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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2023

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38890

Quince Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**90-1024039**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
601 Gateway Boulevard, Suite 1250. South San Francisco, California	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (415) 910-5717

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	QNCX	The Nasdaq Stock Market LLC
Series A Junior Participating Preferred Purchase Rights	N/A	The Nasdaq Stock Market LLC

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, a 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 May 5, 2023, the registrant had 36,269,897 shares of common stock, $0.001 par value per share, outstanding.

Table of Contents

		Page
PART I.	FINANCIAL INFORMATION	
Item 1.	Financial Statements (Unaudited)	1
	Condensed Consolidated Balance Sheets	1
	Condensed Consolidated Statements of Operations and Comprehensive Loss	2
	Condensed Consolidated Statements of Stockholders' Equity	3
	Condensed Consolidated Statements of Cash Flows	4
	Notes to Unaudited Condensed Consolidated Financial Statements	5
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	23
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	31
Item 4.	Controls and Procedures	31
PART II.	OTHER INFORMATION	
Item 1.	Legal Proceedings	32
Item 1A.	Risk Factors	32
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	75
Item 3.	Defaults Upon Senior Securities	75
Item 4.	Mine Safety Disclosures	75
Item 5.	Other Information	75
Item 6.	Exhibits	76
Signatures		76

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	March 31, 2023	December 31, 2022 [1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 46,714	$ 44,579
Short term investments	43,489	45,602
Prepaid expenses and other current assets	2,288	3,567
Total current assets	92,491	93,748
Assets held for sale	105	—
Property and equipment, net	6	393
Operating lease right-of-use assets, net	171	291
Long term investments	475	3,578
Intangible asset	—	5,900
Equity investment in Lighthouse, Inc.	70	—
Total assets	$ 93,318	$ 103,910
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,651	$ 570
Accrued expenses and other current liabilities	1,464	2,499
Total current liabilities	3,115	3,069
Deferred tax liabilities	—	248
Total liabilities	3,115	3,317
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 authorized, no shares issued and outstanding as of March 31, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized, 36,278,433 and 36,136,480 issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	36	36
Additional paid in capital	390,642	389,105
Accumulated other comprehensive income (loss)	38	(289)
Accumulated deficit	(300,513)	(288,259)
Total stockholders' equity	90,203	100,593
Total liabilities and stockholders' equity	$ 93,318	$ 103,910

[1]The balance sheet as of December 31, 2022 is derived from the audited financial statements as of that date.

See accompanying notes.

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

	Three Months Ended March 31,	
	2023	2022
Operating expenses:		
Research and development	$ 3,230	$ 12,757
General and administrative	3,826	9,106
Intangible asset impairment charge	5,900	—
Total operating expenses	12,956	21,863
Loss from operations	(12,956)	(21,863)
Interest income	700	72
Other income (expense), net	(246)	150
Net loss before income tax benefit	(12,502)	(21,641)
Income tax benefit	248	—
Net loss	(12,254)	(21,641)
Other comprehensive income (loss):		
Foreign currency translation adjustments	92	(114)
Unrealized gain (loss) on available for sales securities	235	(313)
Total comprehensive loss	$ (11,927)	$ (22,068)
Net loss per share - basic and diluted	$ (0.34)	$ (0.72)
Weighted average shares of common stock outstanding - basic and diluted	35,855,200	30,134,445

See accompanying notes.

Quince Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(In thousands, except share and per share amounts)

For the three months ended March 31, 2023 and 2022						
	Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Income / (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance January 1, 2023	36,136,480	$ 36	$ 389,105	$ (289)	$ (288,259)	$ 100,593
Issuance of common stock on exercise of stock options and vesting of restricted stock units	141,953	—	56	—	—	56
Stock based compensation	—	—	1,481	—	—	1,481
Foreign currency translation adjustment	—	—	—	92	—	92
Unrealized gain on available for sale investments	—	—	—	235	—	235
Net loss	—	—	—	—	(12,254)	(12,254)
Balance March 31, 2023	36,278,433	$ 36	$ 390,642	$ 38	$ (300,513)	$ 90,203
Balance January 1, 2022	30,074,412	$ 30	$ 355,234	$ (79)	$ (236,599)	$ 118,586
Issuance of common stock in connection with open market sales agreement, net of issuance costs of $19	51,769	—	608	—	—	608
Exercise of stock options	23,389	—	14	—	—	14
Stock based compensation	—	—	9,240	—	—	9,240
Foreign currency translation adjustment	—	—	—	(114)	—	(114)
Unrealized loss on available for sale investments	—	—	—	(313)	—	(313)
Net loss	—	—	—	—	(21,641)	(21,641)
Balance March 31, 2022	30,149,570	$ 30	$ 365,096	$ (506)	$ (258,240)	$ 106,380

See accompanying notes.

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

	For the Three Months Ended March 31,	
	2023	**2022**
Cash flows from operating activities		
Net Loss	$ (12,254)	$ (21,641)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation	1,481	9,240
Depreciation and amortization	17	38
Impairment loss on operating lease	66	—
Loss on disposal of fixed assets	73	—
Equity investment in Lighthouse, Inc.	(70)	—
Non-cash intangible impairment charge	5,900	—
Amortization of (discount) premium on available for sale investments	(139)	135
Change in deferred tax liabilities	(248)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,413	42
Right of use assets and lease liabilities	(45)	—
Other assets	—	165
Accounts payable	1,081	(1,180)
Accrued expenses and other current liabilities	(844)	(2,890)
Net cash used in operating activities	(3,569)	(16,091)
Cash flow from investing activities:		
Purchase of investments	(7,691)	(8,957)
Proceeds from maturities of investments	13,277	22,375
Proceeds from disposal of fixed assets	90	—
Purchase of property and equipment	(136)	(5)
Net cash provided by investing activities	5,540	13,413
Cash flows from financing activities:		
Payments of finance leases	(6)	—
Proceeds from issuance of common stock on exercise of stock options	56	14
Proceeds from issuance of common stock in connection with open market sales agreement, net of issuance costs	—	608
Net cash provided by financing activities	50	622
Effect of exchange rate changes on cash	114	(104)
Net increase (decrease) in cash and cash equivalents	2,135	(2,160)
Cash and cash equivalents at beginning of period	44,579	69,724
Cash and cash equivalents at end of period	$ 46,714	$ 67,564
Supplemental disclosures of non-cash information:		
Right-of-use asset and financing lease liability reduction as a result of lease modification	$ (70)	$ —
Right-of-use asset and operating lease liability reduction as a result of lease modification	$ —	$ (640)

See accompanying notes.

Note 1. Organization

Description of Business

Effective August 1, 2022, Cortexyme Inc. changed its name to Quince Therapeutics, Inc (the "Company"). The Company was incorporated in the State of Delaware in June 2012 and is headquartered in South San Francisco, California. In April 2021, the Company established a wholly owned subsidiary in Australia, Cortexyme Australia, Pty Ltd. The Company is a preclinical stage biopharmaceutical company focused on acquiring, developing, and commercializing innovative therapeutics for patients suffering from debilitating and rare diseases.

From inception, the Company has been focused on novel therapeutic approaches to improve the lives of patients diagnosed with Alzheimer's and other degenerative diseases. The Company, previously named Cortexyme, Inc. ("Cortexyme") was initially founded on the seminal discovery of the presence of Porphyromonas gingivalis ("P. gingivalis"), and its secreted toxic virulence factor proteases, called gingipains, in the relevant brain areas of both Alzheimer's and Parkinson's disease patients.

In May 2022, the Company completed the acquisition of Novosteo, Inc. ("Novosteo"), a Delaware corporation, a privately held biotech focused on targeted therapeutics to treat rare skeletal diseases, bone fractures and injury. The acquisition of Novosteo, Inc. in 2022, and the addition of new executive management has allowed us to strategically shift focus and prioritize the internal development of our innovative bone-targeting drug platform and lead compound NOV004 for development for rare skeletal diseases, bone fractures, and injury. Following the Acquisition, the Company changed the corporate name to Quince Therapeutics, Inc. The Company is actively seeking compelling clinical-stage assets available for in-licensing and acquisition to expand our development pipeline.

On January 30, 2023, the Company provided an update on its development pipeline and business outlook for 2023. The Company intends to prioritize capital resources toward the expansion of its development pipeline through opportunistic in-licensing and acquisition of clinical-stage assets targeting debilitating and rare diseases. The Company plans to out-license its bone-targeting drug platform and precision bone growth molecule NOV004 designed for accelerated fracture repair in patients with bone fractures and osteogenesis imperfecta.

Novosteo, Inc. Acquisition

On May 9, 2022, the Company entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") with Novosteo, Quince Merger Sub I, Inc., a Delaware corporation and a wholly owned subsidiary of the Company, Quince Merger Sub II, LLC, a Delaware limited liability company and a wholly owned subsidiary of Company, Novosteo, and Fortis Advisors LLC, a Delaware limited liability company, solely in its capacity as the securityholders' representative. The transaction closed on May 19, 2022. Pursuant to the terms of the Merger Agreement, at the closing of the Acquisition (the "Acquisition"), each share of capital stock of Novosteo that was issued and outstanding immediately prior to the Effective Time was automatically canceled and converted into the right to receive 0.0911 shares of common stock, par value $0.001 per share, of the Company. The Company issued 5,520,000 shares and assumed 507,108 outstanding Novosteo options after conversion with the awards, retaining the same vesting and other terms and conditions as in effect immediately prior to consummation of the Acquisition.

Pursuant to the Merger Agreement, upon the terms and subject to the conditions set forth therein, Merger Sub I merged with and into Novosteo (the "First Merger"), with Novosteo as the surviving entity in the First Merger (the "First Step Surviving Corporation"). Immediately following the First Merger, the First Step Surviving Corporation merged with and into Merger Sub II, with Merger Sub II surviving the Acquisition. Merger Sub II was renamed Novosteo, LLC and is a wholly-owned single member limited liability corporation. Novosteo, LLC has a wholly owned subsidiary in Australia, Novosteo Pty Ltd.

Sale of Legacy Portfolio

On January 27, 2023, the Company sold its legacy small molecule protease inhibitor portfolio, including COR588, COR388, COR852, and COR803, pursuant to an asset purchase agreement with Lighthouse Pharmaceuticals, Inc., (the "Purchaser") an entity co-founded by Casey Lynch, former chief executive officer of Quince's predecessor company Cortexyme, Inc.

Upon the consummation of the transaction, the Company received shares of common stock of Purchaser ("Common Stock") equal to seven and a half percent (7.5%) of the currently issued and outstanding Common Stock. The issuance is governed by a Stock

Issuance Agreement entered into by the Company and the Purchaser on January 27, 2023 (the "Stock Agreement"). The Stock Agreement contains certain anti-dilution rights and certain transfer restrictions on the Common Stock, including a right of first offer in favor of Purchaser and certain restrictions with respect to non-U.S. persons.

Pursuant to the terms of the asset purchase agreement, the Company is eligible to receive milestone payments up to $150 million on a product by product basis for the achievement of certain regulatory approvals and global net sales thresholds. Additionally, the Company is eligible to receive certain sales-based royalty payments on a product by product basis, ranging from high single-digit to mid-teens of annual net sales related to the two existing clinical stage programs, and low single-digit royalties for the preclinical programs, and certain sublicense income on a product by product basis, either in addition to milestone payments and royalties prior to Phase 2 initiation for COR588 or COR388, or in lieu of milestones payments and royalties after initiation of Phase 2 for COR588 or COR388 or for the preclinical programs.

The Company and the Purchaser have made certain covenants in the asset purchase agreement with respect to the transfer of the assets, including requisite filings to be made with regulatory authorities, and the milestone, royalty and sublicense payments and have agreed to indemnify each other for any breaches of such party's covenants, assumed liabilities (in the case of Purchaser) and retained liabilities, subject to certain customary survival periods and mitigation requirements. In addition, Purchaser granted to the Company an exclusive option until June 30, 2023 to obtain worldwide, royalty-free, fully-paid up, irrevocable and perpetual right and license under the transferred intellectual property related to COR388 to research, develop, manufacture, use, commercialize and otherwise exploit COR388 in any animal health indication.

Liquidity and Capital Resources

The Company has incurred losses and negative cash flows from operations since inception and expects to continue to generate operating losses for the foreseeable future. As of March 31, 2023, the Company had an accumulated deficit of $300.5 million. Since inception through March 31, 2023, the Company has funded operations primarily with the net proceeds from the issuance of convertible promissory notes, from the issuance of redeemable convertible preferred stock, from the net proceeds from the Company's initial public offering (the "IPO"), a private investment in public equity transaction ("PIPE Financing"), and an at-the-market offering under an open market sales agreement. As of March 31, 2023, the Company had cash, cash equivalents, and short-term investments of $90.2 million, which it believes will be sufficient to fund its planned operations for a period of at least 12 months from the date of the issuance of the accompanying unaudited consolidated financial statements. The Company also has long-term investments of $0.5 million.

Management expects to incur additional losses in the future to fund the Company's operations and conduct product research and development and may need to raise additional capital to fully implement its business plan. If the Company is successful in its plan to in-license or acquire at least one clinical stage asset, management anticipates that the Company will need to raise substantial additional capital. The Company may raise additional capital through the issuance of equity securities, debt financings or other sources including out-licensing or partnerships, in order to further implement its business plan. However, if such financing is not available when needed and at adequate levels, the Company will need to reevaluate its operating plan and may be required to delay the development of in-licensed or acquired clinical stage assets if successful.

Note 2. Summary of Significant Accounting Policies

Basis of Consolidation

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

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and pursuant to the instructions of the SEC on Form 10-Q and Article 8 of Regulation S-X of the SEC. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the management's opinion, all adjustments (consisting only of normal recurring adjustments) considered necessary for a fair presentation of the results of operations and cash flows for the periods presented have been included.

The condensed consolidated balance sheet as of March 31, 2023, the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2023 and 2022, the condensed consolidated statements of stockholders' equity for the three months ended March 31, 2023 and 2022, the condensed consolidated statements of cash flows for the three months

ended March 31, 2023 and 2022, and the financial data and other financial information disclosed in the notes to the condensed consolidated financial statements are unaudited. These financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2022 included in the Company's Form 10-K filed with the SEC on March 15, 2023. The results of operations for the three months ended March 31, 2023 are not necessarily indicative of the results to be expected for the year ending December 31, 2023 or for any other future annual or interim period.

Risks and Uncertainties

The Company's future results of operations involve a number of risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of results of clinical trials and reaching milestones, uncertainty of regulatory approval of the Company's potential drug candidates, uncertainty of market acceptance of the Company's drug candidates, competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals and sole source suppliers. The Company's drug candidates will require approvals from the U.S. Food and Drug Administration ("FDA") and comparable foreign regulatory agencies prior to commercial sales in their respective jurisdictions. There can be no assurance that any drug candidate will receive the necessary approvals.

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, and expenses, as well as related disclosure of contingent assets and liabilities. The most significant estimates used in the Company's consolidated financial statements relate to the determination of the fair value of stock-based awards and other issuances, determination of the fair value of identifiable assets and liabilities in connection with the acquisition of Novosteo, Inc., including associated intangible assets and goodwill, accruals for research and development costs, useful lives of long-lived assets, stock-based compensation and related assumptions, the incremental borrowing rate for leases and income tax uncertainties, including a valuation allowance for deferred tax assets, eligibility of expenses for the Australia research and development refundable tax credits, impairment of intangible assets or goodwill; and contingencies. The Company bases its estimates on historical experience and on various other market specific and other relevant assumptions that it believes to be reasonable under 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 could differ materially from the Company's estimates.

Foreign Currency Translation and Transactions

The functional currency of two of the Company's wholly-owned subsidiaries is the Australian Dollar. Its financial results and financial position are translated into U.S. dollars using exchange rates at balance sheet dates for assets and liabilities and using average exchange rates for income and expenses. The resulting translation differences are presented as a separate component of accumulated other comprehensive income (loss), as a separate component of equity.

Foreign currency transactions are translated into the functional currencies using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses, resulting from the settlement of such transactions and from the re-measurement of monetary assets and liabilities denominated in foreign currencies using exchange rates at balance sheet date and non-monetary assets and liabilities using historical exchange rates, are recognized in the condensed consolidated statements of operations and comprehensive loss.

Significant Accounting Policies

There have been no significant changes to the accounting policies during the three months ended March 31, 2023, as compared to the significant accounting policies described in our Annual Report on Form 10-K.

Business Combinations

The Company accounts for business combinations using the acquisition method pursuant to the Financial Accounting Standards Board (the "FASB") Accounting Standards Codification ("ASC") Topic 805. This method requires, among other things, that results of operations of acquired companies are included in the Company's financial results beginning on the respective acquisition dates, and that identifiable assets acquired and liabilities assumed are recognized at fair value as of the acquisition date. Intangible assets acquired in a business combination are recorded at fair value using one of three valuation approaches, the income approach, the market approach or the cost approach. The Company reviewed the three valuation approaches and determined the income approach was the most appropriate model to approximate fair value for the Acquisition. The income approach model requires

assumptions about the timing and amount of future net cash flows, the cost of capital and terminal values from the perspective of a market participant. Any excess of the fair value of consideration transferred (the "Purchase Price") over the fair values of the net assets acquired is recognized as goodwill. The fair value of identifiable assets acquired and liabilities assumed in certain cases may be subject to revision based on the final determination of fair value during a period of time not to exceed 12 months from the acquisition date. Legal costs, due diligence costs, business valuation costs and all other acquisition-related costs are expensed when incurred.

Assets Held for Sale

Assets held for sale represent lab equipment that have met the criteria of "held for sale" accounting, as specified by Accounting Standards Codification ("ASC") 360, "Long-lived Assets." As of March 31, 2023, there were $0.1 million of lab equipment that are recorded as assets held for sale. The effect of suspending depreciation on the equipment held for sale is immaterial to the results of operations. The assets held for sale are being marketed for sale and it is the Company's intention to complete the sales of these assets within the upcoming year.

Intangible Assets

Intangible assets with a definite useful life are amortized on a straight-line basis over the estimated useful life of the related assets. Intangible assets with an indefinite useful life are not amortized. Intangible assets acquired in a business combination or an acquisition that are used in research and development activities (regardless of whether they have an alternative future use) shall be considered indefinite lived until the completion or abandonment of the associated research and development efforts. Intangible assets acquired in a business combination are initially recorded at fair value. During the period that those assets are considered indefinite lived, they shall not be amortized but shall be tested for impairment. Once the research and development efforts are completed or abandoned, the entity shall determine the useful life of the assets. An intangible asset shall be tested for impairment annually and more frequently if events or changes in circumstances indicate that it is more likely than not that the asset is impaired The Company first assesses qualitative factors to determine whether it is more likely than not that the fair value of the intangible asset is less than its carrying amount, If that is the case, the Company performs a quantitative impairment test, and, if the carrying amount of the Company exceeds its fair value, then the Company will recognize an impairment charge for the amount by which its carrying amount exceeds its fair value, not to exceed the carrying amount of the intangible asset. Qualitative factors to be considered include but are not limited to:

- Cost factors such as increases in raw materials, labor, or other costs that have a negative effect on future expected earnings and cash flows
- Legal/regulatory factors or progress and results of clinical trials
- Other relevant entity-specific events such as changes in management, key personnel, strategy, or customers; contemplation of bankruptcy; or litigation that could affect significant inputs used to determine the fair value of the indefinite-lived intangible asset
- Industry and market considerations such as a deterioration in the environment in which an entity operates, an increased competitive environment
- Macroeconomic conditions such as deterioration in general economic conditions, limitations on accessing capital, fluctuations in foreign exchange rates, or other developments in equity and credit markets that could affect significant inputs used to determine the fair value of the indefinite-lived intangible asset

Goodwill

Goodwill represents the excess of the purchase price over the fair value of the net assets acquired as of the acquisition date. Goodwill has an indefinite useful life and is not amortized. The Company reviews its goodwill for impairment at least annually or whenever events or changes in circumstances indicate that the carrying amount of the Company may exceed its fair value. The Company first assesses qualitative factors to determine whether it is more likely than not that the fair value of the Company is less than its carrying amount, including goodwill. If that is the case, the Company performs a quantitative impairment test, and, if the carrying amount of the Company exceeds its fair value, then the Company will recognize an impairment charge for the amount by which its carrying amount exceeds its fair value, not to exceed the carrying amount of the goodwill.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash and cash equivalents. Cash equivalents, which consist of amounts invested in money market funds, are stated at fair value. There are no unrealized gains or losses on the money market funds for the periods presented.

Investments

The Company's marketable securities primarily consist of U.S. Government and corporate debt securities. The Company classifies its marketable securities as available-for-sale and records such assets at estimated fair value in the condensed balance sheets, with unrealized gains and losses, if any, reported as a component of other comprehensive income (loss) within the condensed statements of operations and comprehensive loss and as a separate component of stockholders' equity. The Company classifies marketable securities with remaining maturities greater than one year as current assets because such marketable securities are available to fund the Company's current operations. Realized gains and losses are calculated on the specific identification method and recorded as interest income. There were no realized gains and losses during the periods presented

At each balance sheet date, the Company assesses available-for-sale debt securities in an unrealized loss position to determine whether the unrealized loss or any potential credit losses should be recognized in net income (loss). For available-for-sale debt securities in an unrealized loss position, the Company first assesses whether it intends to sell, or it is more likely than not that it will be required to sell, the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value through net income (loss). For available-for-sale securities that do not meet the aforementioned criteria, the Company evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the severity of the impairment, any changes in interest rates, underlying credit ratings and forecasted recovery, among other factors. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded as an allowance in interest income. There have been no impairment or credit losses recognized during the periods presented.

The Company excludes the applicable accrued interest from both the fair value and amortized costs basis of the Company's available-for-sale securities for the purpose of identifying and measuring an impairment. Accrued interest receivable on available-for-sale securities is recorded within prepaid and other assets on the balance sheets. The Company made an accounting policy election to (1) not measure an allowance for credit loss for accrued interest receivable, and (2) to write-off any uncollectible accrued interest receivable as a reversal of interest income in a timely manner, which the Company considers to be in the period in which it determines the accrued interest will not be collected.

See Note 3 (Fair Value Measurements) for further information.

Fair Value Measurements

The fair value of the Company's financial instruments reflects the amounts that the Company estimates that it would receive in connection with the sale of an asset or pay in connection with the transfer of a liability in an orderly transaction between market participants at the measurement date (exit price). The Company discloses and recognizes the fair value of its assets and liabilities using a hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to valuations based upon unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to valuations based upon unobservable inputs that are significant to the valuation (Level 3 measurements). The guidance establishes three levels of the fair value hierarchy as follows:

Level 1 - Inputs that reflect 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 other than quoted prices that are observable for the assets or liability either directly or indirectly, including inputs in markets that are not considered to be active;

Level 3 - Inputs that are unobservable. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period.

Equity Investments without Readily Determinable Fair Values

Equity investments without readily determinable fair values include ownership rights that either (i) do not meet the definition of in-substance common stock or (ii) do not provide the Company with control or significant influence and these investments do not have readily determinable fair values. Equity investments without readily determinable fair values are recorded at cost, less any impairment, and adjusted for subsequent observable price changes as of the date that an observable transaction takes place and are recorded in other income (expense), net (See Note 4).

Recent Accounting Pronouncements Adopted

Financial Instruments—Credit Losses: In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses* (Topic 326): Measurement of Credit Losses on Financial Instruments which amends the principles around the recognition of credit losses by mandating entities incorporate an estimate of current expected credit losses when determining the value of certain assets. The guidance also amends reporting around allowances for credit losses on available-for-sale marketable securities. In November 2019, the FASB issued ASU 2019-10, Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815) and Leases (Topic 842): Effective Dates, which established that a one-time determination of the effective date for ASU 2016-13 would be based on the Company's SEC reporting status as of November 15, 2019. The Company was a "smaller reporting company" as defined by Item 10 of Regulation S-K, and therefore, ASU 2016-13 is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. This guidance helps to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. To achieve this objective, the amendments in Topic 326 replace the incurred loss impairment methodology in current U.S. GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The Company has adopted the new guidance as of January 1, 2023, and it did not have a material impact on its financial statements and related disclosures.

Recent Accounting Pronouncements Not Yet Adopted

The following are new accounting pronouncements that the Company is evaluating for future impacts on its financial statements:

Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions (ASC 820); In June 2022, the FASB issued ASU No. 2022-03, "*Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions*." This ASU clarifies that a contractual restriction on the sale of equity security should not be considered in measuring the fair value. In addition, the ASU requires specific disclosures related to contractual sale restrictions. The ASU is effective in January 2024 under a prospective approach. Early adoption is permitted. Adoption of this ASU is not expected to have a material impact on the Company's condensed consolidated financial statements.

Note 3. Fair Value Measurements

The Company measures and reports its cash equivalents and investments at fair value.

Money market funds are measured at fair value on a recurring basis using quoted prices and are classified as Level 1. Investments in debt securities are measured at fair value based on inputs other than quoted prices that are derived from observable market data and are classified as Level 2 inputs.

Financial assets and liabilities subject to fair value measurements on a recurring basis and the level of inputs used in such measurements by major security type as of March 31, 2023 and December 31, 2022 are presented in the following tables (in thousands):

	Fair Value Measurements at March 31, 2023			
	Total	**Level 1**	**Level 2**	**Level 3**
Money market funds	$ 15,863	$ 15,863	$ —	$ —
Certificates of Deposit	5,641	—	5,641	—
Corporate notes	7,799	—	7,799	—
Government and agency notes	56,526	—	56,526	—
Municipal notes	400	—	400	—
Total	$ 86,229	$ 15,863	$ 70,366	$ —

	Fair Value Measurements at December 31, 2022			
	Total	**Level 1**	**Level 2**	**Level 3**
Money market funds	$ 10,988	$ 10,988	$ —	$ —
Certificates of Deposit	6,102	—	6,102	—
Repurchase Agreements	9,000	—	9,000	—
Corporate notes	12,411	—	12,411	—
Government and agency notes	50,766	—	50,766	—
Municipal notes	506	—	506	—
Total	$ 89,773	$ 10,988	$ 78,785	$ —

The following table summarizes the available-for-sale securities (in thousands):

	Fair Value Measurements at March 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	$ 15,863	$ —	$ —	$ 15,863
Certificates of Deposit	5,738	—	(97)	5,641
Corporate notes	7,869	—	(70)	7,799
Government and agency notes	56,681	9	(164)	56,526
Municipal notes	400	—	—	400
Total cash equivalents and investments	$ 86,551	$ 9	$ (331)	$ 86,229
Classified as:				
Cash equivalents (original maturities within 90 days)				$ 42,265
Short-term investments (maturities within one year)				43,489
Long-term investments (maturities beyond 1 year)				475
Total				$ 86,229

	Fair Value Measurements at December 31, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	$ 10,988	$ —	$ —	$ 10,988
Certificates of Deposit	6,237	1	(136)	6,102
Repurchase Agreements	9,000	—	—	9,000
Corporate notes	12,575	—	(164)	12,411
Government and agency notes	51,020	4	(258)	50,766
Municipal notes	510	—	(4)	506
Total cash equivalents and investments	$ 90,330	$ 5	$ (562)	$ 89,773
Classified as:				
Cash equivalents (original maturities within 90 days)				$ 40,593
Short-term investments (maturities within one year)				45,602
Long-term investments (maturities beyond 1 year)				3,578
Total cash equivalents and investments				$ 89,773

As of March 31, 2023, the remaining contractual maturities of available-for-sale debt securities was approximately 4 months. There have been no significant realized gains or losses on available-for-sale securities for the periods presented. The Company records its available-for-sale debt securities at fair value, with changes in fair value reported as a component of accumulated other comprehensive income (loss). We periodically assess our investment in available-for-sale securities for impairment losses and credit losses. The amount of credit losses are determined by comparing the difference between the present value of future cash flows expected to be collected on these securities and the amortized cost. Factors considered in assessing credit losses include the position in the capital structure, vintage and amount of collateral, delinquency rates, current credit support, and geographic concentration. There have been no impairment and credit losses related to available-for-sale securities for the three months ended March 31, 2023 and 2022.

The table below summarizes the unrealized losses of the Company's investments in debt securities measured at fair value as of March 31, 2023 (in thousands):

	Less than twelve months		Twelve months or greater		Total	
	Fair value	Gross unrealized loss	Fair value	Gross unrealized loss	Fair value	Gross unrealized loss
Certificates of Deposit	$ 1,133	$ (20)	$ 4,508	$ (76)	$ 5,641	$ (96)
Corporate notes	—	—	7,799	(70)	7,799	(70)
Government and agency notes	16,829	(44)	5,583	(121)	22,412	(165)
Total cash equivalents and investments	$ 17,962	$ (64)	$ 17,890	$ (267)	$ 35,852	$ (331)

The investments are classified as available-for-sale securities. At March 31, 2023 and December 31, 2022, the balance in the Company's accumulated other comprehensive income was comprised primarily of activity related to the Company's available-for-sale securities. There were no realized gains or losses recognized on the sale or maturity of available-for-sale securities for the three months ended March 31, 2023, and as a result, the Company did not reclassify any amounts out of accumulated other comprehensive income for the quarter.

There were no transfers between Levels 1, 2 or 3 for the period presented.

The table below summarizes the contractual maturities of the Company's investments in debt securities measured at fair value as of March 31, 2023 (in thousands):

	Maturities by Period				
	Total	Less Than 1 Year	1-5 Years	6-10 Years	More Than 10 Years
Fair value of debt securities	$ 43,964	$ 43,489	$ 475	$ —	$ —

Note 4. Cash, Cash Equivalents and Investments

The following tables categorize the fair values of cash, cash equivalents, short-term investments and long-term investments measured at fair value on a recurring basis on our balance sheets (in thousands):

	March 31, 2023	December 31, 2022
Cash and cash equivalents:		
Cash	$ 4,449	$ 3,986
Money market funds	15,863	10,988
Repurchase agreements	—	9,000
Government and agency notes	26,402	20,605
Total cash and cash equivalents	$ 46,714	$ 44,579
Short-term investments:		
Certificates of deposit	$ 5,166	$ 5,390
Municipal notes	400	506
Corporate notes	7,799	12,411
Government and agency notes	30,124	27,295
Total short-term investments	$ 43,489	$ 45,602
Long-term investments		
Certificates of deposit	$ 475	712
Government and agency notes	—	2,866
Total long-term investments	$ 475	$ 3,578

Equity investments without readily determinable fair values assessed under the measurement alternative

Equity investments without readily determinable fair value include ownership rights that either (i) do not meet the definition of in-substance common stock or (ii) do not provide the Company with control or significant influence and these investments do not have readily determinable fair values.

During the three months ended March 31, 2023, the Company received approximately $70,000 in equity investments without readily determinable fair values of Lighthouse, Inc. in exchange for the Legacy Assets. As of March 31, 2023, the Company has not recorded any cumulative upward adjustments or cumulative impairments for its equity investments without readily determinable fair values.

Note 5. Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	March 31, 2023	December 31, 2022
Prepaid expenses	$ 304	$ 223
Prepaid insurance	657	977
Prepaid research and development expenses	676	1,088
Australia research and development refundable tax credit	472	1,003
Other current assets	179	276
Total prepaid expenses and other current assets	$ 2,288	$ 3,567

Cortexyme Australia, Pty, Ltd is eligible to obtain a cash refund from the Australian Taxation Office for eligible R&D expenditures under the Australian R&D Tax Incentive Program (the “Australian Tax Incentive”). The Australian Tax Incentive is recognized as a reduction to R&D expense when there is reasonable assurance that the relevant expenditure has been incurred, the amount can be reliably measured and the Australian Tax Incentive will be received. The Company recognized reductions to R&D expense of $0 for the three months ended March 31, 2023 and $0.4 million reductions to R&D expense for the three months ended March 31, 2022.

Novosteo Pty, Ltd is eligible to obtain a cash refund from the Australian Taxation Office for eligible R&D expenditures under the Australian Tax Incentive as well. The Company received a refundable tax credit of $0.5 million in the first quarter of 2023, which reduced prepaid expenses and other current assets by $0.5 million as of March 31, 2023.

Assets Held for Sale

Assets held for sale consist of the following (in thousands):

	March 31, 2023	December 31, 2022
Assets Held for Sale	105	—
Total Assets Held for Sale	$ 105	$ —

In response to the reprioritization of the Company's pipeline following the decision to discontinue internal development of NOV004 and to pursue out-licensing opportunities the Company reclassified the equipment on consignment of $0.1 million to Assets held for sale.

Property and Equipment, Net

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

	March 31, 2023	December 31, 2022
Computer equipment	$ 18	$ 18
Lab equipment	—	415
Finance lease right of use assets	—	124
Leasehold improvement	—	21
Less: accumulated amortization and depreciation	(12)	(185)
Property and equipment, net	$ 6	$ 393

Accrued Expenses and Other Current Liabilities

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

	March 31, 2023	December 31, 2022
Personnel expenses	$ 457	$ 1,130
Professional fees	627	234
Research and development expenses	54	497
Current portion of operating lease liabilities	269	377
Current portion of finance lease liability	—	76
Other	57	185
Total accrued expenses and other current liabilities	$ 1,464	$ 2,499

Below is the severance accrual activity related to a cost reduction program during the period ended March 31, 2023 (in thousands):

	For the Three Months Ended March 31, 2023
Beginning accrued severance	$ —
Incurred during the period	268
Severance paid during the period	(237)
Ending accrued severance	$ 31

In response to the reprioritization of the Company's pipeline following the decision to discontinue internal development of NOV004 and to pursue out-licensing opportunities, the Board approved a cost reduction program to reorganize operations and allow continued support for the needs of the business. Under the cost reduction program, the Company lowered headcount through a reduction in workforce. The Company recognized the severance and related expenses over the requisite employment obligation period. The reduction in force has been completed in April 2023.

Note 6. Leases

Real Estate Operating Leases

In May 2020, the Company entered into a lease agreement to rent space in San Diego, California. The lease agreement is for three years, which commenced August 1, 2020. Total payments under the lease will be $337,000. In June 2022 the Company determined the San Diego facility was no longer required. In June 2022, the Company determined the San Diego facility was no longer required and, as a result of this decision, recorded an impairment loss of approximately $136,000 at that date. The Company paid a security deposit of $29,000 which is included in Prepaid Expenses and Other Current Assets on the March 31, 2023 condensed consolidated balance sheets.

In June 2022, the Company entered into a Sublease Agreement to rent office space in South San Francisco, California. The Sublease agreement commenced on June 18, 2022 and ends on November 30, 2023. The total payments under the term of the lease are expected to be approximately $271,000. The Company paid a security deposit of $17,000 which is included in Prepaid Expenses and Other Current Assets on the March 31, 2023 condensed consolidated balance sheets. At the commencement of the lease, the Company recorded an operating lease right of use asset and liability of $256,000.

In October 2022, the Company entered into a lease agreement to rent space in West Lafayette, Indiana. The lease agreement amended the original lease to transfer liability to the Company due to the Acquisition. The lease agreement is for 15 months, which commenced on October 1, 2022 and ends on December 31, 2023. The total payments under the term of the lease are expected to be approximately $151,000. At the commencement of the lease, the Company recorded an operating lease right of use asset and liability of $145,000.

In December 2022, the Company entered into an amendment to the lease agreement of the rental space in West Lafayette to rent additional space in the same facility under the same terms as its existing facility lease except the terms of payment. Under the

terms of the amendment, the Company will pay rent monthly for the additional space. The Company recorded an operating lease right of use asset and liability of $10,000.

In February 2023, as a result of the decision to discontinue internal development of NOV004 and to pursue out-licensing opportunities, the Company entered into a sublease agreement as the lessor for the majority of the West Lafayette facility. The lease commenced on March 17, 2023 and ends on December 31, 2023. The sublessee paid the Company a security deposit of $6,000 which is included in Accrued expenses and other current liabilities on the March 31, 2023 condensed consolidated balance sheets. Under the terms of the sublease, the Company is entitled to receive a total rental income that is expected to offset rent expense of $57,000. As a result of this decision and the sublease agreement, the Company recorded an impairment loss of approximately $66,000 which is included in Other income (expense), net for the three months ended March 31, 2023 condensed consolidated statement of operations and comprehensive loss.

The Company recognizes lease expense on a straight-line basis over the term of its operating lease. As of March 31, 2023, total future rent expense from all real estate operating leases of $176,000 will be recognized over the remaining term of 8 to 9 months on a straight-line basis over the respective lease period.

Clinical Equipment Financing Lease

As part of the Acquisition, the Company acquired a financing lease for certain lab equipment. The Company recognizes the depreciation expense in research and development expenses in the condensed consolidated statements of operations and comprehensive loss and recognizes expense on a straight-line basis starting when the equipment is placed into service until the end of the remaining contract term of 18 months. Amortization expense of the financing lease right of use asset for the three months ended March 31, 2023 was $3,000.

In February 2023, as a result of the decision to discontinue internal development of NOV004 and to pursue out-licensing opportunities, the Company exercised its purchase option for the financed equipment in order to resell and this equipment is currently held on consignment and is included in Assets held for sale on the March 31, 2023 condensed consolidated balance sheets. As a result of this action, the Company reduced the Finance lease ROU asset and Finance lease liability by approximately $70,000.

Supplemental balance sheet information related to leases as follows (in thousands except lease terms and discount rates):

	March 31, 2023	December 31, 2022
Operating lease right of use asset, net	$ 171	$ 291
Short-term operating lease liability	$ 269	$ 377
Finance lease right of use asset	—	124
Finance lease accumulated amortization	—	(50)
Total finance lease right of use asset, net	$ —	$ 74
Weighted average remaining lease term		
Operating leases	0.6 years	0.9 years
Finance leases	—	1.0 year
Weighted average discount rate		
Operating leases	5.88%	5.71%
Finance leases	—%	4.45%

Year ended December 31,	**Operating Lease**	**Operating Lease**
2023 (excluding the three months ended March 31, 2023)	$ 275	$ 388
Total lease payments	275	388
Less: imputed interest	(6)	(11)
Total remaining lease liability	$ 269	$ 377

Note 7. Stock-Based Compensation

The Company operates three stock plans as of March 31, 2023.

- 2019 Equity Incentive Plan (Quince)
- 2019 Equity Incentive Plan (Novosteo)
- 2022 Inducement Plan (Quince)

2019 Equity Incentive Plan (Quince)

On December 4, 2014, the Company's stockholders approved the 2014 Stock Plan ("2014 Plan"), and on April 25, 2019 amended, restated and re-named the 2014 Plan as the 2019 Equity Incentive Plan (the "Quince 2019 Plan"), which became effective as of May 7, 2019, the day prior to the effectiveness of the registration statement filed in connection with the IPO. The remaining shares available for issuance under the 2014 Plan were added to the shares reserved for issuance under the Quince 2019 Plan.

The Quince 2019 Plan provides for the grant of stock options (including incentive stock options and non-qualified stock options), stock appreciation rights, restricted stock, RSUs, performance units, and performance shares to the Company's employees, directors, and consultants. As of March 31, 2023, the maximum aggregate number of shares that remain available for issuance under the Quince 2019 Plan is 10,036,489 shares of the Company's common stock. In addition, the number of shares available for issuance under the Quince 2019 Plan will be annually increased on the first day of each fiscal years beginning with fiscal 2020, by an amount equal to the least of (i) 2,146,354 shares of common stock; (ii) 4% of the outstanding shares of its common stock as of the last day of its immediately preceding fiscal year; and (iii) such other amount as the Board may determine.

The Quince 2019 Plan may be amended, suspended or terminated by the Board at any time, provided such action does not impair the existing rights of any participant, subject to stockholder approval of any amendment to the Quince 2019 Plan as required by applicable law or listing requirements. Unless sooner terminated by the Board, the Quince 2019 Plan will automatically terminate on April 23, 2029.

As of March 31, 2023, the Company had 4,981,502 shares available for future issuance under the Quince 2019 Plan.

Stock Options

Activity for service-based stock options under the Quince 2019 Plan is as follows:

	Number of Options and Unvested Shares	Weighted Average Exercise Price	Weighted average remaining contractual life (years)	Aggregate intrinsic value
				(In thousands)
Balance at December 31, 2022	**3,319,711**	$ 16.07	4.77	$ 65
Options granted	1,384,958	0.87	—	—
Options exercised	(136,215)	0.41	—	104
Options cancelled / forfeited	(1,154,504)	12.12	—	—
Balance at March 31, 2023	**3,413,950**	$ 11.86	6.74	$ 952
Options vested and expected to vest as of March 31, 2023	3,413,950	11.86	6.74	952
Options exercisable as of March 31, 2023	1,506,826	$ 22.80	3.21	$ 174

For the three months ended March 31, 2023 and 2022 the Company recognized stock-based compensation expense of $774,000 and $7,024,000, respectively, related to options granted to employees and non-employees. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the condensed consolidated statement of operations and comprehensive loss for stock-based compensation arrangements. As of March 31, 2023, total unamortized employee stock-based compensation was $4.3 million, which is expected to be recognized over the remaining estimated vesting period of 2.45 years.

Performance Stock Options ("PSOs")

There was no activity or balance of any PSOs from the 2019 plan for the three months ended March 31, 2023. For the three months ended March 31, 2023 and 2022, the Company recognized stock-based compensation expense of $0 and $2,044,000, respectively, related to these PSOs. As of March 31, 2023 and December 31, 2022, there was no remaining unamortized stock-based compensation related to PSOs.

Restricted Stock Units ("RSUs")

The following table summarizes activity under the Company's RSUs from the Quince 2019 Plan and related information:

	Restricted Stock Units Outstanding	
	Number of Shares	Weighted Average Grant Date Fair Value
Unvested - December 31, 2022	**30,876**	$ 4.30
RSUs granted	—	$ —
RSUs vested	(5,738)	$ 4.30
RSUs cancelled	(19,188)	$ 4.30
Unvested - March 31, 2023	**5,950**	$ 4.30

The fair value of the RSUs is determined on the grant date based on the fair value of the Company's common stock. The fair value of the RSUs is recognized as expense ratably over the vesting period of two years. The total grant date fair value of the RSUs vested during the three months ended March 31, 2023 was $24,700. The aggregate intrinsic value of the shares of the RSUs vested during the three months ended March 31, 2023 was $5,700.

For the three months ended March 31, 2023 and 2022, the Company recognized stock-based compensation expense of $18,000 and $172,000 respectively, related to these RSUs. As of March 31, 2023, total unamortized stock-based compensation related to RSUs was $23,600, which is expected to be recognized over the remaining estimated vesting period of 0.93 years.

2019 Equity Incentive Plan (Novosteo)

On May 19, 2022, in accordance with the term of the Merger Agreement, the Company assumed the 2019 Novosteo, Inc Equity Incentive Plan (the "2019 Novosteo Plan"). The 2019 Novosteo Plan provides for the grant of stock options (including incentive stock options and non-qualified stock options), stock appreciation rights, restricted stock, RSUs, performance units, and performance shares to the Novosteo legacy employees. On the closing date, each outstanding Novosteo stock option granted under Novosteo's equity compensation plans was converted into a corresponding stock option with the number of shares underlying such option and the applicable exercise price adjusted based on the exchange ratio of 0.0911. Each such converted stock option continues to be subject to substantially the same terms and conditions as applied to the corresponding Novosteo stock option prior to the Acquisition. The maximum aggregate number of shares that may be issued under the 2019 Novosteo Plan is 544,985 shares of the Company's common stock.

The 2019 Novosteo Plan may be amended, suspended or terminated by the Board at any time, provided such action does not impair the existing rights of any participant, subject to stockholder approval of any amendment to the 2019 Novosteo Plan as required by applicable law or listing requirements. Unless sooner terminated by the Board, the 2019 Novosteo Plan will automatically terminate on May 20, 2029.

As of March 31, 2023, the Company had 70,644 shares available for future issuance under the 2019 Novosteo Plan.

Activity for service-based stock options under the 2019 Novosteo Plan is as follows:

	Number of Options and Unvested Shares	Weighted Average Exercise Price	Weighted average remaining contractual life (years)	Aggregate intrinsic value
				(In thousands)
Balance at December 31, 2022	**503,105**	$ 0.55	9.23	$ 44
Options granted	—	—	—	—
Options exercised	—	—	—	—
Options cancelled / forfeited	(28,764)	0.55	—	—
Balance at March 31, 2023	**474,341**	$ 0.55	8.76	$ 479
Options vested and expected to vest as of March 31, 2023	474,341	0.55	8.76	479
Options exercisable as of March 31, 2023	118,582	0.55	8.76	120

For the three months ended March 31, 2023 and 2022, the Company recognized stock-based compensation expense of $59,000 and $0, respectively, related to options granted to employees and non-employees for the 2019 Novosteo plan. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the condensed consolidated statement of operations and comprehensive loss for stock-based compensation arrangements. As of March 31, 2023, total unamortized employee stock-based compensation was $0.9 million, which is expected to be recognized over the remaining estimated vesting period of 2.98 years.

On May 19, 2022, in accordance with the term of the Merger Agreement, the Company assumed a number of restricted stock awards ("RSAs") agreements with certain employees. Each outstanding Novosteo RSA was converted into a corresponding RSA with the number of shares underlying such RSA adjusted based on the exchange ratio of 0.0911. Each such converted RSA will continue to be subject to substantially the same terms and conditions as applied to the corresponding Novosteo RSA prior to the Acquisition.

Restricted Stock Awards

	Restricted Stock Awards Outstanding	
	Number of Shares	**Weighted Average Grant Date Fair Value**
Unvested - December 31, 2022	**427,401**	$ 3.30
RSAs granted	—	$ —
RSAs vested	(39,350)	$ 3.30
RSAs cancelled	—	$ —
Unvested - March 31, 2023	**388,051**	$ 3.30

For the three months ended March 31, 2023 and 2022, the Company recognized stock-based compensation expense of $128,000 and $0, respectively, related to restricted stock awards. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the condensed consolidated statement of operations and comprehensive loss for stock-based compensation arrangements. As of March 31, 2023, total unamortized employee stock-based compensation was $1.2 million, which is expected to be recognized over the remaining estimated vesting period of 2.50 years.

2022 Inducement Plan

On May 9, 2022, the Board approved 4,000,000 shares of the Company’s common stock that may be offered or issued under the Quince Therapeutics, Inc. 2022 Inducement Plan (the "2022 Inducement Plan"). The 2022 Inducement Plan was adopted by the independent members of the Board without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules. In accordance with rule awards under those plans may only be made to an employee who has not previously been an employee or member of the Board or of any board of directors of any parent or subsidiary of the Company, or following a bona fide period of non-employment by the Company or a parent or subsidiary, if he or she is granted such award in connection with his or her commencement of employment with the Company or a subsidiary and such grant is an inducement material to his or her entering into employment with the Company or such subsidiary. The terms and conditions of the 2022 Inducement Plan are substantially similar to those of the Quince 2019 Plan.

As of March 31, 2023, the Company had 296,245 shares available for future issuance under the 2022 Inducement Plan.

Activity for service-based stock options under the 2022 Inducement Plan is as follows:

	Number of Options and Unvested Shares	Weighted Average Exercise Price	Weighted average remaining contractual life (years)	Aggregate intrinsic value
				(In thousands)
Balance at December 31, 2022	**3,742,255**	$ 2.98	9.39	—
Options granted	—	—	—	—
Options exercised	—	—	—	—
Options cancelled / forfeited	(38,500)	2.98	—	—
Balance at March 31, 2023	**3,703,755**	$ 2.98	9.14	$ —
Options vested and expected to vest as of March 31, 2023	3,703,755	2.98	9.14	—
Options exercisable as of March 31, 2023	—	—	—	—

For the three months ended March 31, 2023 and 2022, the Company recognized stock-based compensation expense of and $503,000 and $0, respectively, related to options granted to employees and non-employees for the 2022 Inducement Plan. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the condensed consolidated statement of operations and comprehensive for stock-based compensation arrangements. As of March 31, 2023, total unamortized employee stock-based compensation was $6.6 million, which is expected to be recognized over the remaining estimated vesting period of 3.15 years.

Stock-Based Compensation Expense

The following table summarizes employee and non-employee stock-based compensation expense for the three months ended March 31, 2023 and 2022 and the allocation within the condensed consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended March 31,	
	2023	2022
General and administrative expense	$ 1,123	$ 4,431
Research and development expense	358	4,809
Total stock-based compensation	$ 1,481	$ 9,240

Employee Stock Purchase Plan

On April 24, 2019, the Board adopted its 2019 Employee Stock Purchase Plan (“2019 ESPP”), which was subsequently approved by the Company’s stockholders and became effective on May 7, 2019, the day immediately prior to the effectiveness of the registration statement filed in connection with the IPO. The 2019 ESPP is intended to qualify as an “employee stock purchase plan” within the meaning of Section 423 of the Internal Revenue Code (the “Code”) for U.S. employees. In addition, the 2019 ESPP authorizes grants of purchase rights that do not comply with Section 423 of the Code under a separate non-423 component for non-U.S. employees and certain non-U.S. service providers. The Company has reserved 1,494,530 shares of common stock for issuance under the 2019 ESPP. In addition, the number of shares reserved for issuance under the 2019 ESPP will be increased automatically on the first day of each fiscal year for a period of up to ten years, starting with the 2020 fiscal year, by a number equal to the least of: (i) 536,589 shares; (ii) 1% of the shares of common stock outstanding on the last day of the prior fiscal year; or (iii) such lesser number of shares determined by the Board. The 2019 ESPP is expected to be implemented through a series of offerings under which participants are granted purchase rights to purchase shares of the Company’s common stock on specified dates during such offerings. The Company has not yet approved an offering under the 2019 ESPP.

Note 8. Related Party Transactions

David Lamond, Chairperson of the Board was a director and an equity holder in Novosteo, Inc. which Quince acquired on May 19, 2022. The shares of Novosteo, Inc. beneficially owned by Mr. Lamond were automatically canceled and converted into the right to receive shares of Quince common stock in accordance with the terms of the Merger Agreement. The respective boards of directors of Quince and Novosteo have approved the Merger Agreement, and the Novosteo’s stockholders adopted the Merger

Agreement upon recommendation of the Novosteo board of directors. Mr. Lamond was not part of either company's special committees that evaluated the Acquisition and recused himself from board meetings where the Acquisition was discussed.

Philip Low, a former Board member of Quince Therapeutics, Inc., is employed as a professor at Purdue University. The Company rents a lab facility and office space from Purdue Research Foundation, a private, nonprofit foundation of Purdue University. Purdue Research Foundation also owns 154,497 shares of Quince Therapeutics, Inc. and has provided the Company an exclusive worldwide license under certain bone fracture repair and oncology therapeutics related patents and technology developed by the Purdue University and owned by Purdue Research Foundation. In addition, we are required to pay Purdue Research Foundation annual license maintenance fees, development milestones (up to $4.25 million for each licensed product), royalties on the gross receipts of the licensed products (subject to annual minimums), and a share of certain payments that we may receive from our sublicensees.

Dirk Thye, Chief Executive Officer, is an investor in Morphimmune Inc. and Philip Low, a former Board member of Quince Therapeutics, Inc., is a co-founder and Board member of Morphimmune Inc. In the quarter ended March 31, 2023, the Company sold certain lab equipment to Morphimmune Inc. for $80,000 as well as signed a sublease with Morphimmune as the sublessee with total payments of approximately $57,000 for the lease term of March 17, 2023 through December 31, 2023.

Note 9. Income Taxes

The Company has a history of losses and expects to record a loss in 2023. The Company accounts for income taxes under ASC Topic 740 – *Income Taxes*.

A valuation allowance is provided for significant deferred tax assets when it is more likely than not that such assets will not be realized through future operations. Future tax benefits which may arise as a result of these losses have not been recognized in these financial statements, as their realization is determined not likely to occur and accordingly, the Company has maintained a valuation allowance for the future deferred tax assets.

The Company recorded a discrete tax benefit of $0.2 million in the three months ended March 31, 2023 due to the release of valuation allowance in connection with the write down of the in-process research and development ("IPR&D") intangible asset related to NOV004. As a result of the impairment, the Company reversed the Deferred tax liabilities associated with the intangible asset resulting in the tax benefit of $0.2 million as of March 31, 2023.

On August 16, 2022, the President signed into law H.R. 5376 (commonly called the “Inflation Reduction Act of 2022”). The primary tax provisions in the new law include an alternative minimum tax (AMT) on certain large corporations, a tax on stock buybacks and certain energy-related tax credits each of which became effective after December 31, 2022. The provisions of the Inflation Reduction Act are not expected to have a material effect on the Company’s 2023 tax provision and related disclosures. The Company will continue to evaluate changes and revisions of the Inflation Reduction Act of 2022 and its impact on the Company’s financial position, results of operations and cash flows.

Note 10. Net Loss Per Share

The following outstanding potentially dilutive shares have been excluded from the calculation of diluted net loss per share for the period presented due to their anti-dilutive effect:

	March 31,	
	2023	2022
Stock options issued and outstanding	7,592,046	6,223,398
Performance stock options	—	275,000
Restricted stock units	5,950	1,013,500
Restricted stock awards	388,051	—
Total	7,986,047	7,511,898

Note 11. Business Combination

On May 19, 2022, the Company completed the Acquisition. Pursuant to the terms of the Merger Agreement, at the closing of the Acquisition (the “Effective Time”), each share of capital stock of Novosteo (the “Novosteo Capital Stock”) that was issued and outstanding immediately prior to the Effective Time was automatically canceled and converted into the right to receive 0.0911 shares of common stock, par value $0.001 per share, of the Company (the “Company Common Stock”). These shares included options to

purchase an aggregate of 507,108 shares of the Company Common Stock upon conversion of the outstanding Novosteo options based on the Company Option Exchange Ratio (as defined in the Merger Agreement), with the awards retaining the same vesting and other terms and conditions as in effect immediately prior to consummation of the Acquisition. These options, as well as 519,216 unvested restricted shares were concluded to be post-combination expense and were excluded from purchase consideration.

The transaction costs associated with the Acquisition were approximately $1.1 million and were recorded in general and administrative expense. The acquisition date fair value of the consideration transferred for Novosteo was approximately $16,502,587, which consisted of 5,000,784 shares at $3.30 per share.

The Company accounted for the Acquisition as a business combination in accordance with ASC Topic 805, Business Combinations ("ASC 805"). The Company applied the acquisition method, which requires the identifiable assets acquired and liabilities assumed be recorded at fair value with limited exceptions. The following table summarizes the fair values of the identifiable assets acquired and liabilities assumed as of the date of acquisition (in thousands):

	May 19, 2022
Identifiable assets acquired and liabilities assumed:	
Cash and cash equivalents	$ 10,593
Prepaid expenses and other current assets	1,040
ROU asset	124
Property and equipment	279
Intangible assets	5,900
Accounts payable and accrued liabilities	(1,726)
Deferred tax liabilities	(532)
Net assets acquired	$ 15,678
Goodwill	$ 825

The final determination of the fair value of assets and liabilities will be completed within the one-year measurement period as required by ASC 805. The Novosteo, Inc. Acquisition will necessitate the use of this measurement period to adequately analyze and assess the factors used in establishing the fair values of the net assets acquired as of the acquisition date, primarily involving deferred tax liabilities.

The excess of the fair value of purchase consideration over the fair value of net tangible and identifiable intangible assets acquired was recorded as goodwill, which is primarily attributed to the assembled workforce and expanded market opportunities, for which there is no basis for U.S. income tax purposes. Goodwill amounts are not amortized but are rather tested for impairment at least annually, see Note 12 for this assessment. Goodwill is not deductible for tax purposes.

The Intangible asset balance above is attributable to in-process research and development with an indefinite useful life.

The amounts of the Company's revenue and net loss included in the acquirer's condensed consolidated statement of operations and comprehensive loss for the three months ended March 31, 2023 and 2022, and the unaudited pro forma revenue and net loss of the combined entity had the acquisition date been January 1, 2022 are as follows:

	Three Months Ended March 31,	
	2023	2022
Revenue	$ 6	$ —
Net loss	(12,502)	(20,113)

Note 12. Intangible Assets

The intangible asset acquired as a result of the Acquisition consists of IPR&D related to NOV004, the Company's bone targeting molecule designed to accelerate fracture repair. The value of the IPR&D was determined using discounted probable future cash flows.

Significant assumptions used in determining the value of the intellectual property include the timing and costs of clinical trials and NDA approval with respect to NOV004, probability of reaching various phases of development, costs and cost of goods sold, and the risk adjusted discount rate applied to the cash flows.

All intangible assets acquired in a business combination that are used in research and development activities are capitalized as indefinite-lived intangible assets. During the period that those assets are considered indefinite lived, they are not amortized but are tested for impairment. Once the research and development efforts are completed, the asset will be amortized over its remaining useful life. If the research and development efforts are abandoned, the intangible asset will be expensed in that period.

The following table provides details of the carrying amount of our indefinite-lived intangible asset (in thousands):

	March 31, 2023
Unamortized intangible assets:	
In-process research and development	$ 5,900
Impairment charge	(5,900)
Balance as of March 31, 2023	—

In January 2023, the Company decided to abandon internal development of NOV004 and pursue out-licensing opportunities. As a result, several of the assumptions used in determining the initial fair value have changed including discount rate and expected cash flows and thus triggered the need for an interim impairment assessment as required under ASC 350. And so, the Company performed a fair value assessment of the Intellectual Property as of March 31, 2023, and based upon this assessment, the fair value was determined to be significantly below its carrying value and resulted in an asset impairment charge of $5.9 million during the three months ended March 31, 2023.

Goodwill

The excess of the fair value of purchase consideration over the fair value of net tangible and identifiable intangible assets acquired was recorded as goodwill.

There was no amount related to goodwill reflected on the condensed consolidated balance sheet for the Company as of March 31, 2023 and December 31, 2022. In 2022, management performed an impairment evaluation of goodwill after assessing qualitative factors that indicated a possible impairment of goodwill. Under the qualitative assessment, management considers relevant events and circumstances including but not limited to macroeconomic conditions, industry and market considerations, overall Company performance and events directly affecting the Company. It was noted during our assessment that the Company's market capitalization was significantly below its carrying value and a further quantitative analysis was conducted to determine to the extent, if any, the Company's carrying value exceeded its fair value as of September 30, 2022. The quantitative analysis used fair value based on market capitalization adjusted for control premium based on market comparable transactions. This quantitative analysis resulted in the Company's fair value being significantly below its carrying value, resulting in a non-cash goodwill impairment charge of $0.8 million being recorded during the year ended December 31, 2022.

Note 12. Subsequent Events

Rights Plan

On April 5, 2023, the Board declared a dividend of one preferred share purchase right (a “Right”) for each outstanding share of the common stock, par value $0.001 per share (the “Common Shares”), of the Company. The dividend is effective as of April 17, 2023 (the “Record Date”) with respect to stockholders of record on that date. The Rights will also attach to new Common Shares issued after the Record Date. Each Right entitles the registered holder to purchase from the Company one one-thousandth of a share of Series A Junior Participating Preferred Stock, par value $0.001 per share, (the “Preferred Shares”), of the Company at a price of $6.00 per one one-thousandth of a Preferred Share, subject to adjustment. The descriptions and terms of the Rights are set forth in a Rights Agreement, dated as of April 5, 2023 (the “Rights Agreement"), between the Company and American Stock Transfer & Trust Company, LLC. The Rights will expire on April 5, 2024, unless the Rights are earlier redeemed or exchanged by the Company.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with (i) our unaudited condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and (ii) our audited financial statements and related notes and management's discussion and analysis of financial condition and results of operations included in our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the Securities and Exchange Commission (the "SEC"), on March 15, 2023. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to the "Company," "Quince," "we," "us" and "our" refer to Quince Therapeutics, Inc. and "our legacy assets" refer to atuzaginstat (COR388), COR588, COR852, and COR803, collectively.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this quarterly report, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations, adequacy of our cash resources and working capital, and potential acquisitions on in-licensing of new products, are forward-looking statements. These statements 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.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this quarterly report are only predictions. 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 are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this Quarterly Report in Part II, Item 1A -"Risk Factors," and in our Annual Report on Form 10-K for the year ended December 31, 2022 and elsewhere in this Quarterly Report on Form 10-Q and in other filings we make with the SEC from time to time. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking 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. These forward-looking statements speak only as of the date hereof. 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.

Overview

We are a preclinical stage biopharmaceutical company focused on acquiring, developing, and commercializing innovative therapeutics for patients suffering from debilitating and rare diseases. From our inception, we have been focused on novel therapeutic approaches to improve the lives of patients diagnosed with Alzheimer's and other degenerative diseases. Our predecessor company, Cortexyme, Inc. ("Cortexyme") was initially founded on the seminal discovery of the presence of P. gingivalis and its secreted toxic virulence factor proteases, called gingipains, in the relevant brain areas of both Alzheimer's and Parkinson's disease patients. The acquisition of Novosteo, Inc. in 2022, and the addition of new executive management has allowed us to strategically shift focus. We are actively seeking compelling clinical-stage assets available for in-licensing and acquisition to expand our development pipeline.

Business Acquisition

On May 19, 2022, we acquired all of the equity voting interests and completed the acquisition of Novosteo, Inc. ("Novosteo"), a Delaware corporation, pursuant to that certain Agreement and Plan of Merger and Reorganization dated as of May 9, 2022, by and among the Company, Quince Merger Sub I, Inc., a Delaware corporation and a wholly owned subsidiary of the Company, Quince Merger Sub II, LLC, a Delaware limited liability company and a wholly owned subsidiary of Company, Novosteo, and Fortis Advisors LLC, a Delaware limited liability company, solely in its capacity as the securityholders' representative (the "Merger Agreement", and such transaction, the "Acquisition"). To effect this transaction a combination of transactions was executed with the intention of being treated as integrated steps in a single transaction resulting in Novosteo being a wholly owned subsidiary of the Company.

Pursuant to the terms of the Merger Agreement, at the closing of the Acquisition (the "Effective Time"), each share of capital stock of Novosteo that was issued and outstanding immediately prior to the Effective Time was automatically canceled and

converted into the right to receive 0.0911 shares of common stock, par value $0.001 per share. We issued 5,520,000 shares of common stock representing approximately 15.5% of outstanding stock on the completion of the Acquisition. We also assumed 507,108 options to purchase shares of our common stock upon conversion of the outstanding Novosteo options with awards retaining the same vesting and other terms and conditions as in effect immediately prior to consummation of the Acquisition.

In conjunction with the Acquisition, we appointed Novosteo executives Dirk Thye, M.D. as Chief Executive Officer, Dr. Karen Smith, M.D., Ph.D. as Chief Medical Officer and Brendan Hannah as Chief Business Officer. We also appointed Dr. Thye and Phillip S. Low, Ph.D. to our Board of Directors as Class II and Class I directors, respectively.

Effective August 1, 2022, we changed our corporate name to Quince Therapeutics, Inc. and our ticker symbol to "QNCX".

Sale of Legacy Portfolio

On January 27, 2023, we sold our legacy small molecule protease inhibitor portfolio, including COR588, COR388, COR852, and COR803, pursuant to an asset purchase agreement with Lighthouse Pharmaceuticals, Inc., (the "Purchaser") an entity co-founded by Casey Lynch, former chief executive officer of Cortexyme.

Upon the consummation of the transaction, we received shares of common stock of Purchaser (“Common Stock”) equal to seven and a half percent (7.5%) of the currently issued and outstanding Common Stock. The issuance is governed by a Stock Issuance Agreement entered into by us and the Purchaser on January 27, 2023 (the “Stock Agreement”). The Stock Agreement contains certain anti-dilution rights and certain transfer restrictions on the Common Stock, including a right of first offer in favor of Purchaser and certain restrictions with respect to non-U.S. persons.

Pursuant to the terms of the asset purchase agreement, we are eligible to receive milestone payments up to $150 million on a product by product basis for the achievement of certain regulatory approvals and global net sales thresholds. Additionally, we are eligible to receive certain sales-based royalty payments on a product by product basis, ranging from high single-digit to mid-teens of annual net sales related to the two existing clinical stage programs, and low single-digit royalties for the preclinical programs, and certain sublicense income on a product by product basis, either in addition to milestone payments and royalties prior to Phase 2 initiation for COR588 or COR388, or in lieu of milestones payments and royalties after initiation of Phase 2 for COR588 or COR388 or for the preclinical programs.

We and the Purchaser have made certain covenants in the asset purchase agreement with respect to the transfer of the assets, including requisite filings to be made with regulatory authorities, and the milestone, royalty and sublicense payments and have agreed to indemnify each other for any breaches of such party’s covenants, assumed liabilities (in the case of Purchaser) and retained liabilities, subject to certain customary survival periods and mitigation requirements. In addition, Purchaser granted to us an exclusive option until June 30, 2023 to obtain worldwide, royalty-free, fully-paid up, irrevocable and perpetual right and license under the transferred intellectual property related to COR388 to research, develop, manufacture, use, commercialize and otherwise exploit COR388 in any animal health indication.

Out-licensing of NOV004 and Development Pipeline

From our inception, we have been focused on novel therapeutic approaches to improve the lives of patients diagnosed with Alzheimer’s and other degenerative diseases. Our predecessor company, Cortexyme, was initially founded on the seminal discovery of the presence of Porphyromonas gingivalis, or P. gingivalis, and its secreted toxic virulence factor proteases, called gingipains, in the relevant brain areas of both Alzheimer's and Parkinson's disease patients. The acquisition of Novosteo, Inc. in 2022, and the addition of new executive management has allowed us to strategically shift focus and prioritize the internal development of our innovative bone-targeting drug platform and lead compound NOV004 for development for rare skeletal diseases, bone fractures, and injury.

On January 30, 2023, we provided an update on its development pipeline and business outlook for 2023. We intend to prioritize capital resources toward the expansion of our development pipeline through opportunistic in-licensing and acquisition of clinical-stage assets targeting debilitating and rare diseases. We plan to out-license our bone-targeting drug platform and precision bone growth molecule NOV004 designed for accelerated fracture repair in patients with bone fractures and osteogenesis imperfecta.

In April, we adopted a limited duration stockholder rights plan and retained a financial advisor to support and enable the Board and management to review and evaluate strategic alternatives intended to maximize long-term value for the Company’s stockholders.

Corporate Restructuring

We approved the cost reduction program (the "Plan") to align operations with the changes in corporate strategy. Under the Plan, we reduced headcount by approximately 47% through a reduction in its workforce. The reduction in force began in February 2023 and was completed in April 2023.

In connection with the Plan, we estimate that we will incur expenses of approximately $0.4 million, substantially all of which will be cash expenditures relating to severance through April 2023. We may incur other charges, including contract termination costs, retirement of fixed assets and facility-related costs and will record these expenses in the appropriate period as they are determined. These estimates are subject to a number of assumptions, and actual results may differ. We may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with the Plan.

Financial Overview

Since commencing material operations in 2014, we have devoted substantially all of our efforts and financial resources to building our research and development capabilities, establishing our corporate infrastructure and most recently, executing our Phase1a, Phase 1b and Phase 2/3 clinical trials of atuzaginstat (COR388), our Phase I SAD/MAD clinical trial of COR588 and to a lesser extent readying NOV004 for Phase 1 clinical trials. We have sold our legacy small molecule protease inhibitor portfolio and intend to outlicense our NOV004 bone targeting drug. We are focused on acquiring, developing, and commercializing innovative therapeutics for patients suffering from debilitating and rare diseases.

To date, we have not generated any revenue and we have never been profitable. We have incurred net losses since the commencement of our operations. As of March 31, 2023, we had an accumulated deficit of $300.5 million. We incurred a net loss of $12.5 million in the three months ended March 31, 2023. We do not expect to generate product revenue unless and until we obtain marketing approval for and commercialize a drug candidate, and we cannot assure you that we will ever generate significant revenue or profits.

To date, we have financed our operations primarily through the issuance and sale of convertible promissory notes and redeemable convertible preferred stock and common stock. From inception through March 31, 2023, we received net proceeds of approximately $303.8 million from the issuance of redeemable convertible preferred stock, convertible promissory notes and common stock.

On December 23, 2021, we entered into an Open Market Sales Agreement, with Jefferies LLC (the "Sales Agreement"). During the three months ended March 31, 2023 and 2022, we sold zero and 51,769 shares of common stock, respectively, under the Sales Agreement and received net proceeds of $0 and $0.6 million, respectively.

As of March 31, 2023 and December 31, 2022, we had cash, cash equivalents and short-term investments of $90.2 million and $90.2 million, respectively. The balances exclude long-term investments of $0.5 million and $3.6 million as of those same periods. Our cash equivalents, short-term and long-term investments are held in money market funds, certificate of deposits, repurchase agreements, investments in corporate debt securities, municipal debt obligations and government agency obligations.

We believe that our existing cash, cash equivalents and investments will be sufficient to fund our planned operations into at least 2026, but does not include any costs or cash expenditures associated with our in-licensing activities. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

In response to the reprioritization of our pipeline on January 30, 2023, the Board of Directors approved a cost reduction program to align operations with the change in corporate strategy to prioritize capital resources toward the expansion of its development pipeline through opportunistic in-licensing and acquisition of clinical-stage assets targeting debilitating and rare diseases. Under the Plan, we reduced headcount by approximately 47% through a reduction in our workforce. The reduction in force began in February 2023 was completed in April 2023. In connection with the cost reduction program, we estimate that we will incur expenses of approximately $0.4 million, substantially all of which will be cash expenditures relating to severance through April 2023. These estimates are subject to a number of assumptions, and actual results may differ.

We will need substantial additional funding to support our continuing operations and pursue our development strategy. Until such time as we can generate significant revenue from sales of an approved drug, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of our drug candidates or delay our efforts to expand our product pipeline.

Critical Accounting Policies and Significant Judgments and Estimates

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

We believe that the assumptions and estimates associated with accrued research and development expenditures, stock-based compensation, and assumptions regarding intangible asset valuation resulting from the Acquisition have the most significant impact on our condensed consolidated financial statements. Therefore, we consider these to be our critical accounting policies and estimates.

The following critical accounting policies are described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies, Significant Judgments and Use Estimates" in our 2022 Annual Report on Form 10-K and the notes to the unaudited condensed consolidated financial statements included in Part I, Item 1, "Unaudited Financial Statements," of this Quarterly Report on Form 10-Q. We believe that of our critical accounting policies, the following accounting policies are the most critical to fully understanding and evaluating our financial condition and results of operations:

- Research and Development Expenses
- Stock-based Compensation Expenses
- Income Taxes
- Business Combination
- Goodwill
- Identifiable Intangible Assets

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

Components of Results of Operations

Operating Expenses

Research and Development Expenses

Our research and development expenses consist of expenses incurred in connection with the research and development of our research programs. These expenses include payroll and personnel expenses, including stock-based compensation, for our research and product development employees, laboratory supplies, product licenses, consulting costs, contract research, regulatory, quality assurance, preclinical and clinical expenses, allocated rent, facilities costs and depreciation. We expense both internal and external research and development costs as they are incurred. Non-refundable advance payments and deposits for services that will be used or rendered for future research and development activities are recorded as prepaid expenses and recognized as an expense as the related services are performed.

To date, our research and development expenses have supported the advancement of atuzaginstat (COR388) and COR588 and to a lesser extent the clinical and regulatory development of NOV004. We expect our research and development expenses to decrease significantly from current levels until such time as we in-license a new product candidate. Predicting the timing or the costs to in-license a new drug candidate is difficult because of many factors.

In addition, the probability of success of any in-licensed product candidate will depend on numerous factors, including safety, efficacy, competition, manufacturing capability and commercial viability. We will need to determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate's commercial potential.

Because our product candidates have not been in-licensed the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidate or whether, or when, we may achieve profitability.

General and Administrative

General and administrative expenses consist principally of personnel-related costs, including payroll and stock-based compensation, for personnel in executive, finance, human resources, business and corporate development, and other administrative functions, professional fees for legal, consulting, insurance and accounting services, allocated rent and other facilities costs, depreciation, and other general operating expenses not otherwise classified as research and development expenses.

We anticipate that our general and administrative expenses will remain consistent for the remainder of 2023 until we in-license a new drug candidate. We anticipate an increase of our general and administrative expense after potential in-licensing of a drug candidate as the size of our business and research and development operations would need to grow to support additional research and development activities.

Interest Income

Interest and other income, net consists primarily of interest earned on our short-term and long-term investments portfolio.

Results of Operations

Comparison of the three months ended March 31, 2023 to the three months ended March 31, 2022

The following sets forth our results of operations for the three months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31,		Change	
	2023	2022	$	%
Operating expenses:				
Research and development	$ 3,230	$ 12,757	$ (9,527)	(74.7) %
General and administrative	3,826	9,106	(5,280)	(58.0) %
Intangible Asset Impairment charge	5,900	—	5,900	100.0 %
Loss from operations	(12,956)	(21,863)	8,907	(40.7) %
Interest income	700	72	628	872.2 %
Other income (expense), net	(246)	150	(396)	(264.0) %
Net loss before income tax benefit	(12,502)	(21,641)	9,139	(42.2) %
Income tax benefit	248	—	248	100.0 %
Net loss	$ (12,254)	$ (21,641)	9,387	(43.4) %

Research and Development Expenses *(in thousands):*

	Three Months Ended March 31,		Change	
	2023	2022	$	%
Direct research and development expenses:				
Atuzaginstat (COR388)	$ 151	$ 1,118	$ (967)	(86.5) %
COR588	11	2,157	(2,146)	(99.5) %
NOV004	1,608	—	1,608	100.0 %
Other direct research costs	3	837	(834)	(99.6) %
Indirect research and development expenses:				
Personnel related (including stock-based compensation)	1,292	8,303	(7,011)	(84.4) %
Facilities and other research and development expenses	165	342	(177)	(51.8) %
Total research and development expenses	$ 3,230	$ 12,757	$ (9,527)	(74.7) %

Research and development expenses were $3.2 million for the three months ended March 31, 2023, compared to $12.8 million for the three months ended March 31, 2022, a decrease of $9.5 million.

The costs for atuzaginstat (COR388) decreased $1.0 million from the prior year due to conclusion of GAIN trial in the fourth quarter of 2021 and minimal related costs being incurred in the first quarter of 2023. As a result, we experienced a decrease of $0.1 million in clinical trial costs, a $0.5 million decrease in drug manufacturing costs, and a decrease in non-clinical studies and analysis related to the GAIN trial of $0.1 million, and a $0.2 million decrease in consulting expenses related to atuzaginstat (COR388).

Our Phase 1 SAD/MAD testing in healthy volunteers was completed in the second quarter of 2022. As a result, the costs for COR588 decreased $2.1 million from the prior year due to $0.5 million decrease in clinical trial costs and a $0.5 million decrease in drug manufacturing costs, as well as a $1.1 million decrease for non-clinical work supporting COR588.

As we sold our legacy protease inhibitor portfolio including COR388 and COR588 to Lighthouse Pharmaceuticals, Inc. in January 2023, we do not expect any additional expenses related to these legacy assets from the second quarter of 2023 onward.

In the quarter ended March 31, 2023, the costs for NOV004 increased by $1.6 million after the acquisition of Novosteo, Inc. on May 19, 2022, primarily as a result of the increase in drug manufacturing costs as we prepared our compound for Phase 1 clinical trials. Due to the decision made on January 30, 2023 to align with our updated corporate strategy, our NOV004 costs will be minimal for the remainder of 2023.

Other direct research costs decreased $0.8 million primarily due to the winddown of pipeline development of our two arginine gingipain inhibitors, COR788 and COR822, our 3CLpro inhibitor, COR803, COR852 and other preclinical research which were sold to Lighthouse Pharmaceutical in January 2023.

Our personnel related costs decreased by $7.0 million in the first quarter of 2023 as compared to the first quarter of 2022, as a result of a $4.5 million decrease in allocated stock-based compensation costs, a decrease of $0.6 million of severance incurred, and a decrease of $1.9 million related to reduced headcount year over year.

Facilities and other research and development expenses decreased $0.2 million for the three months ended March 31, 2023, as compared to the three months ended March 31, 2022 primarily due to a $0.1 million decrease in allocated rent and facilities expenses and $0.1 million decrease in the purchase of non-clinical supplies as a result of our previously announced cost reduction program initiated in the first quarter of 2023.

General and Administrative Expenses

General and administrative expenses decreased by $5.3 million to $3.8 million for the three months ended March 31, 2023 from $9.1 million for the three months ended March 31, 2022. The decrease in general and administrative expenses is primarily due to a decrease of $4.6 million in personnel related expenses due to a $3.3 million decrease in allocated stock-based compensation expense, a $0.8 million decrease of severance incurred, and a decrease of $0.5 million related to reduced headcount year over year. We also incurred a $0.7 million decrease in corporate insurance expenses and other professional and administrative expense due to our cost reductions efforts announced in the first quarter of 2023 and lower Director & Officers insurance premiums.

Intangible Asset Impairment Charge

As of March 31, 2023, we conducted an impairment analysis of our intangible asset IPR&D that resulted from the purchase of Novosteo, Inc. in May 2022. To determine the extent, if any, by which our IPR&D Intangible Asset was impaired, we conducted a quantitative analysis which resulted in our fair value being significantly below our current carrying value due to the assumptions changing as a result of the decision to hold this asset for sale in January 2023. As a result of the analyses, we recorded a non-cash intangible asset IPR&D impairment charge of $5.9 million for the three months ended March 31, 2023.

Interest Income

Interest income increased by $0.6 million for the three months ended March 31, 2023, as compared to the three months ended March 31, 2022. The increase was due to increased yields on our investment portfolio which were partially offset by decreased average balances.

Other Income/(Expense)

Other income/(expense) decreased by $0.4 million for the three months ended March 31, 2023 primarily due to the impairment loss on the Indiana facility lease and the loss on disposal of fixed assets of $0.2 million and unrealized losses resulting from changes in foreign exchange rates of $0.3 million, offset by the gain on sale related to the Equity investment in Lighthouse, Inc. in exchange for the Legacy Assets of $0.1 million.

Income Tax

We recorded an $0.2 million income tax benefit for the three months ended March 31, 2023 as a result of the quantitative and qualitative analysis that concluded in the NOV004 asset being fully impaired and written off.

Liquidity, Capital Resources and Plan of Operations

We have incurred cumulative net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future. As of March 31, 2023, we had an accumulated deficit of $300.5 million and we had cash, cash equivalents and investments of $90.7 million.

Based on our existing business plan, we believe that our existing cash, cash equivalents and investments will be sufficient to fund our anticipated level of operations into at least 2026, but does not include any costs or cash expenditures associated with in-licensing activities.

Capital Resources

Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures related to NOV004 and general and administrative expenditures. 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.

In January 2023 we successfully out-licensed our legacy protease inhibitors to Lighthouse Pharmaceuticals, Inc. and announced our intention to out-license our current preclinical drug candidate NOV004. We also intend to concentrate our efforts on in-licensing clinical-stage assets targeting debilitating and rare diseases. Accordingly, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of any potential future product candidates or whether, or when, we may achieve profitability.

In the near term, our primary uses of cash will be to fund our operations, including business development activities, and administrative personnel related expenses. Our uses of cash beyond the next 12 months will depend on many factors, including the general economic environment in which we operate and our ability to progress on our out-licensing and in-licensing timelines, which are uncertain.

We may continue to require additional capital to develop our drug candidates and fund operations for the foreseeable future. We may seek to raise capital through private or public equity or debt financings, collaborative or other arrangements with other companies, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. If we are able to in-license or acquire at least one clinical stage asset, we anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the progress, costs, trial design, results of and timing of any potential future trials;
- the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals;
- the number and characteristics of drug candidates that we pursue;
- our need to expand our research and development activities in connection with any assets that we may in-license;
- the costs of acquiring, licensing or investing in businesses, drug candidates and technologies;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to retain management and hire scientific and clinical personnel;

- the effect of competing drugs and drug candidates and other market developments;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing of and success of any collaboration, licensing or other arrangements into which we may enter in the future.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to other rights to our drug candidates in certain territories or indications that we would prefer to develop and commercialize ourselves.

Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide. However, based on our current business plans, we believe that our existing cash, cash equivalents and investments will be sufficient to fund our planned operations through at least 2026, but does not include any costs or cash expenditures associated with our in-licensing activities.

Summary Statement of Cash Flows

Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below (in thousands):

	Three Months Ended March 31,	
	2023	**2022**
Net cash (used in) provided by:		
Operating activities	$ (3,569)	$ (16,091)
Investing activities	5,540	13,413
Financing activities	50	622
Effect of exchange rate changes on cash	114	(104)
Net increase (decrease) in cash and cash equivalents	$ 2,135	$ (2,160)

Operating Activities

Net cash used in operating activities was $3.6 million for the three months ended March 31, 2023. Cash used in operating activities was primarily due to our net loss of $12.3 million for the period, adjusted for $7.1 million of non-cash items, including $1.5 million in stock-based compensation and $5.9 million in impairment loss due to the write down of the IPR&D asset, as well as a net decrease in our current assets of $1.4 million, and a net increase in accounts payable, accrued expenses and other current liabilities of $0.2 million.

Net cash used in operating activities was $16.1 million for the three months ended March 31, 2022. Cash used in operating activities was primarily due to our net loss of $21.6 million for the period, adjusted for $9.4 million of non-cash items, including $9.2 million in stock-based compensation and a net increase in prepaid expenses and other assets of $0.2 million and a net decrease in accounts payable, accrued expenses and other current liabilities of $4.1 million.

Investing Activities

Cash used by investing activities was $5.5 million in the three months ended March 31, 2023, primarily related to the purchase of investments of $7.7 million, and maturities of short-term investments of $13.3 million.

Cash provided by investing activities was $13.4 million in the three months ended March 31, 2022, primarily related to the purchase of investments of $9.0 million, and maturities of short-term investments of $22.4 million.

Financing Activities

Cash provided by financing activities was $0.1 million in the three months ended March 31, 2023, which consisted of net proceeds from the exercise of stock options in the period.

Cash provided by financing activities was $0.6 million in the three months ended March 31, 2022, which consisted of proceeds from the issuance of common stock in connection with the Sales Agreement, net of issuance costs as well as net proceeds from the exercise of options.

Contractual Obligations and Commitments

Except as discussed below, there have been no material changes to our contractual obligations and other commitments as of March 31, 2023, as compared to those disclosed in our Annual Report on Form 10-K.

Our contractual obligations primarily consist of our obligations under non-cancellable operating leases and other purchase obligations.

We enter into contracts in the normal course of business with third party contract organizations for clinical trials, non-clinical studies and testing, manufacturing, and other services and products for operating purposes. The amount and timing of the payments under these contracts varies based upon the timing of the services. We have recorded accrued expense of approximately $0.7 million in our condensed consolidated balance sheet for expenditures incurred by these vendors as of March 31, 2023. Other than our operating lease commitments, we do not have any material non-cancellable future commitments based on existing contracts as of March 31, 2023.

Recent Accounting Pronouncements

Please refer to Note 2 to our unaudited condensed consolidated financial statements appearing under Part 1, Item 1 of this report for a discussion of new accounting standards updates that may impact us.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act, and are not required to provide the information required under this item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act, is recorded, communicated to our management to allow timely decisions regarding required disclosure, summarized and reported within the time periods specified in the SEC's rules and forms. Any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including the Chief Executive Officer and Principal Financial Officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures, as such term is defined under Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of March 31, 2023. Based on that evaluation, the Chief Executive Officer and Principal Financial Officer have concluded that, as of such date, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended March 31, 2023 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.

We are not currently a party to any material legal proceedings.

Item 1A. Risk Factors.

Our operations and financial results are subject to various risks and uncertainties, including those described below that could adversely affect our business, financial condition, results of operations, cash flows and the trading price of our common stock. You should carefully consider the following risks, together with all of the other information in this Quarterly Report on Form 10-Q, including our financial statements and the related notes included elsewhere in this Quarterly Report on Form 10-Q.

Summary of Risk Factors

We may be unable for many reasons, including those that are beyond our control, to implement our business strategy successfully. The occurrence of any single risk or any combination of risks could materially and adversely affect our business, financial condition, results of operations, cash flows and the trading price of our common stock. Some of these risks are:

- The impact and results of our previously announced strategic direction are uncertain and may not be successful.
- We have no drug candidates approved for commercial sale, we have never generated any revenue from sales, and we may never be profitable.
- We may require additional capital, and our existing stockholders may experience additional equity dilution, to fund our pursuit and consummation of the acquisition of one or more clinical-stage assets targeting debilitating and rare diseases.
- We may experience difficulties integrating Quince and Novosteo's operations and realizing the expected benefits of the Acquisition, or any potential acquisition of new assets that we may pursue.
- If we are unable to successfully out-license our bone targeting assets, our business could materially suffer.
- Because the potential rare disease target patient populations of NOV004 are small, and the addressable patient population even smaller, we may not be able to successfully out-license this asset.
- Clinical drug development is a lengthy, expensive and uncertain process. The results of preclinical studies and early clinical trials are not always predictive of future results. Any drug candidate that we may advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval.
- We may not be successful in our efforts to acquire new drug candidates or to develop commercially successful drugs. If we fail to successfully identify and develop drug candidates, we may not be able to continue our operations.
- We are a preclinical stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate the prospects for our future viability.
- We will require substantial additional funding to finance our operations and evaluate future drug candidates. If we are unable to raise this funding when needed or on acceptable terms, we may be forced to delay, reduce or eliminate our drug development programs or other operations.
- We cannot be certain that the FDA or foreign regulatory authorities will permit us to proceed with any future proposed clinical trial designs. Our potential drug candidates may not receive regulatory approval, and without regulatory approval we will not be able to market our drug candidates.
- Clinical failure can occur at any stage of clinical development, and we have never conducted a Phase 3 trial or submitted an NDA before.
- If any future clinical trials of our potential drug candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce positive results, or are put on clinical holds imposed by the FDA or similar regulatory authorities outside the United States, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our potential drug candidates.

- We have in the past and may in the future rely on third parties to conduct some of our preclinical studies and clinical trials and some aspects of our research and preclinical testing and on third-party contract manufacturing organizations to manufacture and supply our preclinical and clinical materials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research, manufacturing or testing.
- If we or any of our third-party manufacturers encounter difficulties in production of our future drug candidates, or fail to meet rigorously enforced regulatory standards, our ability to provide supply of our future drug candidates for clinical trials or for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.
- If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any drug candidates we may develop, we may not be successful in commercializing those drug candidates if and when they are approved.
- If we are unable to obtain and maintain sufficient intellectual property protection for our current drug candidates, any future drug candidates, and other proprietary technology we develop, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize drug candidates similar or identical to ours, and our ability to successfully commercialize our current drug candidate, if approved, any future drug candidates, and other proprietary technologies if approved, may be adversely affected.

We have marked with an asterisk (*) those risks described below that reflect substantive changes from, or additions to, the risks described in our Annual Report on Form 10-K for the year ended December 31, 2022.

Risks Relating to Our Evaluation of Strategic Alternatives and Our Business

The impact and results of our previously announced strategic direction are uncertain and may not be successful.

As announced in January 2023, we intend to prioritize capital resources toward the expansion of our development pipeline through opportunistic in-licensing and acquisition of clinical-stage assets targeting debilitating and rare diseases. Since that time, our management has been actively engaged in identifying and evaluating numerous biopharmaceutical assets for their potential fit with our corporate objectives.

Our Board remains dedicated to diligently deliberating upon and making informed decisions that the directors believe are in the best interests of the company and its shareholders. There can be no assurance, however, that our current strategic direction, or the Board's evaluation of strategic alternatives, will result in any initiatives, agreements, transactions or plans that will enhance shareholder value.

We have no drug candidates approved for commercial sale, we have never generated any revenue from sales, and we may never be profitable.

We have no drug candidates approved for sale and none in development, have never generated any revenue from sales, have never been profitable and do not expect to be profitable in the foreseeable future. We have incurred net losses in each year since our inception. For the years ended December 31, 2022 and 2021, our net losses were $51.7 million and $89.9 million, respectively. We had an accumulated deficit of $300.5 million as of March 31, 2023.

Before we are able to generate any revenue, we will need to commit substantial funds to in-license or acquire new drug candidates, then continue development of any drug candidates, and we may not be able to obtain sufficient funds on acceptable terms, if at all. Any additional debt financing or additional equity that we raise may contain terms that are not favorable to us and/or result in dilution to our stockholders.

We expect that it will be several years, if ever, before we may have a potential drug candidate ready for commercialization. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we pursue our current strategic direction, and seek regulatory approvals for any potential drug candidates, prepare for and begin the commercialization of any approved drug candidates, and add infrastructure and personnel to support our drug development efforts and operations as a public company. We anticipate that any such losses could be significant for the next several years. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Further, these net losses have fluctuated significantly in the past and are expected to continue to significantly fluctuate from quarter-to-quarter or year-to-year. To become and remain profitable, we must develop and eventually commercialize a drug with significant revenue.

We may never succeed in developing a commercial drug. On January 25, 2022, the FDA placed a full clinical hold on the IND for atuzaginstat (COR388), one of our assets that has since been out-licensed. The FDA may place additional clinical holds on our current or currently contemplated clinical programs or otherwise limit our ability to proceed with other clinical programs in our pipeline, which will harm our business, financial condition, results of operations and may force us to cease our operations.

We expect to explore partnership and licensing opportunities to support the future development of NOV004, our bone targeting molecule designed to accelerate fracture repair, but we may not be able to find a suitable partner. See also the risk factor titled "*Because the potential rare disease target patient populations of NOV004 are small, and the addressable patient population even smaller, we may not be able to successfully identify potential patients to out-license this asset.*" We may also encounter other unforeseen expenses, difficulties, complications, delays and other known and unknown challenges as we pursue our current strategic direction.

There are numerous risks and uncertainties, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to generate revenues or achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we will continue to incur substantial research and development and other expenditures to develop and market additional drug candidates.

We may require additional capital, and our existing stockholders may experience additional equity dilution, to fund our pursuit and consummation of the acquisition of one or more clinical-stage assets targeting debilitating and rare diseases.

The pursuit of our strategy to acquire one or more clinical-stage assets targeting debilitating and rare diseases involves significant management time, effort and associated expense, and if such assets are identified, will require us to incur significant additional expenses to consummate. Moreover, we expect to require substantial additional funding to finance such acquisitions and to advance the development and optimize the commercialization of such assets, and there can be no assurance that such additional funding will be available on terms that are acceptable to us, or at all. If adequate funds are not available on a timely basis, we may not be able to effectively implement our strategic plan.

We may seek to raise any necessary funds through public or private equity offerings, debt financings or strategic alliances and licensing arrangements. We currently have an effective universal shelf registration statement pursuant to which we may offer and sell any combination of the securities described in the registration statement from time to time. We may not be able to obtain additional financing on terms favorable to us, if at all. General market conditions may make it very difficult for us to seek financing from the capital markets.

Our acquisition strategy involves numerous risks and uncertainties, including intense competition for suitable acquisition targets, which could increase valuations or adversely affect our ability to consummate deals on favorable or acceptable terms, the potential unavailability of financial resources necessary to consummate acquisitions in the future, the risk that we improperly value and price a target, the inability to identify all of the risks and liabilities inherent in a target company notwithstanding our due diligence efforts, the diversion of management's attention from the operations of our business and strain on our existing personnel, increased leverage due to additional debt financing that may be required to complete an acquisition, dilution of our stockholder's net current book value per share if we issue additional equity securities to finance an acquisition, difficulties in identifying suitable acquisition targets or in completing any transactions identified on sufficiently favorable terms and the need to obtain regulatory or other governmental approvals that may be necessary to complete acquisitions.

We may experience difficulties integrating Quince and Novosteo's operations and realizing the expected benefits of the Acquisition, or any potential acquisition of new assets that we may pursue.

On May 19, 2022, we completed our previously announced Acquisition, and our new business strategy anticipated additional acquisition of one or more clinical-stage assets targeting debilitating and rare diseases. The anticipated benefits we expect from the Acquisition or any future acquisitions will depend in part on our ability to realize the expected operational efficiencies and associated cost synergies and anticipated business opportunities and growth prospects from combining new businesses in an efficient and effective manner. We may not be able to fully realize the operational efficiencies and associated cost synergies or leverage the potential business opportunities and growth prospects to the extent anticipated or at all.

Challenges associated with the integration may include those related to retaining and motivating executives and other key employees, blending corporate cultures, eliminating duplicative operations, and making necessary modifications to internal control over financial reporting and other policies and procedures in accordance with applicable laws.

Our management may face significant challenges in consolidating the operations of potential new businesses, integrating the technologies, procedures, and policies. Some of these factors are outside our control, and any of them could delay or increase the cost of our integration or out-licensing efforts.

The integration process could take longer than anticipated and could result in the loss of key employees, the disruption of each company's ongoing businesses, increased tax costs, inefficiencies, and inconsistencies in standards, controls, information technology systems, policies and procedures, any of which could adversely affect our ability to maintain relationships with employees or third parties, or our ability to achieve the anticipated benefits of the transaction, and could harm our financial performance. If we are unable to successfully integrate certain aspects of the new operations or experience delays, we may incur unanticipated liabilities and be unable to fully realize the potential benefit of future revenue and other anticipated benefits resulting from the arrangement, and our business, results of operations and financial condition could be adversely affected.

Our stockholders may realize little or no value from the divestiture of our legacy assets or potential out-license of NOV004, and as a result our stock price may decline, we could be subject to litigation, and our business may be adversely affected.

We have recently sold our legacy small molecule protease inhibitor portfolio to Lighthouse Pharmaceuticals, which is a newly organized, private development stage company in the start-up phase, and has only recently commenced its operations. There is currently no existing public market for the shares of Lighthouse Pharmaceuticals' common stock, and there can be no assurance that an active public market will ever develop. The absence of an active public market for these securities would make it difficult for us to sell the shares of Lighthouse Pharmaceuticals' common stock and realize any value from them. To date, Lighthouse's operations have been primarily limited to organizing and staffing its company and completing the acquisition of our legacy assets. Accordingly, it is difficult if not impossible to predict Lighthouse's future performance or to evaluate its business and prospects, or ability to develop our legacy assets. For these and other reasons, our stockholders may realize little or no value from the divestiture of our legacy assets.

The divestiture of our legacy assets or recently announced change in our corporate strategy, including potential partnership or licensing of NOV004, could result in litigation against us, including litigation arising from or related to the value, received in the sale of our legacy assets to Lighthouse. For example, some of our investors purchased shares of our common stock because they were interested in the opportunities presented by our small molecule protease inhibitor portfolio, others because they were interested in our bone-targeting drug platform. Thus, certain stockholders may attribute substantial financial value to our legacy assets or NOV004. If our stockholders believe that the financial value which is or may be received by us or them from the divestiture of our assets is inadequate, our stock price may decline and litigation may occur. As a result of these and other factors, we may be exposed to a number of risks, including declines or fluctuations in our stock price, additional legal fees, and distractions to our management caused by activities undertaken in connection with resolving any disputes related to these transactions. The occurrence of any one or more of the above could have an adverse impact on our business and financial condition.

Our future results could suffer if we do not effectively manage our operations.

In connection with our new strategic pursuits, we may expand our size and operations through acquisitions or other strategic transactions. Our future success depends, in part, upon our ability to manage such expanded business, which may pose substantial challenges for management, including challenges related to the management and monitoring of new operations and associated increased costs and complexity. There can be no assurances that we will be successful or that we will realize the expected synergies and other benefits anticipated from any future acquisitions or strategic transactions that we may undertake in the future.

Our financial results have been in the past and may in the future be adversely by impairment charges from the recording of goodwill and intangible assets.*

Our financial results have been in the past and may in the future be adversely affected by impairment charges from the recording of goodwill and intangible assets incurred in connection with acquisitions. For example, we incurred a $0.8 million goodwill impairment charge in the quarter ended September 30, 2022 and a $5.9 million IPR&D Intangible Asset impairment charge for the quarter ended March 31, 2023 in connection with the Novosteo Acquisition. Further, our failure to identify or accurately assess the magnitude of necessary technology investments we assumed as a result of the Novosteo Acquisition could result in unexpected litigation or regulatory exposure, unfavorable accounting charges, a loss of anticipated tax benefits or other adverse effects on our business, operating results or financial condition.

The success of our business depends in part on our ability to successfully acquire or in-license new product candidates.

The success of our business depends in part on our ability to successfully acquire or in-license new product candidates. Our acquisition and in-licensing efforts focus on identifying assets in development by third parties across a diverse range of therapeutic

areas that, in our view, are underserved or undervalued. We may decide to proceed with the development of a product candidate and later determine that the more costly and time intensive trials do not support the initial value the product candidate was thought to hold. Even if a product candidate does prove to be valuable, its value may be less than anticipated at the time of investment. We may also face competition for attractive investment opportunities. A number of entities compete with us for such opportunities, many of which have considerably greater financial and technical resources. If we are unable to identify a sufficient number of such product candidates, or if the product candidates that we identify do not prove to be as valuable as anticipated, we will not be able to generate returns and implement our investment strategy and our business and results of operations may suffer materially.

If we fail to properly evaluate potential acquisitions, in-licenses, investments or other transactions associated with the creation of new research and development programs or the maintenance of existing ones, we might not achieve the anticipated benefits of any such transaction.

We have developed our innovative bone-targeting drug platform and lead compound NOV004 for development for rare skeletal diseases, bone fractures, and injury. NOV004 is a systemically administered bone anabolic peptide engineered to target and concentrate at bone fracture sites. We are actively exploring partnership and licensing opportunities, including out-licenses, for our now suspended development program related to NOV004. We face significant competition in our pursuit of these opportunities, and any arrangements will likely be complex and time-consuming to negotiate and document. If we are unable to identify suitable partners for our indications or if we are required to enter into agreements with such partners on unfavorable terms, our business and prospects could materially suffer.

Risks Related to Our Business and the Development of Our Drug Candidates

If we are unable to successfully out-license our bone targeting assets, our business could materially suffer.*

We have developed our innovative bone-targeting drug platform and lead compound NOV004 for development for rare skeletal diseases, bone fractures, and injury. NOV004 is a systemically administered bone anabolic peptide engineered to target and concentrate at bone fracture sites. Currently, we intend to explore partnership and licensing opportunities to support the future development of NOV004. However, we may not be able to identify suitable partners. If we are unable to identify suitable partners for our indications or if we are required to enter into agreements with such partners on unfavorable terms, our business and prospects could materially suffer.

Because the potential rare disease target patient populations of NOV004 are small, and the addressable patient population even smaller, we may not be able to successfully out-license this asset.

NOV004 is a precision bone growth molecule for rare disease. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with NOV004, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, or patient foundations, and may prove to be incorrect or contain errors. New studies have in the past and may continue to change the estimated incidence or prevalence of these diseases. We cannot accurately predict the number of patients for whom treatment might be possible. Additionally, since the potentially addressable patient population for this product candidates is limited, even if we successfully license these assets, and our partners obtain commercial approval, they may not be able to achieve significant market share for NOV004. Because the potential target populations are very small, we may not realize any significant return from the potential sale of this asset.

Clinical drug development is a lengthy, expensive and uncertain process. The results of preclinical studies and early clinical trials are not always predictive of future results. Any drug candidate that we may advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval.

The research and development of drugs is extremely risky. Only a small percentage of drug candidates that enter the development process ever receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain.

The results of preclinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidate may not be further developed or have favorable results in later studies or trials. Clinical trial failure may result from a multitude of factors including, but not limited to, flaws in study design, dose selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing. A number of companies in the pharmaceutical industry have suffered setbacks in the advancement of their drug candidates into later-stage clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding results in earlier preclinical studies or clinical

trials. In addition, data obtained from preclinical trials and clinical trials are susceptible to varying interpretations, and regulatory authorities may not interpret our data as favorably as we do, which may further delay, limit or prevent development efforts, clinical trials or marketing approval. Furthermore, as more competing drug candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change.

If we are unable to complete preclinical studies or clinical trials of any future drug candidates, due to safety or efficacy concerns, or if the results of these trials are not sufficient to convince regulatory authorities of their safety or efficacy, we will not be able to obtain marketing approval for commercialization on a timely basis or at all. Even if we are able to obtain marketing approval for our current and any future drug candidates, those approvals may be for indications or dose levels that deviate from our desired approach or may contain other limitations that would adversely affect our ability to generate revenue from sales of those drug candidates. Moreover, if we are not able to differentiate our drug candidate against other approved drug candidates within the same class of drugs, or if any of the other circumstances described above occur, our business would be harmed and our ability to generate revenue from that class of drugs would be severely impaired.

We may not be successful in our efforts to acquire new drug candidates or to develop commercially successful drugs. If we fail to successfully identify and develop drug candidates, we may not be able to continue our operations.

Our strategy is to identify and pursue clinical development of drug candidates. Identifying, developing, obtaining regulatory approval and commercializing drug candidates will require substantial additional funding and is prone to the risks of failure inherent in drug development. We cannot provide you any assurance that we will be able to successfully identify or acquire drug candidates, advance any drug candidates through the development process, successfully commercialize any such drug candidates, if approved, or assemble sufficient resources to identify, acquire, develop or, if approved, commercialize drug candidates. If we are unable to successfully identify, acquire, develop and commercialize drug candidates, we may not be able to continue our operations.

We will incur additional costs and may experience delays in completing, or ultimately be unable to complete, the development and commercialization of our potential drug candidates.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our potential drug candidates, including:

- regulatory authorities, institutional review boards ("IRBs") or ethics committees ("ECs") may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or we may fail to reach a consensus with regulatory authorities on trial design;
- regulatory authorities in jurisdictions in which we seek to conduct clinical trials may differ from each other on our trial design, and it may be difficult or impossible to satisfy all such authorities with one approach;
- we may not be able to generate sufficient preclinical data to support clinical development for potential drug candidates;
- we may require preclinical studies or manufacturing of drug supplies for our potential drug candidates, which may delay our timeline for the clinical development for our potential drug candidates;
- we may experience delays in reaching a consensus with regulatory agencies on preclinical and clinical study design;
- we may not be able to obtain appropriate or sufficient test agents or preclinical animal models in connection with the indications out potential drug candidates are meant to address;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different contract research organizations ("CROs") and trial sites;
- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulatory authorities may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate;
- enrollment in our clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- changes to clinical trial protocols;

- our third-party contractors, including clinical investigators, contract manufacturers and vendors may fail to comply with applicable regulatory requirements, lose their licenses or permits, or otherwise fail, or lose the ability to, meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of our drug candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulatory authorities or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our drug candidates may be greater than we anticipate, and we may lack adequate funding to continue one or more clinical trials;
- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate;
- our drug candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulatory authorities or institutional review boards to suspend or terminate the trials;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies; and
- the occurrence of natural disasters, such as earthquakes, tsunamis, power shortages or outages, floods, or monsoons, public health crises, such as pandemics and epidemics, political crisis, such as terrorism, war, political instability or other conflict, cyberattacks, or other events outside of our control occurring at or around our clinical trials sites in the United States, Australia or Europe.

Preclinical studies and clinical trials are expensive and time consuming, additional or unsuccessful clinical trials could cause our clinical development activities to be delayed or otherwise adversely affected.

The risk of failure is high for any potential drug candidates we may acquire that are in clinical and preclinical development. The clinical trials and manufacturing of our potential drug candidates are, and the manufacturing and marketing of our potential drug candidates, if approved, will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our drug candidates. Before obtaining regulatory approvals for the commercial sale of any of our potential drug candidates, we must demonstrate thorough lengthy, complex and expensive preclinical testing and clinical trials that our potential drug candidates are both safe and effective for use in each target indication. We may not be able to develop a trial design that the FDA and other foreign regulatory authorities can accept. Each potential drug candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical trials are expensive and can take many years to complete, and their outcomes are inherently uncertain. We cannot guarantee that any future clinical trials will be conducted as planned or completed on schedule, if at all. Failure can occur at any time during the clinical trial process. Even if any future clinical trials are completed as planned, we cannot be certain that their results will support the safety and effectiveness of our potential product candidates for their targeted indications or support continued clinical development of such product candidates. Our ongoing and any future clinical trial results may not be successful.

In addition, even if such trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our potential drug candidates for approval. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our potential drug candidates.

If we are required to conduct preclinical studies, clinical trials or other testing of our potential drug candidates beyond those that we currently contemplate, if we are unable to successfully complete preclinical studies, clinical trials of our potential drug candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our potential drug candidates;
- not obtain marketing approval at all;
- obtain approval for indications, dosages 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, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the medicine removed from the market after obtaining marketing approval.

Drug development costs will also increase if we experience delays in testing or in obtaining marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be amended or will be completed on schedule, or at all. Significant preclinical studies and clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our potential drug candidates, could allow our competitors to bring drug candidates to market before we do, and could impair our ability to successfully commercialize our potential drug candidates, if approved, any of which may harm our business and results of operations. In addition, many of the factors that cause, or lead to a delay in the commencement or completion of, clinical trials may also ultimately lead to termination or suspension of a clinical trial. Any of these occurrences may harm our business, financial condition and prospects significantly. Any termination of any clinical trial of our potential drug candidates will harm our commercial prospects and our ability to generate revenues.

Risks Relating Our Financial Position

We are a preclinical stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate the prospects for our future viability.

From our inception, we have been focused on novel therapeutic approaches to improve the lives of patients diagnosed with Alzheimer's and other degenerative diseases. After the Acquisition in 2022, we shifted our operational focus on the development of our bone-targeting drug platform and lead compound NOV004 for development for rare skeletal diseases, bone fractures, and injury. In January 2023, we made a strategic decision to out-license our bone-targeting drug platform and prioritize capital resources toward the expansion of our development pipeline through opportunistic in-licensing and acquisition of other clinical-stage assets targeting debilitating and rare diseases. We have a limited operating history, which may make it difficult to evaluate the success of our business to date and assess our future viability. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. To date, we have only initiated one late stage clinical trial, and have not obtained marketing approval for any drug candidate, manufactured a commercial scale drug candidate, arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful drug candidate commercialization. Our short operating history as a company makes any assessment of our future success and viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to overcome such risks and difficulties successfully. If we do not address these risks and difficulties successfully, our business will suffer.

We will require substantial additional funding to finance our operations and evaluate future drug candidates. If we are unable to raise this funding when needed or on acceptable terms, we may be forced to delay, reduce or eliminate our drug development programs or other operations.

Since our inception, we have used substantial amounts of cash to fund our operations, and we expect our expenses to increase substantially in the foreseeable future in connection with our ongoing activities, particularly as we evaluate potential drug candidates. In addition, if we obtain marketing approval for any future drug candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution.

Accordingly, we will need to obtain substantial additional funding in order to fully execute on our corporate strategy. As of March 31, 2023, we had $90.7 million in cash, cash equivalents and investments. Our balance sheet includes publicly-traded corporate debt securities. We may be required to recognize impairments in the value of these investments if the relevant companies are materially adversely effected, become unable to repay debt securities when due, or experience credit rating downgrades, or if the public trading price of these securities decreases.

We believe that our existing capital resources will be sufficient to fund our projected operations through at least 2026, but does not include any costs or cash expenditures associated with our in-licensing activities. However, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may need to raise additional funds sooner than we anticipate if we choose to expand more rapidly than we presently anticipate. The amount and timing of our future funding requirements will depend on many factors, some of which are outside of our control, including but not limited to:

- our ability to successfully identify partnership and licensing opportunities to support the future development of NOV004;

- the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals;
- the number and characteristics of drug candidates that we pursue;
- our ability to manufacture sufficient quantities of our potential drug candidates;
- our need to expand our research and development activities;
- the costs associated with securing and establishing commercialization and manufacturing capabilities;
- the costs of acquiring, licensing or investing in businesses, drug candidates and technologies;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to retain management and hire scientific and clinical personnel;
- the effect of competing drugs and drug candidates and other market developments;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing of and success of any collaboration, licensing or other arrangements into which we may enter in the future.

Additional funding may not be available to us on acceptable terms or at all. Any such funding may result in dilution to stockholders, imposition of debt covenants and repayment obligations, or other restrictions that may affect our business. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to some of our technologies or drug candidates or otherwise agree to terms unfavorable to us. Additionally, while the potential global economic impact and the continuing effects of the COVID-19 pandemic may be difficult to assess or predict, a widespread pandemic could result in significant long-term disruption of global financial markets, which could in the future reduce our ability to access capital and negatively affect our liquidity. In addition, the trading prices for our common stock and other biopharmaceutical companies, as well as the broader equity and debt markets, have been highly volatile as a result of the COVID-19 pandemic and the resulting impact on economic activity.

Unstable market and global economic conditions, including adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions, may have adverse consequences on our business, financial condition and stock price.*

The global credit and financial markets have experienced volatility, including as a result of the COVID-19 pandemic, changes in interest rates, and economic inflation, which has included diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, high inflation, uncertainty about economic stability and changes in unemployment rates. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, acts of terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also continue to adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could heighten market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our royalty aggregator strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. Failure to secure any necessary financing in a timely manner could have a material adverse effect on our growth strategy, financial performance and stock price.

We regularly maintain cash balances at third-party financial institutions in excess of the FDIC insurance limit. Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

Risks Relating to Regulatory Review and Approval of Our Drug Candidates and Other Legal Compliance Matters

We cannot be certain that the FDA or foreign regulatory authorities will permit us to proceed with any future proposed clinical trial designs. Our potential drug candidates may not receive regulatory approval, and without regulatory approval we will not be able to market our drug candidates.

We currently have no drug candidates approved for sale and we cannot guarantee that we will ever have marketable drug candidates. Our ability to generate revenue related to sales, if ever, will depend on the successful development and regulatory approval of our potential product candidates.

The development of a drug candidate and issues relating to its approval and marketing are subject to extensive regulation by the FDA in the United States and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market any potential drug candidates in the United States until we receive approval of a new drug application ("NDA") from the FDA. We have not submitted any marketing applications for a drug candidate.

NDAs must include extensive preclinical and clinical data and supporting information to establish the drug candidate's safety and effectiveness for each desired indication. NDAs must also include significant information regarding the chemistry, manufacturing and controls for the drug. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. The FDA review processes can take years to complete and approval is never guaranteed. If we submit an NDA to the FDA, the FDA must decide whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the FDA. Regulators of other jurisdictions have their own procedures for approval of drug candidates. Even if a drug is approved, the FDA may limit the indications for which the drug may be marketed, require extensive warnings on the drug labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States also have requirements for approval of drug candidates with which we must comply prior to marketing in those countries. Obtaining regulatory approval for marketing of a drug candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays in approvals or rejections of marketing applications in the United States or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of drug development and the emergence of new information regarding our drug candidates or other drug candidates. Also, regulatory approval for any of our drug candidates may be withdrawn.

Clinical failure can occur at any stage of clinical development, and we have never conducted a Phase 3 trial or submitted an NDA before.

The FDA or other foreign regulatory authorities may limit our ability to proceed with potential clinical programs, which could have a materially adverse impact on us. The submission of a successful NDA is a complicated process. As an organization, we have never conducted a registrational clinical trial and have limited experience in preparing, submitting and prosecuting regulatory filings, and have not submitted an NDA. Failure to commence or complete, or delays in, our planned clinical trials would prevent us from or delay us in seeking approval for, and if approved, commercializing our drug candidates, and failure to successfully complete any of these activities in a timely manner for any of our drug candidates could have a material adverse impact on our business and financial performance. The commencement, enrollment and completion of clinical trials can be delayed or suspended for a variety of reasons, including:

- inability to obtain sufficient funds required for a clinical trial;
- inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical holds, other regulatory objections to commencing or continuing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;
- discussions with the FDA or non-U.S. regulators regarding the scope or design of our clinical trials;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indications targeted by our drug candidates;
- inability to obtain approval from IRBs to conduct a clinical trial at their respective sites;
- severe or unexpected drug-related adverse effects experienced by patients, which have resulted and may result in a full or partial clinical hold by the FDA or non-U.S. regulators;
- inability to timely manufacture sufficient quantities of the drug candidate required for a clinical trial;
- difficulty recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our study and competition from other clinical trial programs for the same indications as our drug candidates;
- inability to retain enrolled patients after a clinical trial is underway; and

- enrollment may be delayed or interrupted or patients may drop out of clinical trials due to or the fear of natural disasters, such as earthquakes, tsunamis, power shortages or outages, floods, or monsoons, public health crises, such as pandemics and epidemics, political crisis, such as terrorism, war, political instability or other conflict, cyberattacks, or other events outside of our control occurring at or around our clinical trials sites in the United States or Europe. For example, the coronavirus outbreak may delay or impede enrollment in our clinical trials due to prioritization of hospital resources toward the outbreak, and some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay our ability to release clinical results and could impact our product candidates testing, development and timelines.

In addition, the design of a clinical trial can determine whether its results will support approval of a drug and flaws in the design of a clinical trial may not become apparent until the clinical trial is well-advanced. Changes in regulatory requirements and guidance may also occur and we may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us to resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

In addition, if we are required to conduct additional clinical trials or other preclinical studies of our drug candidates beyond those contemplated, our ability to obtain regulatory approval of these drug candidates and generate revenue from their sales would be similarly harmed.

If any future clinical trials of our potential drug candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce positive results, or are put on clinical holds imposed by the FDA or similar regulatory authorities outside the United States, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our potential drug candidates.

Before obtaining regulatory approvals for the commercial sale of any of our potential drug candidates, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our potential drug candidates are both safe and effective for use in each target indication. Each drug candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies of our potential drug candidates may not be predictive of the results of early-stage or later-stage clinical trials, and results of early clinical trials of our potential drug candidates may not be predictive of the results of later-stage clinical trials. The results of clinical trials in one set of patients or disease indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. This is particularly true in degenerative diseases, where failure rates historically have been higher than in many other disease areas. Most drug candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our drug candidates for approval. Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or other regulatory authorities. The FDA or other regulatory authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected the integrity of the study. The FDA or other regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or other regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of any of our drug candidates. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our drug candidates. Even if regulatory approval is secured for any of our drug candidates, the terms of such approval may limit the scope and use of our drug candidate, which may also limit its commercial potential.

We have in the past and may in the future rely on third parties to conduct some of our preclinical studies and clinical trials and some aspects of our research and preclinical testing and on third-party contract manufacturing organizations to manufacture and supply our preclinical and clinical materials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research, manufacturing or testing.

We rely and expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct some aspects of our research and preclinical testing and our clinical trials. We also rely on third-party contract manufacturing organizations to manufacture and supply our preclinical and clinical materials. Any of these third parties may terminate their engagements with us or be unable to fulfill their contractual obligations. If we need to enter into alternative arrangements, it would delay our future drug development activities.

Our reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with current good clinical practice regulations ("GCP") for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible, reproducible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. We also are required to register any future clinical trials and post the results of completed clinical trials on a government-sponsored database within certain timeframes. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions.

Reliance on third-party manufacturers entails additional risks, such as the possible breach of the manufacturing agreement by the third party, the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us and reliance on the third party for regulatory compliance, quality assurance, safety and related reporting. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for any drug candidates we may develop and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines.

We also expect to rely on other third parties to store and distribute drug supplies for our future clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of any drug candidates we may develop or commercialization of our medicines, producing additional losses and depriving us of potential drug revenue.

If we or any of our third-party manufacturers encounter difficulties in production of our future drug candidates, or fail to meet rigorously enforced regulatory standards, our ability to provide supply of our future drug candidates for clinical trials or for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

The processes involved in manufacturing our potential drug candidates are highly regulated and subject to multiple risks. As drug candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our potential drug candidates to perform differently and affect the results of planned clinical trials or other future clinical trials.

In order to conduct clinical trials of our potential drug candidates, or supply future commercial drug candidates, if approved, we will need to manufacture them in small and large quantities. Our manufacturing partners may be unable to successfully modify or scale-up the manufacturing capacity for any of our drug candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If our manufacturing partners are unable to successfully scale-up the manufacture of our potential drug candidates in sufficient quality and quantity, the development, testing and clinical trials of that drug candidate may be delayed or become infeasible, and regulatory approval or commercial launch of any resulting drug may be delayed or not obtained, which could significantly harm our business. The same risks would apply to our internal manufacturing facilities, should we in the future decide to build internal manufacturing capacity. In addition, building internal manufacturing capacity would carry significant risks in terms of being able to plan, design and execute on a complex project to build manufacturing facilities in a timely and cost-efficient manner.

In addition, the manufacturing process for any potential drug candidates that we may develop is subject to FDA and foreign regulatory requirements, and continuous oversight, and we will need to contract with manufacturers who can meet all applicable FDA and foreign regulatory authority requirements, including complying with current good manufacturing practices ("cGMPs"), on an

ongoing basis. If we or our third-party manufacturers are unable to reliably produce drug candidates in accordance with the requirements of the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such future drug candidates. Even if we obtain regulatory approval for any of our potential drug candidates, there is no assurance that either we or our third party contract manufacturers will be able to manufacture the approved drug in accordance with the requirements of the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the drug, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our drug candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects.

If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any drug candidates we may develop, we may not be successful in commercializing those drug candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing, or distribution of pharmaceutical drug candidates. To achieve commercial success for any approved potential drug candidate for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing, and commercial support infrastructure to sell, or participate in sales activities with collaborators for, some of our potential drug candidates if and when they are approved.

There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, factors that may inhibit our efforts to commercialize any potential drug candidates, if and when approved, whether alone or in collaboration with others:

- our inability to recruit and retain adequate numbers of effective sales, marketing, coverage or reimbursement, customer service, medical affairs, and other support personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future approved drug candidates;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement, and other acceptance by payors;
- the inability to price our drug candidates at a sufficient price point to ensure an adequate and attractive level of profitability;
- the pricing of our products, particularly as compared to alternative treatments;
- availability of alternative effective treatments for indications our therapeutic candidates are intended to treat and the relative risks, benefits and costs of those treatments;
- restricted or closed distribution channels that make it difficult to distribute our drug candidates to segments of the patient population;
- the lack of complementary drug candidates to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive drug candidate lines; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

If the commercial launch of a future drug candidate for which we recruit a sales force and establish marketing and other commercialization 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 commercialization personnel.

If we enter into arrangements with third parties to perform sales, marketing, commercial support, and distribution services, our sales revenue or the profitability of sales revenue may be lower than if we were to market and sell any drug candidates we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize our potential drug candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our drug candidates effectively. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our potential drug candidates if approved in the future.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our drug candidates.

We face an inherent risk of product liability as a result of the clinical testing of our drug candidates and will face an even greater risk when and if we commercialize any drug candidates. For example, we may be sued if our drug candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Product liability claims may be brought against us by participants enrolled in our clinical trials, patients, health care providers or others using, administering or selling our drug candidates. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit testing and commercialization of our drug candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased or interrupted demand for our drug candidates;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- drug recalls, withdrawals or labeling, marketing or promotional restrictions;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any drug candidate; and
- a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of drug candidates we develop, alone or with potential collaborators. Our insurance policies may have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

We may be exposed to a variety of international risks that could materially adversely affect our business.

Our business is subject to risks associated with conducting business internationally. Some of our suppliers and clinical trial centers are located outside of the United States. In particular, we are conducting clinical trial operations in Australia. We may enter into agreements with third parties for the development and commercialization of drug candidates in international markets. International business relationships will subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- differing regulatory requirements for drug approvals internationally;
- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property;
- potential third-party patent rights in countries outside of the United States;

- the potential for so-called “parallel importing,” which is what occurs when a local seller, faced with relatively high local prices, opts to import goods from another jurisdiction with relatively low prices, rather than buying them locally;
- the potential for so-called “parallel exporting,” which is what occurs when a local seller buys goods meant for the locals and sells the goods for a higher price in another country, potentially causing or aggravating supply problems;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, bank failures, or political instability, particularly in non-U.S. economies and markets, including several countries in Europe;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its accounting provisions or its anti-bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries;
- taxes in other countries;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, public health crises, such as pandemics and epidemics, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

Any of these factors could harm our ongoing international clinical operations and supply chain, as well as any future international expansion and operations and, consequently, our business, financial condition, prospects and results of operations.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants, and the loss of such persons could negatively impact the operations of the company.

We may not be able to attract or retain qualified management, finance, scientific and clinical personnel and consultants due to the intense competition for qualified personnel and consultants among biotechnology, pharmaceutical and other businesses or any other circumstances that would cause them no longer to provide their professional services to us in the near future. If we are not able to attract and retain necessary personnel and consultants to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy. In addition, we may need to adjust the size of our workforce as a result of changes to our expectations for our business, which can result in diversion of management attention, disruptions to our business, and related expenses.

In addition, we recently announced a reduction in force, impacting a number of employees. Any further reduction in force may yield unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond the intended reduction in force, the distraction of employees, reduced employee morale and could adversely affect our reputation as an employer, which could make it more difficult for us to hire new employees in the future and increase the risk that we may not achieve the anticipated benefits from the cost reduction program.

Our industry has experienced a high rate of turnover of management personnel in recent years. Potential changes in management could be disruptive to our business and may also result in our loss of unique skills and loss of knowledge about our business. Such turnover may also result in the departure of other existing employees or partners.

Replacing executive officers, key employees and consultants may be difficult and may take an extended period because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize drug candidates successfully. Competition to hire and retain employees and consultants from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel and consultants. Our failure to retain or replace key personnel or consultants could materially harm our business. Additionally, the members of our management team have limited experience managing a public company, interacting with public company investors, and complying with the increasingly complex laws, rules and regulations that specifically govern public companies, which could cause our management to have to expend time and resources helping them become familiar with such requirements. We may lose our ability to implement our business strategy successfully and could be seriously harmed. Any of our executive officers or key employees or consultants may terminate their employment at any time.

We have scientific and clinical advisors and consultants who assist us in formulating our research, development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. Non-compete agreements are not permissible or are limited by law in certain jurisdictions and, even where they are permitted, these individuals typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, our advisors may have arrangements with other companies to assist those companies in developing drug candidates or technologies that may compete with ours.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could significantly harm our business.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with health care fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care 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. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, products liability and directors' and officers' insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions, which could include civil or criminal penalties, private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and any of our potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"). Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we violate HIPAA.

Several foreign jurisdictions, including the European Union (the "EU") its member states, the United Kingdom and Australia, among others, have adopted legislation and regulations that increase or change the requirements governing the collection, use, disclosure and transfer of the personal information of individuals in these jurisdictions. These laws and regulations are complex and change frequently, at times due to changes in political climate, and existing laws and regulations are subject to different and conflicting interpretations, which adds to the complexity of processing personal data from these jurisdictions. These laws have the potential to increase costs of compliance, risks of noncompliance and penalties for noncompliance.

The General Data Protection Regulation ("GDPR") imposes numerous new requirements for the collection, use and disclosure of personal information, including more stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulatory authorities and affected individuals of personal data breaches, extensive new internal privacy governance obligations, and obligations to honor expanded rights of individuals in relation to their personal information (for example, the right to access, correct and delete their data). In addition, the GDPR generally maintains restrictions on cross-border data transfer. The GDPR will increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional potential mechanisms to ensure compliance.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and may have a significant adverse effect on our business and results of operations.*

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of drug candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any drug candidates for which we obtain marketing approval. Among policy makers and payors in the United States and elsewhere, including in the EU, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively the "ACA") substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures will impact the ACA and our business. Other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products that we successfully commercialize or to successfully commercialize our drug candidates, if approved. In addition to the ACA, there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to keep healthcare costs down while expanding individual healthcare benefits. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA 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 unclear how these or similar policy initiatives will impact the ACA and our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011 and subsequent laws, which began in 2013 and, due to subsequent legislative amendments to the statute, will remain in effect until 2032, unless additional Congressional action is taken. New laws may result in additional reductions in Medicare and other healthcare funding, which may adversely affect customer demand and affordability for our drug candidates and, accordingly, the results of our financial operations.

Also, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed drug candidates, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, in July 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, on September 9, 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. Further, the IRA will, among other things (i) allow HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the "negotiated fair price" under the law and (ii) impose rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare & Medicaid Services (CMS) Innovation Center 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. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved drug candidate. Any reduction in reimbursement from Medicare or other government-funded 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 drug candidates, once marketing approval is obtained.

Our ability to successfully commercialize any drugs that we develop depends in part on the extent to which coverage and adequate reimbursement are available from government health administration authorities, private health insurers, and other organizations.

Our ability to successfully commercialize any drugs that we develop depends in part on the extent to which coverage and adequate reimbursement are available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, each individually decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Government authorities currently impose mandatory discounts for certain patient groups, such as Medicare, Medicaid and Veterans Affairs ("VA") hospitals, and may seek to increase such discounts at any time. Future regulation may negatively impact the price of our product candidates, if approved. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage or reimbursement will be available for any drug candidate that we commercialize and, if coverage or reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any drug candidate for which we obtain marketing approval. In order to get coverage and reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. It is possible that a third-party payor may consider our product candidates, once approved, 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, once approved, compared to existing products, pricing of existing products may limit the amount we will be able to charge for our product candidates. once approved. Third-party payors may deny or revoke the reimbursement status of a given drug 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. Because NOV004 is in the early stages of development, we are unable at this time to determine the likely level or method of coverage and reimbursement from third-party payors. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidate for which we obtain marketing approval. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors, and coverage decisions and reimbursement levels 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 may 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.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the medicine is approved by the FDA or other comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but make their determinations independently and may impose additional restrictions. Our inability to promptly obtain and maintain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drug candidates, and our overall financial condition. Further, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

In the EU, coverage and reimbursement status of any drug candidates for which we obtain regulatory approval are provided for by the national laws of EU member states. The requirements may differ across the EU member states. Also, at national level, actions have been taken to enact transparency laws regarding payments between pharmaceutical companies and health care professionals.

If we engage in acquisitions, we will incur a variety of costs and we may never realize the anticipated benefits of such acquisitions.

We are presently engaging in a strategy to acquire businesses, technologies or drug candidates that we believe are a strategic fit with our business. If we do undertake any acquisitions, the process of integrating an acquired business, technology or drug candidate into our business may result in unforeseen operating difficulties and expenditures, including diversion of resources and management's attention from our core business. In addition, we may fail to retain key executives and employees of the companies we acquire, which may reduce the value of the acquisition or give rise to additional integration costs. Future acquisitions could result in additional issuances of equity securities that would dilute the ownership of existing stockholders. Future acquisitions could also result in the incurrence of debt, contingent liabilities or the amortization of expenses related to other intangible assets, any of which could adversely affect our operating results. In addition, we may fail to realize the anticipated benefits of any acquisition.

Interim, top-line and preliminary data from our future 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 top-line data from our future clinical studies, which are 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 top-line 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. Top-line 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, top-line data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical studies.

In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from future 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, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock. Further, others, including regulatory agencies, 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 the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the top-line 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 drug candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Changes in funding for the FDA and other government agencies or other disruptions at these agencies could prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA and other agencies to review and approve new drugs can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may prolong the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Even if we obtain regulatory approval for a potential drug candidate, it will remain subject to extensive ongoing regulatory review and requirements.

If any of our future drug candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive requirements imposed by the FDA and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMPs regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our potential drug candidates will be subject to limitations on the approved indicated uses for which the drug candidate may be marketed and promoted or to the conditions of approval (including the potential for a requirement to implement a Risk Evaluation and Mitigation Strategy) or contain requirements for potentially costly post-marketing testing. We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in drug development or commercialization, or increased costs to assure compliance. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of drug candidates to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. We will have to comply with requirements concerning advertising and promotion for our potential drug candidates. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the drug candidate's approved label. As such, we may not promote our potential drug candidates for indications or uses for which they do not have approval. The holder of an approved NDA must submit new or supplemental applications and obtain approval for certain changes to the approved drug candidate labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our potential drug candidates in general or in specific patient subsets. If original marketing approval was obtained via the accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm clinical benefit for our drug candidates. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a drug, such as adverse events of unanticipated severity or frequency, or problems with the facility where the drug candidate is manufactured, or disagrees with the promotion, marketing or labeling of a drug candidate, such regulatory agency may impose restrictions on that drug candidate or us, including requiring withdrawal of the drug candidate from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning or untitled letters that would result in adverse publicity;
- impose civil or criminal penalties;

- suspend or withdraw regulatory approvals;
- suspend any of our ongoing clinical trials;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree or permanent injunction, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- withdraw regulatory approval;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities;
- seize or detain drug candidates; or
- require a drug candidate recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our drug candidates. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our potential drug candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any future marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population can also result in significant financial penalties.

If we fail to comply with healthcare laws, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Our operations are subject to various federal and state fraud and abuse and other healthcare laws. The laws that may impact our operations include:

- federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, 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 a federal healthcare program, such as the Medicare and Medicaid programs. 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. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- federal civil and criminal false claims laws, including the False Claims Act, and civil monetary penalty laws, which impose criminal and civil penalties, including through civil "qui tam" or "whistleblower" actions, against individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third-party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation;

- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created new federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates and their subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal Physician Payment Sunshine Act, created under the ACA, and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services under the Open Payments Program, information related to payments or other transfers of value made 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 physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial 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 federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require the registration of sales representatives; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities, including compensating physicians with stock or stock options, could, despite our efforts to comply, be subject to challenge under one or more of such laws. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our drug candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

If we or any contract manufacturers and suppliers we engage fail to comply with 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 and any contract manufacturers and suppliers we engage are subject to numerous federal, state, and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation,

handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air, and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and radioactive materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, drug development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our business activities may be subject to the Foreign Corrupt Practices Act ("FCPA") and similar anti-bribery and anti-corruption laws.

Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we may operate, including the U.K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the Securities and Exchange Commission ("SEC") and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our drug candidates in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize potential future drug candidates.

We may consider collaboration arrangements with pharmaceutical or biotechnology companies for the development or commercialization of drug candidates depending on the merits of retaining or divesting some or all commercialization rights. We will face, to the extent that we decide to enter into collaboration agreements, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we so chose to enter into such arrangements. The terms of any collaborations or other arrangements that we may establish may not be favorable to us.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our drug candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their

strategic focus due to the acquisition of competitive drug candidates, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a drug candidate, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, drug candidates that compete directly or indirectly with our drug candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more drug candidates may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or future drug candidates or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future drug candidates;
- collaborators may own or co-own intellectual property covering our drug candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Risks Relating to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our current drug candidates, any future drug candidates, and other proprietary technology we develop, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize drug candidates similar or identical to ours, and our ability to successfully commercialize our current drug candidate, if approved, any future drug candidates, and other proprietary technologies if approved, may be adversely affected.*

Our commercial success will depend in part on obtaining and maintaining a combination of patent protection, trade secret protection and confidentiality agreements to protect the intellectual property related to our current and future drug candidates and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our drug candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States or in many jurisdictions outside of the United States. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the issued patents that we currently own, or in patents that may issue from the applications we currently or may in the future own or license from third parties. Further, if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

Others may have filed, and in the future are likely to file, patent applications covering drug candidates that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition or invalidity proceedings before U.S. or non-U.S. patent offices.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our current or future drug candidates and proprietary technologies and erode or negate any competitive advantage we may have, which could have a material adverse effect on our financial condition and results of operations. For example:

- others may be able to make compounds that are similar to our drug candidates but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by our pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- any patents that we obtain may not provide us with any competitive advantages;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they would significantly harm our business, results of operations and prospects.

We have applied, and we intend to continue applying, for patents covering aspects of our current drug candidates, any future drug candidates, or other proprietary technologies and their uses that we deem appropriate. However, we may not be able to apply for patents on certain aspects of our current or future drug candidates, proprietary technologies and their uses in a timely fashion, at a reasonable cost, in all jurisdictions, or at all, and any potential patent coverage we obtain may not be sufficient to prevent substantial competition. As of March 31, 2023, Novosteo LLC, our wholly owned subsidiary, is the owner of record of one additional pending Patent Cooperation Treaty patent application.

One issued U.S. patent relates to NOV004, with claims directed to NOV004 and related pharmaceutical compounds and use of these compounds in the treatment of bone fractures. Pending U.S. and non-U.S. patent applications relate to NOV004 and related pharmaceutical compounds, pharmaceutical compositions containing these compounds, and methods of using these compounds in the treatment of various indications.

Without patent protection on the composition of matter of our current or future drug candidates, our ability to assert our patents to stop others from using or selling our current or future drug candidates may be limited. Due to the patent laws of a country, or the decisions of a patent examiner in a country, or our own filing strategies, we may not obtain patent coverage for all of our current or future drug candidates or methods involving the use of these candidates in a particular patent application. We plan to pursue divisional patent applications or continuation patent applications in the United States and other countries, where applicable, to obtain claim coverage for inventions which were disclosed but not claimed in a particular parent patent application.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our actual or potential future collaborators will be successful in protecting our current drug candidates, any future drug candidate, and other proprietary technologies and their uses by obtaining, defending, and enforcing patents. These risks and uncertainties include the following:

- the U.S. Patent and Trademark Office, or USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential drug candidates;

- other parties may have designed around our claims or developed technologies that may be related or competitive to our platform, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same compounds, compositions of matter, or methods, or formulations, or by claiming subject matter that could dominate our patent position;
- any successful opposition to any patents owned by or licensed to us could deprive us of rights necessary to prevent others from practicing our technologies or to successfully commercialize any drug candidates that we may develop;
- because patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we or our licensors were the first to file any patent application related to our current drug candidates, any future drug candidates, and other proprietary technologies and their uses;
- an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of applications we may in-license which have an effective filing date before March 16, 2013;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing drug candidates in those countries.

The patent prosecution process is also expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection for such output. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in any of our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. We may also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or feasible. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

We depend on a license agreement with Purdue and termination of this license could result in the loss of significant rights, which would harm our business.

On June 3, 2020, Novosteo entered into a License Agreement with Purdue Research Foundation, as amended on March 21, 2022 and July 22, 2022 (the “Purdue Agreement”). Under the Purdue Agreement, we obtained an exclusive worldwide license under certain bone fracture repair and oncology therapeutics related patents and technology developed by the Purdue University and owned by Purdue Research Foundation to make or have made, use, sell or have sold, and import, and otherwise exploit products that are covered by such patents and technology, including the right to grant and authorize sublicenses, subject to Purdue Research Foundation’s consent. Such exclusive license is subject to certain rights retained by the U.S. government and Purdue Research Foundation.

In addition, we are required to pay Purdue Research Foundation annual license maintenance fee, development milestones (up to $4.25 million for each licensed product), low single digit running royalty on the gross receipts of the licensed products (subject to minimum annual royalty), and a share of certain payments that we may receive from our sublicensees. As a result, it may not be possible for us to develop and manufacture any drug candidates at a cost or in quantities sufficient to make these drugs commercially

viable or to maintain current operating margins. The Purdue Agreement also requires us to bear the cost of the prosecution and maintenance of the licensed patents.

Pursuant to the Purdue Agreement, we are required to use commercially reasonable efforts to develop, manufacture and commercialize the licensed product in accordance with a mutually agreed development timelines and commercialization plan.

If we fail to pay any sum due, miss any milestone timelines or otherwise materially breach the agreement or fail to cure such breach within specified cure period), Purdue has the right to terminate our license, and upon the effective date of such termination, we must cease all activities licensed all rights, data, information, know-how, and material licensed or transferred to us under this license agreement will revert to Purdue and all rights, data, information, know-how, material, records and registrations developed or made by us that relate in whole or in part to the activities contemplated by our amended and restated license agreement with Purdue will be transferred to Purdue. Any uncured, material breach under the license agreement could result in loss in our rights to develop and market NOV004 and experience significant delays in the development or commercialization of NOV004, which could have a material adverse impact on our operations and financial condition and results.

Further, Purdue Research Foundation or any future licensors may not always act in our best interest. If disputes over intellectual property rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, our business, results of operations, financial condition, and prospects may be adversely affected. We may enter into additional licenses in the future and if we fail to comply with obligations under those agreements, we could suffer adverse consequences.

In addition, the United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act, or the Bayh-Dole Act. Under the Bayh-Dole Act, the federal government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” for its own benefit in invention produced with its financial assistance. The Bayh-Dole Act also provides federal agencies with “march-in rights.” March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a “nonexclusive, partially exclusive, or exclusive license” to a “responsible applicant or applicants.” If the patent owner refuses to do so, the government may grant the license itself. We sometimes collaborate with academic institutions to accelerate our preclinical research or development. While it is our policy to avoid engaging our university partners in projects in which there is a risk that federal funds may be commingled, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming, and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court, and we may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

Third parties, including competitors, may infringe, misappropriate or otherwise violate our patents, patents that may issue to us in the future, or the patents of our licensors that are licensed to us. To counter infringement or unauthorized use, we may need to choose to file infringement claims, which can be expensive and time-consuming. We may not be able to prevent, alone or with our licensors, infringement, misappropriation, or other violation of our intellectual property, particularly in countries where the laws may not protect those rights as fully as in the United States. If we choose to go to court to stop another party from using the inventions claimed in any patents we obtain, that individual or company has the right to ask the court to rule that such patents are invalid or should not be enforced against that third party for any number of reasons. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements for patentability, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could include 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, even outside the context of litigation. Similar mechanisms for challenging the validity and enforceability of a patent exist in non-U.S. patent offices and may result in the revocation, cancellation, or amendment of any non-U.S. patents we hold in the future. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents, or those of our licensor’s, invalid. 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 one or more drug candidates. Such a loss of patent protection would have a material adverse impact on our business.

These lawsuits are expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents. In addition, there is a risk that the court will decide that such patents are not valid and that we do not have the right to stop the other party from using the claimed inventions. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other

party's activities do not infringe our rights to such patents. In addition, the U.S. Supreme Court has recently modified some tests used by the USPTO in granting patents over the past 20 years, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood of challenge of any patents we obtain or license.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications, or those of our licensor's. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on 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 or manufacturing partnerships that would help us bring our current and any future drug candidates to market.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. 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.

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. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their drug candidates. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's drug candidate. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents, including those of our licensor's, could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering our drug candidates are invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our drug candidates, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights. If we initiate lawsuits to protect or enforce our patents, or litigate against third party claims, such proceedings would be expensive and would divert the attention of our management and technical personnel.

We may infringe the intellectual property rights of others, which may prevent or delay our drug development efforts and stop us from commercializing or increase the costs of commercializing our drug candidates.

Our success will depend in part on our ability to operate without infringing the intellectual property rights of third parties. We cannot guarantee that our drug candidates, or manufacture or use of our drug candidates, will not infringe third-party patents.

Furthermore, a third party may claim that we or our manufacturing or commercialization collaborators are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our drug candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and scientific personnel. There is a risk that a court would decide that we or our commercialization collaborators are infringing the third party's patents and would order us or our collaborators to stop the activities covered by the patents. In that event, we or our commercialization collaborators may not have a viable way around the patent and may need to halt commercialization of the relevant drug candidate. In addition, there is a risk that a court will order us or our collaborators to pay the other party damages for having violated the other party's patents. If we collaborate with third parties in the development of technology in the future, our collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability. Further, our collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability. In the future, we may agree to indemnify our collaborators against certain intellectual property infringement claims brought by third parties. The pharmaceutical and biotechnology industries have produced a

proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of drug candidates or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform.

Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from out-licensing our legacy assets or commercializing NOV004, or our other drug candidates until the asserted patent expires or is finally held invalid, unenforceable, or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- require us to pay damages to the party whose intellectual property rights we may be found to be infringing, which may include treble damages if we are found to have been willfully infringing such intellectual property;
- require us to pay the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing; and/or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all.

If we are sued for patent infringement, we would need to demonstrate that our drug candidates or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity or unenforceability is difficult.

For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity or enforceability of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid or unenforceable, we may incur substantial monetary damages, encounter significant delays in bringing our drug candidates to market and be precluded from manufacturing or selling our drug candidates.

We do not routinely conduct independent reviews of pending patent applications of and patents issued to third parties. We cannot be certain that others have not filed patent applications for technology covered by our pending applications, or that we were the first to invent the technology, because:

- some patent applications in the United States may be maintained in secrecy until the patents are issued;
- patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived;
- pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our drug candidates or the use of our drug candidates;
- identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims;
- patent applications in the United States are typically not published until 18 months after the priority date; and
- publications in the scientific literature often lag behind actual discoveries.

Furthermore, 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 and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a pending application may be incorrect, which may negatively impact our ability to market our drug

candidates. Further, we may incorrectly determine that our technologies, or drug candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our drug candidates.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours, and others may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our drug candidates and future approved products or impair our competitive position. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing drug candidates. There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our drug candidates. Any such patent application may have priority over our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar inventions prior to our own inventions, resulting in a loss of our U.S. patent position with respect to such inventions. Other countries have similar laws that permit secrecy of patent applications, and may be entitled to priority over our applications in such jurisdictions.

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

We may not identify relevant third-party patents 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 products.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. There can be no assurance that our operations do not, or will not in the future, infringe existing or future third-party patents. Identification of third-party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, 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 application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Patent applications in the United States and elsewhere are typically 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. Certain U.S. applications that will not be filed outside the U.S. can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our products or the use of our products. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products.

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 application may be incorrect. For example, we may incorrectly determine that our products are not covered by a third-party patent 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 United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, including our research programs, product candidates, their respective methods of use, manufacture and formulations

thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on any issued patents and/or pending applications are due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm to pay these fees due to the USPTO and non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. If we license intellectual property, we may have to rely upon our licensors to comply with these requirements and effect payment of these fees with respect to any patents and patent applications that we license. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and drug candidate could be significantly diminished.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. We may also be subject to claims that former employees, or other third parties have an ownership interest in our patents or other intellectual property. In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. 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 rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, and invention assignment agreements with employees, consultants and advisors, to protect our trade secrets and other proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and these agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

In addition, such security measures may not provide adequate protection for our proprietary information, for example, in the case of misappropriation of a trade secret by an employee, consultant, customer or third party with authorized access. Our security

measures may not prevent an employee, consultant or customer from misappropriating our trade secrets and providing them to a competitor, and any recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our drug candidates that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, the criteria for protection of trade secrets can vary among different jurisdictions.

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 United States are less willing or unwilling to protect trade secrets. Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. Trade secrets could over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions.

Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Because from time to time we expect to rely on third parties in the development, manufacture, and distribution of our drug candidates and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets 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. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed.

In the future, we may need to obtain licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

From time to time we may be required to license technology from third parties to further develop or commercialize our drug candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our drug candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of our drug candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

Where we obtain licenses from or collaborate with third parties, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties, or such activities, if controlled by us, may require the input of such third parties. We may also require the cooperation of our licensors and collaborators to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business, in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, including making royalty and milestone payments, and any failure to satisfy those obligations could give our licensor the right to terminate the license.

Termination of a necessary license, or expiration of licensed patents or patent applications, could have a material adverse impact on our business. Our business would suffer if any such licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Furthermore, if any exclusive licenses terminate, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties may gain the freedom to seek regulatory approval of, and to market, drug candidates identical to ours. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor’s rights. In addition, while we cannot currently determine the amount of the royalty obligations, we would be required to pay on sales of future drug candidates, if any, the amounts may be significant. The amount of our future royalty obligations will likely depend on the technology and intellectual property we use in drug candidates that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize drug candidates, we may be unable to achieve or maintain profitability.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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 drug candidates that are similar to ours but that are not covered by the claims of the patents that we own;
- we or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive drug candidates for sale in our major commercial markets;
- we cannot ensure that any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our drug candidates;
- we cannot ensure that any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable drug candidates or will provide us with any competitive advantages;
- we cannot ensure that our commercial activities or drug candidates will not infringe upon the patents of others;
- we cannot ensure that we will be able to successfully commercialize our drug candidates on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications; and
- should any of these events occur, they would significantly harm our business, results of operations and prospects.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. 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, in-license needed technology or other product candidates, or enter into development partnerships that would help us bring our product candidates to market. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

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

Patents are of national or regional effect, and filing, prosecuting and defending patents on all of our drug candidates throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States

can be less extensive than those in the United States. As such, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing drug candidates made using our inventions in and into the United States or other jurisdictions. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing drug candidates in violation of our proprietary rights generally. In addition, certain developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit, and in those countries, we and our licensors and licensees may have limited remedies if patents are infringed or if we or our licensors or licensees are compelled to grant a license to a third party, which could diminish the value of those patents. This could limit our potential revenue opportunities. Further, competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drug candidates and, further, may export otherwise infringing drug candidates to territories where we have patent protection but where enforcement is not as strong as that in the United States. These drug candidates may compete with our drug candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

In Europe, beginning June 1, 2023, European applications and patent may be subjected to the jurisdiction of the Unified Patent Court (UPC). Also, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the UPC. This will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty. As a single court system can invalidate a European patent, we, where applicable may opt out of the UPC and as such, each European patent would need to be challenged in each individual country.

Geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Our patent rights may be affected by developments or uncertainty in U.S. or non-U.S. patent statutes, patent case laws in USPTO rules and regulations or in the rules and regulations of non-U.S. patent offices.

Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the Leahy-Smith Act), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. 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 parties review, and derivation proceedings. After March 2013, under the Leahy-Smith Act, the United States transitioned

to a first inventor to file system in which, assuming that the other statutory requirements 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. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, Congress may pass patent reform legislation that is unfavorable to us.

The U.S. Supreme Court has ruled on several patent cases in recent years, narrowing the scope of patent protection available in certain circumstances and weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our drug candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

In addition, we may be unsuccessful in executing agreements assigning such intellectual property to us with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Patent terms may be inadequate to protect our competitive position on our drug candidates for an adequate amount of time, and if we do not obtain patent term extension for our drug candidates, our business may be materially harmed.

Patent rights are of limited duration. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date. In addition, although upon issuance a U.S. patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such drug candidates are commercialized. Even if patents covering our drug candidates are obtained, once the patent life has expired for a drug candidate, we may be open to competition from generic products. A patent term extension of up to five years based on regulatory delay may be available in the United States under the Hatch- Waxman Act. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single drug candidate. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the drug candidate as approved. Further, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug candidate approval and only those claims covering such approved drug candidate, a method for using it or a method for manufacturing it may be extended. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our drug candidate will be

shortened and our competitors may obtain approval of competing drug candidates following our patent expiration, and our revenue could be reduced.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

Moreover, any name we have proposed to use with our drug candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed drug candidate names, including an evaluation of potential for confusion with other drug candidate names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary drug candidate names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that patents based on our patent applications will not be challenged and rendered invalid and/or unenforceable.*

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. We have pending U.S. and foreign patent applications in our portfolio; however, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries; and/or
- whether we may experience patent office interruption or delays to our ability to timely secure patent coverage to our product candidates.

We cannot be certain that the claims in our pending patent applications directed to our product candidates and/or technologies will be considered patentable by the USPTO or by patent offices in foreign countries. There can be no assurance that any such patent applications will issue as granted patents. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.*

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of 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 and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates, there may be times when the filing and prosecution activities for patents and patent applications relating to our product candidates are controlled by our future licensors or collaboration partners. If any of our future licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

We may enter into license agreements in the future with others to advance our existing or future research or allow commercialization of our existing or future product candidates. These licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our future licensors fail to prosecute, maintain, enforce, and defend such patents or patent applications, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our future product candidates that are subject of such licensed rights could be adversely affected.

Our future licensors may rely on third-party consultants or collaborators or on funds from third parties such that our future licensors are not the sole and exclusive owners of the patents we in-license. If other third parties have ownership rights to our future in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products

and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

It is possible that we may be unable to obtain licenses at a reasonable cost or on reasonable terms, if at all. 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. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Disputes may arise between us and our future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we license in the future prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

In spite of our best efforts, our future licensors might conclude that we materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

From time to time, we may be required to license technologies relating to our therapeutic research programs from additional third parties to further develop or commercialize our product candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our product candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of our product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our future product candidates or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable future product candidates;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Risks Relating to Owning Our Common Stock

The market price of our common stock is likely to be volatile and could fluctuate or decline, resulting in a substantial loss of your investment.

The market price of our common stock has been and may continue to be volatile and could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- the outcome of our review and evaluation of strategic alternatives;
- changes in our business strategy;
- results of clinical trials;
- our ability to identify partnership and licensing opportunities to support the future development of NOV004;
- our ability to in-license or acquire clinical stage therapeutics
- any delays in manufacturing of drug supplies, results of preclinical studies and clinical trials for potential drug candidates;
- regulatory actions with respect to our potential drug candidates or our competitors' drug candidates;
- actual or anticipated fluctuations in our financial condition and operating results, including fluctuations in our quarterly and annual results;
- announcement of actual or anticipated reduction in force, including our recent reduction in force;
- announcements of technological innovations by us or our competitors;
- overall conditions in our industry and the markets in which we operate;
- addition or loss of significant customers, or other developments with respect to significant customers;
- changes in laws or regulations applicable to our drug candidates;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- additions or departures of key personnel;

- competition from existing drug candidates or new drug candidates that may emerge;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain intellectual property protection for our technologies;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us or our stockholders;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- market conditions for pharmaceutical stocks in general;
- the expiration of contractual lock-up agreements with our executive officers, directors and stockholders;
- general economic and market conditions; and
- ineffectiveness of our disclosure controls or internal controls.

Furthermore, the stock markets have experienced price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations, may negatively impact the market price of our common stock. In the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

We may be subject to securities class action and stockholder derivative actions. These, and potential similar or related litigation, could result in substantial damages and may divert management's time and attention from our business and adversely impact our business, results of operations and financial condition.

We may become the target of securities class actions or stockholder derivative claims. Securities-related class action litigation has often been brought against companies, including many biotechnology companies, which experience volatility in the market price of their securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies often experience significant stock price volatility in connection with their product development programs. Any preclinical or clinical trial results that the investors may deem as unfavorable, volatility in our stock price and other matters affecting our business and operations may subject us to actual and threatened securities class actions or stockholder derivative claims. In addition, we may be exposed to increased litigation from stockholders, customers, suppliers, consumers and other third parties due to the combination of Novosteo's business and ours following the Acquisition, out-licensing of our legacy assets or any potential strategic transactions. These types of proceedings may result in substantial costs, divert management's attention from other business concerns and adversely impact our business, results of operations and financial condition.

Future sales of our common stock in the public market could cause our share price to fall.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. Certain holders of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in Securities Act registration statements that we may file for ourselves or other stockholders. Once we register these shares, they can be freely sold in the public market. Moreover, we have also registered under the Securities Act shares of common stock that we may issue under our equity compensation plans.

In addition, the issuance of shares under awards granted under existing or future employee equity benefit plans may cause immediate and substantial dilution to our existing stockholders. In the future, we may issue additional shares of common stock or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

We have in the past and may in the future fail to continue to meet the listing standards of Nasdaq, and as a result our common stock may be delisted, which could have a material adverse effect on the liquidity of our common stock.*

Our common stock currently trades on The Nasdaq Global Select Market. The Nasdaq Stock Market LLC ("Nasdaq") has requirements that a company must meet in order to remain listed on Nasdaq. For example, Nasdaq rules require us to maintain a minimum closing bid price of $1.00 per share of our common stock.

On December 13, 2022, we received a letter from the Listing Qualifications Staff, or the "Nasdaq Staff" of Nasdaq notifying us that for the last 30 consecutive business days, the bid price of our common stock had closed below $1.00 per share, the minimum closing bid price required by the continued listing requirements of Nasdaq Listing Rule 5450(a)(1). The notification received had no immediate effect on the listing of our common stock on the Nasdaq Global Select Market. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we had 180 calendar days to regain compliance with the minimum bid price requirement by having shares of our common stock maintain a minimum closing bid price of at least $1.00 per share for a minimum of 10 consecutive trading days. On April [4], 2023, we received a letter from the Nasdaq Staff notifying us that the closing bid price of our common stock had been at $1.00 per share or greater for 10 consecutive business days, from March 21, 2023 to April 3, 2023, and accordingly, we had regained compliance with Nasdaq Listing Rule 5450(a)(1).

There can be no assurance that we will continue to meet the minimum bid price requirement, or any other Nasdaq requirements, in the future.

In addition, we may be unable to meet other applicable Nasdaq listing requirements, including maintaining minimum levels of stockholders' equity or market values of our common stock, in which case our common stock could be delisted. If our common stock were to be delisted, the liquidity of our common stock would be adversely affected, and the market price of our common stock could decrease.

We may be treated as a "public shell" company, which could have negative consequences, including potential Nasdaq delisting of our common stock.

We may be treated as a "public shell" company under the Nasdaq rules and the Securities Act. Although the evaluation of whether a listed company is a public shell company is based on a facts and circumstances determination, a Nasdaq-listed company with no or nominal operations and either no or nominal assets, assets consisting solely of cash and cash equivalents, or assets consisting of any amount of cash and cash equivalents and nominal other assets is generally considered to be a public shell. Listed companies determined to be public shells by Nasdaq may be subject to delisting proceedings or additional and more stringent listing criteria.

If Nasdaq should delist our common stock from trading, a reduction in some or all of the following may occur, each of which could have a material adverse effect on holders of our common stock: the liquidity of our common stock; the market price of our common stock; the number of institutional and general investors that will consider investing in our common stock; the number of investors in general that will consider investing in our common stock; the number of market makers in our common stock; the availability of information concerning the trading prices and volume of our common stock; and the number of broker-dealers willing to execute trades in our common stock. In addition to the foregoing, there are certain consequences under the Securities Act of being a public shell, including the unavailability of Rule 144 thereunder for the resale of restricted securities, the inability to utilize Form S-8 for the registration of employee benefit plan securities; and the inability to utilize Form S-3 under the "baby shelf" rules applicable to companies with a non-affiliate market capitalization of less than $75 million. In addition, the potential determination that we are a public shell company or the prospective loss of our listing on Nasdaq could make us less attractive as a partner in any potential strategic transaction.

We have never paid dividends on our common stock and we do not intend to pay dividends for the foreseeable future. Consequently, any gains from an investment in our common stock will likely depend on whether the price of our common stock increases.

We have never declared or paid any dividends on our common stock and do not intend to pay any dividends in the foreseeable future. We anticipate that we will retain all of our future earnings for use in the operation of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our board of directors. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

General Risk Factors

Our charter documents and Delaware law could prevent a takeover that stockholders consider favorable and could also reduce the market price of our stock.*

Our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it more difficult for stockholders to elect directors and take other corporate actions. These provisions include:

- providing for a classified board of directors with staggered, three-year terms;
- authorizing our board of directors to issue preferred stock with voting or other rights or preferences that could discourage a takeover attempt or delay changes in control;
- prohibiting cumulative voting in the election of directors;
- providing that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- prohibiting the adoption, amendment or repeal of our amended and restated bylaws or the repeal of the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors without the required approval of at least 66.67% of the shares entitled to vote at an election of directors;
- prohibiting stockholder action by written consent;
- limiting the persons who may call special meetings of stockholders; and
- requiring advance notification of stockholder nominations and proposals.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, the provisions of Section 203 of the Delaware General Corporate Law, or the DGCL, govern us. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time without the consent of our board of directors.

In addition, in April 2023, we implemented the Rights Agreement, also called a “poison pill,” that may have the effect of discouraging or preventing a change of control by, among other things, making it uneconomical for a third party to acquire us without the consent of our board of directors.

These and other provisions in our amended and restated certificate of incorporation and our amended and restated bylaws and under Delaware law could discourage potential takeover attempts, reduce the price investors might be willing to pay in the future for shares of our common stock and result in the market price of our common stock being lower than it would be without these provisions.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders’ abilities 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, unless we consent to the selection of an alternative forum, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by, or other wrongdoing by, any of our directors, officers, employees or agents or our stockholders;
- any action asserting a claim against us arising under the DGCL, 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;

provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation also

provides that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees or agents and arising under the Securities Act.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, these 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. While the Delaware Supreme Court recently determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring such a claim arising under the Securities Act against us, our directors, officers, or other employees in a venue other than in the federal district courts of the United States of America. 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, and this may require significant additional costs associated with resolving such action in other jurisdictions.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the DGCL, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- we will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification;
- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

Our internal computer systems, or those used by our third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our future CROs and other contractors and consultants may be vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on our third-party research institution collaborators for research and development of our drug candidates and other third parties for the manufacture of our drug candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or

inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our drug candidates could be delayed.

Our ability to utilize our federal net operating loss and tax credit carryforwards may be limited.

Our net operating loss, or NOL, carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 taxable years under applicable U.S. federal tax law. Moreover, under the Tax Act as modified by the CARES Act, federal NOLs generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs may be limited to 80% of taxable income for tax years beginning January 1, 2018.

Under Sections 382 and 383 of the Internal Revenue Code, limitations on a corporation's ability to use its NOLs and tax credit carryforwards apply if a corporation undergoes an "ownership change," which is generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period. If we have experienced an ownership change at any time since our incorporation, we may already be subject to limitations on our ability to utilize our existing NOL carryforwards and other tax attributes to offset taxable income or tax liability. In addition, future changes in our stock ownership, which may be outside of our control, may trigger an ownership change. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. As a result, even if we earn net taxable income in the future, our ability to use our pre-change NOL carryforwards and other tax attributes to offset such taxable income or tax liability may be subject to limitations, which could potentially result in increased future income tax liability to us.

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

None.

Item 3. Defaults Upon Senior Securities.

Not Applicable.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The exhibits filed or furnished as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, timely and successful completion which Exhibit Index is incorporated herein by reference.

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation	8-K	5/13/2019	001-38890	
3.2	Certificate of Amendment to the registrant's Certificate of Incorporation, effective August 1, 2022	8-K	8/1/2022	001-38890	
3.3	Amended and Restated Bylaws	8-K	8/1/2022	001-38890	
3.4	Certificate of Designation of Series A Junior Participating Preferred Stock	8-K	4/5/2023	001-38890	
4.1	Rights Agreement dated as of April 5, 2023, between Quince Therapeutics, Inc. and American Stock Transfer & Trust Company, LLC	8-K	4/5/2023	001-38890	
10.1**	Lighthouse Purchase Agreement				X
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and Rule 15d-14(a) of the Exchange Act				X
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and Rule 15d-14(a) of the Exchange Act				X
32.1#	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
32.2#	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				X
101.INS	Inline XBRL Instance Document				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				X
104	Cover Page Interactive Data File, formatted in Inline XBRL (included in Exhibit 101)				

** Portions of this exhibit have been redacted pursuant to Item 601(b)(10) of Regulation S-K as the Registrant has determined that (i) the omitted information is not material and (ii) the omitted material is of the type that the Registrant treats as private or confidential.
# In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release Nos. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Quarterly Report on Form 10-Q and will not be deemed "filed" for purpose of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

SIGNATURES

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

Quince Therapeutics, Inc.

Date: May 15, 2023

By: /s/ Dirk Thye
Dirk Thye
Chief Executive Officer

(Principal Executive Officer)

Date: May 15, 2023

By: /s/ Brendan Hannah

Brendan Hannah
Chief Business Officer
(Principal Financial Officer)

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) the type that the registrant treats as private or confidential.

Exhibit 10.1

ASSET PURCHASE AGREEMENT

by and between

QUINCE THERAPEUTICS, INC.

and

LIGHTHOUSE PHARMACEUTICALS, INC.

dated January 27, 2023

TABLE OF CONTENTS

Page

ARTICLE I - DEFINITIONS AND RULES OF CONSTRUCTION 4

Section 1.01 Definitions 4

ARTICLE II - PURCHASE AND SALE; IMPLEMENTATION 4

Section 2.01 General 4

Section 2.02 Closing 5

Section 2.03 Transferred APA Assets 5

Section 2.04 Implementation Agreements 5

Section 2.05 Seller Subsidiary; Purchaser Affiliates 5

Section 2.06 Excluded Assets 6

Section 2.07 Assumed Liabilities 6

Section 2.08 Retained Liabilities 6

ARTICLE III - PURCHASE PRICE 6

Section 3.01 Purchase Price 6

Section 3.02 Milestone Event Payment 7
Section 3.03 Milestone Reporting 8
Section 3.04 Milestone Payment Timing 8
Section 3.05 Royalty Payments 8
Section 3.06 Royalty Payment Reduction 9
Section 3.07 Sublicense Income Payment 10
Section 3.08 Reimbursement of Legal Fees 12
Section 3.09 Purchase Price Allocation 12
Section 3.10 Audit Rights 13
ARTICLE IV - IMPLEMENTATION AGREEMENTS 13
Section 4.01 Product Files 13
Section 4.02 Business Transfer Documents 14
ARTICLE V - KNOW-HOW TRANSFER 14
Section 5.01 Transfer of Know-How 14
Section 5.02 Covenant Not to Sue 14
ARTICLE VI - REPRESENTATION AND WARRANTIES 15
Section 6.01 Title to Transferred APA Assets 15
Section 6.02 No Outside Reliance; No Other Representations and Warranties 15
Section 6.03 As-Is Where-Is Sale 15
ARTICLE VII - CLOSING DELIVERABLES 16
Section 7.01 Closing Deliverables of Seller 16
Section 7.02 Closing Deliverables of Purchaser 16
ARTICLE VIII - COVENANTS 16
Section 8.01 Transfer of INDs 16
Section 8.02 Taxes 16
Section 8.03 Publicity 18
Section 8.04 Transferred IP 18
ARTICLE IX - INDEMNIFICATION; LIMITATIONS ON LIABILITY 19
Section 9.01 By Seller 19
Section 9.02 By Purchaser 19
Section 9.03 Indemnification 19
Section 9.04 Indemnification Procedures 19
Section 9.05 Expiration 21
Section 9.06 Sole Remedy; Waiver 21
Section 9.07 Payments 22
Section 9.08 Claims Net of Insurance, Etc 22
Section 9.09 Mitigation 22

ARTICLE X - GOVERNING LAW AND ENFORCEMENT 22
Section 10.01 Governing Law 22
Section 10.02 Enforcement and Specific Performance 22
Section 10.03 Consent to Jurisdiction 22
Section 10.04 Waivers 23
ARTICLE XI - MISCELLANEOUS 23
Section 11.01 Further Assurances 23
Section 11.02 Performance by Affiliates 23
Section 11.03 Notices 24
Section 11.04 Amendment; Waiver 24
Section 11.05 Assignment 25
Section 11.06 Entire Agreement 25
Section 11.07 Parties in Interest 25
Section 11.08 Expenses 25
Section 11.09 Counterparts 25
Section 11.10 Headings; Interpretation 26
Section 11.11 Severability 26
Section 11.12 Language 26
Section 11.13 Confidentiality 26
Section 11.14 Time is of the Essence 27

ASSET PURCHASE AGREEMENT

THIS ASSET PURCHASE AGREEMENT (this "APA" or "Agreement"), dated as of January 27, 2023 (the "Execution Date"), is made by and between Quince Therapeutics, Inc., a Delaware corporation ("Seller"), and Lighthouse Pharmaceuticals, Inc., a Delaware corporation ("Purchaser"). In this APA, Seller and Purchaser are individually referred to as a "Party" and collectively as the "Parties."

WHEREAS:

A. Seller and certain of its Affiliates are engaged in the Development of the Products in the Territory;

B. Seller wishes to sell to Purchaser, and Purchaser desires to purchase from Seller, certain assets and rights comprising or associated with the Development, Manufacture and Commercialization of the Products, upon the terms and conditions hereinafter set forth; and

C. at the Closing, Seller and Purchaser intend to enter into, or cause certain of their respective Affiliates to enter into, the Ancillary Agreements.

TERMS:

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby

acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

ARTICLE I - DEFINITIONS AND RULES OF CONSTRUCTION

Section 1.01 Definitions. Capitalized terms used herein (including in the recitals above) and not otherwise defined have the respective meanings set forth in Annex A hereto. Annex A further includes other definitions and rules of construction applicable to this APA.

ARTICLE II - PURCHASE AND SALE; IMPLEMENTATION

Section 2.01 General. Pursuant to the terms and subject to the conditions set forth herein and in the Implementation Agreements, Seller hereby sells, transfers, assigns, conveys, grants and delivers to Purchaser, and Purchaser hereby purchases, acquires and accepts from Seller at the Closing, all of Seller's right, title and interest in, to and under the Transferred APA Assets. On the terms and subject to the conditions of this Agreement, at the Closing, Purchaser shall assume, discharge and perform all of the Assumed Liabilities.

Section 2.02 Closing.

(a) Subject to the terms and conditions of this APA, the closing of the purchase and sale of the Transferred APA Assets and the assumption of the Assumed Liabilities

(the "Closing") shall take place remotely by exchange of documents and signatures (or their electronic counterparts), at 10:00 a.m. Pacific time, on the Execution Date, which date shall be referred to herein as the "Closing Date".

(b) At the Closing, Seller shall deliver, or cause to be delivered, to Purchaser the instruments and documents set forth in Section 7.01.

(c) At the Closing, Purchaser shall deliver to Seller (i) the Purchase Price in accordance with Section 3.01, and (ii) the instruments and documents set forth in Section 7.02.

(d) At the Closing, Purchaser shall pay the amounts incurred by Seller and its Affiliates in accordance with Section 3.08.

Section 2.03 Transferred APA Assets. For purposes of this APA, the "Transferred APA Assets" means all of Seller's and the Seller Subsidiary's right, title and interest in, to and under the following:

(a) the INDs;

(b) the Transferred IP and all goodwill appurtenant or attributable to the Transferred IP, including (to the extent in existence as of the Closing) claims, causes of action, rights of recovery and rights of set-off of any kind (including the right to sue and recover for past infringements or misappropriations) against any Person;

(c) the Product Files, to be transferred in electronic form, subject to the rights expressly retained by Seller pursuant to this APA;

(d) all tangible Product Compounds, including any drug substance, drug product (and corresponding placebo) and related materials exclusively held for the Product Compounds, as and to the extent in the possession of Seller at Closing; and

(e) all tangible scientific reagents, clinical samples, manufacturing starting materials, activity probes, anti-Pg antibodies, gingipains, brain samples, data analyses, bacterial strains, and GAIN trial samples) exclusively held for the Product Compounds, as and to the extent in the possession of Seller at Closing.

Section 2.04 Implementation Agreements. In order to implement their respective obligations to sell and purchase the Transferred APA Assets under Section 2.01, the Parties shall enter into and perform their respective obligations under the Implementation Agreements (as applicable), and to implement the transactions contemplated hereby and thereby in accordance with the terms and conditions of this Agreement.

Section 2.05 Seller Subsidiary; Purchaser Affiliates. In the event the Seller Subsidiary holds any right, title or interest in, to or under any of the Transferred APA Assets, Seller shall cause the Seller Subsidiary to, including through the exercise of any contractual rights available to it, take any and all actions necessary in order to

transfer promptly to Purchaser or its designee, such right, title or interest in, to or under the Transferred APA Assets including any regulatory and technical documents held by such Seller Subsidiary which would be considered to be Product Files. In the event any Affiliate of Purchaser assumes, or becomes obligated for, any Assumed Liability, Purchaser shall cause such Affiliate to discharge and perform such Assumed Liability.

Section 2.06 Excluded Assets. Nothing in this APA shall operate to transfer from Seller or the Seller Subsidiary, or create an obligation on Seller or the Seller Subsidiary, to transfer or have transferred any right, title or interest in or to any assets other than the Transferred APA Assets (the "Excluded Assets") or create any Liability on the part of Purchaser with respect thereto. Purchaser agrees that anything to the contrary in this Agreement or an Implementation Agreement notwithstanding, the Excluded Assets shall in all cases include any assets, properties, and rights of Seller or the Seller Subsidiary (other than the Transferred APA Assets), including any cash, cash equivalents, checks, short term instruments, funds in time or demand deposits, marketable securities or any similar accounts.

Section 2.07 Assumed Liabilities. Purchaser agrees, effective at the Closing and from and after the Closing Date, to assume and discharge all of the Liabilities (other than the Retained Liabilities) relating to the Transferred APA Assets from and after the date hereof (such Liabilities being collectively referred to hereinafter as the "Assumed Liabilities").

Section 2.08 Retained Liabilities. Seller and its Affiliates shall retain and be responsible for all Liabilities to the extent arising out of or relating to the Excluded Assets and the following:

(a) all Liabilities that are "Excluded Liabilities" under the Bill of Sale and Assignment and Assumption Agreement;

(b) all Liabilities of Seller or any of its Affiliates arising under this APA and the Implementation Agreements; and

(c) all Liabilities in respect of the ownership, operation and/or development of the Transferred APA Assets prior to the Closing;

(together, the "Retained Liabilities").

ARTICLE III - PURCHASE PRICE

Section 3.01 Purchase Price. In consideration for the purchase and sale of the Transferred APA Assets and the consummation of the transactions contemplated by this APA or the Implementation Agreements, Purchaser hereby agrees to pay Seller the following:

(a) at Closing, [*] shares of common stock of Purchaser (the "Common Stock"), which shares of Common Stock will represent 7.5% of Purchaser's

Fully-Diluted Capital Stock (as defined in the Stock Issuance Agreement) as of the Closing and are hereby issued pursuant to, and in accordance with the terms and conditions of the Stock Issuance Agreement (the "Closing Capital Stock Consideration"); and

(b) following Closing, as applicable and subject to the terms and conditions of this Article III, each of (i) the Milestone Payments in accordance with the terms and conditions of Sections 3.02, 3.03 and 3.04 below; (ii) the Royalties in accordance with the terms and conditions of Sections 3.05 and 3.06 below; and
(iii) the Sublicense Income Payments in accordance with the terms and conditions of Section 3.07 below (each of the Milestone Payments and Royalties and Sublicense Income Payments referred to in clauses (i), (ii) and (iii), the "Post-Closing Consideration" and, together with the Closing Capital Stock Consideration, collectively, the "Purchase Price").

(c) The Purchase Price shall be paid in full, without deduction for any Taxes unless required to do so by applicable Law, by Purchaser and, in the case of the Post-Closing Consideration which constitutes cash, by wire transfer of immediately available funds on the applicable payment date, to an account or accounts specified in writing by Seller to Purchaser from time to time.

Section 3.02 Milestone Event Payment. Subject to the terms and conditions of this Article III, Purchaser shall pay to Seller the following milestone payments on a Product-by- Product basis (each a "Milestone Payment") upon the achievement of the corresponding Milestone Events described below:

Row	Milestone Event	Milestone Payment
1.	[*]	[*]
2.	[*]	[*]
3.	[*]	[*]
4.	[*]	[*]

Notwithstanding anything to the contrary, each Milestone Payment shall only be payable one time per Product upon the first achievement of each such milestone by such Product, other than the Milestone Payments in row [*] above (which shall be payable with respect to each such applicable [*]).

Section 3.03 Milestone Reporting. Purchaser shall notify Seller (a) with respect to each of Milestone Payments in rows [*] above, within [*] days following achievement of each such applicable Milestone Event, and (b) with respect to the Milestone Payment in row [*] above, within [*] days

following the end of the Calendar Quarter in which such Milestone Event was achieved (each such notice, a

"Milestone Achievement Notice"). In addition, commencing on the date that is [*] after the Closing Date, Purchaser shall, within [*] Business Days after the end of each [*] period following the Closing Date, deliver to the Seller a report regarding the status of each pending Milestone Event and the efforts undertaken to achieve each such Milestone Event during the reporting period (each such report, an "Update Report"); *provided*, *however*, that such Purchaser obligation to deliver any Update Report shall terminate at 11:59 p.m. (Pacific time) on the earlier to occur of (A) the date Milestone [*] is achieved; and (B) the [*] anniversary of the Closing Date. Within [*] Business Days after receipt of an Update Report, if the Seller has reasonable inquiries regarding the activities described in such Update Report, the Seller may request a meeting with employees of Purchaser with appropriate expertise and knowledge of the activities undertaken to achieve the Milestone Events to discuss such Update Report, and Purchaser shall make available for such a meeting such of its employees as Purchaser may reasonably deem appropriate, including an officer with operating responsibility for such activities.

Section 3.04 Milestone Payment Timing. Each Milestone Payment due and payable under this Article III shall be paid by Purchaser to Seller within [*] Business Days following the date of delivery to Seller of the Milestone Achievement Notice.

Section 3.05 Royalty Payments. Subject to the terms and conditions of this Article III, Purchaser will pay to Seller, on a Product-by-Product basis during the applicable Royalty Term, royalty payments on Net Sales (collectively, the "Royalties") equal to the following:

(a) For each Product, other than Products containing COR388 and COR588, the applicable Royalty shall be equal to [*] of all Net Sales for such Products in the Territory; and

(b) For each Products containing COR388 and/or COR588, the applicable Royalty shall be as follows:

Row	**Annual Net Sales for Products containing COR388 and COR588**	**Royalty Rate**
1.	On the portion of annual aggregate Net Sales for such Product in a given Calendar Year in the Territory equal to or less than [*]	[*]
2.	On the portion of annual aggregate Net Sales for such Product in a given Calendar Year in the Territory greater than [*] and equal to or less than [*]	[*]
3.	On the portion of annual aggregate Net Sales for such Product in a given Calendar Year in the Territory greater than [*] and equal to or less than [*]	[*]
4.	On the portion of annual aggregate Net Sales for such Product in a given Calendar Year in the Territory greater than [*]	[*]

Within [*] days after the end of each Calendar Quarter in which any Net Sales occur, Purchaser shall (i) deliver

to the Seller a report setting forth the aggregate Net Sales of each Product, to the extent applicable, during the prior Calendar Quarter, showing with reasonable specificity the calculation of Net Sales as provided for in the definition of Net Sales (each such report, a "Net Sales Report"), and (ii) pay the Royalty due to Seller.

Section 3.06 Royalty Payment Reduction.

(a) Subject to Section 3.06(d), on a country-by-country basis, if one or more products being sold in a particular country during a Calendar Quarter are Generic Products for which all such Generic Products exceed [*] of the market for all such Generic Products and applicable Product combined (calculated on a unit volume basis) in any Calendar Quarter in such country, then the Royalty rate otherwise applicable to the Net Sales of the applicable Product in such country during such Calendar Quarter and thereafter (for as long as such Generic Product is sold in such country and for which all such Generic Products exceed [*] of the market for all such Generic Products and applicable Product combined (calculated on a unit volume basis) in such Calendar Quarter in such country) shall be reduced by [*], starting with the Calendar Quarter in which the first sale of all such Generic Products reaches the above threshold in such country. All determinations of the unit equivalent volume of sales shall be identified and calculated based on relevant information published by a reputable Third Party data source such as IQVIA, any successor to IQVIA, or any other similar Third Party source reasonably agreed upon by the Parties. For purposes of clarity, in any Calendar Quarter during which there are sales of a Generic Product, the applicable Royalty reduction shall be effective beginning in the Calendar Quarter in which the sales of such Competing Product reaches the above threshold in such country. A quarterly true-up will occur following the completion of any such Calendar Quarter to ensure any balances owed/due have been settled.

(b) Subject to Section 3.06(d), in the event that during the applicable Royalty Term that a Royalty is required to be made, the Commercialization or Manufacturing of a Product in any country is not Covered by a Valid Claim of any Milestone Patent, then in such event, the Royalty rate in such country will be reduced to [*] of the then applicable rate in Section 3.05 in such country.

(c) Subject to Section 3.06(d), Purchaser shall be entitled to deduct from any Royalty payments otherwise due under this Article III an amount equal to [*] of any royalty payments owed by Purchaser or any Sublicensee to a Third Party in consideration for a license under such Third Party's interest in any Patents that are necessary for the use or sale of the Products in the Territory.

(d) Notwithstanding anything to the contrary, in no event shall the Royalty reductions described in this Section 3.06, alone or together, reduce the Royalties payable by Purchaser for a Product in a country in any given Calendar Quarter to less than [*] of the amounts otherwise payable by Purchaser for such Calendar Quarter in Section 3.05 (without giving effect to any royalty deductions in this Section 3.06); *provided*, *however*, that to the extent Purchaser cannot deduct any amounts because of this Section 3.06(d), Purchaser may deduct such amounts from Royalties payable in future Calendar Quarters, subject to the limitation set forth in this Section 3.06(d).

Section 3.07 Sublicense Income Payment. Purchaser will pay to Seller, on a Product-by- Product (or in the case of a Change in Control, all Products) basis to the extent applicable, the following payments based on Sublicense Income received from time to time (whether by Purchaser or any of its security holders) in connection with such Change of Control or under such Sublicense as applicable ("Sublicense Income Payment"):

(a) In *addition* to the Milestone Payments and Royalties provided in Article III above, if a Change of Control occurs or Sublicense involving either (or both) of each of COR388 and COR588, as applicable, is first executed prior to the Initiation of a Phase 2 Clinical Trial that is first Initiated after the Closing, then Purchaser shall pay Seller, within [*] Business Days following receipt, [*] of all applicable Sublicense Income received from time to time (whether by Purchaser or any of its security holders) in connection with such Change of Control or under such Sublicense as applicable.

(b) If a Change of Control occurs, then Purchaser shall pay Seller, within [*] Business Days following receipt, the specified percentages of the corresponding Sublicense Income Payment according to the following:

(i) in *addition* to the Milestone Payments and Royalties provided in Article III above, [*] of all Sublicense Income received from time to time (whether by Purchaser or any of its security holders) in connection with such Change of Control that is consummated prior to the Initiation of the first Phase 2 Clinical Trial for either COR388 or COR588 that is first Initiated after the Closing;

(ii) in *lieu* of the Milestone Payments and Royalties provided in Article III above, [*] of Sublicense Income received from time to time (whether by Purchaser or any of its security holders) in connection with such Change of Control that is consummated after Initiation of the first Phase 2 Clinical Trial for COR588 that is first Initiated after the Closing and prior to [*];

(iii) in *lieu* of the Milestone Payments and Royalties provided in Article III above, [*] of Sublicense Income received from time to time (whether by Purchaser or any of its security holders) in connection with such Change of Control that is consummated after [*]; and

(iv) in *lieu* of the Milestone Payments and Royalties provided in Article III above, [*] of Sublicense Income received from time to time (whether by Purchaser or any of its security holders) in connection with such Change of Control that is consummated after [*].

(c) Notwithstanding anything to the contrary, in *lieu* of all Milestone Payments and Royalties provided in Article III above, if a Sublicense involving any Product (other than COR388 and COR588) occurs, then Purchaser shall pay Seller, within [*] Business Days following receipt, the specified percentages of the corresponding Sublicense Income Payment according to the following:

(i) [*] of Sublicense Income if the Sublicense is first executed prior to [*];

(ii) [*] of Sublicense Income if the Sublicense is first executed after [*] and prior to [*];

(iii) [*] of Sublicense Income if the Sublicense is first executed after [*]; and

(iv) [*] of Sublicense Income if the Sublicense is first executed after [*].

(d) Notwithstanding anything to the contrary, in *lieu* of all Milestone Payments and Royalties provided in Article III above, if a Sublicense involving either (or both) of COR388 and COR588 occurs, then Purchaser shall pay Seller, within [*] Business Days following receipt,

the specified percentages of the corresponding Sublicense Income Payment according to the following:

(i) [*] of Sublicense Income if the Sublicense is first executed after Initiation of the first Phase 2 Clinical Trial that is initiated after the Closing and prior to [*];

(ii) [*] of Sublicense Income if the Sublicense is first executed after [*]; and

(iii) [*] of Sublicense Income if the Sublicense is first executed after [*].

(e) Notwithstanding anything to the contrary, all calculations of Sublicense Income in this Section 3.07 shall exclude all Milestone Payments and Royalties paid pursuant to Article III above.

Section 3.08 Reimbursement of Legal Fees. Effective as of the Closing, Purchaser will reimburse Seller for the following legal costs and fees actually incurred of [*] by Cooley LLP in connection with the Transaction.

Section 3.09 Purchase Price Allocation. Within [*] days after the Closing Date, Seller shall prepare a draft allocation schedule (the "Allocation") allocating the Purchase Price (together with any applicable Assumed Liabilities and any other amounts treated as consideration for applicable income Tax purposes) among the Transferred APA Assets and the Transferred Assets in accordance with the rules under Section 1060 of the Internal Revenue Code of 1986, as amended (the

"Code"), and the Treasury Regulations promulgated thereunder. Seller shall deliver the Allocation to Purchaser for review and comment within [*] calendar days after the Closing Date. Purchaser shall deliver its comments to Seller within [*] calendar days thereafter. Seller shall consult with Purchaser concerning such comments, shall consider such comments in good faith, and shall incorporate any agreed revisions thereto (the "Revised Allocation"). In the event Purchaser and Seller agree upon the Allocation or the Revised Allocation or the Independent Accounting Firm determines the Allocation following an applicable dispute between the Parties, such Allocation or, if applicable, Revised Allocation shall be conclusive and binding on the Parties and none of Purchaser, Seller, or their Affiliates shall take any Tax position (whether in Tax audits, Tax Returns or otherwise) that is inconsistent with such Allocation or Revised Allocation unless required to do so by applicable Law. If the Parties fail to reach such an agreement within [*] following the delivery of the Allocation, the Parties shall submit the dispute on the next Business Day to [*] or, if [*] is unavailable or conflicted, another nationally recognized independent accounting firm selected jointly by Seller and Purchaser (the "Independent Accounting Firm"), the cost of which will be allocated to and borne by Seller, on the one hand, and Purchaser, on the other hand, based on [*], as applicable,. In resolving such disputes, the Independent Accounting Firm shall (a) solely use materials provided by Purchaser and Seller,
(b) not conduct its own investigation, (c) act as an expert and not an arbitrator,
(d) address only the disputed items, and (e) not assign a value greater than the greatest value claimed for such item by either Party or smaller than the smallest value claimed for such item by either Party. Any such adjustment to the Allocation shall be allocated to the asset or assets (if any) to which such adjustment is attributable; *provided* that, to the extent there is or are no such asset or assets, such adjustment shall be allocated in a manner consistent with Section 1060 of the Code and the Treasury Regulations promulgated thereunder and any other applicable Law.

Section 3.10 Audit Rights. Upon the written request of Seller, Seller shall have the right to have an independent certified public accounting firm reasonably acceptable to Purchaser be provided access during normal business hours, upon reasonable prior written notice, to such books and records of Purchaser and each other Selling Party as may be required to verify the accuracy of any Net Sales Report. Such examinations may not (a) be conducted for any calendar quarter more than [*] years after the end of such calendar quarter, (b) be conducted more than once in any [*] period, or (c) be repeated for any calendar quarter. Any and all records examined by such independent certified public accounting firm shall be deemed to be confidential information of the audited Selling Party, and, prior to providing such certified public accounting firm with such access, the audited Selling Party and such certified public accounting firm shall have entered into a customary confidentiality agreement which shall provide. Seller shall bear all costs of such audit. If, based on the results of any audit conducted under this Section 3.10, any additional amounts are owed with respect to the Royalty due under this Agreement, then Purchaser shall make such additional payments within 10 Business Days after the accounting firm's written report is delivered to the Seller

and to Purchaser. If the results of the audit indicate an underpayment by Purchaser in excess of [*], then Purchaser shall reimburse the Seller's reasonable costs of such audit.

ARTICLE IV - IMPLEMENTATION AGREEMENTS

Section 4.01 Product Files. As of Closing, Seller shall, and shall cause its Affiliates to, give Purchaser and its Affiliates access, through a Box data website (https://www.box.com/) (the "Electronic Data Site"), to all portions of the Product Files available in electronic form for the Product in the Territory, as well as the Global Safety Database (inclusive of all source documentation files) for the Product. Should portions of the Product Files not be available in electronic form at that time, electronic copies of such portions of the Product Files prepared in the Ordinary Course of Business or necessary or useful in the conduct of the business relating to the Product shall be made available to Purchaser (or its designated Affiliate) as soon as reasonably available, and originals of Product Files (if any) will be made available for inspection and copying, at Purchaser's cost, as reasonably requested in writing by Purchaser or its Affiliates at the facilities where they are maintained by Seller and its Affiliates in the Ordinary Course of Business, on reasonable prior notice to Seller and during normal working hours at such facilities, taking into account the time necessary to identify, locate and retrieve such portions of the Product Files as may be maintained in any archive or storage facilities. Seller will instruct its archiving service to provide Purchaser [*] calendar days' prior written notice of its intent to destroy or discard any originals of Product Files and provide Purchaser with copies of such Product Files at Purchaser's written request and cost. Copies of portions of such Product Files can be taken by Purchaser or its designated Affiliate to its offices or the offices of its designated Affiliate, and Seller shall retain the originals. In addition, paper documentation which is not available electronically will be requested from off- site storage, scanned at Purchaser's request and cost, and provided to Purchaser in electronic form promptly when available.

Section 4.02 Business Transfer Documents. To the extent required under applicable Law or as reasonably deemed necessary by either of the Parties, to effect the transactions contemplated hereunder, the Parties shall execute and deliver, or cause their respective Affiliates to execute and deliver, such asset and/or business transfer agreements, bills of sale, deeds, assignments, assumptions and other documents and instruments of sale, conveyance, assignment, novation, transfer and assumption as are necessary to effect any transfer of the Transferred APA Assets or related Assumed Liability at the Closing or any assumption of the Assumed Liabilities at the Closing. Such documents shall be in form and substance reasonably agreed to by the Parties and as is

usual and customary in the applicable jurisdiction; *provided* that the Parties agree and acknowledge that such documents are intended solely to formalize the terms and conditions of this APA in order to comply with any applicable Law and shall be, in all respects, consistent with the terms and conditions set forth in this APA, and, in the event of any inconsistency

between the APA and such documents, the APA shall control to the extent it would not be incompatible with applicable Law.

ARTICLE V - KNOW-HOW TRANSFER

Section 5.01 Transfer of Know-How. As and to the extent not contained in the Electronic Data Site and subject to Article IV, Seller will use commercially reasonable efforts, at the request of Purchaser, to initiate and complete an electronic transfer to Purchaser of any and all remaining Transferred Know-How, documentation and other materials that exclusively relate to any of the Products.

Section 5.02 Covenant Not to Sue. Effective as of the Closing, Seller, on behalf of itself and its controlled Affiliates, hereby covenants and agrees not to initiate a Proceeding, institute litigation or otherwise sue, or cause or support any other Person to initiate a Proceeding, institute litigation or otherwise sue, Purchaser, any of its Affiliates or Sublicensees, or any of their respective manufacturers, suppliers, distributors or customers solely for using or otherwise exploiting the Transferred APA Assets to Develop, Manufacture and/or Commercialize the Products in the Territory. Despite the foregoing, Seller and its controlled Affiliates retain all rights to initiate a Proceeding, institute litigation or otherwise sue, or cause or support any other Person to initiate a Proceeding, institute litigation or otherwise sue Purchaser or any of its Affiliates, in any such case, to enforce its rights under this Agreement or any Implementation Agreement.

ARTICLE VI - REPRESENTATION AND WARRANTIES

Except as set forth in any Implementation Agreement or in any certificate delivered pursuant to this APA, the Parties hereby agree that the representations and warranties set forth below exclude all others, express or implied.

Section 6.01 Title to Transferred APA Assets. Seller represents and warrants to Purchaser as of the Execution Date that Seller and the Seller Subsidiary collectively own and have good and valid title to the Transferred APA Assets free and clear of all Liens other than Permitted Liens.

Section 6.02 No Outside Reliance; No Other Representations and Warranties. In connection with the due diligence investigation of the Transferred APA Assets, the Assumed Liabilities, the Excluded Assets, the Retained Liabilities and the Business by Purchaser, Purchaser agrees that, except for the representations and warranties set forth in Section 6.01, neither Seller nor any Representative of Seller makes, and Purchaser acknowledges that it has not relied upon or otherwise been induced by,
(a) any other express or implied representation or warranty, whether written or oral, or (b) any other information provided or made available to Purchaser in connection with the transactions contemplated by this Agreement or any Implementation Agreement, including any information, documents, projections, forecasts or other material made available to Purchaser or Purchaser’s Representatives in written form. Without limiting the foregoing, Purchaser

further agrees that Purchaser has made its own investigation of the Transferred APA Assets and Assumed Liabilities and that neither Seller nor any of its Representatives is making any representation or warranty whatsoever, express or implied, beyond those expressly given by

Seller in Section 6.01, including any implied warranty or representation as to condition, merchantability, suitability or fitness for a particular purpose or trade as to any Transferred APA Asset.

Section 6.03 As-Is Where-Is Sale. Purchaser agrees that no representation or warranty is made as to the accuracy or completeness of any information provided to Purchaser, except to the extent any such representation or warranty is made in Section 6.01. Except as otherwise expressly set forth in this Agreement, Purchaser agrees that any assets, properties and business of Seller and the Seller Subsidiary, including the Transferred APA Assets, are furnished "as is", "where is" and subject to and except as otherwise provided in the representations and warranties contained in Section 6.01, with all faults and without any other representation or warranty of any nature whatsoever.

ARTICLE VII- CLOSING DELIVERABLES

Section 7.01 Closing Deliverables of Seller. At Closing:

(a) Seller has delivered to Purchaser a certificate of a secretary or other authorized signatory of Seller enclosing a copy of the board of directors resolutions or equivalent documents authorizing the signature of this APA and the other Implementation Agreements and the consummation of the Transactions contemplated hereby and thereby.

(b) Seller delivered to Purchaser the Transferred APA Assets.

(c) Seller has signed and delivered to Purchaser:

(i) a duly executed counterpart to each Implementation Agreement; and

(ii) the Seller Transfer Letter.

Section 7.02 Closing Deliverables of Purchaser. At Closing:

(a) Purchaser has delivered to Seller a certificate of a secretary or other authorized signatory of Purchaser enclosing a copy of board of directors or equivalent documents resolutions or equivalent documents authorizing Purchaser to enter into the APA and the other Implementation Agreements and to consummate the Transactions.

(b) Purchaser has paid the Closing Capital Stock Consideration in accordance with Section 3.01.

(c) Purchaser has signed and delivered to Seller:

(i) a duly executed counterpart to each Implementation Agreement; and

(ii) the Purchaser Transfer Letter.

ARTICLE VIII- COVENANTS

Section 8.01 Transfer of INDs. Seller will file the final clinical study report for COR388 with the FDA within [*] days following the Closing and will notify Purchaser in writing of such filing within [*] days thereafter. Within [*] days following the written notice from Seller referred to immediately in the preceding sentence, Purchaser and Seller shall file the Transfer Letters with

the FDA for COR388 to transfer ownership of the U.S. IND to Purchaser.

Section 8.02 Taxes.

(a) Withholding. Purchaser and its agents shall be entitled to deduct and withhold any amounts required to be withheld under applicable law from any payments to be made with respect to the transactions contemplated by this APA. Purchaser and its agents shall notify Seller in writing of any deduction or withholding it believes is applicable to amounts payable hereunder at least [*] days prior to the date of the applicable payment, and shall cooperate with Seller to reduce or eliminate any such deduction or withholding. If Purchaser (or any Purchaser Affiliate) is required to deduct or withhold any Taxes on any payments under this Agreement (a "Withholding Tax"), Purchaser will (i) pay such Withholding Tax on behalf of Seller (or the applicable Seller Affiliate) to the appropriate Governmental Authority, and (ii) furnish Seller with proof of payment of such Withholding Tax within [*] Business Days following such payment. The Parties shall cooperate with one another and use reasonable efforts to mitigate or reduce Withholding Tax or similar obligations in respect of payments made between the Parties under this Agreement. Without limiting the generality of the foregoing, each Party shall provide the other Party with any Tax forms and other information that may be reasonably necessary in order to eliminate or reduce withholding based on an applicable treaty or otherwise, including a properly completed Internal Revenue Service ("IRS") Form W-9 or appropriate IRS Form W-8, as applicable, before a payment is made under this Agreement. If any Tax form or other information a Party previously delivered expires or becomes obsolete or inaccurate in any respect, it shall promptly provide the other Party with an updated version of such form or certification or promptly notify the other Party in writing of its legal inability to do so. Upon Purchaser's request, Seller shall, and shall cause its applicable Affiliates to, provide reasonable assistance to Purchaser for Purchaser to recover any such Withholding Tax.

(b) Transfer Taxes. Notwithstanding anything in this APA to the contrary, Purchaser and Seller shall [*] Transfer Taxes. Purchaser and Seller shall cooperate in timely making all filings, returns, reports and forms as may be required to comply with the provisions of applicable law in connection with the payment of any such Transfer Taxes or other amounts and Purchaser and Seller shall cooperate in good

faith to minimize, to the fullest extent permitted by applicable Law, the amount of any such Transfer Taxes or other amounts payable in connection with the sale and transfer of the Transferred APA Assets hereunder, including providing resale certificates or such other certifications or documents as will relieve Purchaser and Seller from liability for any Transfer Taxes, where applicable. The party customarily responsible for filing Tax Returns on applicable Transfer Taxes will be responsible for the timely remittance of any such Transfer Taxes to the appropriate Taxing Authority and will, at its expense, file all necessary Tax Returns and other documentation with respect to all such Transfer Taxes, subject to reimbursement for the portion attributable to the other Party's share of such Transfer Taxes at least [*] Business Days prior to the deadline for remittance of such Transfer Taxes to the appropriate Taxing Authority.

(c) Bulk Sales. The Parties hereby waive compliance with any requirements or provisions of any "bulk transfer" laws of any jurisdiction that may otherwise be applicable with respect to the sale of any or all of the Transferred APA Assets; *provided*, that any liability (other than an Assumed Liability) arising from such waiver shall constitute a Retained Liability to the extent any such liability would otherwise be treated as a Retained Liability had the Parties

complied with any such "bulk transfer" laws.

(d) Intended Tax Treatment. For U.S. federal and applicable state and local income tax purposes, Purchaser's acquisition of the Transferred APA Assets shall be treated as a taxable sale by Seller of the Transferred APA Assets in exchange for the Purchase Price.

(e) Tax Treatment of Certain Payments. All Post-Closing Consideration and payments made pursuant to Article IX shall be deemed adjustments to the Purchase Price for U.S. federal and applicable and local income Tax purposes to the maximum extent permitted by applicable Tax law.

Section 8.03 Publicity. The Parties shall issue a joint press release on the Closing Date. Except as may be required to comply with any applicable Legal Requirements or the rules and regulations of any applicable stock exchange, no public announcement shall be made by either Party with respect to the existence, terms and conditions, or performance of this APA, the Implementation Agreements or the transactions contemplated hereby or thereby without the prior written consent of the other Party. The Parties acknowledge and agree that the determination that a disclosure is required by applicable Legal Requirements or the rules or regulations of any applicable stock exchange shall be made in the sole, but reasonably exercised, discretion of the Party making such disclosure. To the extent a Party determines that a disclosure is necessary under this Section 8.03, to the extent permissible under Legal Requirements, the Parties will work in good faith to attempt to agree upon the content of such disclosure. If either Party, based on the reasonable advice of such Party's outside legal counsel, determines that this APA, or any Implementation Agreement, must be filed with the United States Securities and Exchange Commission ("SEC") or any other applicable

Governmental Authority, then such Party, prior to making any such filing, shall provide the other Party and its counsel with a redacted version of this APA (and any Implementation Agreement) which it intends to file and any draft correspondence with the SEC (or such other Governmental Authority, as applicable) requesting the confidential treatment by the SEC or other Governmental Authority of those redacted sections, and will give due consideration to any comments and redactions provided by the other Party or its counsel and use commercially reasonable efforts to ensure the confidential treatment by the SEC or other Governmental Authority of those sections specified by the other Party or its counsel.

Section 8.04 Transferred IP. Seller shall, or shall cause its applicable Affiliates to, execute, any and all papers and/or documents that may be reasonably necessary to effectuate the assignment, transfer, prosecution or enforcement of the Transferred Patents and Transferred Trademarks. Seller shall, or shall cause its applicable Affiliates to, release and transfer possession and control of the Transferred Patents and Transferred Trademarks to Purchaser (or its designated Affiliate) by initiating the transfer with the current registrar of each Transferred Patents and Transferred Trademarks and Seller shall, and shall cause its applicable Affiliates to, cooperate with Purchaser on all procedures and actions specified by each registrar. Seller hereby authorizes each such registrar to transfer the ownership and control of the Transferred Patents and Transferred Trademarks to Purchaser (or its designated Affiliate).

Section 8.05 COR388 Animal Health License. Purchaser hereby grants to Seller the exclusive option to obtain an exclusive, worldwide, royalty-free, fully-paid up, irrevocable and perpetual right and license, including the right to sublicense through multiple tiers of sublicense, under all Milestone Patents that Cover COR388 and all Transferred Know-How related to COR388 (the "COR388 Animal Health IP"), to research, Develop, Manufacture, use, Commercialize and

otherwise exploit COR388 in any animal health indication. Such option shall commence on the date hereof and expire upon June 30, 2023. Purchaser agrees that, during such option period, and during any license negotiations with Seller arising therefrom, it shall not offer to any Third Party the opportunity to obtain a license, or enter into any license with any Third Party, under the COR388 Animal Health IP for any purpose in animal health, unless Seller expressly rejects in writing its exclusive option set forth herein. At Seller's sole discretion, Seller shall exercise its option hereunder by providing Purchaser written notice of such exercise during such option period. Following receipt of such election notice, the Parties shall commence, in good faith, negotiations of the terms of such license. The Parties shall have a maximum of [*] days from the date of election to conclude a license agreement. Such period may be extended by mutual agreement. Such license agreement shall contain commercially reasonable terms typically contained in license agreements pertaining to inventions of similar nature and market potential. If the Parties do not conclude a license agreement prior to the expiration of the foregoing negotiation period or any extension mutually agreed upon by the

Parties, then such negotiation shall be subject to the expedited resolution procedures in accordance with Annex J.

ARTICLE IX- INDEMNIFICATION; LIMITATIONS ON LIABILITY

Section 9.01 By Seller. Subject to the other terms and conditions of this Article IX, Seller shall indemnify Purchaser and its officers, directors, agents, employees, members, partners, advisors, Affiliates and assigns ("Purchaser Indemnified Persons") for, and hold each Purchaser Indemnified Person harmless from and against, any and all Losses made or brought against, suffered or incurred by, or imposed on the Purchaser Indemnified Persons arising out of or resulting from:

(a) the Retained Liabilities; or

(b) breaches of, or failure to perform covenants, agreements or obligations of Seller or its Affiliates in this APA or any Implementation Agreement.

Section 9.02 By Purchaser. Subject to the other terms and conditions of this Article IX, Purchaser shall indemnify Seller and its officers, directors, agents, employees, members, partners, advisors, Affiliates and assigns ("Seller Indemnified Persons") for, and hold each Seller Indemnified Person harmless from and against, any and all Losses made or brought against, suffered or incurred by, or imposed on the Seller Indemnified Persons arising out of or resulting from:

(a) the Assumed Liabilities; or

(b) breaches of, or failure to perform, covenants, agreements or obligations of Purchaser or its Affiliates in this APA or any Implementation Agreement.

Section 9.03 Indemnification. Except as otherwise specified herein, Section 9.04 hereof shall apply to any and all Direct Claims and Third Party Claims (together, "Claims") for Losses under this APA made by a Purchaser Indemnified Person or a Seller Indemnified Person, as applicable (each, an "Indemnified Party"), against Seller or Purchaser, as applicable (each, an "Indemnifying Party").

Section 9.04 Indemnification Procedures.

(a) Third Party Claims. If a claim by a Third Party is made against an Indemnified Party arising

out of a matter for which the Indemnified Party may be entitled to be indemnified pursuant to Article IX (a "Third Party Claim"), the Indemnified Party shall give the Indemnifying Party (i) prompt (but no later than [*] calendar days after receiving notice of the Third Party Claim) written notice of the Third Party Claim for which the Indemnified Party reasonably may be liable, which notice shall include, among other things, the description of such Third Party Claim in reasonable detail and the estimated amount, if reasonably practicable to estimate, of the Loss that has been or may be sustained by the Indemnified Party and (ii) the opportunity to defend, negotiate and settle such Third Party Claim at the Indemnifying Party's sole cost and expense with counsel reasonably satisfactory

to the Indemnified Party; *provided* that the failure to give such notice shall not affect the Indemnified Party's rights to indemnification hereunder, except to the extent that the Indemnifying Party is actually and materially prejudiced thereby and then only to the extent of such prejudice; *provided further* that the Indemnifying Party shall not be entitled to assume and control the defense, compromise or settlement of any Third Party Claim if (w) such Third Party Claim in respect of an Assumed Liability is also a Claim with respect to a Retained Liability, (x) such Third Party Claim seeks as the sole remedy injunctive relief, other equitable relief or any other non-monetary relief against the Indemnified Party, (y) the Third Party Claim relates to or arises in connection with any criminal proceeding, action, indictment, allegation or investigation, or (z) the Third Party Claim seeks monetary damages and the sum of the amount of the monetary damages would reasonably be expected to be greater than the maximum amount from which the Indemnifying Party is required to indemnify the Indemnified Party pursuant to this Article IX, but the Indemnifying Party shall be entitled to participate in the defense of any such Third Party Claim (at its cost and expense). The Indemnifying Party shall have [*] Business Days after receiving notice from the Indemnified Party of such Third Party Claim and upon written notice to the Indemnified Party to assume the conduct and control of the defense, negotiation and settlement of such Third Party Claim. The Indemnified Party shall provide the Indemnifying Party with all material information in its possession related to the Third Party Claim, all authority and all assistance reasonably necessary to enable the Indemnifying Party to carry on the defense of such suit; *provided*, that the Indemnified Party, at its own expense, reserves the right to retain its own counsel to participate in the defense of such suit. In no event shall the Indemnifying Party agree to any compromise or settlement of a Third Party Claim without the prior written consent of the Indemnified Party unless such judgment or settlement (a) is for monetary damages only and such judgment or settlement includes a complete release of the Indemnified Party from further Liability and (b) does not involve any finding or admission of any violation of Law or admission of any wrongdoing by the Indemnified Party and provides a full and complete release of the Indemnified Party. In no event shall the Indemnified Party agree to any compromise or settlement of a Third Party Claim without the prior written consent of the Indemnifying Party.

(b) In the event an Indemnified Party may have a claim against the Indemnifying Party that does not involve a Third Party Claim being asserted against or sought to be collected from such Indemnified Party (a "Direct Claim"), the Indemnified Party shall promptly (but no later than [*] calendar days following the Indemnified Party becoming aware of such claim) notify the Indemnifying Party in writing of such Direct Claim. The failure of the Indemnified Party to notify the Indemnifying Party hereunder promptly shall not relieve the Indemnifying Party of its obligations hereunder except to the extent that the Indemnifying Party is actually and materially prejudiced thereby and then only to the extent of such prejudice. Such notice by the Indemnified Party shall describe the Direct Claim in reasonable detail and shall indicate the estimated amount, if reasonably practicable, of the Loss that has been or may be sustained by the Indemnified

Party. The Indemnifying Party shall have [*] calendar days after its receipt of any such notice to respond in writing to such Direct Claim. During such [*] day period, the Indemnified Party shall allow the Indemnifying Party and its advisors to investigate the matter or circumstance alleged to give rise to the Direct Claim, and whether and to what extent any amount is payable in respect of the Direct Claim, and the Indemnified Party shall assist the Indemnifying Party's investigation by giving such information and assistance (including access to the Indemnified Party's premises and personnel and the right to examine and copy any accounts, documents or records) as the Indemnifying Party or any of its advisors may reasonably request. If the Indemnifying Party does not so respond within such [*] day period, the Indemnifying Party shall be deemed to have rejected such claim, in which case the Indemnified Party shall be free to pursue such remedies as may be available to the Indemnified Party on the terms and subject to the provisions of this APA. If the Indemnifying Party disputes a Direct Claim within the [*] day period, the Indemnifying Party and Indemnified Party shall attempt to resolve in good faith such dispute within the [*] day period after the Indemnifying Party delivers notice of such dispute. If such Direct Claim is not so resolved within such [*] day period, then either Party may initiate a Proceeding with respect to the subject matter of such Direct Claim in accordance with this APA.

Section 9.05 Expiration. Except in connection with Fraud or as otherwise set forth in this APA, demands for indemnification under this Article IX must be notified by the Indemnified Party to the Indemnifying Party during the following periods, following which no indemnification shall be due; *provided* that any Claim brought prior to the expiration of the applicable period below shall be preserved until final resolution thereof:

(a) for Claims arising from [*], until [*]; and

(b) for Claims for [*], until [*].

Section 9.06 Sole Remedy; Waiver. Except in connection with Fraud or as otherwise expressly set forth in this APA, the indemnification set forth in this Article IX shall be the sole and exclusive remedy with respect to the matters set forth herein. In furtherance of the foregoing, each of the Parties hereby waives, from and after the Closing Date, to the fullest extent permitted by applicable Legal Requirement, any and all other rights, claims and causes of action (including rights of contributions, if any) known or unknown, foreseen or unforeseen, which exist or may arise in the future, that it may have against Seller or any of its Affiliates, or Purchaser or any of its Affiliates, as the case may be, arising under or based on warranty, in contract, in tort (including negligence or strict liability) or any other applicable Legal Requirement, except that nothing herein shall limit the liability of either Party for Fraud.

Section 9.07 Payments. The Indemnifying Party shall pay to the Indemnified Party all sums owed by the latter under this Article IX as soon as said sums have become due and payable, as a result of a judgment, settlement or enforceable decision.

Section 9.08 Claims Net of Insurance, Etc. If subsequent to the payment of any amount by an Indemnifying Party with respect to a payment made by an Indemnified Party to a Third Party, the Indemnified Party receives reimbursement of the sum paid to a Third Party from a Third Party or such payment is no longer required, the Indemnified Party shall promptly refund the amount of the payment received (net of any costs or expenses of recovery) to the Indemnifying Party.

Section 9.09 Mitigation. Upon becoming aware of any event or condition that would reasonably be expected to give rise to any Loss, the applicable Indemnified Parties will use or procure the using by its

relevant Affiliates of commercially reasonable efforts to mitigate any Losses, *provided* that the Parties agree that the reasonable costs of such mitigation may be Losses hereunder. If an Indemnified Party fails to use its commercially reasonable efforts to mitigate a Loss, the Losses to which such Indemnified Party is entitled to be indemnified pursuant to this Article IX shall be reduced to the extent the Indemnifying Party demonstrates that the Indemnified Party's failure to use its commercially reasonable efforts to mitigate such Loss increased the amount of such Loss.

ARTICLE X- GOVERNING LAW AND ENFORCEMENT

Section 10.01 Governing Law. This APA shall be governed by and construed in accordance with the Laws of the State of Delaware, U.S.A., without regard to the choice or conflict of law principles (whether of the State of Delaware or any other jurisdiction) that would result in the application of the Laws of a different jurisdiction.

Section 10.02 Enforcement and Specific Performance. Each of the Parties acknowledges that the rights of each party to consummate the transactions contemplated hereby are unique and recognizes and affirms that in the event of a breach of this APA by any Party, money damages may be inadequate, and the non-breaching Party may have no adequate remedy at law. Accordingly, the Parties agree that such non-breaching Party shall have the right, in addition to any other rights and remedies existing in their favor at law or in equity, to enforce their rights and the other Party's obligations hereunder not only by an action or actions for damages but also by an action or actions for specific performance, injunctive and/or other equitable relief (without posting of bond or other security).

Section 10.03 Consent to Jurisdiction. All actions and Proceedings arising out of or relating to this APA shall be brought only in the courts of the State of Delaware or in a United States District Court sitting in the State of Delaware. Each Party irrevocably consents to and confers personal jurisdiction on the courts of the State of Delaware and the United States District Courts sitting in the State of Delaware, and expressly waives any objection to the venue of such court, as the case may be,

and agrees that service of process may be made on such Party by mailing a copy of the pleading or other document by registered or certified mail, return receipt requested, to its addresses for the giving of notice provided for in Section 11.03 hereof, with service being deemed to be made five (5) Business Days after the giving of such notice.

Section 10.04 Waivers. **IN CONNECTION WITH ANY DISPUTE HEREUNDER OR RELATED HERETO, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, EACH PARTY HERETO WAIVES ITS RIGHT TO TRIAL OF ANY ISSUE BY JURY**.

IN CONNECTION WITH ANY DISPUTE HEREUNDER, EACH PARTY HERETO WAIVES (i) ANY CLAIM TO PUNITIVE, EXEMPLARY OR MULTIPLIED DAMAGES AND (ii) ANY CLAIM OF INDIRECT, INCIDENTAL OR SPECIAL DAMAGES, IN EACH CASE FROM THE OTHER PARTY HERETO (OR ANY AFFILIATE OF SUCH OTHER PARTY HERETO), EXCEPT THAT THE COURT SHALL HAVE THE POWER TO AWARD ANY RELIEF PROVIDED BY GOVERNING STATUTE.

IN CONNECTION WITH ANY DISPUTE HEREUNDER, EACH PARTY HERETO WAIVES ANY CLAIM OF CONSEQUENTIAL OR LOST PROFITS DAMAGES FROM THE OTHER EXCEPT FOR CLAIMS ARISING OUT OF OR RESULTING

FROM A BREACH OF CONFIDENTIALITY OR INTELLECTUAL PROPERTY RIGHTS.

ARTICLE XI- MISCELLANEOUS

Section 11.01 Further Assurances. Each Party undertakes to execute and deliver all other papers, agreements, documents and instruments that are reasonably necessary to fulfill the purpose of this APA. Upon Purchaser's reasonable request, Seller and its Affiliates shall execute and deliver assignment agreements and other transfer documentation, including duly executed assignments of the Transferred IP for recording with the applicable Governmental Authority, and to take such further actions, in each case at Purchaser's reasonable cost and expense and as may be required, to give effect to the foregoing assignments. Purchaser shall proceed with the recording of such duly executed intellectual property assignment agreements or similar transfer documentation, as applicable, at Purchaser's sole cost and expense.

Section 11.02 Performance by Affiliates. To the extent that this APA refers to an obligation of a Party that must be performed, satisfied or fulfilled by an Affiliate of such Party, such Party agrees to cause its Affiliate to perform, satisfy or fulfill such obligations, it being understood and agreed that such Affiliates are not parties to this APA or bound hereby. Any obligation of a Party to the other Party under this APA, which obligation is performed, satisfied or fulfilled by an Affiliate of such Party, shall be deemed to have been performed, satisfied or fulfilled by such

Party. For the avoidance of doubt, only Seller and Purchaser shall be bound by obligations of indemnification hereunder or under the Implementation Agreements, each for itself and for any claims arising from the actions or omissions of any of its Affiliates that become parties to such Implementation Agreements.

Section 11.03 Notices. All notices, requests, permissions, waivers and other communications hereunder shall be in writing and shall be deemed to have been duly given or delivered (a) when sent, if sent by electronic mail; *provided* the electronic mail receipt is promptly confirmed by telephone or electronic mail or so long as the sender has not received an automatic notification indicating delivery failure,
(b) when delivered, if delivered personally to the intended recipient and (c) one
(1) Business Day following sending by overnight delivery via a reputable international courier service that maintains record of receipt and, in each case, addressed to a party at the following address for such party:

if to Seller, to:

Quince Therapeutics, Inc.
601 Gateway Blvd., Suite 1250 San Francisco,
CA 94080 Attention: Brendan
with a copy (which shall not constitute notice) to: Cooley LLP
10265 Science Center Drive
San Diego, CA 92121 Attention: Charity

if to Purchaser, to:

Lighthouse Pharmaceuticals, Inc. 5214F Diamond Heights
Blvd #3470 San Francisco, CA 94131

Attention: Casey Lynch
with a copy (which shall not constitute notice) to: Orrick, Herrington & Sutcliffe LLP
1000 Marsh Road Menlo Park, CA
94025 Attention: Scott Iyama

David Schulman

or to such other address(es) as shall be furnished in writing by any such party to the other parties in accordance with the provisions of this Section 11.03.

Section 11.04 Amendment; Waiver. Any provision of this APA and any Implementation Agreement may be amended, discharged, released or waived if, and only if, such amendment or waiver is in writing and signed by a duly authorized representative of: (a) in the case of an amendment, Purchaser and Seller, and (b) in the case of a waiver, the Party or entity against whom the discharge, release or waiver is to be effective. No failure or delay by either Party or entity in exercising any right, power or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege. No waiver by one of the Parties of one or several provisions of this APA or any Implementation Agreement or, in the event of the violation thereof, shall constitute a precedent for another case involving this provision or any other provision. Furthermore, in the event of the waiver of a particular provision, all the other provisions of this APA or any Implementation Agreement shall remain in full force and effect.

Section 11.05 Assignment. Neither Party to this APA may assign any of its rights or obligations under this APA, including by operation of Law in connection with a merger or sale of substantially all the assets or otherwise, without the prior written consent of the other Party, except that either Party may, without such consent, assign its rights to, or have its obligations discharged by, an Affiliate of such Party, in whole or in part, *provided* that such Party shall remain liable for the timely and complete performance of its obligations hereunder, and *provided*, *further*, that such assignment or sublicense will not cause adverse tax consequences to the non-assigning Party (or such Party's Affiliates).

Section 11.06 Entire Agreement. This APA, the Bill of Sale and Assignment and Assumption Agreement, the Implementation Agreements and the Annexes hereto and thereto and all other documents and agreements referred to expressly herein and therein, contains the entire agreement among the Parties with respect to the subject matter hereof and supersedes all prior agreements, understandings, negotiations, commitments and documents, whether oral or written, with respect to such matters.

Section 11.07 Parties in Interest. This APA shall inure to the benefit of and be binding upon the Parties and their respective successors and permitted assigns. Nothing in this APA, express or implied, is intended to confer upon any Person other than Purchaser and Seller, or their successors or permitted assigns, any rights or remedies under or by reason of this APA.

Section 11.08 Expenses. Except as otherwise expressly provided in this APA, whether or not the transactions contemplated by this APA are consummated, all other costs and

expenses incurred in connection with this APA and the transactions contemplated hereby shall be borne by the Party incurring such expenses.

Section 11.09 Counterparts. This APA may be executed in one or more counterparts and in PDF format, each of which shall be deemed an original, and together shall constitute one and the same agreement and shall become effective when one or more counterparts have been signed by each of the Parties and delivered to the other Party, it being understood that both Parties need not sign the same counterpart.

Section 11.10 Headings; Interpretation. The heading references herein and the table of contents hereto and in the Implementation Agreements are for convenience purposes only, do not constitute a part of such agreements and shall not be deemed to limit or affect any of the provisions hereof or thereof.

Section 11.11 Severability. The provisions of this APA and the Implementation Agreements shall be deemed severable and the invalidity or unenforceability of any provision shall not affect the validity or enforceability of the other provisions hereof or thereof. If any term or other provision of the APA or the Implementation Agreements or the application thereof to any Person or any circumstance, is held to be invalid, illegal or unenforceable, (a) a suitable and equitable provision shall be substituted therefore in order to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid or unenforceable provision and
(b) the remainder of the APA or the Implementation Agreements and the application of such provision to other Persons or circumstances shall not be affected by such invalidity, illegality or unenforceability, nor shall such invalidity, illegality or unenforceability affect the validity or enforceability of such provision, or the application thereof, in any other jurisdiction. To the extent permitted under applicable Law, each Party waives any legal provision making a provision of the APA or the Implementation Agreements invalid, illegal or non- enforceable in all respects.

Section 11.12 Language. This APA and the Implementation Agreements have been prepared in the English language and all issues of interpretation shall be determined by reference to the English language original. To the extent that the original version of any document to be provided, or any communication to be given or made, to Seller under this APA or any Implementation Agreement is in a language other than English, the document or communication shall be accompanied by an English translation certified by an authorized representative of Purchaser to be a true and correct translation of the original. Seller may, if it so requires, obtain an English translation of any document or communication received in another language other than English at the cost and expense of Purchaser. Seller may deem any such English translation to be the governing version between Seller and Purchaser.

Section 11.13 Confidentiality. For purposes of duties of confidentiality and obligations related thereto and to public statements with respect to the transactions contemplated by

this APA or any Implementation Agreement, the Parties acknowledge and agree that (a) effective as of Closing, all of the Transferred Know-How shall be deemed to be "Confidential Information" of Purchaser (but no longer Seller) under the Confidentiality Agreement and (b) the terms of the Confidentiality Agreement shall govern and apply *mutatis mutandis* to Seller and, in the case of Purchaser, to Purchaser in substitution for Casey Lynch and (c) the definition of "Opportunity" shall be deemed to include the evaluation of the rights to Develop, Manufacture and Commercialize the Product Compounds and the Products and the Transferred Assets. Notwithstanding any term or survival periods set forth in the Confidentiality Agreement, the Parties acknowledge and agree that, with regard to this APA, the terms of the Confidentiality Agreement shall be effective for as long as any provision of this APA remains

in effect and shall remain in force indefinitely for provisions related to intellectual property and trade secrets, and that the obligations of confidentiality and non-disclosure shall survive indefinitely for so long as the Parties shall possess or control Confidential Information (as defined in the Confidentiality Agreement) of the other Party.

Section 11.14 Time is of the Essence. The Parties hereby expressly acknowledge and agree that time is of the essence for each and every provision of this APA.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Parties have duly executed this Agreement effective as of the Execution Date.

QUINCE THERAPEUTICS, INC.

By:
Name:
Title:

IN WITNESS WHEREOF, the Parties have duly executed this Agreement effective as of the Execution Date.

LIGHTHOUSE PHARMACEUTICALS, INC.

By:
Name:
Title:

List of Annexes:

Annex A – Definitions

Annex B – Stock Issuance Agreement

Annex C – Confidentiality Agreement

Annex D – Patent Assignment Agreement

Annex E – Trademark Assignment Agreement

Annex F – Transferred Patents

Annex G – Product Compounds

Annex H – Transferred Trademarks

Annex I-1 – Seller Transfer Letter

Annex I-2 – Purchaser Transfer Letter

Annex A

Definitions, Definitional Provisions and Rules of Construction

Section 1. Definitions.

In this APA, unless the context otherwise requires:

"Adverse Event" means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related, including an adverse event occurring in the course of the use of a drug product in professional practice, an adverse event occurring from drug overdose whether accidental or intentional, an adverse event occurring from drug abuse or drug withdrawal, and any failure of expected pharmacological action.

"Affiliate" means, with respect to any Person, any other Person directly or indirectly controlling, controlled by, or under common control with, such Person at any time during the period for which the determination of affiliation is being made. For purposes of this definition, "control" of a Person means the power, direct or indirect, to direct or cause the direction of the management and policies of such Person whether by contract or otherwise and, in any event and, without limitation of the previous sentence, any Person owning more than fifty percent (50%) or more of the voting securities of another Person shall be deemed to control that Person.

"Allocation" has the meaning set forth in Section 3.09.

"Ancillary Agreements" shall mean any agreement between Seller and Purchaser, or any of their respective Affiliates entered, executed or delivered in accordance with, in connection with or required by this Agreement, and any other agreement or certificate specifically identified as an Ancillary Agreement for purposes of this Agreement.

"APA" and "Agreement" each has the meaning set forth in the preamble.

"Approval" shall mean any approval, registration, license or authorization from any Governmental Authority in any jurisdiction required for the Manufacture, Development or Commercialization of a Product in such jurisdiction.

"Assumed Liabilities" shall have the meaning set forth in Section 2.07.

"Bill of Sale and Assignment and Assumption Agreement" means the Bill of Sale and Assignment and Assumption Agreement, dated as of December 2, 2022, by and between Purchaser and Seller.

"Business" shall mean the Development and Manufacture of the Products by and on behalf of the Seller on or prior to the Effective Date.

"Business Day" means any weekday other than a day that is a public holiday in San Diego, California.

"Calendar Quarter" shall mean each successive period of three (3) months ending on March

31, June 30, September 30 and December 31 of each Calendar Year; *provided* that the first Calendar Quarter for the first Calendar Year extends from the Effective Date to the end of the then-current Calendar Quarter and the last Calendar Quarter extends from the first day of such Calendar Quarter until the effective date of the termination or expiration of this APA.

"Calendar Year" shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31; *provided* that the first Calendar Year under this APA will be the period beginning on the Effective Date and ending on the end of the Calendar Year in which the Effective Date is encompassed and the last Calendar Year of the Term will be the period beginning on January 1 of the Calendar Year in which the expiration or termination of the APA occurs and ending on the effective date of expiration or termination of the APA.

"Change of Control" means with respect to Purchaser: (a) the acquisition by a Third Party, in one transaction or a series of related transactions, of direct or indirect beneficial ownership of more than fifty percent (50%) of the outstanding voting equity securities of Purchaser; (b) a merger, reorganization or consolidation involving Purchaser, as a result of which a Third Party acquires direct or indirect beneficial ownership of more than fifty percent (50%) of the voting power in the surviving entity immediately after such merger, reorganization or consolidation; or (c) a sale of all or substantially all of the assets of Purchaser in one transaction or a series of related transactions to a Third Party; it being understood and agreed that in no event shall a "Change of Control" include any "Sublicense" under this Agreement.

"Claims" shall have the meaning set forth in Section 9.03. "Closing" shall have the meaning set forth in Section 2.02. "Closing Date" shall have the meaning set forth in Section 2.02. "Code" has the meaning set forth in Section 3.09.
"Combination Product" means a Product that is: (a) sold in the form of a combination that contains or comprises the therapeutically active pharmaceutical agent contained in a Product together with one or more other therapeutically active pharmaceutical agents (whether co-formulated or co-packaged or otherwise sold for a single price); (b) sold for a single invoice price together with any
(i) delivery device or component therefor; (ii) companion diagnostic related to any Product; or (iii) product, process, service or therapy other than a Product

(such additional therapeutically active pharmaceutical agent and each of (i) through (iii), an "Other Component").

"Commercialize" means to market, promote, distribute, offer to sell, sell and/or have sold a Product and/or conduct other commercialization activities, and "Commercialization" means commercialization activities relating to a Product, including activities relating to marketing, promoting, distributing, offering for sale, and/or selling of such Product or having such Product sold to trade, institutional, prescriber, payer, pharmacist and patient customers or otherwise.

"Completion" means, with respect to any clinical trial, the date the tables, figures and listings for such clinical trial are finalized.

"Confidentiality Agreement" means the Confidentiality Agreement, dated [*], by and between Seller and Casey Lynch attached hereto as Annex C.

"COR388" means (a) the compound identified on Annex G hereto as "COR388", (b) any Derivative thereof, and (c) any isotope, stereoisomers, salt, solvate, hydrate, ester, isomer, or polymorph of any of the foregoing.

"COR388 Animal Health IP" shall have the meaning set forth in Section 8.05.

"COR588" means (a) the compound identified on Annex G hereto as "COR588", (b) any Derivative thereof, and (c) any isotope, stereoisomers, salt, solvate, hydrate, ester, isomer, or polymorph of any of the foregoing.

"COR803" means (a) the compound identified on Annex G hereto as "COR803", (b) any Derivative thereof, and (c) any isotope, stereoisomers, salt, solvate, hydrate, ester, isomer, or polymorph of any of the foregoing.

"COR852" means (a) the compound identified on Annex G hereto as "COR852", (b) any Derivative thereof, and (c) any isotope, stereoisomers, salt, solvate, hydrate, ester, isomer, or polymorph of any of the foregoing.

"Cover" or "Covering" means, with respect to a Milestone Patent, that the making, using, selling, importing or offering for sale of the Product, or the practice of a method to make or use such Product would infringe a Valid Claim of the relevant Milestone Patent in the Territory or in the country where any such act relating to such Product occurs.

"Derivative" means any pharmaceutical compound that (a) is a derivative of a Product Compound and (b) following Closing, does not require any new preclinical toxicology study to be conducted in order to initiate a clinical trial in humans for the dosing of such pharmaceutical compound.

"Develop" or "Development" means activities with respect to developing a Product and obtaining Marketing Authorization or Approvals, including pre-

clinical research and development, clinical development, preparation and submission of regulatory filings, and product registration.

"Direct Claim" shall have the meaning set forth in Section 9.04(b). "Electronic Data Site" has the meaning set forth in Section 4.01. "Excluded Assets" has the meaning set forth in Section 2.06. "Execution Date" has the meaning set forth in the preamble.
"Europe Major Markets" shall mean each of the United Kingdom, Germany, Italy, France and Spain.

"EMA" shall mean the European Medicines Agency and any successor agency thereto.

"FDA" shall mean the United States Food and Drug Administration and any successor agency thereto.

"First Commercial Sale" means, on a country-by-country basis, the first sale of a Product by

Purchaser, its Affiliates or its Sublicensees to an end user or prescriber for use, consumption or resale of the Product in a country in the Territory where Regulatory Approval of the Product has been obtained. Sale of a Product under this Agreement by Purchaser or any Sublicensee to an Affiliate (or by Purchaser to a Sublicensee) shall not constitute a First Commercial Sale unless such Affiliate or such Sublicensee is the commercial end user of such Product and such sale results in a Net Sale. First Commercial Sale excludes any transfers of Product to Third Parties for clinical trials or for any so-called treatment investigational new drug sales, named patient sales, expanded access program, compassionate or emergency use sales or pre-license sales made for non-commercial, compassionate use purposes, sales at or below cost for purposes of testing any Product prior to Regulatory Approval, or any indigent program or promotional or educational purposes, *provided* that such sales are made at or below cost.

"Fraud" shall mean actual fraud (as defined under the laws of the State of Delaware) with respect to the making of the representations or warranties contained in Article VI (and not, for the avoidance of doubt, constructive fraud, equitable fraud or promissory fraud or negligent misrepresentation or omission, or any form of fraud based on recklessness or negligence).

"Generic Product" means, on a country-by-country and Product-by-Product basis, any pharmaceutical product that (a) is lawfully sold by a Third Party that is not a (sub)licensee of Purchaser or any of its Affiliates under a Regulatory Approval granted to a Third Party that is not (sub)licensee of Purchaser or any of its Affiliates by a Regulatory Authority in such country to such Third Party and (b) contains the same compound as such Product and is approved, as applicable, (i) in the United States pursuant to section 505(j) of the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 355(j)) and designated as automatically substitutable or therapeutically equivalent in the FDA's Orange Book or (ii) in any other country pursuant to any equivalent applicable Law and designated as automatically substitutable or therapeutically equivalent thereunder.

"Global Safety Database" means the database (or portion thereof) containing Adverse Events for the Product that supports regulatory reporting, overall drug safety surveillance and responses to safety queries relating to Product from Governmental Authorities and includes safety reports relating to Product collected worldwide.

"Governmental Authority" means any (i) supranational, national, regional, state, county, city, town, village, district or other jurisdiction; (ii) federal, state, local, municipal, foreign or other government; (iii) governmental or quasi-governmental authority of any nature (including any agency, branch, department or instrumentality thereof, including any business, company, enterprise or other entity owned or controlled, in whole or in part, by any government and any court or other tribunal); (iv) multinational organization; (v) body exercising, or entitled to exercise, any administrative, executive, judicial, legislative, police, regulatory or Taxing Authority or power of any nature; or (vi) any arbitral authority.

"Governmental Authorization" means all filings with any Governmental Authority, consents, approvals, or notices (to the extent required from a Governmental Authority), licenses, franchises, permits, concessions, exemptions, orders, certificates, registrations, re-registrations, applications, declarations and filings pertaining to the aforesaid issued, granted, given or otherwise made available by or under the authority of any Governmental Authority or pursuant to any applicable Legal Requirements.

"Implementation Agreements" means (i) the Patent Assignment Agreement;

(ii) the Trademark Assignment Agreement; and (iii) the Stock Issuance Agreement.

"Indemnified Party" has the meaning set forth in Section 9.03. "Indemnifying Party" has the meaning set forth in Section 9.03.

"Indication" means any human disease, condition or syndrome, or sign or symptom of, or associated with, a human disease, condition or syndrome in a particular target patient population; it being understood that [*].

"Initiation" or "Initiated" means, with respect to any clinical trial for a Product, the date that a human subject or patient enrolls in a clinical trial by executing the informed consent form to participate in such clinical trial.

"Investigational New Drug Application" or "IND" means each of: (a) the Investigational New Drug application #134303 filed with the FDA pursuant to 21 C.F.R. §321 with respect to COR388 (the "U.S. IND"); and (b) the Clinical

Trial Notification #CT-2021-CTN-02193-1 filed pursuant to Australian regulations detailed in the "Integrated Addendum to ICH E6(Rl): Guideline for Good Clinical Practice ICH E6(R2)" with the Therapeutic Goods Administration ("TGA") with respect to COR588 (the "Australian CTN").

"Know-How" means, as and to the extent specifically related to any Products, any and all information, knowledge and materials, whether or not in written form, including but not limited to all technical information, know-how and trade secrets, formulas, prototypes, specifications, directions, instructions, inventory, test protocols, procedures, processes and results, studies, analyses, raw material sources, data, manufacturing data, formulation or production technology, inventions (whether patentable or not), patent disclosures, discoveries, techniques, systems, algorithms, processes and methods, including without limitation, all chemical, pharmaceutical, toxicological, biochemical, and biological, technical and non-technical data, and information relating to the results of tests, assays, methods and processes, and specifications and/or other documents containing information and related data, and any preclinical, clinical, assay control, manufacturing, regulatory.

"Law" or "Laws" means any statute, law, ordinance, treaty, rule, code, regulation, judgment or other directive issued, promulgated or enforced by any Governmental Authority.

"Legal Requirements" means any applicable Law, legislation, statutes, directives, regulations, rules and other legislative instruments, measures, treaties, conventions and other agreements between states, or between states and supranational bodies, and rules of common or civil law, in each case, having the force of law and having effect in any jurisdiction.

"Liabilities" means any and all debts, liabilities, assessments, expenses, deficiencies, judgments, losses, damages, fines, demands for payment, penalties and obligations of any nature, whether accrued or unaccrued, known or unknown, express or implied, primary or secondary, direct or indirect, liquidated, disputed or undisputed, absolute or contingent, matured or un-matured or determined or determinable and whether due or to become due.

"Lien" means, with respect to any property or asset, any charge, claim, mortgage (including equitable mortgage and mortgage by deposit of title deeds), hypothecation, servitude, easement, right of way, adverse ownership claim, title defect, covenant, equitable interest,

license, lease, sub-lease or other possessory interest, lien, Tax lien, option, pledge, security interest, preference, priority, right of first refusal, restriction or other encumbrance of any kind or nature whatsoever (whether absolute or contingent).

"Losses" means, with respect to any Person, any and all actual losses, damages, Liabilities, costs and expenses, including reasonable attorneys' fees and expenses, imposed upon or incurred by such Person; *provided* that "Losses" shall (i) not

include any exemplary, consequential, special or punitive damages (except to the extent paid or payable to an unaffiliated third party) and (ii) shall be calculated on the basis of actual losses without regard to reductions in value, lost opportunities, speculative damages or any multiple of damages (including any multiple of revenue, EBITDA or the like).

"Manufacture" or "Manufacturing" shall mean any activities directed to making, having made, producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing, test method development and stability testing, manufacturing process development, formulation development, delivery system development, quality assurance and quality control development, statistical analysis and release, shipping and storage of a drug or biologic product or compound, or any raw materials thereof, directly or through one or more Third Parties, whether for Development or Commercialization.

"Marketing Authorization" means each of the registrations, approvals, or other licenses, permits or other authorization granted by a Governmental Authority and held by Seller, any Sublicensees or any of their respective Affiliates relating to a Product in the Territory necessary for the marketing and sale of such Product in such Territory.

"Milestone Patent" means, as and to the extent it Covers a Product Compound or any Derivative thereof: (a) each Transferred Patent, any patent application claiming priority to any Transferred Patent, any foreign counterparts of any of the foregoing, any patents issued or granted with respect to any of the foregoing; and (b) any other Patent owned or controlled by (i) Purchaser or its Affiliates or (ii) in the case of any sale or other transfer of Transferred Know-How to a Sublicensee (excluding any merger, demerger, consolidation, or license but including any sale or transfer of Transferred Know-How to any subsidiary or other Affiliate of Purchaser), any Sublicensee, in each case, as and to the extent that such Patent claims any of the Transferred Know-How.

"Net Sales" means, with respect to a Product, the gross sales amount invoiced by Purchaser, its Affiliates or any Sublicensee thereof (individually and collectively, the "Selling Parties") to Third Parties (including Third Party Distributors), excluding any Sublicensee if such sale is for resale, but the subsequent resale of such Product to a Third Party shall be included, for the Product in the Territory, less:

(a) Trade, quantity and cash discounts allowed;

(b) Discounts, refunds, rebates, chargebacks, retroactive price adjustments and any other allowances which effectively reduce the net selling price;

(c) Product returns and allowances;

(d) Any tax imposed on the production, sale, delivery or use of the Product, including sales, use, excise or value added taxes, or the portion of the annual fee imposed on the pharmaceutical

manufacturers by the U.S. government that the Selling Party allocates to sales of such Product in accordance with its standard policies and procedures consistently applied across its products;

(e) That portion of the sales value associated with drug delivery systems;

(f) Wholesaler inventory management fees;

(g) Allowance for distribution expenses; and

(h) [*] in accordance with U.S. Generally Accepted Accounting Principles ("U.S. GAAP") or International Financial Reporting Standards ("IFRS"), as applicable (and U.S. GAAP and IFRS, the "Accounting Standards"), in each case, consistently applied across such Selling Party's therapeutic product portfolio.

Net Sales will exclude any samples of Product transferred or disposed of for clinical trials or at or below costs of goods therefor for any so-called treatment investigational new drug sales, named patient sales, expanded access program, compassionate or emergency use sales or pre-license sales made for non-commercial, compassionate purpose, or any indigent program or promotional or educational purposes, in all cases if such sale or disposition is at or below costs of goods therefor.

Such amounts shall be determined from the books and records of Purchaser, its Affiliate or Sublicensee, as applicable, maintained in accordance with U.S. GAAP or, in the case of Sublicensees, such other Accounting Standards, as are used by the Sublicensee, consistently applied. Purchaser further agrees in determining such amounts, it, its Affiliates and Sublicensees will use their respective current standard procedures and methodology, including their respective then current standard exchange rate methodology for the translation of foreign currency sales into U.S. Dollars consistently applied. In no event will any particular amount be deducted more than once in calculating Net Sales.

In the event that the Product is sold as part of a Combination Product, the Net Sales of the Product, for the purposes of determining royalty payments, shall be determined by multiplying the Net Sales of the Combination Product (as defined in the standard Net Sales definition) by the fraction, A / (A+B) where A is the weighted average sale price of the Product when sold separately without any Other Component in finished form, and B is the weighted average sale price of the Other Component(s) sold separately in finished form.

In the event that the weighted average sale price of the Product can be determined but the weighted average sale price of the Other Component(s) cannot be determined, Net Sales for purposes of determining royalty payments shall be

calculated by multiplying the Net Sales of the Combination Product by the fraction A / C where A is the weighted average sale price of the Product when sold separately without any Other Component in finished form and C is the weighted average sale price of the Combination Product.

In the event that the weighted average sale price of the Other Component(s) can be determined but the weighted average sale price of the Product without any Other Component therein cannot be determined, Net Sales for purposes of determining royalty payments shall be calculated by multiplying the Net Sales of the Combination Product by the following formula: one (1) minus (B / C) where B is the weighted average sale price of the Other Component(s) when sold

separately in finished form and C is the weighted average sale price of the Combination Product.

In the event that the weighted average sale price of both the Product without any Other Component and the Other Component(s), when sold separately, in the Combination Product cannot be determined, the Net Sales of the Product shall be deemed to be equal to a mutually agreed percentage of the Net Sales of the Combination Product that reflects the relative value of the Product Compound in such Combination Product; *provided*, that if the Parties are unable to agree on such relative value within [*] days of commencement of discussions with respect to such relative value, despite their good faith efforts, then such percentage shall be [*].

The weighted average sale price for a Product without any Other Component(s) or Combination Product shall be calculated once each Calendar Year and such price shall be used during all applicable royalty reporting periods for the entire following Calendar Year. When determining the weighted average sale price of a Product without any Other Component(s) or Combination Product, the weighted average sale price shall be calculated by dividing the sales dollars (translated into Dollars) 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 without any Other Component(s) or Combination Product. In the initial Calendar Year, a forecasted weighted average sale price will be used for the Product without any Other Component(s) or Combination Product. 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.

"Net Sales Report" has the meaning set forth in Section 3.05.

"Ordinary Course of Business" means the usual, regular and ordinary course of business with respect to the development and/or manufacturing of the Product consistent with the past custom and practice of Seller.

"Party" has the meaning set forth in the preamble.

"Patent" means any patents, patent applications and patent rights, in each case, of any kind.

"Patent Assignment Agreement" means the Patent Assignment Agreement attached hereto as Annex D.

"Person" means a natural person, a limited liability company, a joint venture, a corporation, a partnership, an association, a trust, a division or an operating group of any of the foregoing or any other entity or organization, including any Governmental Authority.

"Permitted Lien" means any Lien in effect as of Closing for current Taxes not yet due and payable (or being contested in good faith and for which reserves have been established in accordance with U.S. GAAP).

"Phase I Clinical Trial" means a clinical trial (or any arm thereof) in which a Product is first administered in humans and includes any clinical trial that is generally consistent with 21 C.F.R. 312.21 (a) (or the non-United States equivalent thereof).

"Phase II Clinical Trial" means a clinical trial (or any arm thereof) of a Product generally consistent with 21 C.F.R. 312.21 (b) (or the non-United States equivalent thereof) which, for

avoidance of doubt, is a clinical study conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study.

"Phase III Clinical Trial" means a clinical trial (or any arm thereof) of a Product generally consistent with 21 C.F.R. 312.21 (c) (or the non-United States equivalent thereof) which, for avoidance of doubt, is intended to gather information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug.

"Pricing and Reimbursement Approval" means, with respect to a Product, the governmental approval, agreement, determination or decision of any Regulatory Authority establishing the price, maximum price or level of reimbursement for such Product in a jurisdiction where the applicable Regulatory Authority approves or determines the pricing of pharmaceutical products.

"Proceeding" means any action, arbitration, audit, examination, investigation, hearing, litigation or suit (whether civil, criminal, administrative, judicial or investigative, whether formal or informal, and whether public or private) commenced, brought, conducted or heard by or before, or otherwise involving, any Governmental Authority, excluding, in each case, routine administrative activities with respect to obtaining, maintaining and renewing MA and Governmental Authorization required for manufacturing, storage and distribution of Product, and prosecution, renewals, re-examination, inter-partes review, post- grant review or opposition proceeding and similar activities pertaining to

intellectual property before the United States Patent and Trademark Office or the United States Copyright Office.

"Product" means any pharmaceutical product that contains any of the Product Compounds and all (current and future) forms, presentations, strengths, formulations, dosages and delivery modes thereof.

"Product Compound" means each small molecule within the definition of COR388, COR588, COR803 or COR852 or that is claimed by any Milestone Patent.

"Product Files" means all electronic and other books and records containing regulatory, scientific and technical Transferred Know-How, documents, and information existing as of the Closing exclusively related to the Product in the Territory, including: (i) copies of the INDs, dossiers and submissions to and correspondence to and from the Governmental Authorities responsible for the grant of the INDs; (ii) the list of the composition thereof; and (iii) all scientific information underlying the INDs, including pre-clinical, clinical and other reports and publications related to characterizing the Product.

"Purchase Price" has the meaning set forth in Section 3.01. "Purchaser" has the meaning set forth in preamble.
"Purchaser Indemnified Persons" has the meaning set forth in Section 9.01.

"Regulatory Approval" means, with respect to a particular country or other regulatory jurisdiction, any approval of a Marketing Authorization, or other approval, product, or establishment license, registration, or authorization of any Regulatory Authority necessary for the Development, Manufacture, Commercialization of a Product in such country or other regulatory jurisdiction, excluding, in each case, Pricing and Reimbursement Approval.

"Regulatory Authority" means any applicable Governmental Authority involved in granting Regulatory Approval in a country or jurisdiction in the Territory, including in the U.S., the FDA and any other applicable Governmental Authority having jurisdiction over the Product; in the EU, the EMA or any competent Governmental Authority in the EU; in Japan, the PMDA; and any other applicable Governmental Authority having jurisdiction over a Product.

"Regulatory Exclusivity" means any exclusive marketing rights or data protection or other exclusivity rights conferred by any Governmental Authority with respect to a Product in a country or jurisdiction in the Territory (other than a Patent right), including orphan drug exclusivity, pediatric exclusivity, rights conferred in the
U.S. under the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. 355, as amended, in the EU under Directive 2001/83/EC, as amended, and Regulation (EC) No. 1901/2006, as amended, or rights similar thereto in other countries or regulatory jurisdictions in the Territory.

"Representative" means any officer, director, employee, agent, advisor or other representative of a Person.

"Retained Liability" has the meaning set forth in Section 2.08. "Revised Allocation" has
the meaning set forth in Section 3.09.
"Royalty Term" means, with respect to the payment of Royalties pursuant to Article III on a country-by-country and Product-by-Product basis, the period beginning upon the First Commercial Sale of a Product in a country and ending on the later of (a) expiration of the last-to-expire Valid Claim of any Milestone Patents Covering the Product in such country or (b) [*] years after the First Commercial Sale of such Product in such country or (c) the expiration of Regulatory Exclusivity in relation to such Product in such country.

"SEC has the meaning set forth in Section 8.03. "Seller" has the meaning set
forth in the preamble.
"Seller Indemnified Persons" has the meaning set forth in Section 9.02. "Seller Subsidiary"
means Cortexyme Australia, Pty Ltd.
"Stock Issuance Agreement" means the Stock Issuance Agreement attached hereto as Annex B.

"Subcontract" means any agreement or combination of agreements in which Purchaser or any of its Affiliates, with respect to the Transferred IP, permits any Third Party to provide services on a fee-for-service basis to Purchaser or any of its Affiliates and such agreement is or agreements are entered into solely for such fee-for-service purpose.

"Sublicense" means: (a) any license or right under the Transferred IP granted to a Third Party for the Development, Manufacture, use and/or Commercialization of any Product; (b) any agreement not to assert any of the Transferred IP against a Third Party; and/or (c) any future right to do any of the foregoing, including by an option; it being understood and agreed that in no event shall a "Sublicense" include (i) any "Change of Control" under this Agreement or (ii) any license or right under the Transferred IP to develop, manufacture and/or use any Product

granted under a Subcontract.

"Sublicense Income" mean any consideration (a) received by Purchaser or any of its Affiliates with respect to any Sublicense or (b) for the Change of Control of Purchaser; it being understood and agreed that "Sublicense Income" shall exclude all of the following: (a) net proceeds under a credit facility extended to Purchaser;
(b) direct cost reimbursement for (i) any supply of Products by or on behalf of Purchaser or any Affiliate, or (ii) any reimbursement for the conduct of future research or development activities for Products that Purchaser or any Affiliate

performs on behalf of a Sublicensee; (c) reimbursement of actual out-of-pocket patent prosecution and patent maintenance expenses; and (d) net proceeds resulting from any sale of any securities of Purchaser to Sublicensees up to the fair-market valuation of said securities on the date of closing.

"Sublicensee" shall mean a Third Party that is granted a Sublicense by Purchaser or any of its Affiliates.

"Tax" or "Taxes" means (a) any kind of tax, charge, assessment, fee, levy, duty or other similar charge in the nature of a Tax (including any tax on actual or deemed income, profits or gains, value added tax, sales tax, turnover tax, real or personal property tax, transfer tax, ad valorem tax, estimated tax, excise and custom duties, stamp duties, taxes similar to stamp duties, withholding tax, payroll tax, registration and mortgage duties and environmental taxes), any social security contributions or similar payments, charges and levies, together with all penalties, charges, increases and interests related to any of the foregoing, whether disputed or not, and (b) any obligation to indemnify or otherwise assume, succeed to or pay the Tax Liability of another Person as a transferee or successor, by contract or otherwise by operation of Law.

"Tax Return" means any return, report, declaration, information return, statement or other document filed or required to be filed with any Taxing Authority in connection with the determination, assessment or collection of any Tax or the administration of any Legal Requirements relating to any Tax.

"Taxing Authority" means any Governmental Authority having authority under Legal Requirements to assess, impose, collect, regulate or administer Taxes.

"Territory" means the entire world.

"Third Party" means any Person other than Seller, Purchaser or one of their respective Affiliates.

"Third Party Claim" has the meaning set forth in Section 9.04(a).

"Third Party Distributor" means, with respect to a country, any Third Party that purchases its requirements for Products in such country from Purchaser or its Affiliates or Sublicensees and is appointed as a distributor to distribute, market and resell such Product in such country.

"Trademark Assignment Agreement" means the Trademark Assignment Agreement attached hereto as Annex E.

"Trademarks" means trademarks, service marks, trade names, logos, slogans, designs, trade dress, common law trademarks and service marks and trade dress registrations and any registrations and applications for the foregoing with respect to the Product, together with all goodwill associated therewith.

"Transactions" mean, collectively, the transactions contemplated by the APA and the Implementation Agreements, including the purchase and sale of the Transferred APA Assets and the assumption of the Assumed Liabilities.

"Transfer Letters" means with respect to the U.S. IND, the letters to be filed with the FDA, substantially in the forms attached to this APA as Annex I-1 (the "Seller Transfer Letter") and Annex I-2 (the "Purchaser Transfer Letter"), respectively, to transfer the U.S. IND for the Product from Seller or its Affiliates to Purchaser in accordance with 21 C.F.R. Part 312.

"Transfer Taxes" means any U.S., state, county, local, non-U.S. and other sales, use, transfer, goods and services, value added, VAT, ad valorem, turnover, excise and customs duties, conveyance, documentary transfer, stamp duty and taxes similar to stamp duties, recording or other similar Tax imposed on or in connection with the transactions contemplated by or the instruments executed under or in connection with this APA or the recording of any sale, transfer, or assignment or property (or any interest therein) effected pursuant to this APA.

"Transferred APA Assets" has the meaning set forth in Section 2.03.

"Transferred Assets" has the meaning set forth in the Bill of Sale and Assignment and Assumption Agreement.

"Transferred Contracts" has the meaning set forth in the Bill of Sale and Assignment and Assumption Agreement.

"Transferred Know-How" means all Know-How (including Know-How contained in the Electronic Data Site) owned or otherwise controlled by Seller or its Affiliates which exclusively relates to the Products as of the Closing, including without limitation: (i) all of the Know-How relating to the manufacturing, nonclinical studies and clinical trials for the Product; and (ii) all of the Know- How relating to all Porphyromonas gingivalis ("P. gingivalis") related treatment and diagnostic assets, programs for all uses and Indications in the Territory, including COR588, COR388, COR803, and COR852 related small molecule families of lysine and arginine gingipain and other P. gingivalis targeted molecules.

"Transferred IP" means (i) Transferred Trademarks, (ii) Transferred Know-How and (iii) Transferred Patents.

"Transferred Patents" means the Patents identified on Annex F "Transferred Trademarks" means the Trademarks identified on Annex H. "Update Report" has the meaning set forth in Section 3.03.
"Valid Claim" shall mean, with respect to a particular country, either: (a) a claim in an issued and unexpired Milestone Patent in such country that has not

(i) expired, lapsed, been cancelled or abandoned, (ii) been disclaimed, revoked, held

unenforceable, unpatentable or invalid by a decision of a court or other governmental agency of competent jurisdiction in an order or decision which is unappealable or unappealed within the time allowed for appeal, (iii) been finally rejected by an administrative agency in an action that is unappealable or unappealed within the time allowed for appeal, or (iv) been admitted to be invalid or unenforceable through re-examination, re-issue, disclaimer or otherwise, or lost in an interference proceeding; or (b) a bona fide claim of a pending Patent application included within the Milestone Patents, and which has not been (i) cancelled, withdrawn or abandoned without being refiled in another application in the applicable jurisdiction or (ii) finally rejected by an administrative agency action from which no appeal can be taken or that has not been appealed within the time allowed for appeal; *provided*, that any claim in any Patent application pending for more than [*] years from the earliest date on which such Patent application claims priority shall not be considered a Valid Claim for purposes of the APA from and after such [*] year date unless and until a Patent containing such claim issues from such Patent application.

Section 2.Definitional Provisions and Rules of Construction.

(a) The words "hereof", "herein", "hereto" and "hereunder" and words of similar import when used herein shall refer to this APA as a whole and not to any particular provision of this APA.

(b) The terms defined in the singular shall have a comparable meaning when used in the plural, and vice versa.

(c) "Extent" in the phrase "to the extent" means the degree to which a subject or other thing extends, and such phrase does not mean simply "if."

(d) The term "including" shall mean "including, without limitation."

(e) All references to currency herein shall be to the currency specified or, if none is specified, to U.S. dollars. Unless otherwise specifically indicated, all references to "dollars" or "$" shall refer to the lawful money of the United States of America.

Annex B

Stock Issuance Agreement

[*]

Annex C

Confidentiality Agreement

[*]

Annex D

Patent Assignment Agreement

[*]

Annex E

Trademark Assignment Agreement

[*]

Annex F

Transferred Patents

[*]

Annex G

Product Compounds

[*]

Annex H

Transferred Trademarks

[*]

Annex I-1

Seller Transfer Letter

[*]

Annex I-2

Purchaser Transfer Letter

[*]

Annex J

Expedited Resolution

Notwithstanding anything to the contrary in the Agreement, if the Parties cannot agree on the terms of the license agreement pursuant to Section 8.05 (such dispute, an "Expert Matter"), such Expert Matter will be resolved through binding "baseball" arbitration pursuant to this Annex J rather than pursuant to the dispute

resolution procedures under Section 10.03. Either Party may send the other Party a written notice requesting to resolve the Expert Matter by using an independent expert who shall have no less than [*] of relevant expertise and experience with respect to the Expert Matter ("***Expert***") and shall be selected by mutual agreement of the Parties. If the Parties are unable to agree upon an Expert within [*] days after a Party gives the written notice requesting expert resolution, then each Party will have [*] days to choose a single independent expert meeting the criteria, and the Parties shall instruct such experts to use best efforts to mutually select within [*] days following the selection of the second of such expert, an independent third expert who meets such criteria to be the Expert. Within [*] days after appointment of the Expert, each Party shall submit to the expert one (1) proposal for resolving the applicable Expert Matter. The Expert will be instructed to select one Party's proposal no later than [*] days following the receipt of both Parties' proposals and to select the proposal that he or she determines is the most commercially reasonable under the circumstances and best gives effect to the intent of the Parties under this Agreement. The Expert shall accept only one (1) of the proposals submitted by the Parties (without making any changes to such proposal) and shall render such proposal as the Expert's final decision. Notwithstanding anything to the contrary in this Agreement, the Expert shall not have the authority to render any decision other than selecting one (1) proposal submitted by a Party pursuant to this Annex J. The Expert's decision shall be final and binding on the Parties. The costs of the expert determination shall be shared by the Parties, regardless of the outcome of the determination. All activities undertaken by the Expert will be conducted subject to obligations of confidentiality no less restrictive than those set forth in Section 11.13. Further, the Parties acknowledge and agree that their respective proposals and all information exchanged in connection with the expert proceedings, and the conduct of such proceedings and any information produced thereunder shall be Confidential Information under this Agreement and subject to the provisions of Section 11.13.

Exhibit 31.1

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Dirk Thye, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Quince Therapeutics, Inc. for the quarter ended March 31, 2023;

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of 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 15, 2023

/s/ Dirk Thye

Dirk Thye
President, Chief Executive Officer and Chairman of our Board of Directors
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brendan Hannah, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Quince Therapeutics, Inc. for the quarter ended March 31, 2023;

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of 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 15, 2023

/s/ Brendan Hannah

Brendan Hannah
Chief Business Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 (18 U.S.C. SECTION 1350)

In connection with the Quarterly Report of Quince Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2023 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 results of operations of the Company.

Date: May 15, 2023

By: /s/ Dirk Thye

Dirk Thye
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 (18 U.S.C. SECTION 1350)

In connection with the Quarterly Report of Quince Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2023 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 results of operations of the Company.

Date: May 15, 2023

By: /s/ Brendan Hannah

Brendan Hannah
Chief Business Officer
(Principal Financial Officer)