi Sankyo or its designee some or all of such clinical trials and the activities related to or supporting such trials; or (ii) terminate such clinical trials; in each case upon request from Daiichi Sankyo and at Daiichi Sankyo's sole discretion. Notwithstanding the foregoing, if the clinical trials in the Terminated Country are required or useful for Regulatory Filings or permitted activities with respect to a Product outside the Terminated Country, then AnHeart will, upon sending written notice of its decision to terminate its activities in the Terminated Country, have the option of completing such clinical trials.

(b) If requested by Daiichi Sankyo, AnHeart will: (i) promptly transfer to Daiichi Sankyo or its designee copies of all data, reports, records, materials that relate to a Product in such Terminated Country, (ii) provide Daiichi Sankyo or its designee with all information necessary or desirable to cross-reference or assume responsibility for any Regulatory Filings, as the case may be, in AnHeart's name with respect to the Product, in such Terminated Country, and (iii) return to Daiichi Sankyo all relevant records and materials in AnHeart's possession or control containing Confidential Information of Daiichi Sankyo relating solely to the Licensed Compound and the Product in such Terminated Country, provided that AnHeart may keep one copy of such Confidential Information for archival purposes or as may be necessary or useful in connection with AnHeart's activities under this Agreement outside of the Terminated Country. If AnHeart elects to terminate this Agreement in its entirety, within **[**Redacted**]** days of such termination, AnHeart shall also provide Daiichi Sankyo with copies of all preclinical and clinical data (including investigator reports, both preliminary and final, statistical analyses, expert opinions and reports, safety and other electronic databases if available) and, subject to Section 10.5.1(c), other Know-How Controlled by AnHeart.

(c) Notwithstanding other provisions in this Section 10.5.1, if requested by Daiichi Sankyo after receiving a notice of termination under Section 10.3, AnHeart will engage in good faith negotiation regarding the commercial terms and conditions for an exclusive royalty bearing license, with the right to sublicense, under any Foreground AnHeart Patents and Foreground AnHeart Know-How that are Controlled by AnHeart that are necessary or useful for Daiichi Sankyo to make, have made, use, sell, offer for sale, import and export the Licensed Compound or Product(s) in such Terminated Country.

(d) Notwithstanding other provisions in this Section 10.5.1, if requested by Daiichi Sankyo after receiving a notice of termination under Section 10.3, AnHeart will engage in good faith negotiation regarding the commercial terms and conditions for an exclusive, royalty bearing license, with the right to sublicense, to use any trademarks specific to Product(s) in such Terminated Country. It is understood that such assignment will not include the AnHeart name or any company trademark, trade name, or logo of AnHeart itself.

(e) The licenses granted to AnHeart under Section 2.1 shall terminate in the Terminated Country or throughout the Territory if this Agreement is terminated in its entirety.

(f) If requested by Daiichi Sankyo, AnHeart will assign all sublicense agreements granted by AnHeart under this Agreement in the Terminated Country to Daiichi Sankyo or its designee to the extent permitted under those agreements and not adversely affecting AnHeart's activities outside of the Terminated Country. If Daiichi Sankyo does not request assignment of such sublicense agreements, then such sublicense agreements shall terminate upon termination of AnHeart's rights with respect to the Licensed Compound or Product(s)) in the Terminated Country.

(g) If AnHeart elects to terminate this Agreement in its entirety, AnHeart shall return all relevant records and materials in its possession or control containing Daiichi Sankyo's Confidential Information to Daiichi Sankyo, provided that AnHeart may keep one copy of such Confidential Information for archival purposes only.

10.5.2. If Daiichi Sankyo terminates this Agreement in its entirety pursuant to Section 10.2:

(a) If there are any ongoing clinical trials with respect to Product(s) being conducted by or on behalf of AnHeart, its Affiliates, or its Sublicensees at the time of notice of termination, AnHeart will, free of charge as of the effective date of termination, promptly transfer some or all of such clinical trials and the activities related to or supporting such trials to Daiichi Sankyo or its designee, or complete or terminate such clinical trials, in each case as requested by Daiichi Sankyo.

(b) If requested by Daiichi Sankyo, AnHeart shall, free of charge, promptly assign and transfer to Daiichi Sankyo or its designee all Regulatory Filings for Product(s) that are held by AnHeart, its Affiliates or its Sublicensees, and shall take such actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights under the Regulatory Filings to Daiichi Sankyo or its designee. If applicable law prevents or delays the transfer of ownership of a Regulatory Filing, AnHeart shall grant Daiichi Sankyo or its designee a permanent, exclusive and irrevocable right of access

and reference to such Regulatory Filings for Product(s), and will fully cooperate to make the benefits of such Regulatory Filings available to Daiichi Sankyo or its designee. At the request of Daiichi Sankyo, within **[**Redacted**]** days of such termination, AnHeart shall provide, free of charge, to Daiichi Sankyo or its designee copies of all such Regulatory Filings and of all preclinical and clinical data (including investigator reports, both preliminary and final, statistical analyses, expert opinions and reports, safety and other electronic databases) and other Know-How Controlled by AnHeart that are necessary for Daiichi Sankyo to submit an application for Marketing Approval for a Product in the Territory..

(c) Notwithstanding other provisions in this Section 10.5.2, (i) if Daiichi Sankyo terminates this Agreement in its entirety pursuant to Section 10.2.1 or Section 10.2.3, upon Daiichi Sankyo's request, AnHeart shall grant Daiichi Sankyo an exclusive, irrevocable, fully paid up license, with the right to sublicense, under any Patents and Know-How that are Controlled by AnHeart that are reasonably necessary or useful to make, have made, use, sell, offer for sale, import and export the Licensed Compound or Product(s); and (ii) if Daiichi Sankyo terminates this Agreement in its entirety pursuant to Section 10.2.2, upon Daiichi Sankyo's request, AnHeart shall engage in good faith negotiation regarding the commercial terms and consideration for a separate exclusive royalty-bearing license, with the right to sublicense, under any Patents and Know-how that are Controlled by AnHeart that are reasonably necessary or useful for Daiichi Sankyo to make, have made, use, sell, offer for sale, import and export the Licensed Compound or the Product(s).

(d) Notwithstanding other provisions in this Section 10.5.2, (i) if Daiichi Sankyo terminates this Agreement in its entirety pursuant to Section 10.2.1 or Section 10.2.3, upon Daiichi Sankyo's request, AnHeart shall grant Daiichi Sankyo or its designee an exclusive, irrevocable, fully paid up license, with the right to sublicense, to use any trademarks specific to Product(s) in the Territory. It is understood that such license shall not include the AnHeart name or any trademark, trade name, or logo of AnHeart itself; and (ii) if Daiichi Sankyo terminates this Agreement in its entirety pursuant to Section 10.2.2, upon Daiichi Sankyo's request, AnHeart shall engage in good faith negotiation regarding the commercial terms and consideration for an exclusive royalty-bearing license, with the right to sublicense for Daiichi Sankyo or it designee to use any trademarks specific to the Product(s). It is understood that such license will not include the AnHeart name or any trademark, trade name, or logo of AnHeart itself.

(e) If requested by Daiichi Sankyo, AnHeart shall assign any or all of the sublicense agreements executed by AnHeart under this Agreement to Daiichi Sankyo or its designee to the fullest extent permitted under those agreements. If Daiichi Sankyo does not request such assignment(s), then such sublicense agreements will terminate upon termination of AnHeart's rights with respect to the Licensed Compound and Product(s).

(f) If requested by Daiichi Sankyo, AnHeart shall fully cooperate with Daiichi Sankyo or its designee to facilitate a smooth, orderly and prompt transition of the development and commercialization of Product(s) to Daiichi Sankyo or its designee upon termination. Without limiting the foregoing, and if applicable, AnHeart shall promptly provide Daiichi Sankyo copies of customer lists, customer data and other customer information relating to the Product(s), which Daiichi Sankyo shall have the right to use and disclose for any purpose.

(g) If requested by Daiichi Sankyo, AnHeart shall complete, or shall cause its Affiliate, or its Sublicensee to complete, all work-in-process to manufacture finished Product and will transfer any quantities of the Licensed Compound and finished Product (including work-in-process when finished) in its or its Affiliates' or Sublicensee's possession to Daiichi Sankyo or its designee, for which Daiichi Sankyo shall reimburse AnHeart one hundred percent (100%) of its (or its Affiliate's) cost of goods within **[**Redacted**]** Business Days of such transfer. Daiichi Sankyo will pay all shipping, insurance and customs charges associates with such transfer.

(h) If AnHeart, its Affiliate or Sublicensee is manufacturing Product(s) at the time the termination becomes effective, then AnHeart, its Affiliate or Sublicensee shall continue to manufacture such Product(s) for Daiichi Sankyo, at one hundred percent (100%) of the cost of goods plus a reasonable profit, from the date of notice of such termination until such time as Daiichi Sankyo is able to secure an acceptable alternative commercial manufacturing source, which period shall not exceed **[**Redacted**]** months. If requested by Daiichi Sankyo, AnHeart shall engage in good faith negotiation regarding the commercial terms and consideration for, effective upon termination of this Agreement, a separate agreement to transfer the technology necessary to manufacture the Product(s) for sale in the Territory.

(i) Upon receiving instructions from Daiichi Sankyo, AnHeart shall return, and shall cause its Affiliates and its Sublicensees to return, to Daiichi Sankyo or destroy all relevant records and materials in its possession or control containing Confidential Information of Daiichi Sankyo, provided that AnHeart may keep one copy of such Confidential Information for archival purposes only.

10.5.3. Each Party acknowledges that the other Party's obligations following any termination are subject to, and may be limited by, all Applicable Laws, rules, regulations, or contractual restrictions.

11. Dispute Resolution.

11.1 Between the Parties. In the event of a dispute between the Parties arising out of or related to the terms of this Agreement (except for a dispute stipulated in Section 3.1), either Party may request that the Parties engage in good faith discussions to resolve such dispute. Within **[**Redacted**]** days of such request, each Party will appoint an appropriate representative of such Party to engage in discussions to resolve the dispute in a mutually acceptable manner. Such representative will have a reasonable level of expertise in the subject matter of the dispute and possess the requisite authority to resolve the dispute. If such representatives are unable to resolve the dispute within **[**Redacted**]** days, either Party may provide a written request to submit the dispute for discussions between Executive Officers appointed by the respective Chief Executive Officers of each Party. If the Executive Officers are unable to resolve the dispute within **[**Redacted**]** days after referral, either Party may provide a written request to refer the dispute for arbitration.

11.2 Arbitration. If a dispute has not been resolved by negotiation as provided in Section 11.1, such disputes arising out of or in connection with this Agreement shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by three (3) arbitrators appointed in accordance with the said Rules. The place of the arbitration shall be

New York, New York. The language of the arbitration shall be English. The arbitrators will render their award in writing and, unless all Parties agree otherwise, will include an explanation in reasonable detail of the reasons for their award. Any arbitration award may be entered in and enforced by a court in accordance with Section 12.10. Should such courts for any reason lack jurisdiction, any court with jurisdiction may act in the same fashion. The existence, nature and results of, as well as any documents relating to, any arbitration shall be treated as Confidential Information by the Parties. Each Party shall have the right to seek injunctive or other equitable relief from a court of competent jurisdiction pursuant to Section 12.10 that may be necessary to avoid irreparable harm, maintain the status quo or preserve the subject matter of the arbitration. The arbitrators will, in rendering its decision, apply the substantive law of New York, without regard to its conflict of laws provisions. The decision and/or award rendered by the arbitrators will be final and non-appealable (except for an alleged act of corruption or fraud on the part of the arbitrator).

12. Miscellaneous Provisions.

12.1. Relationship of the Parties. AnHeart and Daiichi Sankyo agree that the relationship between them established by this Agreement is that of independent contractors. The Parties further agree that this Agreement does not, is not intended to, and should not be construed to establish an employment, agency, partnership, joint venture, or any other relationship between them. Except as may be specifically provided herein, neither Party has any right, power or authority, nor may they represent themselves as having any right, power or authority, to assume, create or incur any expense, liability or obligation, express or implied, on behalf of the other Party, or otherwise act as an agent for the other Party for any purpose.

12.2. No Third-Party Beneficiaries. No person or entity other than AnHeart, Daiichi Sankyo and their respective Affiliates, permitted assignees and sublicensees may be deemed an intended beneficiary or have any right to enforce any obligation of this Agreement.

12.3. Assignments Neither Party may assign this Agreement or any of its rights or obligations hereunder to any Affiliate or Third Party without the prior written consent of the other Party including in connection with the transfer, sale or other disposition of all or substantially all of the assets of the assigning Party to which this Agreement relates, whether by merger, sale of stock, sale of assets or otherwise, such consent not to be unreasonably withheld. **[**Redacted**]**. No assignment or transfer of this Agreement is valid or effective unless and until the assignee/transferee agrees in writing to be bound by the provisions of this Agreement. The terms and conditions of this Agreement will be binding on and inure to the benefit of the successors and permitted assigns of the Parties. Any attempted assignment not in accordance with the terms of this Agreement will be void.

12.4. Performance by Affiliates. Either Party may perform its obligations under this Agreement through one or more Affiliates as of the Effective Date without prior approval of the other Party. The Party will nonetheless remain solely responsible for the performance of its obligations under this Agreement by its Affiliate(s) and for any breach of the terms of this Agreement by its Affiliate(s).

12.5. No Implied Waivers; Rights Cumulative. The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement does not constitute a waiver of that right or excuse a similar subsequent failure to perform such term

or condition. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver is effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. No waiver by any Party of any term or condition of this Agreement, in any one or more instances, may be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any future occasion. Except as expressly set forth in this Agreement, all rights and remedies available to a Party, whether under this Agreement or afforded by law or otherwise, are cumulative and not in the alternative to any other rights or remedies that may be available to such Party.

12.6. Severability. If any provision of this Agreement is held to be invalid, illegal or unenforceable under law in any jurisdiction, the Parties will negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions of this Agreement will remain in full force and effect in such jurisdiction and will be liberally construed in order to carry out the intentions of the Parties as nearly as may be possible. A holding of invalidity, illegality or unenforceability of a provision in one jurisdiction will not affect the validity, legality or enforceability of such provision in any other jurisdiction.

12.7. Entire Agreement; Amendments. This Agreement, together with all Exhibits, constitutes the entire agreement between the Parties with respect to the subject matter hereof, and supersedes all previous arrangements, whether written or oral, with respect to the subject matter contained herein. Any amendment or modification to this Agreement must be made in a writing signed by both Parties.

12.8. Force Majeure. Neither Party will be liable to the other Party for failure or delay in performing of any of its obligations under this Agreement for the time and to the extent such failure or delay is caused by: epidemic, earthquake, riot, civil commotion, rebellion, insurrection, invasion, fire, acts of God, war, terrorist acts, strike, storm, flood, or governmental acts or restriction, or other cause that is beyond the reasonable control of the affected Party. The Party affected by such force majeure must provide the other Party with full particulars thereof (including its best estimate of the likely extent and duration of the interference with its activities) as soon as it becomes aware of the same, but in no event more than **[**Redacted**]** Business Days after becoming aware of it. The affected Party will use Commercially Reasonable Efforts to overcome the difficulties created by the force majeure and to resume performance of its obligations as soon as practicable. In such event, the Parties will meet promptly to determine an equitable solution to minimize or accommodate the effects of any such event, including the possibility of terminating this Agreement.

12.9. Governing Law. This Agreement shall be governed by, and any disputes, claims or controversies in connection with this Agreement, including any question regarding its formation, existence, validity, enforceability, performance, interpretation or termination, shall be resolved in accordance with, the laws of the State of New York without regard to its conflict of laws rules.

12.10. Submission to Jurisdiction. Each Party submits to the exclusive jurisdiction of the United States District Court for the Southern District of New York and the Supreme Court of the State of New York, New York County (collectively, the "Courts" xe \t "12.10" ""), for purposes of any action, suit or other proceeding arising out of this Agreement, and except to the

extent it is inconsistent with the other provisions of this Agreement (including obligations hereunder to resolve disputes by binding arbitration), agrees not to raise any objection at any time to the laying or maintaining of the venue of any such action, suit or proceeding in any of such Courts, irrevocably waives any claim that such action, suit or other proceeding has been brought in an inconvenient forum and further irrevocably waives the right to object, with respect to such action, suit or other proceeding, that such Court does not have any jurisdiction over such Party. Each Party may serve on the other Party by sending or delivering a copy of the process to the Party to be served at the address and in the manner provided for giving notices, as provided in Section 12.11. Each Party hereto waives its right to trial of any issue by jury. Nothing in this Section 12.10, however, shall affect the right of any Party to serve legal process in any other manner permitted by law.

12.11. Notices. Any notice, request, delivery, approval or consent required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given if delivered in person, transmitted by e-mail (receipt verified) or by express courier service (signature required) or **[**Redacted**]** days after it was sent by registered letter, return receipt requested (or its equivalent), provided that no postal strike or other disruption is then in effect or comes into effect within **[**Redacted**]** days after such mailing, to the Party to which it is directed at its address or e-mail address shown below or such other address or e-mail address as such Party shall have last given by notice to the other Party.

If to Daiichi Sankyo, addressed to:

Daiichi Sankyo Company, Limited
5-1 Nihonbashi-honcho 3-Chome
Chuo-ku, Tokyo 103-8426 Japan

Attention: **[**Redacted**]**

Telephone: **[**Redacted**]**
Email: **[**Redacted**]**

If to AnHeart, addressed to:

AnHeart Therapeutics Inc.
5 Penn Plaza, 23rd floor
New York, NY 10001

Attention: **[**Redacted**]**
Telephone: **[**Redacted**]**
Email: **[**Redacted**]**

12.12. No Strict Construction. This Agreement has been prepared jointly by the Parties and should not be strictly construed against either Party.

12.13. Interpretation. The captions and headings in this Agreement are for convenience only and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Sections or Exhibits mean those particular Sections and Exhibits to this Agreement and references to this Agreement include all attachments hereto. The definitions of the terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. Unless context otherwise clearly requires, whenever used in this Agreement: (a) the words "include" or "including" shall be construed as incorporating, also, "but not limited to" or "without limitation;" (b) the word "day" or "year" means a calendar day or year unless otherwise specified; (c) the word "notice" means notice in writing (whether or not specifically stated); (d) the words "hereof," "herein," "hereby" and derivative or similar words refer to this Agreement (including any Exhibits); (e) the word "or" shall be construed as the inclusive meaning identified with the phrase "and/or;"; (f) words using the singular or plural number also include the plural or singular number, respectively; (g) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement law, rule or regulation thereof; and (h) the word "country" shall be construed as including administrative region (e.g., Hong Kong) and other quasi-national region as appropriate from the context.

12.14. Counterparts. This Agreement may be executed in any number of counterparts, each of which will be deemed an original, and all of which together, will constitute one and the same.

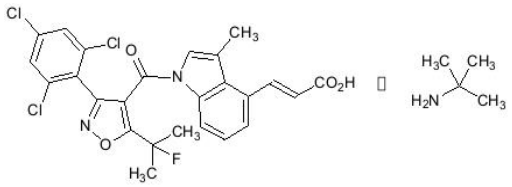
[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, AnHeart and Daiichi Sankyo have caused this Agreement to be executed by their duly authorized representatives as of the date first written above.

DAIICHI SANKYO COMPANY, LIMITED	**ANHEART THERAPEUTICS INC.**
Signature:/s/Sunao Manabe	Signature:/s/Junyuan Wang
Printed Name: Sunao Manabe	Printed Name: Junyuan Wang
Title: President and Chief Executive Officer	Title: Chief Executive Officer

Exhibit A
DS-1001b

The molecular structure of DS-1001b



DS-1001 code number
□ DS-1001a: Free Form
□ DS-1001b: DS-1001a･$C_4H_{11}N$

Nomenclature System: IUPAC

Chemical Name of DS-1001b: Mono(2-methylpropan-2-ammonium) (2E)-3-(1-{[5-(2-fluoropropan-2-yl)-3-(2,4,6-trichlorophenyl)-1,2-oxazol-4-yl]carbonyl}-3-methyl-1H-indol-4-yl)prop-2-enoate

Molecular formula: Molecular weight of DS-1001b: C25H18Cl3FN2O4・C4H11N : 608.92

Correction factor to DS-1001a (free form): 0.8799

Exhibit B
Patent Portfolio

[Redacted**]**

Exhibit C
Existing Clinical Trials

DS1001-A-J101 Phase 1 in Japan
DS1001-A-J201 Phase 2 in Japan

Exhibit D
Existing Stock of Materials

[Redacted**]**

Exhibit E
Non-Clinical Data

[Redacted**]**

Exhibit F
CLINICAL DATA

[Redacted**]**

Exhibit G
Manufacturing Technology

[Redacted**]**

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David Hung, M.D. certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Nuvation Bio, Inc.;

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: May 14, 2024

By: /s/ David Hung, M.D.
David Hung, M.D.
Founder, President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Moses Makunje, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Nuvation Bio, Inc.;

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: May 14, 2024

By: /s/ Moses Makunje
Moses Makunje
VP, Finance
(Principal Financial and Accounting 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 Nuvation Bio, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: May 14, 2024

By: /s/ David Hung, M.D.
David Hung, M.D.
Founder, President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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 Nuvation Bio, Inc. (the "Company"), on Form 10-Q for the period ending March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: May 14, 2024

By: /s/ Moses Makunje
Moses Makunje
VP, Finance
(Principal Financial and Accounting Officer)