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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2022

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38890

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	Nasdaq Global Select Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 November 4, 2022, the registrant had 36,130,306 shares of common stock, $0.001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	September 30, 2022	December 31, 2021 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,809	$ 69,724
Short term investments	62,534	37,078
Prepaid expenses and other current assets	3,933	4,871
Total current assets	98,276	111,673
Property and equipment, net	375	263
Operating lease right-of-use assets, net	208	1,165
Long term investments	5,001	19,933
Intangible asset	5,900	—
Other assets	17	194
Total assets	$ 109,777	$ 133,228
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,181	$ 4,911
Accrued expenses and other current liabilities	3,764	9,311
Total current liabilities	4,945	14,222
Long-term financing lease liabilities	19	—
Long-term operating lease liabilities	34	420
Deferred tax liabilities	248	—
Total liabilities	5,246	14,642
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 authorized, no shares issued and outstanding as of September 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized, 36,130,306 and 30,074,412 issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	36	30
Additional paid in capital	387,473	355,234
Accumulated other comprehensive loss	(253)	(79)
Accumulated deficit	(282,725)	(236,599)
Total stockholders' equity	104,531	118,586
Total liabilities and stockholders' equity	$ 109,777	$ 133,228

(1) The balance sheet as of December 31, 2021 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 2,451	$ 14,038	$ 22,410	$ 45,582
General and administrative	4,344	7,639	22,461	21,192
Goodwill impairment charge	825	—	825	—
Total operating expenses	7,620	21,677	45,696	66,774
Loss from operations	(7,620)	(21,677)	(45,696)	(66,774)
Interest income	315	128	532	515
Other expense, net	(616)	(157)	(1,246)	(287)
Net loss before income tax benefit	(7,921)	(21,706)	(46,410)	(66,546)
Income tax benefit	—	—	284	—
Net loss	(7,921)	(21,706)	(46,126)	(66,546)
Other comprehensive income (loss):				
Foreign currency translation adjustments	343	18	481	18
Unrealized loss on available for sales securities	(130)	(64)	(655)	(260)
Total comprehensive loss	$ (7,708)	$ (21,752)	$ (46,300)	$ (66,788)
Net loss per share - basic and diluted	$ (0.22)	$ (0.73)	$ (1.41)	$ (2.25)
Weighted average shares of common stock outstanding - basic and diluted	35,612,749	29,767,376	32,758,132	29,637,328

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 September 30, 2022 and 2021						
	Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Income / (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance June 30, 2022	35,977,688	$ 36	$ 386,766	$ (466)	$ (274,804)	$ 111,532
Issuance of common stock on exercise of stock options and vesting of restricted stock units	152,618	—	13	—	—	13
Stock based compensation	—	—	694	—	—	694
Foreign currency translation adjustment	—	—	—	343	—	343
Other comprehensive loss	—	—	—	(130)	—	(130)
Net loss	—	—	—	—	(7,921)	(7,921)
Balance September 30, 2022	36,130,306	$ 36	$ 387,473	$ (253)	$ (282,725)	$ 104,531
Balance June 30, 2021	29,655,786	$ 30	$ 333,427	$ 117	$ (191,494)	$ 142,080
Exercise of stock options	211,477	—	4,706	—	—	4,706
Stock based compensation	—	—	7,618	—	—	7,618
Foreign currency translation adjustment	—	—	—	18	—	18
Other comprehensive loss	—	—	—	(64)	—	(64)
Net loss	—	—	—	—	(21,706)	(21,706)
Balance September 30, 2021	29,867,263	$ 30	$ 345,751	$ 71	$ (213,200)	$ 132,652

See accompanying notes.

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

For the nine months ended September 30, 2022 and 2021						
	Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Income / (Loss)	Accumulated Deficit	Shareholders' Equity
	Shares	Amount				
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
Issuance of common stock on exercise of stock options and vesting of restricted stock units	484,125		148			148
Stock based compensation	—	—	14,986	—	—	14,986
Share issuance in connection with acquisition of Novosteo, Inc.	5,520,000	6	16,497			16,503
Foreign currency translation adjustment				481		481
Other comprehensive loss	—	—	—	(655)	—	(655)
Net loss	—	—	—	—	(46,126)	(46,126)
Balance September 30, 2022	36,130,306	$ 36	$ 387,473	$ (253)	$ (282,725)	$ 104,531
Balance January 1, 2021	29,543,222	$ 29	$ 318,574	$ 313	$ (146,654)	$ 172,262
Exercise of stock options	324,041	1	5,817	—	—	5,818
Stock based compensation	—	—	21,360	—	—	21,360
Foreign currency translation adjustment	—	—	—	18	—	18
Other comprehensive loss	—	—	—	(260)	—	(260)
Net loss	—	—	—	—	(66,546)	(66,546)
Balance September 30, 2021	29,867,263	$ 30	$ 345,751	$ 71	$ (213,200)	$ 132,652

See accompanying notes.

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

	For the Nine Months Ended September 30,	
	2022	**2021**
Cash flows from operating activities		
Net Loss	$ (46,126)	$ (66,546)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash rent expense	—	199
Stock based compensation	14,986	21,360
Depreciation and amortization	162	260
Impairment loss on operating lease	136	—
Loss on disposal of fixed assets	77	—
Non-cash goodwill impairment charge	825	—
Amortization of premium on available for sale investments	83	679
Change in deferred tax liabilities due to acquisition of Novosteo, Inc.	(284)	—
Changes in operating assets and liabilities, net of acquisitions:		
Prepaid expenses and other current assets	2,396	(973)
Other assets	175	(154)
Accounts payable	(5,329)	(675)
Accrued expenses and other current liabilities	(5,304)	(2,664)
Net cash used in operating activities	(38,203)	(48,514)
Cash flow from investing activities:		
Purchase of investments	(66,767)	(35,778)
Proceeds from maturities of investments	55,495	73,947
Cash acquired from Novosteo, Inc.	10,593	—
Proceeds from disposal of assets	70	—
Purchase of property and equipment	(55)	(136)
Net cash provided by / (used in) investing activities	(664)	38,033
Cash flows from financing activities:		
Payments of finance leases	(31)	—
Proceeds from issuance of common stock upon exercise of stock options	148	5,818
Proceeds from issuance of common stock in connection with open market sales agreement, net of issuance costs	608	—
Net cash provided by financing activities	725	5,818
Effect of exchange rate changes on cash	227	29
Net decrease in cash and cash equivalents	(37,915)	(4,634)
Cash and cash equivalents at beginning of period	69,724	66,841
Cash and cash equivalents at end of period	$ 31,809	$ 62,207
Supplemental disclosures of non-cash information:		
Net assets acquired of Novosteo, Inc. in exchange for common stock	$ 16,503	$ —
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 256	$ 1,254
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 advancing innovative precision therapeutics for debilitating and rare diseases. 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. In addition to the skeletal disease candidate, the Company's pipeline includes proprietary drug candidates for the treatment of Central Nervous System ("CNS") disorders including Alzheimer's disease, oncology applications designed to prevent the development of oral squamous cell carcinoma, as well as for the treatment of underserved and chronic conditions like periodontitis. The Company's pipeline also includes a proprietary irreversible protease inhibitor under development for the treatment of coronavirus infection.

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 ("Acquisition"), each share of capital stock of Novosteo that was issued and outstanding immediately prior to the Effective Time was automatically cancelled 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.

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 September 30, 2022, the Company had an accumulated deficit of $282.7 million. Since inception through September 30, 2022, 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 September 30, 2022, the Company had cash, cash equivalents, and short-term investments of $94.3 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 $5.0 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. 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 its product candidates.

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 September 30, 2022, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2022 and 2021, the condensed consolidated statements of stockholders' equity for the three and nine months ended September 30, 2022 and 2021, the condensed consolidated statements of cash flows for the nine months ended September 30, 2022 and 2021, 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, 2021 included in the Company's Form 10-K filed with the SEC on March 1, 2022. The results of operations for the three and nine months ended September 30, 2022 are not necessarily indicative of the results to be expected for the year ending December 31, 2022 or for any other 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. On January 25, 2022, the Company received a letter from the FDA Division of Neurology 1 placing a full clinical hold on atuzaginstat (COR388) IND application. Other divisions of the FDA may impose a clinical hold on atuzaginstat (COR388). This clinical hold may reduce the Company's ability to out-license this product candidate to third parties which could have a materially adverse impact on the Company.

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; 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 consolidated statements of operations and comprehensive loss.

Significant Accounting Policies

There have been no significant changes to the accounting policies during the nine months ended September 30, 2022, as compared to the significant accounting policies described in our Annual Report on Form 10-K other than as noted below:

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.

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.

The Company recognized a $0.8 million impairment charge for the three and nine months ended September 30, 2022.

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.

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.

Recent Accounting Pronouncements Adopted

ASU 2021-10, Disclosures by Business Entities about Government Assistance. In November 2021, the FASB issued ASU 2021-10, "Government Assistance (Topic 832)," which requires business entities to disclose information about transactions with a government that are accounted for by applying a grant or contribution model by analogy (for example, IFRS guidance in IAS 20 or guidance on contributions for not-for-profit entities in ASC 958-605). For transactions within scope, the new standard requires the disclosure of information about the nature of the transaction, including significant terms and conditions, as well as the amounts and specific financial statement line items affected by the transaction. The new guidance is effective for annual reporting periods beginning after December 15, 2021. The adoption of this pronouncement in the first quarter of 2022 did not have a material impact on its consolidated financial statements or 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:

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. The Company is evaluating the impact of the guidance on its financial statements.

All other newly issued accounting pronouncements not yet effective have been deemed either immaterial or not applicable.

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 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 September 30, 2022 and December 31, 2021 are presented in the following tables (in thousands):

	Fair Value Measurements at September 30, 2022			
	Total	Level 1	Level 2	Level 3
Money market funds	$ 15,012	$ 15,012	$ —	$ —
Certificates of Deposit	5,748	—	5,748	—
Repurchase Agreements	5,000	—	5,000	—
Corporate notes	16,009	—	16,009	—
Government and agency notes	46,836	—	46,836	—
Municipal notes	506	—	506	—
Total	$ 89,111	$ 15,012	$ 74,099	$ —

	Fair Value Measurements at December 31, 2021			
	Total	Level 1	Level 2	Level 3
Money market funds	$ 15,954	$ 15,954	$ —	$ —
Certificates of Deposit	11,503	—	11,503	—
Repurchase Agreements	13,500	—	13,500	—
Corporate notes	38,397	—	38,397	—
Government and agency notes	5,178	—	5,178	—
Municipal notes	1,933	—	1,933	—
Total	$ 86,465	$ 15,954	$ 70,511	$ —

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

	Fair Value Measurements at September 30, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	$ 15,012	$ —	$ —	$ 15,012
Certificates of Deposit	5,919	—	(171)	5,748
Repurchase Agreements	5,000	—	—	5,000
Corporate notes	16,285	—	(276)	16,009
Government and agency notes	47,133	1	(298)	46,836
Municipal notes	515	—	(9)	506
Total cash equivalents and investments	$ 89,864	$ 1	$ (754)	$ 89,111
Classified as:				
Cash equivalents (maturities within 90 days)				$ 21,576
Short-term investments (maturities within one year)				62,534
Long-term investments (maturities beyond 1 year)				5,001
Total cash equivalents and investments				$ 89,111

	Fair Value Measurements at December 31, 2021			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	$ 15,954	$ —	$ —	$ 15,954
Certificates of Deposit	11,511	12	(20)	11,503
Repurchase Agreements	13,500	—	—	13,500
Corporate notes	38,470	6	(79)	38,397
Government and agency notes	5,195	—	(17)	5,178
Municipal notes	1,934	—	(1)	1,933
Total cash equivalents and investments	$ 86,564	$ 18	$ (117)	$ 86,465
Classified as:				
Cash equivalents (maturities within 90 days)				$ 29,454
Short-term investments (maturities within one year)				37,078
Long-term investments (maturities beyond 1 year)				19,933
Total cash equivalents and investments				$ 86,465

As of September 30, 2022, the remaining contractual maturities of available-for-sale securities was approximately 6 months. There have been no significant realized gains or losses on available-for-sale securities for the periods presented. Based on the Company's review of its available-for-sale securities, the Company has a limited number of available-for-sale securities in insignificant loss positions as of September 30, 2022, none of which have been in a loss position for more than a year. The Company believes it had no other-than-temporary impairments on these securities as of September 30, 2022, because the Company does not intend to sell these securities nor does the Company believe that it will be required to sell these securities before the recovery of their amortized cost basis.

The investments are classified as available-for-sale securities. At September 30, 2022 and December 31, 2021, 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 and nine months ended September 30, 2022 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.

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):

	September 30, 2022	December 31, 2021
Cash and cash equivalents:		
Cash	$ 10,233	$ 40,270
Money market funds	15,012	15,954
Repurchase agreements	5,000	13,500
Corporate notes	1,564	—
Total cash and cash equivalents	$ 31,809	$ 69,724
Short-term investments:		
Certificates of deposit	$ 4,319	$ 6,928
Municipal notes	506	1,283
Corporate notes	14,445	25,675
Government and agency notes	43,264	3,192
Total short-term investments	$ 62,534	$ 37,078
Long-term investments		
Corporate notes	$ —	$ 12,722
Certificates of deposit	1,429	4,575
Municipal notes	—	650
Government and agency notes	3,572	1,986
Total long-term investments	$ 5,001	$ 19,933

Note 5. Balance Sheet Components

Prepaid Expenses and Other Current Assets

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

	September 30, 2022	December 31, 2021
Prepaid expenses	$ 270	$ 333
Prepaid insurance	1,356	1,144
Prepaid research and development expenses	929	1,899
Australia research and development refundable tax credit	1,042	1,128
Other current assets	336	367
Total prepaid expenses and other current assets	$ 3,933	$ 4,871

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 $0.1 million and $0.5 million for the three and nine months ended September 30, 2022 and $0 reductions to R&D expense for the three and nine months ended September 30, 2021.

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 is eligible to receive a refundable tax credit of $0.6 million for the nine months ended September 30, 2022.

Property and Equipment, Net

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

	September 30, 2022	December 31, 2021
Computer equipment	$ 18	$ 53
Lab equipment	392	528
Finance lease right of use assets	124	557
Leasehold improvement	—	58
Office furniture	—	26
Less: accumulated amortization and depreciation	(159)	(959)
Property and equipment, net	$ 375	$ 263

Accrued Expenses and Other Current Liabilities

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

	September 30, 2022	December 31, 2021
Personnel expenses	$ 804	$ 820
Professional fees	278	462
Director and Officer insurance	1,386	—
Research and development expenses	800	7,108
Current portion of operating lease liabilities	292	741
Current portion of finance lease liability	75	—
Other	129	180
Total accrued expenses and other current liabilities	$ 3,764	$ 9,311

In response to the reprioritization of the Company's pipeline following the clinical hold on atuzaginstat (COR388) IND application, on February 2, 2022, 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 reduction in force was completed in July 2022. To be eligible for the severance payments, employees had to remain with the Company through their communicated severance date. The Company recognized the severance and related expenses over the requisite employment obligation period.

	For the Nine Months Ended September 30, 2022
Beginning accrued severance	$ —
Incurred during the period	3,942
Severance paid during the period	(3,942)
Ending accrued severance	$ —

Note 6. Leases

Real Estate Operating Leases

In June 2018, the Company entered into a three-year lease agreement with no renewal options with an investor in the Series B redeemable convertible preferred stock. The lease began on July 16, 2018 and provided 3,185 square feet of office and laboratory space in South San Francisco, California. The Company issued 114,437 shares of its Series B redeemable convertible preferred stock with a fair value of $1.1 million in exchange for the leased facility. No other payments are due under the lease. The common area maintenance and other operating costs are included in the base rent. 100% of the issued shares were initially subject to a repurchase option. Pursuant to the terms of the lease, each month beginning on the one-month anniversary of the commencement date of the lease, $1/36^{th}$ of the total shares are released from the repurchase option until all shares are released over the lease period of three years. The scheduled release of shares ceased immediately upon the IPO which was a terminating event.

The Company completed its IPO on May 13, 2019 and as a result, pursuant to the terms of the lease agreement, all previously unvested shares were fully vested and as part of the IPO process, all outstanding shares of the Company's redeemable convertible preferred stock including the Series B redeemable convertible preferred stock issued in connection with the lease agreement were converted into shares of the Company's common stock on a 1-for-1 basis and the operating lease liability was extinguished.

In May 2019, the Company entered into an amendment to the lease agreement 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 paid a one-time fee of approximately $63,000 for the additional space and the lease agreement was set to terminate in July 2021. No other payments were due under the lease agreement and no renewal option is available. As the entire lease was prepaid, there was no associated lease liability.

In May 2020, the Company entered into a second amendment to the lease agreement 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 paid rent monthly for the additional space and the lease agreement was set to terminate in July 2021. The Company recorded an operating lease asset and liability of $172,000.

In May 2021, the Company entered into a third amendment to the lease agreement to extend the term of its existing facility space to July 15, 2022 under the same terms as its existing facility lease except the terms of payment. The lease amendment provides for one-year extension period under the same terms. As a result of this amendment, the Company recognized an additional right-of-use asset and corresponding lease liability of $1.2 million. In the same agreement, the Company also agreed to rent additional space effective July 16, 2021 for a period of 12 months. The lease amendment provides for one-year extension period and was included in the lease term as it was reasonably certain that the Company would exercise the option. The Company recognized an additional right of use asset and corresponding lease liability of $44,000 in July 2021. Total payments under the third amendment to the lease including the additional space was approximately $1.3 million.

In March 2022, in response to the reprioritization of the Company's pipeline following the clinical hold on atuzaginstat (COR388) IND application, the Company has decided not to exercise the one-year extension period which was previously included in the determination of the lease term at the time the lease was modified in May 2021. This reduction in lease term was determined to be a lease modification and as such, the lease liability was re-measured and corresponding Right of use ("ROU asset") adjusted using an incremental borrowing rate at the date of modification. The Company reduced the ROU asset and lease liability by approximately $640,000. The Company paid a security deposit of $105,000, which is included in Prepaid Expenses and Other Current Assets on the September 30, 2022 condensed consolidated balance sheets.

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 and intends to sublease the facility, if possible. As a result of this decision, the Company recorded an impairment loss of approximately $38,000 and $136,000 for the three and nine months ended September 30, 2022, respectively, as it was determined that a sublease was improbable. The Company paid a security deposit of $29,000 which is included in Prepaid Expenses and Other Current Assets on the September 30, 2022 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 Other Assets on the September 30, 2022 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.

The Company recognizes lease expense on a straight-line basis over the term of its operating lease. As of September 30, 2022, total future rent expense from all real estate operating leases of $218,000 will be recognized over the remaining term of 14 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 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 nine months ended September 30, 2022 was $31,000.

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

	September 30, 2022	December 31, 2021
Operating lease right of use asset, net	$ 208	$ 1,165
Short-term operating lease liability	292	741
Long-term operating lease liability	34	420
	$ 326	$ 1,161
Finance lease right of use asset	124	557
Finance lease accumulated amortization	(31)	(557)
Total finance lease right of use asset, net	$ 93	$ —
Weighted average remaining lease term		
Operating leases	1.1 years	1.6 years
Finance leases	1.3 years	—
Weighted average discount rate		
Operating leases	5.14 %	1.87 %
Finance leases	4.45 %	— %

Year ended December 31,	**Operating Lease**	**Operating Lease**
2022 (excluding the nine months ended September 30, 2022)	$ 80	$ 757
2023	256	422
Total lease payments	336	1,179
Less: imputed interest	(10)	(18)
Total remaining lease liability	$ 326	$ 1,161

Note 7. Stock-Based Compensation

The Company operates three stock plans as of September 30, 2022.

- 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 September 30, 2022, the maximum aggregate number of shares that remain available for issuance under the Quince 2019 Plan is 8,591,030 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 September 30, 2022, the Company had 2,777,330 shares available for future issuance under the 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, 2021	**5,571,293**	$ 28.70	8.26	$ 15,687
Options granted	2,014,058	8.26		
Options exercised	(102,152)	1.45		286
Options cancelled / forfeited	(3,329,572)	30.46		
Balance at September 30, 2022	**4,153,627**	$ 18.06	5.65	$ 238
Options vested and expected to vest as of September 30, 2022	4,153,627	18.06	5.65	238
Options exercisable as of September 30, 2022	2,498,842	$ 20.81	3.31	$ 238

For the three and nine months ended September 30, 2022, the Company recognized stock-based compensation expense of $38,000 and $10,501,000, 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 September 30, 2022, total unamortized employee stock-based compensation was $7.1 million, which is expected to be recognized over the remaining estimated vesting period of 2.47 years.

Performance Stock Options (“PSOs”)

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

	Shares Subject to Outstanding PSOs	Weighted Average Exercise Price	Weighted average remaining contractual life (years)
Balance at December 31, 2021	675,000	$ 29.60	5.74
Surrendered	(675,000)	$ 29.60	—
Vested	—	—	—
Balance at September 30, 2022	—	—	—

In February 2022, the Company and certain executive officers agreed to voluntarily surrender 400,000 of the PSOs. As a result of the surrender, the Company accelerated the total remaining expense on these options and recognized approximately $3.6 million in compensation expense during the quarter ended March 31, 2022.

In February 2022, the Company's Chief Executive Officer and Chief Scientific Officer resigned from the Company. As a result, the unvested PSOs were cancelled and the life to date expense of approximately $1.6 million was reversed in the quarter ended March 31, 2022.

For the three and nine months ended September 30, 2022, the Company recognized stock-based compensation expense of $0 and $2,044,000, respectively, related to these PSOs. As of September 30, 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, 2021	**—**	**—**
RSUs granted	1,013,500	$ 4.30
RSUs vested	(381,973)	$ 4.30
RSUs cancelled	(458,414)	$ 4.30
Unvested - September 30, 2022	**173,113**	$ 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 nine months ended September 30, 2022 was $1.6 million. The aggregate intrinsic value of the shares of the RSUs vested during the nine months ended September 30, 2022 was $1.1 million.

For the three and nine months ended September 30, 2022, the Company recognized stock-based compensation expense of $(87,000) and $1,310,000 respectively, related to these RSUs. As of September 30, 2022, total unamortized stock-based compensation related to RSUs was $0.2 million, which is expected to be recognized over the remaining estimated vesting period of 1.42 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 and adjusted into the right to purchase 0.0911 shares of common stock. Each such converted stock option will continue 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 September 30, 2022, the Company had 41,880 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, 2021	—	—	—	—
Options granted	507,648	0.55	—	—
Options exercised	—	—	—	—
Options cancelled / forfeited	(4,543)	0.55	—	—
Balance at September 30, 2022	**503,105**	$ 0.55	9.48	$ 392
Options vested and expected to vest as of September 30, 2022	503,105	0.55	9.48	392
Options exercisable as of September 30, 2022	—	—	—	—

For the three and nine months ended September 30, 2022, the Company recognized stock-based compensation expense of $79,000 and $165,000, 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 September 30, 2022, total unamortized employee stock-based compensation was $1.1 million, which is expected to be recognized over the remaining estimated vesting period of 3.48 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 into 0.0911 shares of common stock. 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 ("RSAs")

	Restricted Stock Awards Outstanding	
	Number of Shares	Weighted Average Grant Date Fair Value
Unvested - December 31, 2021	**—**	**—**
RSAs granted	519,216	$ 3.30
RSAs vested	(52,466)	$ 3.30
RSAs cancelled	**—**	$ —
Unvested - September 30, 2022	**466,750**	**$ 3.30**

For the three and nine months ended September 30, 2022, the Company recognized stock-based compensation expense of $131,000 and $207,000, 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 September 30, 2022, total unamortized employee stock-based compensation was $1.5 million, which is expected to be recognized over the remaining estimated vesting period of 2.98 years.

2022 Inducement Plan

On May 9, 2022, the Company's stockholders approved 4,000,000 shares of the Registrant's common stock that may be offered or issued under the Quince Therapeutics, Inc. 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 September 30, 2022, the Company had 257,745 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, 2021	—	—	—	—
Options granted	3,744,255	2.98	—	—
Options exercised	—	—	—	—
Options cancelled / forfeited	(2,000)	2.98	—	—
Balance at September 30, 2022	**3,742,255**	$ 2.98	9.65	—
Options vested and expected to vest as of September 30, 2022	3,742,255	2.98	9.65	—
Options exercisable as of September 30, 2022	—	—	—	—

For the three and nine months ended September 30, 2022, the Company recognized stock-based compensation expense of $533,000 and $759,000, 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 September 30, 2022, total unamortized employee stock-based compensation was $7.7 million, which is expected to be recognized over the remaining estimated vesting period of 3.64 years.

Stock-Based Compensation Expense

The following table summarizes employee and non-employee stock-based compensation expense for the three and nine months ended September 30, 2022 and 2021 and the allocation within the condensed consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
General and administrative expense	$ 1,289	$ 3,770	$ 8,988	$ 10,878
Research and development expense	(595)	3,848	5,998	10,482
Total stock-based compensation	$ 694	$ 7,618	$ 14,986	$ 21,360

Employee Stock Purchase Plan

On April 24, 2019, the Company's Board of Directors 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 1,133,165 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 Company's Board of Directors. 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 of Quince Therapeutics 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 cancelled 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, 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.

On February 1, 2022, the Company announced that Casey C. Lynch stepped down as the chairperson of the Board and the President and Chief Executive Officer, effective as of January 28, 2022. As of the effective date of her departure, Ms. Lynch held 26,294 options that were unvested and would have vested in February 2022. In connection with Ms. Lynch’s departure, the Board agreed to accelerate the vesting of the remaining 26,294 options, and extend the exercise period on 574,206 vested options currently held to January 28, 2023, this resulted in a stock based compensation expense of approximately $655,000. Additionally as part of the severance agreement, the Company made a cash severance payment of $604,000 to Ms. Lynch.

On February 1, 2022, the Company announced that Stephen S. Dominy M.D. stepped down as a member of the Board and the Chief Scientific Officer, effective as of January 28, 2022. As of the effective date of his departure, Dr. Dominy held 9,230 options that were unvested and would have vested in February 2022. In connection with Dr. Dominy's departure, the Board agreed to accelerate the vesting of the remaining 9,230 options, and extend the exercise period on 315,659 vested options currently held to January 28, 2023, this resulted in a stock based compensation expense of approximately $230,000. Additionally as part of the severance agreement, the Company made a cash severance payment of $326,250 to Dr. Dominy.

On May 2, 2022, the Company announced that Michael Detke, M.D., Ph.D. stepped down as the Chief Medical Officer of the Company, effective as of May 2, 2022. As part of the severance agreement, the Company made a cash severance payment of $354,750 to Dr. Detke.

On May 20, 2022, the Company announced that Caryn McDowell stepped down as the Chief Legal and Administrative Officer and Corporate Secretary of the Company, effective as of July 8, 2022. As the effective date of her departure Ms. McDowell held 122,500 RSUs that were unvested and would have vested in March 2024. In connection with Ms. McDowell's departure, the Board agreed to accelerate the vesting of the remaining 122,500 RSUs, and to extend the exercise period on 152,079 vested options currently held to July 8, 2023, this resulted in a stock based compensation expense of approximately $459,000. Additionally as part of the severance agreement, the Company made a cash severance payment of $339,000 to Ms. McDowell.

On June 8, 2022, the Company announced that Christopher Lowe stepped down as a member of the Board and the Chief Financial Officer and Chief Operating Officer of the Company, effective as of June 10, 2022. As the effective date of his departure Mr. Lowe held 153,125 RSUs that were unvested and would have vested in March 2024. In connection with Mr. Lowe's departure, the Board agreed to accelerate the vesting of the remaining 153,125 RSUs, and extend the exercise period on 205,896 vested options currently held to June 10, 2023, this resulted in a stock based compensation expense of approximately $645,000. Additionally as part of the severance agreement, the Company made a cash severance payment of $354,750 to Mr. Lowe.

On July 22, 2022, the Company announced the departure of Leslie Holsinger, Ph.D., the Executive Vice President of Research and Development, effective as of July 31, 2022. As part of the severance agreement, the Company made a cash severance payment of $339,000 to Dr. Holsinger. Additionally as part of the severance agreement, the Board agreed to extend the exercise period on 382,000 vested options currently held to July 31, 2023, this resulted in a stock based compensation expense of approximately $126,000.

Note 9. Income Taxes

The income tax provision for interim periods is determined using an estimate of the Company’s annual effective tax rate as adjusted for discrete items arising in that quarter. The effective income tax rate was 0.6% and nil for the three and nine months ended September 30, 2022, respectively. The effective tax rate differs from the U.S. statutory rate primarily due to the full valuation allowance on the Company’s net deferred tax assets as it is more likely than not that all of the deferred tax assets will be realized. The Company recorded a discrete tax benefit of $0.3 million in the nine months ended September 30, 2022 due to the release of valuation allowance in connection with the acquisition of Novosteo.

On March 27, 2020, President Trump signed the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") into law. On December 21, 2020, President Trump also signed into law the Consolidated Appropriations Act, 2021 ("CAA Act") which includes further COVID-19 economic relief and extension of certain expiring tax provisions. The Company has reviewed the aspects of these laws as it relates to the income taxes and has concluded that at this time, the CARES Act and CAA Act will have no material impact to the Company's 2021 provision for income taxes. The Company will continue to evaluate changes and revisions of the CARES Act and CAA Act and their impact on the Company's financial position, results of operations and cash flows.

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 become effective after December 31, 2022. The provisions of the Inflation Reduction Act are not expected to have a material effect on the Company's 2022 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:

	September 30,	
	2022	2021
Stock options issued and outstanding	8,398,987	5,017,442
Performance stock options	—	675,000
Restricted stock units	173,113	—
Restricted stock awards	466,750	—
Total	9,038,850	5,692,442

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 cancelled 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 Company has included the financial results of Novosteo in the condensed consolidated financial statements from the date of the Acquisition and recorded immaterial amounts of expenses and earnings since the period from May 19, 2022 through June 30, 2022. 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 and nine months ended September 30, 2022 and 2021, and the unaudited pro forma revenue and net loss of the combined entity had the acquisition date been January 1, 2021 are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue	$ —	$ 3	$ 262	$ 223
Net loss	(7,921)	(22,478)	(47,057)	(71,046)

The 2022 supplemental pro forma earnings were adjusted to exclude $2.2 million of acquisition-related costs incurred in 2022, the 2021 pro forma earnings were adjusted to include these charges. The Company’s condensed consolidated income statements for the three and nine months ended September 30, 2022 include immaterial net revenue and net loss attributable to the Acquisition.

Note 12. Intangible Assets

The intangible asset acquired as a result of the Acquisition consists of in-process research and development ("IPRD") related to NOV004, the Company's bone targeting molecule designed to accelerate fracture repair. The value of the IPRD 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):

	As of September 30, 2022
Unamortized intangible assets:	
In-process research and development	$ 5,900

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.

The following table sets forth the change in the carrying amount of goodwill for the Company as of and for the three months ended September 30, 2022:

June 30, 2022	$ 825
Impairment charge	(825)
September 30, 2022	—

As of September 30, 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 three months ended September 30, 2022.

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, 2021 filed with the Securities and Exchange Commission (the "SEC"), on March 1, 2022. 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, impact of COVID-19 pandemic on our research and development activities and business operations, and future results of anticipated 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, 2021 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 advancing innovative precision therapeutics for debilitating and rare diseases. The company discovered a broad bone-targeting drug platform designed to precisely deliver small molecules, peptides, or large molecules directly to the site of bone fracture and disease to promote more rapid healing with fewer off-target safety concerns compared to non-targeted therapeutics. Our discovery pipeline is positioned for rapid expansion across multiple skeletal therapeutic indications to address underserved therapeutic areas with major, unmet medical needs, including osteogenesis imperfecta, fractures, spinal fusion, and other severe bone diseases. Additionally, our pipeline includes small molecule therapeutics available for out-licensing that target the infectious pathogen *P. gingivalis'* role in degenerative disease progression, including for indications such as Alzheimer's disease, periodontal disease, and oral potentially malignant disorders, among others.

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. 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 cancelled 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.

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 company 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, 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. We plan to advance the gingipain and 3CLpro inhibitor programs through a proactive out-licensing effort.

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

Company Management and Board Member Changes

On May 20, 2022, we announced the departure of Caryn McDowell, our Chief Legal and Administrative Officer and Corporate Secretary, effective as of July 8, 2022 (the "CLO Departure Date"). In connection with the departure of Ms. McDowell, we entered into a transition agreement (the "CLO Separation Agreement") with Ms. McDowell on May 19, 2022, providing for (i) a release of claims against us; (ii) cash severance payments of $339,000, which equals to nine months of Ms. McDowell's 2022 base salary, to be paid in a lump sum; and (iii) certain health care continuation benefits. The CLO Separation Agreement also provides for an accelerated vesting of the restricted stock award issued to Ms. McDowell on March 3, 2022 and an extension of the post-termination exercise period for all vested stock options or other equity awards held by Ms. McDowell through the twelve-month period following the CLO Departure Date, provided that the specified severance preconditions are met. In addition, in the event we consummate a change in control within three months after the CLO Departure Date, subject to satisfaction of specified conditions, Ms. McDowell would also be entitled to additional cash severance and COBRA coverage, payment of target annual bonus and accelerated vesting with respect to her equity awards.

On June 8, 2022, Christopher Lowe, the Chief Financial Officer, Chief Operating Officer and a member of the Board of Directors, resigned as a member of the Board, effective immediately. Mr. Lowe has also resigned from his roles as the Chief Financial Officer and Chief Operating Officer, effective as of June 10, 2022 (the "CFO Departure Date"). In connection with the departure of Mr. Lowe, we entered into a separation agreement (the "CFO Separation Agreement") with Mr. Lowe on June 10, 2022, providing for (i) a release of claims against us; (ii) cash severance payments of $354,750, which equals to nine months of Mr. Lowe's 2022 base salary, to be paid in accordance with our normal payroll practices; and (iii) certain health care continuation benefits. The CFO Separation Agreement also provides for an accelerated vesting of the restricted stock award issued to Mr. Lowe on March 3, 2022 and an extension of the post-termination exercise period for all vested stock options or other equity awards held by Mr. Lowe through the twelve-month period following the CFO Departure Date, provided that the specified severance preconditions are met. In addition, in the event we consummate a change in control within three months after the CFO Departure Date, subject to satisfaction of specified conditions, Mr. Lowe would also be entitled to additional cash severance and COBRA coverage, payment of target annual bonus and accelerated vesting with respect to his equity awards.

On June 9, 2022, we designated Ted Monohon, Chief Accounting Officer and Vice President of Finance, as the principal financial officer, to fill the vacancy resulting from Mr. Lowe's resignation. Mr. Monohon will serve as the principal financial officer in addition to his role as a principal accounting officer.

On June 9, 2022, upon recommendation of the Nominating and Corporate Governance Committee of the Board, the Board appointed June Bray to serve as a Class III director, effective immediately, to fill the vacant directorship, until her successor is elected and qualified, or sooner in the event of her death, resignation or removal. Ms. Bray joins the class of directors whose term expires at our 2025 annual stockholders' meeting.

On July 22, 2022, we announced the departure of Leslie Holsinger, Ph.D., the Executive Vice President of Research and Development, effective as of July 31, 2022 (the "EVP of Research Departure Date"). The Separation Agreement provides for (i) a

release of claims against the Company, (ii) cash severance payments of $339,000, which equals to nine months of Dr. Holsinger's 2022 base salary, to be paid in a lump sum; and (iii) certain health care continuation benefits. The Separation Agreement also provides for an extension of the post-termination exercise period for all vested stock options or other equity awards held by each of Dr. Holsinger through the twelve-month period following the VP of Research Departure Date, in each case provided that the specified severance preconditions are met. In addition, in the event the Company consummates a change in control of control within three months after the EVP of Research Departure Date, subject to satisfaction of specified conditions, Dr. Holsinger would also be entitled to additional cash severance and COBRA coverage, payment of target annual bonus, and accelerated vesting with respect to her equity awards. The Company and Dr. Holsinger anticipate entering into a consulting agreement to facilitate the transition of activities until the end of the year.

On September 28, 2022, Marwan Sabbagh, M.D., a member of the Board of Directors of Quince Therapeutics, Inc. tendered his resignation from the Board, effective as of September 30, 2022. In connection with the departure of Dr. Sabbagh from the Company, the Board granted Dr. Sabbagh accelerated vesting of a portion of the stock options issued to Dr. Sabbagh on March 14, 2022, corresponding to his service with the Company, and an extension of the post-termination exercise period for the vested stock options held by Dr. Sabbagh through the twelve-month period following the effective date of his resignation. Dr. Sabbagh's resignation from the Board was not a result of any disagreement with the Company, its Board or management.

Drug Candidate Portfolio

NOV004

NOV004 is a systemically administered bone anabolic peptide engineered to target and concentrate at bone fracture sites. By improving fracture site accumulation and retention, NOV004 stimulates a robust healing response in preclinical studies. Notable preclinical observations include:

- In a fracture induction study in healthy mice, at 3 weeks post femur fracture, NOV004 treated mice could withstand greater than 1.5 times the force in a four-point bend test compared to both the vehicle controls and the non-targeted bone anabolic peptide at the same point in time.
- Similar improvements in fracture repair have been observed in mouse bone fracture models with comorbidities such as osteoporosis, diabetes, or osteogenesis imperfecta – a rare genetic bone disease that manifests in skeletal deformities and high fracture rates.
- Other improvements in fracture repair were observed by tracking animal's voluntary movements. As early as 12 days post fracture, mice treated with NOV004 moved significantly faster, as measured by cm/s travelled, than either the mice treated with vehicle or ibuprofen (8.1 cm/s vs 6.0 cm/s and 5.5cm/s respectively). In addition, by day 28, both distances traveled (cm) and time spent (seconds) were also significantly higher in NOV004 treated mice compared to vehicle or ibuprofen controls.

Quince plans to progress towards an IND submission for NOV004 in the first half of 2023.

Atuzaginstat (COR388)

Atuzaginstat (COR388) is a novel, orally-administered, small molecule, bacterial protease inhibitor targeting gingipains produced by the periodontal pathogen Porphyromonas gingivalis (P gingivalis). This pathogen has been associated with several diseases in humans including Alzheimer's disease, periodontal disease and certain head and neck cancers. We are seeking a partner to explore the therapeutic effect of atuzaginstat (COR388) on the below indications.

Alzheimer's Disease

On October 26, 2021, we announced top-line results from our global Phase 2/3 clinical trial of atuzaginstat (COR388), called the GAIN (GingipAIN Inhibitor for Treatment of Alzheimer's Disease) trial, in mild to moderate Alzheimer's patients. The 643-participant study did not meet statistical significance on its co-primary cognitive and functional endpoints as measured by ADAS-Cog11 and ADCS- ADL at end of the treatment period in the overall cohort.

On January 25, 2022, we received a letter from the Food and Drug Administration ("FDA") Division of Neurology 1 placing a full clinical hold on the IND application for atuzaginstat (COR388). We believe atuzaginstat (COR388) holds therapeutic potential in non-CNS indications, including oncology and periodontitis, however, we intend to only continue development of atuzaginstat through external out-licensing or partnership opportunities. Other divisions of the FDA may impose a clinical hold on

atuzaginstat (COR388). This clinical hold may reduce our ability to out license this product candidate to third parties which could have a materially adverse impact on our business.

Periodontal Disease

P. gingivalis has been identified as a key pathogen in the development of periodontal disease. Periodontal disease is a common age-related disease affecting nearly 50% of the population over 50 years of age, or 65 million people, in the United States. The disease presents with symptoms including chronic inflammation, degeneration of gum tissue and tooth loss. Periodontal disease is associated with increased risk of cardiovascular disease, diabetes and certain cancers. The disease is often chronic and recurring due to persistent bacterial infection and antibiotic resistance. Current standard of care for the treatment of periodontal disease commonly involves scaling and root planning to remove bacterial plaque and tartar, in addition to local delivery of antibiotics in some cases. Atuzaginstat (COR388) reduced periodontal disease and associated bone loss in multiple animal models of periodontal disease. Target engagement and efficacy data for atuzaginstat (COR388) in aged dogs was published in January 2020 in the journal Pharmacology Research and Perspectives.

We believe the inhibition of gingipains from *P. gingivalis*, and the disruption of biofilms directly in the oral cavity, may provide a therapeutic benefit to patients. We intend to only continue development of atuzaginstat (COR388) through external out-licensing or partnership opportunities.

Oncology

We examined atuzaginstat (COR388), to prevent the development of oral/head and neck squamous cell carcinoma (O/HNSCC). Most cases of O/HNSCC are preceded by high-risk oral potentially malignant diseases (OPMD), including oral pre-malignant dysplasia, proliferative verrucous leukoplakia (PVL), and carcinoma-in-situ.

We held a pre-IND meeting with FDA in August of 2021 and believe atuzaginstat (COR388) can be advanced in certain oncology indications. We expect to advance this asset only if we are successful in out-licensing or partnering the asset.

COR588

COR588 is a second-generation brain penetrant lysine gingipain inhibitor which has completed IND-enabling studies. We began a Phase 1 SAD/MAD trial of COR588 in a cohort of healthy participants in Australia in August 2021. In March 2022, we announced results from the SAD portion of the Phase 1 trial and in July 2022 we announced results from the MAD portion of the Phase 1 trial. Preliminary results indicate COR588 was well-tolerated across all cohorts in the dose range from 25 mg to 200 mg with no serious adverse events. No clinically significant findings were observed on other safety measures, including vital signs, laboratory findings, telemetry, or ECGs. We expect to advance this program only if we are successful in out-licensing or partnering the asset.

COR 803

COR803 for coronavirus is a novel patent-pending small molecule 3CL pro inhibitor discovered and developed by us based on our expertise in cysteine protease inhibition.

Coronavirus

We selected COR803 as a lead compound for treatment of coronavirus infections, including COVID-19 disease, caused by SARS-CoV-2 infection. 3CLpro,or Mpro, is a validated antiviral drug target shown to be essential in viral replication of SARS-CoV-2. We believe COR803 has potential advantages over other COVID-19 therapeutics and 3CLpro inhibitors in development including high potency as assessed using human lung cell viral replication assays; and high selectivity for 3CLpro versus other cellular proteases.

In June 2022, we announced key findings from our latest mouse study of COR803:

- A decrease of virus titer in lung tissue after four days of treatment compared to vehicle control;
- Comparable efficacy in animals orally dosed twice daily vs dosed once daily; and
- Decreased lung weights in COR803 treated versus vehicle-treated animals, indicating improved pathology.

The target of COR803 is highly conserved across coronavirus strains observed to date and, therefore, has the potential to address both current and future coronavirus infection. We believe COR803 has potential advantages over other COVID-19 therapeutics and 3CLpro inhibitors in development, including:

- A chemical reaction that leads to covalent irreversible binding of the viral 3CLpro enzyme;
- High potency: Antiviral EC90 of 12 nM in human lung cell viral replication assays;
- Broad spectrum activity against multiple coronaviruses;
- Selective for 3CLpro versus other cellular proteases, including Cathepsin L; and
- Ability to reach meaningful systemic exposure in preclinical models utilizing oral, intranasal or subcutaneous administration, allowing for potential clinical use in multiple settings, such as outpatient and inpatient.

We are currently exploring partnership and licensing opportunities to support the future development of COR803.

Platform and Pipeline

NOV004 was discovered using our broad drug-targeting platform designed to precisely deliver small molecules, peptides, or large molecules directly to the site of bone fracture and disease to promote more rapid healing with fewer off-target safety concerns compared to non-targeted therapeutics. Our discovery pipeline is positioned for rapid expansion across multiple skeletal therapeutic indications to address underserved therapeutic areas with major, unmet medical needs, including osteogenesis imperfecta, fractures, spinal fusion, and other severe bone diseases. We plan to expand our discovery efforts utilizing our drug-targeting platform and will advance candidates with internal funding and through external partnerships.

Business Update Regarding COVID-19

The COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting the world economy and financial markets. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets.

At this time the impact of the COVID-19 pandemic has not resulted in changes to our previously stated analysis timelines and milestones. We are continuing to assess the potential impact of the COVID-19 pandemic on our business and operations, including our expenses, preclinical operations and clinical trials. All employees have returned to their pre-pandemic work locations and activities. We continue to assess the risks which take into account applicable public health authority and local government guidelines and are designed to ensure community and employee safety. The Company has not experienced significant hinderances to its operations or material negative financial impacts as compared to prior periods.

The effects of the COVID-19 pandemic continue to rapidly evolve and we may have to resume a more restrictive remote work model or close again certain of our offices, whether as a result of spikes or surges in COVID-19 infection or hospitalization rates or public authority mandates. Also, as long as the pandemic continues, our employees may be exposed to health risks. We are not currently experiencing any significant supply chain disruptions due to COVID-19. We have diversified our vendor relationships geographically for both starting materials and manufacturing. However, in the future, the ongoing COVID-19 pandemic, may result in the inability of some of our suppliers to deliver drug supplies on a timely basis. We will continue to monitor the COVID-19 situation and its impact on the ability to continue the development of, and seek regulatory approvals for, our product candidates.

For additional information on the various risks posed by the COVID-19 pandemic, please read Item 1A. Risk Factors included in this Quarterly Report on Form 10-Q.

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 Phase 1a, Phase 1b and Phase 2/3 clinical trials of atuzaginstat (COR388) and our Phase 1 SAD/MAD clinical trial of COR588.

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 September 30, 2022, we had an accumulated deficit of $282.7 million. We incurred a net loss of $7.9 million and $46.1 million in the three and nine months ended September 30, 2022. 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 September 30, 2022, we received net proceeds of approximately $303.7 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, or sales agreement, whereby we may sell up to $150.0 million in aggregate proceeds of common stock from time to time, through Jefferies as our sales agent. During the three and nine months ended September 30, 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 September 30, 2022 and December 31, 2021, we had cash, cash equivalents and short-term investments of $94.3 million and $106.8 million, respectively. The balances exclude long-term investments of $5.0 million and $19.9 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 the second half of 2025. 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.

We expect to incur substantial expenditures in the foreseeable future as we develop our pipeline and advance our drug candidates through preclinical and clinical development, the regulatory approval process and, if approved, commercial launch activities. Specifically, in the near term we expect to incur substantial expenses relating to our ongoing and planned clinical trials, the development and validation of our manufacturing processes, and other development activities.

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 Judgements and Use Estimates" in our 2021 Annual Report on Form 10-K and the notes to the unaudited condensed consolidated financial statements included in 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 Expense;
- Business Combinations; and
- Income Taxes

Below is a description of our Business Combination accounting policy for the nine months ended September 30, 2022, which is our only change in our critical accounting policies from those as 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.

Business Combination

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 a discounted cash flow model. The discounted cash flow 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.

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 our other drug candidates in preclinical development. We expect that at least for the foreseeable future, a substantial majority of our research and development expense will support the clinical and regulatory development of NOV004.

We expect our research and development expenses to increase during the next few years from current levels as we seek to complete existing and initiate additional clinical trials, pursue regulatory approval of NOV004 and advance other drug candidates into clinical development. Over the next few years, we expect our preclinical, clinical and contract manufacturing expenses to increase relative to our current levels. Predicting the timing or the final cost to complete our clinical program or validation of our manufacturing and supply processes is difficult and delays may occur because of many factors.

The duration, costs and timing of our clinical trial and development of our product candidates will depend on a variety of factors that include, but are not limited to, the following:

- per patient trial costs;
- biomarker analysis costs;
- the cost and timing of drug manufacturing for the trials;

- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the screening, randomization, drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies; and
- the efficacy and safety profile of the product candidates.

In addition, the probability of success for each product candidate will depend on numerous factors, including safety, efficacy, competition, manufacturing capability and commercial viability. We will 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 are still in development and 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 increase as the size of our business operations grows 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 September 30, 2022 to the three months ended September 30, 2021

The following sets forth our results of operations for the three months ended September 30, 2022 and 2021 (in thousands):

	Three Months Ended September 30,		Change	
	2022	2021	$	%
Operating expenses:				
Research and development	$ 2,451	$ 14,038	$ (11,587)	(82.5) %
General and administrative	4,344	7,639	(3,295)	(43.1) %
Goodwill impairment charge	825	—	825	100.0 %
Loss from operations	(7,620)	(21,677)	14,057	(64.8) %
Interest income	315	128	187	146.1 %
Other expense, net	(616)	(157)	(459)	292.4 %
Net loss before income tax benefit	$ (7,921)	$ (21,706)	13,785	(63.5) %
Income tax benefit	—	—	—	— %
Net loss	$ (7,921)	$ (21,706)	$ 13,785	(63.5) %

Research and Development Expenses *(in thousands):*

	Three Months Ended September 30,		Change	
	2022	2021	$	%
Direct research and development expenses:				
Atuzaginstat (COR388)	$ 107	$ 4,502	$ (4,395)	(97.6) %
COR588	841	1,662	(821)	(49.4) %
NOV004	763	—	763	100.0 %
Other direct research costs	82	557	(475)	(85.3) %
Indirect research and development expenses:				
Personnel related (including stock-based compensation)	566	6,497	(5,931)	(91.3) %
Facilities and other research and development expenses	92	820	(728)	(88.8) %
Total research and development expenses	$ 2,451	$ 14,038	$ (11,587)	(82.5) %

Research and development expenses were $2.5 million for the three months ended September 30, 2022, compared to $14.0 million for the three months ended September 30, 2021, a decrease of $11.6 million.

The costs for atuzaginstat (COR388) decreased $4.4 million from the prior year due the GAIN trial concluding in the fourth quarter of 2021. As a result, we experienced a decrease of $1.8 million in clinical trial costs, a $1.0 million decrease in drug manufacturing costs, and a decrease in non-clinical studies and analysis related to the GAIN trial of $0.7 million, and a $0.9 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 $0.8 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, offset by a $0.2 million increase for non-clinical work supporting COR588.

In the quarter ended September 30, 2022, the costs for NOV004 increased by $0.8 million after the acquisition of Novosteo, Inc. on May 19, 2022, primarily in drug manufacturing costs. We anticipate expense increases related to NOV004 to increase from current levels as we advance this asset to a Phase 1 clinical trial in 2023.

Other direct research costs decreased $0.5 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.

We do not expect to incur significant future costs related to atuzaginstat (COR388) or COR588 as we will only advance our legacy neuroscience and antiviral assets through a proactive out-licensing efforts.

We also incurred decreases of $5.9 million in personnel related expenses due to a $4.4 million decrease in allocated stock-based compensation costs and a decrease of $1.5 million for decreased headcount year over year.

Facilities and other research and development expenses decreased $0.7 million for the three months ended September 30, 2022, as compared to the three months ended September 30, 2021 primarily due to a $0.3 million decrease in regulatory, quality assurance, and other consulting expenses, a $0.2 million decrease in allocated rent and facilities expenses and $0.2 million decrease in other non-clinical research.

General and Administrative Expenses

General and administrative expenses decreased by $3.3 million to $4.3 million for the three months ended September 30, 2022 from $7.6 million for the three months ended September 30, 2021. The decrease in general and administrative expenses is primarily due to a decrease of $2.9 million in personnel related expenses due to a $2.5 million decrease in allocated stock-based compensation expense and $0.4 million in wages and related employee benefits, as well as a $0.4 million decrease in corporate marketing related expenses as a result of our previously announced cost reduction program initiated in the first quarter of 2022.

Goodwill impairment charge

We conducted an impairment analysis of our goodwill that resulted from the purchase of Novosteo, Inc. in May 2022. That assessment included a qualitative assessment of deteriorating macro-economic conditions, including inflationary pressures, rising interest rates, and the continuing decline in our market capitalization from the date of acquisition. This qualitative assessment

indicated that our goodwill was potentially impaired. To determine the extent, if any, by which our goodwill was impaired, we conducted additional quantitative analyses which resulted in our fair value being significantly below our current carrying value. As a result of the analyses, we recorded a non-cash goodwill impairment charge of $0.8 million for the three months ended September 30, 2022.

Interest Income

Interest income increased by $0.2 million for the three months ended September 30, 2022, as compared to the three months ended September 30, 2021. The increase was a result of higher yields on our portfolio as interest rates have increased during 2022 from historic lows. We anticipate higher investment yields as we believe short-term interest rates will continue to rise in the near term.

Other Expense

Other expense increased by $0.5 million for the three months ended September 30, 2022, primarily due to unrealized losses resulting from changes in foreign exchange rates.

Comparison of the nine months ended September 30, 2022 to the nine months ended September 30, 2021

The following sets forth our results of operations for the nine months ended September 30, 2022 and 2021 (in thousands):

	Nine Months Ended September 30,		Change	
	2022	2021	$	%
Operating expenses:				
Research and development	$ 22,410	$ 45,582	$ (23,172)	(50.8) %
General and administrative	22,461	21,192	1,269	6.0 %
Goodwill impairment charge	825	—	825	100.0 %
Loss from operations	(45,696)	(66,774)	21,078	(31.6) %
Interest income	532	515	17	3.3 %
Other expense, net	(1,246)	(287)	(959)	334.1 %
Net loss before income tax benefit	$ (46,410)	$ (66,546)	$ 20,136	(30.3) %
Income tax benefit	284	—	284	100.0 %
Net loss	$ (46,126)	$ (66,546)	$ 20,420	(30.7) %

Research and Development Expenses *(in thousands):*

	Nine Months Ended September 30,		Change	
	2022	2021	$	%
Direct research and development expenses:				
Atuzaginstat (COR388)	$ 1,368	$ 19,607	$ (18,239)	(93.0) %
COR588	4,851	4,295	556	12.9 %
NOV004	1,082	-	1,082	100.0 %
Other direct research costs	1,489	2,404	(915)	(38.1) %
Indirect research and development expenses:				
Personnel related (including stock-based compensation)	12,903	17,481	(4,578)	(26.2) %
Facilities and other research and development expenses	717	1,795	(1,078)	(60.1) %
Total research and development expenses	$ 22,410	$ 45,582	$ (23,172)	(50.8) %

Research and development expenses were $22.4 million for the nine months ended September 30, 2022, compared to $45.6 million for the nine months ended September 30, 2021, a decrease of $23.2 million.

The costs for atuzaginstat (COR388) development decreased $18.2 million from the same period in the prior year due to a decrease of $11.0 million in clinical trial costs, a $3.1 million decrease in drug manufacturing costs, a decrease in non-clinical studies and analysis related to the GAIN trial samples of $2.3 million, a $1.6 million decrease in consulting expenses as the GAIN Phase 2/3 clinical trial concluded in late 2021, and a decrease in travel expenses related to COR388 of $0.2 million. Costs incurred in 2022 related primarily to statistical and biomarker analysis.

Our Phase 1 SAD/MAD trial was completed in the second quarter of 2022 for our compound COR588 in healthy participants in Australia. The costs for COR588 increased $0.6 million from the same period in the prior year due to a $0.1 million increase in clinical trial costs and $0.9 million for non-clinical studies and analysis to support COR588, offset by a decrease of $0.4 million in drug manufacturing costs.

Additionally, other direct research costs decreased $0.9 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.

For the nine months ended September 30, 2022, the costs for NOV004 increased by $1.1 million after the Novosteo, Inc. acquisition 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. We anticipate expense increases related to NOV004 to increase from current levels as we advance this asset to a Phase 1 clinical trial in 2023.

For the nine months ended September 30, 2022, we also experienced a net decrease of $4.6 million in personnel related expenses due to a $4.5 million decrease in allocated stock-based compensation costs, a decrease of $2.5 million in wages and related personnel expenses as a result of our decreased headcount, offset by an increase in severance related expenses of $2.4 million as a result of our previously announced cost reduction program initiated in the first quarter of 2022.

Facilities and other research and development expenses decreased $1.1 million from the nine months ended September 30, 2021 due to a $0.5 million decrease in regulatory and quality assurance consulting costs, $0.4 million decrease in the purchase of non-clinical supplies, and a $0.2 million decrease in facilities and rent expense.

General and Administrative Expenses

General and administrative expenses increased approximately $1.3 million to $22.5 million for the nine months ended September 30, 2022 from $21.2 million for the nine months ended September 30, 2021. The increase in general and administrative expenses was primarily due to increased severances expenses of $1.6 million offset by a $1.9 million decrease in allocated stock-based compensation expense related to our previously announced cost reduction program initiated in the first quarter of 2022. We also incurred a $2.7 million increase in legal, audit and other professional expenses related to the acquisition of Novosteo offset by a decrease of $0.4 million in marketing and investor relations expense and a $0.7 million decrease in consulting, corporate insurance expenses and other administrative expense due to our cost reductions efforts announced in the first quarter of 2022.

Goodwill impairment charge

We conducted an impairment analysis of our goodwill that resulted from the purchase of Novosteo, Inc. in May 2022. That assessment included a qualitative assessment of deteriorating macro-economic conditions, including inflationary pressures, rising interest rates, and the continuing decline in our market capitalization. This assessment indicated that our goodwill was potentially impaired. To determine the extent, if any, by which our goodwill was impaired, we conducted additional quantitative analysis which resulted in our fair value being significantly below carrying value. As a result of the analyses, we recorded a non-cash goodwill impairment charge of $0.8 million for the nine months ended September 30, 2022.

Interest Income

Interest income was $0.5 million for the nine months ended September 30, 2022 compared to $0.5 million for the nine months ended September 30, 2021. Increased yields on our investment portfolio were offset by decreased average balances resulting in no change for the periods presented.

Other Expense

Other expense increased by $1.0 million for the nine months ended September 30, 2022, primarily due to unrealized losses resulting from changes in foreign exchange rates of $0.8 million, as well as a $0.2 million increase related to the San Diego lease impairment loss and loss on disposal of fixed assets.

Income tax

We recorded an $0.3 million income tax benefit for the nine months ended September 30, 2022 as a result of the acquisition of Novosteo, Inc. in May 2022.

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 September 30, 2022, we had an accumulated deficit of $282.7 million. and we had cash, cash equivalents and investments of $99.3 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 the second half of 2025.

Capital Resources

Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures related to NOV004, atuzaginstat (COR388), COR588, and other research efforts, and to a lesser extent, 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.

Our product candidate is in preclinical development and the outcome of these efforts is uncertain. Accordingly, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability. We intend to out-license atuzaginstat (COR388), COR588, COR852 and COR803 to third parties as we prioritize the internal development of our innovative bone-targeting drug platform and lead compound NOV004 for development.

In the near term, our primary uses of cash will be to fund our operations, including research and development, preclinical studies, drug manufacturing, other pre-IND activities, and 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 drug development timelines, which are uncertain but include Phase 1 study for NOV004 and development of other pipeline compounds.

We will 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. 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 our NOV004 Phase 1 SAD/MAD clinical trial
- the outcome, costs and timing of seeking and obtaining FDA, EMA and any other regulatory approvals;
- the number and characteristics of drug candidates that we pursue;
- our ability to manufacture sufficient quantities of our 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.

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 others 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 into the second half of 2025.

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):

	Nine Months Ended September 30,	
	2022	2021
Net cash (used in) provided by:		
Operating activities	$ (38,203)	$ (48,514)
Investing activities	(664)	38,033
Financing activities	725	5,818
Effect of exchange rate changes on cash	227	29
Net decrease in cash and cash equivalents	$ (37,915)	$ (4,634)

Operating Activities

Net cash used in operating activities was $38.2 million for the nine months ended September 30, 2022. Cash used in operating activities was primarily due to our net loss of $46.1 million for the period, adjusted for $16.0 million of non-cash items, including $15.0 million in stock-based compensation and a net decrease in our current assets of $2.6 million, offset by a net decrease in accounts payable, accrued expenses and other current liabilities of $10.6 million.

Net cash used in operating activities was $48.5 million for the nine months ended September 30, 2021. Cash used in operating activities was primarily due to our net loss of $66.5 million for the period, adjusted for $22.5 million of non-cash items, including $21.4 million in stock-based compensation and a net decrease in accounts payable, accrued expenses and other current liabilities of $3.4 million and increases in our current assets of $1.1 million.

Investing Activities

Cash used by investing activities was $0.7 million in the nine months ended September 30, 2022, primarily related to the purchase of investments of $66.8 million, maturities of investments of $55.5 million, and cash acquired from the Novosteo, Inc. acquisition of $10.6 million.

Cash provided by investing activities was $38.0 million in the nine months ended September 30, 2021, primarily related to the purchase of investments of $35.8 million, maturities of investments of $73.9 million and the purchase of equipment of $0.1 million.

Financing Activities

Cash provided by financing activities was $0.7 million in the nine months ended September 30, 2022, which consisted of proceeds from the issuance of common stock in connection with an open market sales agreement, net of issuance costs as well as proceeds from the exercise of options.

Cash provided by financing activities was $5.8 million in the nine months ended September 30, 2021, which consisted of net proceeds from the exercise of stock options during the period.

Contractual Obligations and Commitments

Except as discussed below, there have been no material changes to our contractual obligations and other commitments as of September 30, 2022, 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 $2.6 million in our condensed consolidated balance sheet for expenditures incurred by these vendors as of September 30, 2022. We have approximately $4.8 million in cancellable future commitments based on existing contracts as of September 30, 2022.

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 Securities Exchange Act of 1934, as amended, or 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 Securities Exchange Act of 1934, as amended or 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 September 30, 2022. 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 September 30, 2022, 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:

- We may experience difficulties integrating Quince and Novosteo's operations and realizing the expected benefits of the acquisition of Novosteo.
- We are substantially dependent on the success of NOV004, and our successful out-licensing of our legacy assets which will require significant additional clinical testing before we or our partners can seek regulatory approval and potentially launch commercial sales, receive regulatory approval or be successfully commercialized, even if approved. If we are not successful in commercializing NOV004 or out-licensing our legacy assets, or are significantly delayed in doing so, our business will be materially harmed.
- If we are unable to out-license our legacy assets, our business will be entirely dependent on the successful development, regulatory approval and commercialization of NOV004, our only product candidate currently under development.
- Adverse side effects or properties, clinical holds imposed by the FDA, and other safety risks have delayed our development of atuzaginstat (COR388) and could delay or preclude approval, have caused and could cause us to suspend or discontinue clinical trials, abandon further development, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any, and these risks could also impact COR588, potential new indications for atuzaginstat (COR388) and other potential candidates.
- We may not be successful in our efforts to create a pipeline of drug candidates or to develop commercially successful drugs. If we fail to successfully identify, acquire, develop and commercialize additional drug candidates, our commercial opportunity may be limited.
- We are a preclinical stage biopharmaceutical company with a limited operating history. We have no drug candidates approved for commercial sale, we have never generated any revenue from sales, and we may never be profitable.
- We will require substantial additional funding to finance our operations, complete the development and commercialization of NOV004 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 will agree with our proposed clinical trial design for NOV004. Our drug candidate including NOV004 or any of our other potential drug candidates, may not receive regulatory approval, and without regulatory approval we will not be able to market our drug candidates.
- To date we have concentrated our research and development and clinical efforts on the treatment of Alzheimer's and other degenerative diseases and rare skeletal diseases, bone fractures and injury, and fields that have seen very limited success in drug development. Most of our drug candidates are based on new therapeutic approaches and novel technology, which also makes it difficult to predict the time and cost of drug candidate development and the regulatory approval process and exposes us to unforeseen risks, including the risk that the U.S. Food and Drug Administration ("FDA") may impose a clinical hold on, or otherwise limit our ability to proceed with our other clinical programs. We do not know if we will be able to effectively target administered small molecules, peptides or large molecules with our technology or that we will be able to develop drug candidates or approved products using this technology.

- If any of our clinical trials of our 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 additional 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 drug candidates.

- We rely on third parties to conduct some of our 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 current or any future drug candidate, or fail to meet rigorously enforced regulatory standards, our ability to provide supply of our 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.

- The COVID-19 pandemic, as well as other public health crises, catastrophic events or other events outside of our control, may adversely affect our capabilities or the capabilities of third parties on which we depend.

- We have conducted and in the future may conduct clinical trials for our drug candidates outside the United States, and the FDA, European Medicines Agency and applicable foreign regulatory authorities may not accept data from such trials.

- If we are unable to obtain and maintain sufficient intellectual property protection for our drug candidates, 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 drug candidates may be adversely affected.

- We may not be able to successfully partner our legacy assets.

Risks Related to our Recent Acquisition of Novosteo

We may experience difficulties integrating Quince and Novosteo's operations and realizing the expected benefits of the Acquisition.

On May 19, 2022, we completed our previously announced the Acquisition. The anticipated benefits we expect from the Acquisition 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 Quince and Novosteo 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 Quince and Novosteo, integrating the technologies, procedures, and policies. We may not be able to integrate our clinical pipelines given that our product candidates are in separate therapeutic spaces. For example, management may have limited experience with the drug candidates in treatment of Alzheimer's, oncology, COVID-19 and degenerative diseases. 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 operations of Quince and Novosteo 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 ability to be successful will be dependent upon the efforts of our executive officers and key personnel and the loss of such persons could negatively impact the operations of the combined company.

Our ability to be successful following the Acquisition will be dependent upon the efforts of our executive officers and key personnel. We recently announced resignation of our President and Chief Executive Officer, Chief Scientific Officer, Chief Medical Officer, Chief Legal and Administrative Officer and Corporate Secretary, Chief Financial Officer and Chief Operating Officer, and our Executive Vice President of Research and Development. Our business following the Acquisition is made up in part of Novosteo's business, which is different from our historical business. 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.

Our future results could suffer if we do not effectively manage our expanded operations following the Acquisition.

Following the Acquisition, the scope of operations of our business will increase beyond the current scope of operations of either ours or Novosteo's current businesses. In addition, we may continue to expand our size and operations through additional acquisitions or other strategic transactions. Our future success depends, in part, upon its ability to manage our 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 currently anticipated from the Acquisition or anticipated from any additional acquisitions or strategic transactions that we may undertake in the future.

The Novosteo Acquisition may result in impairment charges from the recording of goodwill and intangible assets that could adversely affect our financial results.

Our financial results may be adversely affected by impairment charges from the recording of goodwill and intangible assets incurred in connection with the Novosteo Acquisition. For example the company incurred a $0.8 million goodwill impairment charge in the quarter ended September 30, 2022. The amount and timing of further possible charges are not yet known. If such assets are found to be impaired, they will be written down to their estimated fair value, with a charge against earnings. Further, our failure to identify or accurately assess the magnitude of necessary technology investments we are assuming 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.

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

We are substantially dependent on the success of NOV004, and our successful out-licensing of our legacy assets which will require significant additional clinical testing before we or our partners can seek regulatory approval and potentially launch commercial sales, receive regulatory approval or be successfully commercialized, even if approved. If we are not successful in commercializing NOV004 or out-licensing our legacy assets, or are significantly delayed in doing so, our business will be materially harmed

To date, we have invested substantially all of our efforts and financial resources in the research and development of NOV004 and our legacy assets. Before seeking marketing approval from regulatory authorities for the sale of NOV004 and our legacy assets, we and our partners, respectively, must conduct extensive clinical trials to demonstrate the safety and efficacy of the drug in humans. We are not permitted to market or promote any of our drug candidates before we receive regulatory approval from the FDA, or comparable foreign regulatory authorities, and we may never receive such regulatory approval. We cannot be certain that COR588, atuzaginstat (COR388) or NOV004 will be successful in clinical trials. We do not have an open IND for NOV004 and NOV004 has never been tested in humans. NOV004, COR588 or atuzaginstat (COR388) may not receive regulatory approval even if it is successful in clinical trials. For example, on January 25, 2022, we received a letter from the FDA Division of Neurology 1 placing a full clinical hold on the IND for atuzaginstat (COR388). While we believe atuzaginstat (COR388) and COR588 may hold therapeutic potential in non-CNS indications, including oncology and periodontitis but there is no guarantee that further efforts with regard to atuzaginstat (COR388) or COR588 will be successful, and our ability to apply, and obtain regulatory approval, for any of these indications is uncertain at this time. If we do not receive regulatory approvals for NOV004, COR588 or atuzaginstat (COR388), we may not be able to continue our operations. Our prospects, including our ability to finance our operations and generate revenue, will depend entirely on the commercialization of NOV004 and successful development and partnering and regulatory approval of COR588, atuzaginstat (COR388), COR803 and COR852. The clinical and commercial success of NOV004 and our legacy assets will depend on a number of factors, including the following:

- the results from clinical trials for COR588 or potential additional indications pursued beyond Alzheimer's;
- timely and successful completion of manufacturing of drug supplies and our preclinical studies of NOV004;
- the frequency and severity of adverse effects of COR588, atuzaginstat (COR388) or NOV004;
- the likelihood that the COR588 may have a similar level of hepatotoxicity as atuzaginstat (COR388), which may result in a clinical hold by the FDA
- our ability to out-license our legacy assets;
- our or a potential partner's ability to design a cost effective and feasible Phase 2 clinical study for COR588 in Alzheimer's disease;
- the ability of third-party manufacturers to manufacture supplies of NOV004 and to develop, validate and maintain a commercial-scale manufacturing process that is compliant with current good manufacturing practices, or cGMP;
- our ability to demonstrate safety and efficacy of NOV004 and our legacy assets to the satisfaction of the FDA and foreign regulatory authorities;
- whether we or a potential partner would be required by the FDA to conduct additional clinical trials prior to the approval to market atuzaginstat (COR388) and whether the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the receipt of necessary marketing approvals from the FDA and foreign regulatory authorities;
- whether the FDA may require implementation of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval or post-approval;
- our ability to successfully commercialize NOV004 and out-license our legacy assets, if approved for marketing and sale by the FDA or foreign regulatory authorities, whether alone or in collaboration with others;
- our success in educating physicians and patients about the benefits, administration and use of our legacy assets;
- acceptance of NOV004 and our legacy assets as safe and effective by patients and the medical community;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- achieving and maintaining compliance with all regulatory requirements applicable to NOV004 and our legacy assets;
- the effectiveness of our own or any future collaborators' marketing, pricing, coverage and reimbursement, sales and distribution strategies and operations;
- our ability to maintain our existing patents and obtain newly issued patents that cover NOV004 and our legacy assets and to enforce such patents and other intellectual property rights in and to NOV004 and our legacy assets;
- our ability to avoid third-party intellectual property claims; and
- a continued acceptable safety profile of COR588 and atuzaginstat (COR388) following approval.

Many of these factors are beyond our control. Accordingly, we cannot assure you that we will ever be able to generate revenue through the sale of NOV004 and our legacy assets. If we are not successful in commercializing any of our drug candidates, or are significantly delayed in doing so, our business will be materially harmed.

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

We have discovered and developed a proprietary library of protease inhibitors from which we have selected COR588, to treat Alzheimer's disease, and atuzaginstat (COR388), to treat other degenerative diseases in non-CNS indications, including oncology and periodontitis. Our approach is based on the discovery of *P. gingivalis* and its secreted virulence factor proteases, gingipains, and represents a new approach to disease modification in Alzheimer's disease. There is no current academic or general consensus on the causation of Alzheimer's disease or method of action or current drugs that purport to treat Alzheimer's disease. Based on the results of our preclinical and clinical studies to date, we believe COR588 and atuzaginstat (COR388) are neuroprotective and have potential to modify or prevent further neurodegeneration, reduce amyloid beta levels and reduce inflammation, when administered orally. However, these ideas and this approach are novel, and we currently have only limited data based on physiological mouse models of Alzheimer's disease and our Phase 1 a/b clinical trials which enrolled 67 subjects, including nine patients with mild to moderate Alzheimer's disease and our Phase 2/3 GAIN trial which enrolled 643 patient participants with mild to moderate Alzheimer's disease.

The results from the GAIN trial did not meet statistical significance in its co-primary cognitive and functional endpoints as measured by ADAS-Cog11 and ADCS-ADL at end of the treatment period in the overall cohort. Furthermore, on January 25, 2022, we received a letter from the FDA Division of Neurology 1 placing a full clinical hold on the IND for atuzaginstat (COR388). While we will prioritize the development of our next generation gingipain inhibitor, COR588, in Alzheimer's disease, we may ultimately discover that COR588 or atuzaginstat (COR388), or any of our other protease inhibitors, do not possess certain properties required for therapeutic effectiveness. We have no long-term evidence regarding the efficacy, safety and tolerability of atuzaginstat (COR388) or other compounds in our proprietary library of protease inhibitors in humans. Currently, we intend to enter into strategic partnerships/collaborations to develop atuzaginstat (COR388), COR588, COR852 and COR803. 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.

If we are unable to out-license our legacy assets, our business will be entirely dependent on the successful development, regulatory approval and commercialization of NOV004, our only product candidate under development.

In the event that we are unable to partner or develop COR588, atuzaginstat (COR388), COR803 and COR852, our only product candidate will be NOV004, which is currently in preclinical development and has not been approved for sale, clinical trials or commercial use. In addition, we do not have an IND or trial design for NOV004 which has been reviewed or cleared by the FDA. This may make an investment in our company riskier than similar companies that have multiple product candidates in active development and that therefore may be able to better sustain a failure of a lead candidate. The success of our business, including our ability to finance our company and generate any revenue in the future, will, at that point, depend entirely on the successful development, regulatory approval and commercialization of NOV004, which may never occur. We may have inadequate financial or other resources to advance NOV004 through the clinical trial process, depending on the requirements of the FDA and similar foreign regulatory agencies. In addition, our clinical development program for NOV004 may not lead to regulatory approval from the FDA and similar foreign regulatory agencies if we fail to demonstrate that NOV004 is safe and effective in clinical trials, and we may therefore fail to commercialize NOV004. Further, interpretation of trial results by the FDA and similar foreign regulatory agencies may vary and NOV004 may not receive regulatory approval even if it is successful in planned and future clinical trials. Any failure to obtain regulatory approval of NOV004 would have a material and adverse impact on our business. Even if we successfully obtain regulatory approvals to market NOV004, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval. If the markets or patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of NOV004, even if approved.

If the market opportunities for NOV004 are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer. Because the target patient populations of NOV004 are small, and the addressable patient population even smaller, we must be able to successfully identify patients and capture a significant market share to achieve profitability and growth.

NOV004 is a precision bone growth molecule for rare disease. Given the small number of patients who have the disease that we are targeting, it is critical to our ability to grow and become profitable that we continue to successfully identify patients with these rare diseases. 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 may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. The effort to identify patients with diseases we seek to treat is in early stages, and we cannot accurately predict the number of patients for whom treatment might be possible. Additionally, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business. Further, even if we obtain commercial approval and significant market share for our product candidates, because the potential target populations are very small, we may never achieve profitability despite obtaining such significant market share. In addition, we do not have experience in launching and marketing a product targeting rare disease and cannot assure that we will be able to obtain such market share.

Our target patient populations are relatively small, and as a result, the pricing and reimbursement of our product candidates, if approved, is uncertain, but must be adequate to support commercial infrastructure. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell NOV004 will be adversely affected.

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. We did not meet statistical significance on either of the co-primary endpoints in the

GAIN Trial and any other 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. The Phase 1a and Phase 1b clinical trials for our drug candidate, atuzaginstat (COR388), included only nine Alzheimer's patients and 58 healthy volunteers. Further, the results of our earlier stage clinical trials and our preclinical animal studies may not be predictive of the results of outcomes in later-stage clinical studies. For example, data from six Alzheimer's patients treated with atuzaginstat (COR388) in our Phase 1b clinical trial showed improvements across several exploratory cognitive tests. However, these improvements should be interpreted with caution because they were not all statistically significant. When evaluated in a larger patient population, atuzaginstat (COR388) may not show similar improvements toward cognitive effects or may demonstrate different chemical and pharmacological properties in patients in unforeseen or harmful ways. Additionally, our Phase 2/3 GAIN trial, with 643 patient participants with mild to moderate Alzheimer's disease, did not meet statistical significance in its co-primary cognitive and functional endpoints as measured by ADAS-Cog11 and ADCS-ADL at end of the treatment period in the overall cohort. Based upon negative or inconclusive results, we may decide, or regulatory authorities may require us, to conduct additional clinical trials or preclinical studies. 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 NOV004 or 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.

Adverse side effects or properties, the clinical holds imposed by the FDA, or and other safety risks have delayed our development of atuzaginstat (COR388) and could delay or preclude approval, have caused and could cause us to suspend or discontinue clinical trials, abandon further development, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any, relating to COR588, potential new indications for atuzaginstat (COR388) and other potential candidates. We cannot guarantee that similar serious adverse events or clinical holds will not happen in the future with COR588, atuzaginstat (COR388) or any future drug candidates for any current or additional indications. There may be side effects and adverse events associated with the use of COR588, atuzaginstat (COR388) or any future drug candidates.

Our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics as the clinical trials progress to longer exposures at varying dose levels and a larger number of patients. Side effects could include treatment-related adverse events not seen in our Phase 1a and Phase 1b clinical trials of atuzaginstat (COR388) including hepatic adverse events. Undesirable side effects caused by, or unexpected or unacceptable characteristics associated with, atuzaginstat (COR388) or any future drug candidates could result in the delay, suspension or termination of clinical trials by us, the FDA or other regulatory authorities for a number of reasons. For example, on February 12, 2021, we received a letter from the FDA stating that a partial clinical hold has been placed on atuzaginstat (COR388) impacting the OLE phase of the GAIN Trial. The partial clinical hold was initiated following the review of hepatic adverse events in the atuzaginstat (COR388) trial by the FDA. Under the hold, we have

stopped enrollment and dosing in the OLE phase of the GAIN Trial. Atuzaginstat (COR388) was associated with dose-related liver enzyme elevations >3X the upper limit of normal: 2% on placebo, 7% on 40 mg BID, and 15% on 80 mg BID. Two participants in the 80 mg BID arm had concomitant bilirubin elevations without alternative explanation. On January 25, 2022, we received a letter from the FDA Division of Neurology 1 placing a full clinical hold on atuzaginstat (COR388) IND. 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.

As we or our potential partners assess data from our Phase 2/3 GAIN trial or safety of atuzaginstat (COR388), we or our partners may identify additional adverse events that were not identified or not considered significant in our earlier trials. If such side effects become later known in development or upon approval, if any, such findings may harm our business, financial condition, results of operations and prospects significantly. If we or others later identify undesirable side effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw, suspend or limit approval of atuzaginstat (COR388) or any future drug candidates;
- we may be required to recall a drug or change the way such drug is administered to patients;
- regulatory authorities may require additional warnings or statements in the labeling, such as a boxed warning or a contraindication or issue safety alerts, press releases or other communications containing warnings or other safety information about the drug candidate, for example, field alerts to physicians and pharmacies;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a risk evaluation and mitigation strategy, or REMS, to ensure that the benefits of the drug outweigh its risks; we may be required to change the way a drug is distributed or administered, conduct additional clinical trials or change the labeling of a drug, or be required to conduct additional post-marketing studies or surveillance;
- we could be sued and held liable for harm caused to patients;
- sales of the drug may decrease significantly or atuzaginstat (COR388) or any future drug could become less competitive; and
- our reputation may suffer.

Any of these events could prevent us or our potential partners from achieving or maintaining market acceptance of atuzaginstat (COR388), COR588, NOV004 or any future drug candidates, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials.

Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a drug candidate. Preclinical tests and Phase 1 and Phase 2 clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of drug candidates at various doses and schedules. Success in preclinical or animal studies and early clinical trials does not ensure that later large-scale efficacy trials will be successful, nor does it predict final results. Our drug candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials. Additionally, in future trials there may be unforeseen serious adverse events or side effects that differ from those seen in our preclinical tests, Phase 1 and Phase 2 clinical trials, which may result in a full or partial clinical hold from the FDA, or similar adverse events or additional adverse events that were not identified or not considered significant in our earlier trials that result in additional clinical holds on our current or currently contemplated clinical programs imposed by the FDA 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.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our drug candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

Clinical holds imposed by the FDA could prevent us or a partner from administering atuzaginstat (COR388) in oncology or periodontal or additional studies.

Preclinical data for atuzaginstat (COR388) showed toxicity at very high exposure levels in mice and, as a result, the FDA placed atuzaginstat (COR388) on partial clinical hold to enforce an exposure cap on atuzaginstat (COR388) dosages in humans at approximately 2.4 times the top dose of 80 mg BID in our Phase 2/3 GAIN trial. In addition, the FDA placed a partial clinical hold on atuzaginstat (COR388) impacting the OLE phase of the GAIN Trial following the review of hepatic adverse events in the atuzaginstat (COR388) trial by the FDA. Under the hold, we stopped enrollment and dosing in the OLE phase of the GAIN Trial. The results of our Phase 2/3 GAIN trial revealed atuzaginstat (COR388) was associated with dose-related liver enzyme elevations>3X the upper limit of normal: 2% on placebo,7% on 40 mg BID, and 15% on 80 mg BID. Two participants in the 80 mg BID arm had concomitant bilirubin elevations without alternative explanation. At the conclusion of the Phase 2/3 GAIN trial the FDA division of Neurology 1 placed a full clinical hold on atuzaginstat (COR388) for Alzheimer's disease. As a result, other divisions within the FDA could prevent us from administering atuzaginstat (COR388) in other indications, such as oncology and periodontal, which we are currently pursuing, or even if we are allowed to proceed with such other indications, we may not be ultimately successful because the results of these potential trials may prove to be not clinically significant or have side effects that prevent further clinical development.

We may not be successful in our efforts to continue to create a pipeline of drug candidates or to develop commercially successful drugs. If we fail to successfully identify and develop additional drug candidates, our commercial opportunity may be limited.

One of our strategies is to identify and pursue clinical development of additional drug candidates. We currently have five programs in the research, discovery and preclinical stages of development. Identifying, developing, obtaining regulatory approval and commercializing additional 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 additional drug candidates, advance any additional drug candidates through the development process, successfully commercialize any such additional drug candidates, if approved, or assemble sufficient resources to identify, acquire, develop or, if approved, commercialize additional drug candidates. If we are unable to successfully identify, acquire, develop and commercialize additional drug candidates, our commercial opportunity may be limited.

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

- regulatory authorities, institutional review boards or ethics committees, or IRBs or 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 NOV004;
- we may require additional preclinical studies or manufacturing of drug supplies for NOV004, which may delay our timeline for the clinical development for NOV004;
- 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 indication the drug candidate is 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, or 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.

For example, enrollment in our clinical trials have been and may be delayed or impeded as a result of the COVID-19 pandemic due to prioritization of healthcare resources toward the pandemic, and some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. For example, we have experienced some delays in enrollment in COR588 SAD/MAD Phase 1 clinical trial due to the restrictions related to COVID-19 placed in Australia. In addition, we may experience increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19 or other health conditions or because of quarantines or travel limitations (whether voluntary or required) If the patients involved with our clinical trials contract COVID-19, we may have more adverse events and deaths in our clinical trials as a result. We have taken and continue to take proactive measures to maintain the integrity of our ongoing clinical trial. However, these measures may not be successful, and the occurrence of any of these events could delay or impede our ability to release clinical results, delay or impact our clinical trials, including the integrity and completeness of subject data and clinical study endpoints, and could adversely impact our product candidates testing, development and timelines.

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.

All of our drug candidates are in clinical and preclinical development and their risk of failure is high. The clinical trials and manufacturing of our drug candidates are, and the manufacturing and marketing of our drug, 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. To date, we have not discussed with the FDA about its drug candidate, NOV004. Before obtaining regulatory approvals for the commercial sale of any of our drug candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our 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 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 our ongoing and 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 our ongoing and any future clinical trials are completed as planned, we cannot be certain that their results will support the safety and effectiveness of our 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, EMA or other 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, 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, EMA or other 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.

If we are required to conduct additional preclinical studies, clinical trials or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete preclinical studies, clinical trials of our 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 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 drug candidates, could allow our competitors to bring drug candidates to market before we do, and could impair our ability to successfully commercialize our 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 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.

We are a preclinical stage biopharmaceutical company with a limited operating history advancing innovative precision therapeutics targeting debilitating and rare diseases. We were incorporated in June 2012 and commenced material operations in June 2014. We have a very 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. We have recently completed a Phase I SAD/MAD clinical trial for COR588 and have not initiated clinical trials for any of our other drug candidates. To date, we have reported top-line data in only one Phase 2/3 clinical trial, which is currently subject to a full clinical hold by the FDA, and have not initiated any other late stage clinical trial, 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 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, 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, 2021, 2020, 2019, our net losses were $89.9 million, $76.8 million and $37.0 million, respectively. We had an accumulated deficit of $282.7 million as of September 30, 2022.

Before we are able to generate any revenue, we will need to commit substantial funds to continue development of our drug candidates and bring any drug candidates to commercialization, 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.

To date, we have devoted most of our financial resources to our corporate overhead and research and development of atuzaginstat (COR388) and COR588, including our preclinical development activities and clinical trials of atuzaginstat (COR388) and COR588. With our recent acquisition of Novosteo, Inc in May 2022, we are now focused on developing NOV004, a bone targeting molecule designed to accelerate fracture repair. We expect that it will be several years, if ever, before we have a 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 continue our development of, and seek regulatory approvals for our 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, we received a letter from the FDA Division of Neurology 1 placing a full clinical hold on the IND for atuzaginstat's (COR388). 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. Further, while we believe COR388 holds therapeutic potential in non-CNS indications, including oncology and periodontitis, there is no guarantee that further efforts with regard to COR388 will be successful, and our ability to apply, and obtain regulatory approval, or partner with others for further development for any of these indications is uncertain at this time.

We expect to advance atuzaginstat (COR388) and COR588 only if we are successful in partnering our legacy assets, but we may not be able to find a suitable partner, if at all. See also the risk factor titled "*If we are unable to successfully out-license our legacy assets, our business could materially suffer*."

We may elect to discontinue, delay or modify clinical trials of some drug candidates or focus on others. Any changes in the outcome of any of these variables with respect to the development of our drug candidates in clinical development could mean a significant change in the costs and timing associated with the development of these drug candidates. Even if we succeed in commercializing one or more drug candidates, we may never generate revenues that are significant or large enough to achieve profitability.

We may also encounter other unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. Because of these 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 will require substantial additional funding to finance our operations, complete the development and commercialization of* NOV004 *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 continue the research and development of, initiate clinical trials of, and seek marketing approval for, NOV004. In addition, if we obtain marketing approval for NOV004 or 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 connection with our continuing operations. As of September 30, 2022, we had $99.3 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 as a result of the negative effects arising from the COVID-19 pandemic or for other reasons, 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 the second half of 2025. 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:

- the willingness of the FDA and EMA to approve the implementation of protocols for further development our compounds, including but not limited to, NOV004 in their respective indications;
- the outcome, costs and timing of seeking and obtaining FDA, EMA and any other regulatory approvals;
- the number and characteristics of drug candidates that we pursue;
- our ability to manufacture sufficient quantities of our 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. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our research or development programs. 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 duration 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. Furthermore, a recession or decline in market value resulting from the spread of COVID-19 could materially affect our operations, overall yields from our investment portfolio, including through impairment and loss of investment, and the value of our common stock.

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 our proposed clinical trial designs. Our drug candidates, including NOV004, COR588, atuzaginstat (COR388) or any of our other potential drug candidates, may not receive regulatory approval, and without regulatory approval we will not be able to market our drug candidates.

Currently, we do not have a trial design for COR588 for Alzheimer's or a non-Alzheimer's indication or NOV004 that has been reviewed or cleared by the FDA or any foreign regulatory authorities. Regulatory agencies, including the FDA, or their advisors may disagree with our trial design and our interpretations of data from preclinical studies and clinical trials.

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 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, the EMA in Europe and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market our drug candidates in the United States or Europe until we receive approval of a new drug application, or NDA, from the FDA or a marketing authorization application, or MAA, from the EMA, respectively. We have not submitted any marketing applications for any of our drug candidates.

NDAs and MAAs must include extensive preclinical and clinical data and supporting information to establish the drug candidate's safety and effectiveness for each desired indication. NDAs and MAAs must also include significant information regarding the chemistry, manufacturing and controls for the drug. Obtaining approval of a NDA or a MAA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. The FDA and the EMA review processes can take years to complete and approval is never guaranteed. If we submit a 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, such as the EMA, have their own procedures for approval of drug candidates. Even if a drug is approved, the FDA or the EMA, as the case may be, 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 and Europe 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, Europe 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.

To date we have concentrated our research and development and clinical efforts on the treatment of Alzheimer's and other degenerative diseases and rare skeletal diseases, bone fractures and injury, and fields that have seen very limited success in drug development. Most of our drug candidates are based on new therapeutic approaches and novel technology, which also makes it difficult to predict the time and cost of drug candidate development and the regulatory approval process and exposes us to unforeseen risks, including the risk that the FDA may impose a clinical hold on, or otherwise limit our ability to proceed with, our other clinical programs.

We have focused our research and development efforts on addressing degenerative diseases. Collectively, efforts by pharmaceutical companies in the field of degenerative diseases have seen very limited successes in drug development. There are few effective therapeutic options available for patients with Alzheimer's disease and other degenerative diseases. Our future success is highly dependent on the successful development of our technology and our drug candidates for treating degenerative diseases. Developing and, if approved, commercializing our drug candidates for treatment of degenerative diseases subjects us to a number of challenges, including ensuring that we have selected the optimal dose of the therapeutic to block gingipains in the brain, executing an appropriate trial to test for efficacy and obtaining regulatory approval from the FDA and other regulatory authorities.

Our approach to the treatment of degenerative diseases aims to understand the cause of disease pathogenesis, select the right patient population, discover and develop potent and selective small molecules that act directly in the brain or other organs on these targets, and leverage both preclinical and human pharmacodynamic data for dose selection. This strategy may not prove to be successful. We cannot be sure that our approach will yield satisfactory therapeutic drug candidates that are safe and effective, scalable, or profitable. Moreover, public perception of drug safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical trials, or if approved, of physicians to prescribe novel treatments.

Although we have continued to make advances in our development of NOV004, our research continues to be at an early stage, and we face challenges. Development of any drug candidates utilizing our technology is expected to require significant additional research and funding. For example, we may experience delays in the manufacture of drug supplies or identify suitable animal disease models for our drug candidates, which could delay or frustrate our ability to proceed into clinical trials or obtain

marketing approval. NOV004 is expected to enter Phase 1 clinical trials in 2023 with planned areas of investigation including osteogenesis imperfecta, general fractures and spinal fusion. There is no assurance that we will continue our development of NOV004, that subsequent research will be successful or that we will be able to develop drug candidates or approved products using our technology.

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

We have announced top-line results of our Phase 2/3 GAIN trial for Alzheimer's disease and reported that it did not meet statistical significance in its co-primary cognitive and functional endpoints as measured by ADAS-Cog11 and ADCS- ADL at end of the treatment period in the overall cohort. On January 25, 2022, we received a letter from the FDA Division of Neurology 1 placing a full clinical hold on atuzaginstat (COR388) IND. Other divisions of the FDA may impose a clinical hold on atuzaginstat (COR388) as we explore other indications for this drug, or otherwise limit our ability to proceed with other clinical programs in our pipeline, which could have a materially adverse impact on us. We cannot guarantee that that similar clinical holds will not happen in the future with COR588, atuzaginstat (COR388) or any future drug candidates for any current or additional indications. 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 a 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 of our clinical trials of our 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 additional 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 drug candidates.

Before obtaining regulatory approvals for the commercial sale of any of our drug candidates, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our 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 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 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 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.

Although we have our own lab to conduct some preclinical studies for NOV004, we currently 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 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, or 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 ongoing 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 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.

The lab facilities in which our product candidates are developed could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors.

We presently develop our product candidates at our lab facilities in West Lafayette, Indiana. If our lab facilities were to be damaged or destroyed by fire, flood, other natural disaster or other occurrences of any kind, it would have a material adverse effect on our ability to develop product candidates and on our business, financial condition and results of operations.

We must comply with applicable regulations and guidelines. We may experience shortages in qualified personnel. We are subject to inspections by regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow regulatory requirements or delay, interruption or other issues that arise in the development of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, leading to significant delays in the availability of therapeutic product for clinical studies or the termination or hold on a clinical study, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our product candidates and/or may be subject to product recalls, seizures, injunctions, or criminal prosecution.

We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer, more advanced or more effective than ours.

The development and commercialization of new drugs is highly competitive. Moreover, the degenerative disease field is characterized by strong competition and a strong emphasis on intellectual property. We may face competition with respect to any drug candidates that we seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

There are a number of large pharmaceutical and biotechnology companies that are currently pursuing the development of drug candidates for the treatment of the degenerative disease indications for which we have research programs, including Alzheimer’s

disease. Companies that we are aware are developing therapeutics in the degenerative disease field include large companies with significant financial resources, such as AbbVie Inc., Biogen Inc., Eli Lilly and Company, Eisai Co., Ltd., Merck & Company, Inc., Denali Therapeutics, Inc., Alector, Inc., Cassava Sciences, Inc., Novartis AG and Roche Holding AG (including Genentech, its wholly owned subsidiary), as well as companies pursuing a dysfunctional immune system approach to Alzheimer's disease or other types of therapies.

There are many bone building and osteoporosis drugs currently in development and available in the United States include anti-resorptive agents, anabolic agents, and an agent that has both anabolic and anti-resorptive characteristics. Anti-resorptive agents including bisphosphonates, hormone therapy, selective estrogen receptor modulators (SERMs), and Amgen's Prolia (denosumab), are the most common treatments for osteoporosis. Teriparatide, marketed by Lilly under the name Forteo/Forsteo (outside the U.S.) and abaloparatide, marketed by Radius Health under the name Tymlos are both anabolic drugs targeting the PTH receptor approved in the United States for the treatment of osteoporosis. We are aware of companies pursuing development in the United States of teriparatide through various regulatory pathways, including Teva Pharmaceutical Industries, Ltd., and APOTEX. We believe other companies may be in earlier stages of development of a generic version of teriparatide. Romosozumab, an anti-sclerostin monoclonal antibody for the treatment of osteoporosis, is marketed by Amgen and UCB under the name Evenity, following regulatory approval in the US, Europe and Japan.

There are several therapies in development for osteogenesis imperfecta including setrusumab, an anti-sclerostin monoclonal antibody, in development by Ultragenyx and Mereo BioPharma; SAR439459, and fresolimumab, both anti-TGF-beta monoclonal antibodies, in development by Sanofi; and romosozumab, in development by Amgen.

Fracture repair or spinal fusion therapies and devices available to be applied during surgery include recombinant human bone morphogenetic protein-2 (rhBMP2), marketed by Medtronic under the name Infuse Bone Graft. rhPDGF-BB, marketed by Lynch Biologics and Wright Medical Group N.V., and low-intensity pulsed ultrasound (LIPUS) marketed by BioVentus.

Many of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved drug candidates than we do. Merger and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drug candidates that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any drug candidates that we may develop. Furthermore, currently approved drug candidates could be discovered to have application for treatment of degenerative disease indications, which could give such drug candidates significant regulatory and market timing advantages over any of our drug candidates. Our competitors also may obtain FDA, EMA or other regulatory approval for their drug candidates more rapidly than we may obtain approval for ours from the FDA for indications our drug candidates are targeting, which could result in our competitors establishing a strong market position before we are able to enter the market.

Additionally, drug candidates or technologies developed by our competitors may render our potential drug candidates uneconomical or obsolete, and we may not be successful in marketing any drug candidates we may develop against competitors. If our competitors market drug candidates that are more effective, safer or less expensive than our drug candidates, if approved, or that reach the market sooner than our drug candidates, if approved, we may not achieve commercial success. In addition, the pharmaceutical industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or drug candidates developed by our competitors may render our technologies or drug candidates obsolete, less competitive or not economical.

If we or any of our third-party manufacturers encounter difficulties in production of our current or any future drug candidate, or fail to meet rigorously enforced regulatory standards, our ability to provide supply of our 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 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 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 drug candidates, or supply 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 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 drug candidates that we may develop is subject to FDA, EMA and foreign regulatory requirements, and continuous oversight, and we will need to contract with manufacturers who can meet all applicable FDA, EMA and foreign regulatory authority requirements, including complying with current good manufacturing practices, or 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, EMA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such drug candidates. Even if we obtain regulatory approval for any of our 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, EMA 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 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 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 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 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 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 drug candidates if approved.

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, 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.

The COVID-19 pandemic, as well as other public health crises, catastrophic events or other events outside of our control, may adversely affect our capabilities or the capabilities of third parties on which we depend.

Our headquarters are located in California near major geologic faults that have experienced earthquakes in the past. An earthquake or other natural disaster or power shortages or outages could disrupt operations, impair critical systems or result in loss of clinical samples. Any of these disruptions or other events outside of our control could have a material adverse impact on our business, harming our operating results. In addition, if any of our suppliers or third-party service providers, such as our manufacturing partners or CROs, are affected by natural disasters, such as earthquakes, tsunamis, power shortages or outages, floods or monsoons, public health crises, such as pandemics and epidemics, political crises, such as terrorism, war, political instability or other conflict, cyberattacks, or other events outside of our control, our business and operating results could suffer. Disasters, public health crises and political crises occurring at third-party facilities also could negatively impact our clinical development and regulatory approval timelines, our reputation and the perception of our company. For example, as a result of the COVID-19 pandemic, we and our third- party service providers temporarily limited our operations or implemented limitations, including work-from-home policies. All employees have now returned to their pre-pandemic work locations and activities. However, as long as the pandemic continues, our employees may be exposed to health risks and government directives may require us to close again certain of our offices or our laboratory facility. In addition, as a result of "shelter-in-place" orders or other mandated travel restrictions, our on-site staff conducting research and development activities may not be able to access our laboratories, and these core activities may be significantly limited or curtailed, possibly for an extended period of time. Further, due to travel restrictions and “shelter-in-place” orders, we may experience limitations on the ability to recruit and hire key personnel due to the inability to meet with candidates and reduced ability to engage with the medical and investor communities due to the cancelation of conferences scheduled throughout the year. We also may experience operational challenges caused by sickness of our employees or their families, the desire of employees to avoid contact with large groups of people, and an increased reliance on working from home or mass transit disruptions. Furthermore, new quarantines for COVID-19 or other viruses could impact personnel at contract manufacturing facilities in China, Europe or elsewhere to deliver key materials or the availability or cost of starting materials. Any disruption of our contract manufacturing vendors in China, Europe or elsewhere to deliver key materials on a timely basis could have a material adverse effect on the initiation of new trials, the duration of open label extension studies and overall product development. In addition, we may experience delays or disruptions in non-clinical experiments and supplies for such experiments, including animals required for such experiments. These and other factors arising from the COVID-19 pandemic could worsen in countries that are already afflicted with COVID-19, could continue to spread to additional countries, or could return to countries where the pandemic has been partially contained, each of which could further adversely impact our ability to conduct clinical trials and our business generally, and could have a material adverse impact on our operations and financial condition and results.

We will need to expand our operations and increase the size of our company, and we may experience difficulties in managing growth.

As we increase the number of ongoing drug development programs and advance our drug candidates through preclinical studies and clinical trials, we will need to increase our drug development, scientific and administrative headcount to manage these programs. In addition, to meet our obligations as a public company, we will need to increase our general and administrative capabilities. Our management, personnel and systems currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

- successfully attract and recruit new employees or consultants with the expertise and experience we will require;
- manage our clinical programs effectively, which we anticipate being conducted at numerous clinical sites;
- develop a marketing and sales infrastructure; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

If we are unable to successfully manage this growth and increased complexity of operations, our business may be adversely affected.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants.

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 cost reduction program to reorganize operations and to allow continued support for the needs of its business following the clinical hold on atuzaginstat (COR388) IND, impacting a number of employees. Any 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. We recently announced resignation of our President and Chief Executive Officer, Chief Scientific Officer, Chief Medical Officer, Chief Legal and Administrative Officer and Corporate Secretary, Chief Financial Officer and Chief Operating Officer and our Executive Vice President of Research and Development. Changes in management is disruptive to our business and have also resulted in our loss of unique skills, loss of knowledge about our business. For example, our new management team has limited knowledge of our legacy clinical programs. 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. 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, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or 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, or 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, or 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 European Union, or 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, or 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 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 2031, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. 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. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry. 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, or 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, EMA 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.

On May 19, 2022, we completed the Acquisition. We may attempt to acquire other 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 candidates 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.

We have conducted and may conduct in the future clinical trials for our drug candidates outside the United States, and the FDA, European Medicines Agency and applicable foreign regulatory authorities may not accept data from such trials.

We recently concluded our COR588 Phase 1 trial outside the United States and in the future may choose to conduct one or more of our clinical trials outside the United States. In particular, we are conducting clinical trial operations in Australia. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA, EMA or applicable foreign regulatory authorities may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to Good Clinical Practice regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA or any applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable

jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our drug candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

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

From time to time, we may publicly disclose preliminary or top-line data from our 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 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 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. As a result of the COVID-19 pandemic, health regulatory agencies globally have experienced and may continue to experience disruptions in their operations. The FDA, EMA and comparable foreign regulatory agencies may have slower response times or be under-resourced to continue discussions with us regarding the scope or design of our clinical trials and, as a result, review, inspection, and other timelines may be materially delayed. It is unknown how long these disruptions could continue, were they to occur.

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

If any of our 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, EMA 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 or MAA. 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 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, EMA 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 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 drug candidates for indications or uses for which they do not have approval. The holder of an approved NDA or MAA 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 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 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 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 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 payer, 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, or 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, or 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.

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 September 30, 2022, we were the owner of record of nine issued U.S. patents, 39 non-U.S. patents, and 23 pending U.S. and non-U.S. patent applications. Through the acquisition, we are also the exclusive licensee of 1 issued U.S. patent, and 20 pending U.S. and non U.S. patent applications and the owner of record of 1 additional pending PCT patent application (all issued U.S. patents, non-U.S. patents, and pending U.S. and non-U.S. patent applications mentioned above, collectively, "the Quince patent portfolio").

Seven issued U.S. patents and 37 issued non-U.S. patents in the Quince patent portfolio relate to atuzaginstat (COR388), with claims directed to atuzaginstat (COR388) and related pharmaceutical compounds, pharmaceutical compositions containing these compounds, and use of these compounds in the treatment of various indications. Pending U.S. and non-U.S. patent applications in the Quince patent portfolio relate to atuzaginstat (COR388) and related pharmaceutical compounds, pharmaceutical compositions containing these compounds, methods of using these compounds in the treatment of various indications, and methods of making these compounds.

In addition, two issued U.S. patents and two non-U.S. patent in the Quince patent portfolio relate to pharmaceutical compounds that do not encompass atuzaginstat (COR388), with claims directed to pharmaceutical compounds, pharmaceutical compositions containing these compounds, and use of these compounds in the treatment of various indications. Pending U.S. and non-U.S. patent applications relate to additional compounds in these areas, as well as to diagnostic methods and assay methods.

One issued U.S. patent in the Quince patent portfolio relates to NOV004, with claims directed to NOV004 and related pharmaceutical compounds, pharmaceutical compositions containing these compounds, and use of these compounds in the treatment of bone fractures. Pending U.S. and non-U.S. patent applications in the Quince patent portfolio 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, including delays as a result of the COVID-19 pandemic impacting our or our licensor's operations. 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.

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.

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; and
- 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.

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. 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.

European applications will soon have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court ("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 of any litigation.

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.

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.

If any of our product candidates obtains regulatory approval additional competitors could enter the market with generic versions, which may result in a material decline in sales of affected drugs.

Under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, a pharmaceutical manufacturer may file an abbreviated new drug application, or ANDA, seeking approval of a generic copy of an approved, small molecule innovator drug. Under the Hatch-Waxman Act, a manufacturer may also submit a new drug application, or NDA, under section 505(b)(2) that references the FDA's prior approval of the small molecule innovator drug. A 505(b)(2) NDA drug may be for a new or improved version of the original innovator drug. The Hatch-Waxman Act also provides for certain periods of regulatory exclusivity, which preclude FDA approval (or in some circumstances, FDA filing and reviewing) of an ANDA or 505(b)(2) NDA. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, drug formulation or an approved use of the drug, which would be listed with the drug in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." If there are patents listed in the Orange Book, a generic or 505(b)(2) applicant that seeks to market its drug before expiration of the patents must include in the ANDA a "Paragraph IV certification," challenging the validity or enforceability of, or claiming non-infringement of, the listed patent or patents. Notice of the certification must be given to the innovator, too, and if within 45 days of receiving notice the innovator sues to protect its patents, approval of the ANDA is stayed for 30 months, or as lengthened or shortened by the court.

Accordingly, if any of our small molecule drug candidates receive FDA approval, competitors could file ANDAs for generic versions of our drugs or 505(b)(2) NDAs that reference our drugs, respectively. If there are patents listed for a drug in the Orange Book, those ANDAs and 505(b)(2) NDAs would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict how any generic competitor would address patents we may list in the Orange Book, if any, whether we would sue on any such patents, or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection for drug candidates and technologies we develop or license. Moreover, if any of our owned or in-licensed patents that are listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected drug could immediately face generic competition and its sales would likely decline rapidly and materially. Should sales decline, we may have to write off a portion or all of the intangible assets associated with the affected drug and our results of operations and cash flows could be materially and adversely affected.

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:

- results of clinical trials and, as we experienced following the announcement of the full clinical hold imposed by the FDA;
- our ability to partner our legacy assets;
- results of clinical trials of other drug candidates being evaluated for Alzheimer's disease or other neurodegenerative diseases;

- any delays in manufacturing of drug supplies, results of preclinical studies and clinical trials for NOV004 for the treatment of osteogenesis imperfecta, general fractures and spinal fusion;
- regulatory actions with respect to our drug candidates or our competitors' drug candidates, such as the recently announced clinical hold by the FDA;
- 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;
- 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, such as the recently announced departure of Chief Executive Officer, Chief Scientific Officer, Chief Medical Officer, Chief Legal and Administrative Officer and Corporate Secretary and Chief Operating and Financial Officer and Executive Vice President of Research and Development;
- 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, including developments relating to the COVID-19 pandemic and the associated economic downturn; 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. 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.

On December 23, 2021, we entered into an Open Market Sales Agreement with Jefferies, whereby we may sell up to $150.0 million in aggregate proceeds of common stock from time to time, through Jefferies as our sales agent. 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 may 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 has requirements that a company must meet in order to remain listed on Nasdaq. In particular, Nasdaq rules require us to maintain a minimum closing bid price of $1.00 per share of our common stock. From November 1, 2022 through the date of this filing, the closing price of our common stock was below $0.99 per share. If the closing bid price of our common stock were to remain below $1.00 per share for 30 consecutive trading days, or we do not meet other listing requirements, we would fail to be in compliance with Nasdaq's listing standards. There can be no assurance that we will continue to meet the minimum bid price requirement, or any other requirement in the future. If we fail to meet the minimum bid price requirement once the temporary suspension is lifted, The Nasdaq Stock Market LLC may initiate the delisting process with a notification letter. If we were to receive such a notification, we would be afforded a grace period of 180 calendar days to regain compliance with the minimum bid price requirement. In order to regain compliance, shares of our common stock would need to maintain a minimum closing bid price of at least $1.00 per share for a minimum of 10 consecutive trading days. 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 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.

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	
10.1**	Second Amendment to License Agreement, dated as of July 22, 2022, by and between Purdue Research Foundation and Novosteo, Inc.				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: November 9, 2022

By: /s/ Dirk Thye
Dirk Thye
Chief Executive Officer
(Principal Executive Officer)

Date: November 9, 2022

By: /s/ Ted Monohon
Ted Monohon
Chief Accounting Officer
(Principal Financial and Accounting Officer)

Exhibit 10.1

[Certain confidential portions of this agreement (marked with [***]) have been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K because the Company has determined that such redacted information is (i) not material, and (ii) is the type of information the company treats as private or confidential.]

AMENDMENT #2 TO LICENSE AGREEMENT

THIS AMENDMENT #2 TO LICENSE AGREEMENT (the "**Amendment**"), made and entered into this 22nd day of July, 2022 ("**Amendment Effective Date**") by and between Purdue Research Foundation, a corporation formed and existing under the Indiana Foundation or Holding Companies Act of 1921 with its main offices located at 1281 Win Hentschel Blvd, West Lafayette, IN 47906 ("**PRF**"), and Novosteo, Inc., a Delaware corporation with business offices at 601 Gateway Boulevard, Suite 1250, South San Francisco, CA 94080 ("**LICENSEE**"), collectively referred to hereinafter as the "Parties," and each individually as a "Party," amends the License Agreement dated June 3, 2020 (as amended from time to time), (the "**Agreement**"); and

WHEREAS, the Parties have agreed to certain modifications to the Agreement.

NOW, **THEREFORE**, the Parties hereby revise and amend the Agreement as follows:

1. Section 1.9 "Field of Use" is hereby deleted and replaced with the following:

   "1.9 "Field of Use" means all fields of use."

2. The following sentence is hereby added to the end of Section 1.14:

   "In the event any continuation-in-part application is filed claiming priority to any patent application that is included in the Licensed Patents, only the claims in such continuation-in-part patent application that claim subject matter encompassed by one or more claims presented in the prior patent application shall be included in the scope of the Licensed Patents."

3. Section 2.6 is hereby added to Article 2 (Grant of License) as follows:

   "2.6 Reservation of Rights. PRF retains on behalf of itself, Purdue University, its researchers and students, and any research collaborators the following rights:

   i. To practice under the Licensed Intellectual Property and to make and use the Licensed Intellectual Property and Licensed Product(s) on a royalty-free basis only for non-commercial research, scholarly use, teaching, education, patient care incidental to the foregoing, and other similar uses, including without limitation sponsored research and collaborations, provided that PRF shall not license, transfer or otherwise grant rights to Licensed Intellectual Property to any third party in connection with such sponsored research and collaborations ("Non-Commercial Uses");

   ii. To license (without the right to grant sublicense where permitted by pre-existing contractual requirements) any government agency; university or other educational institution; organization of the type described in §501(c)(3) of the Internal Revenue Code; scientific or educational organization qualified under a state nonprofit organization statute; or a foreign equivalent of the foregoing ("Non-Commercial Organizations") to practice under the Licensed Intellectual Property and to make and use Licensed Products on a royalty-free basis for Non-Commercial Uses;

   iii. To disseminate and publish material and scientific findings from its research related to the Licensed Intellectual Property and/or Licensed Products, and to permit its respective personnel, including Purdue University personnel, to do the same."

4. The following sentence is hereby added to Section 4.6 (Sublicense Income) immediately following the sentence which reads, "Unit Royalties payable to PRF on a Sublicensee's Gross Receipts are not Sublicense Income."
   "For clarity, in the event LICENSEE or an Affiliate receives from a Sublicensee [***], [***] shall be due to PRF. In those cases, Sublicense Income payable to PRF shall be a percentage, as shown below, of Sublicense Income resulting from [***]."

5. Subsection (b) of Section 1.24 "Valid Claim" is hereby deleted and replaced with the following:

   "(b) any pending claim of the Licensed Patents that has not been abandoned or finally and conclusively rejected without the possibility of appeal or re-filing of such application and that has not been pending for more than [***] years from the date

of filing of the earliest effective priority filing date for the patent application from which such claim is entitled to claim priority."

6. Section 2.5 (Sublicenses) is hereby deleted and replaced with the following:

"Section 2.5 Sublicenses. LICENSEE shall have the right to grant Sublicenses in multiple tiers, provided that [***]. Notwithstanding the foregoing, [***]. Each Sublicense shall be consistent with the terms and conditions of this Agreement and in no event shall a Sublicensee be any foreign person, foreign corporation or other business entity, or foreign government, in each case that is designated as the target of any sanction, restriction, or embargo administered by the United States of America. LICENSEE shall be responsible for the acts and omissions of each Sublicensee hereunder, including but not limited to the payment of all fees and royalties due under this Agreement. LICENSEE shall take reasonable efforts to ensure Sublicensee's compliance with the terms and conditions of the license granted by PRF under this Agreement. LICENSEE shall, upon written request by PRF, provide PRF a copy of each executed Sublicense, which may be redacted to the extent the terms thereof are not necessary to determine compliance with this Agreement."

7. Section 3.3 is hereby deleted and replaced with the following:
"Section 3.3 Performance According to Plans. Licensee shall use Commercially Reasonable Efforts to perform in accordance with the Commercialization Plan."

8. The following sentence is hereby added to the end of Section 4.3:

"Notwithstanding the foregoing, the minimum annual royalty payable under this Section 4.3 shall [***] after the expiration of the Royalty Term for the Licensed Products in all of the following countries: the United States, the United Kingdom, Germany, France, Spain and Italy."

9. The following sentence is hereby added to the end of Section 4.9:

"Notwithstanding anything to the contrary in this Agreement, each Milestone Payment shall be payable only once for each Licensed Product, regardless of the number of times the corresponding milestone event is completed or obtained, as the case may be, for such Licensed Product. For clarity and solely for purposes of this Section 4.9, Milestone Payments shall be payable for each Licensed Product required by the relevant regulatory authority to undergo a particular milestone event [***]."

10. The last two sentences of Section 8.2 are hereby replaced with the foregoing:

"Unless otherwise agreed by the Parties in writing, any recovery from such enforcement action shall be used first to reimburse the Parties of their respective costs and expenses incurred in connection with such action, on a pro-rata basis if such recovery is not sufficient to cover all of such costs and expenses. Any remainder, absent a separate written agreement to the contrary, shall be [***] if such recovery is [***], or [***] if such recovery is [***]."

11. Subsection (c) of Section 13.2 is hereby added as follows:
"Section 13.2(c) Tolling of Cure Period. If the LICENSEE reasonably and in good faith disagrees as to whether there has been a default or breach, the LICENSEE may contest the allegation in accordance with Article 10 (Dispute Resolution). Notwithstanding anything to the contrary contained in Section 13.2(b) (Other Breach), the [***] cure period for any disputed default or disputed breach will be tolled from the date that a Dispute Notice received by PRF pursuant to Article 10 (Dispute Resolution) through the earlier of (i) resolution of such dispute pursuant to Article 10 (Dispute Resolution), or [***], and it is understood and acknowledged that, during the pendency of a dispute resolution pursuant this Section 13.2(c) (Tolling of Cure Period), all of the terms and conditions of this Agreement will remain in effect, and the Parties will continue to perform all of their respective obligations under this Agreement."

12. The following sentence is hereby added to the end of Section 13.1 (Term):

"Following the expiration of the Royalty Term for a given Licensed Product in a given country, the license granted to LICENSEE under Section 2.1 with respect to Technical Information disclosed to or known by LICENSEE as of the Effective

Date shall, in such country, automatically become a fully paid-up, perpetual, irrevocable, royalty-free, non-exclusive license."

13. Section 13.5 is hereby replaced in its entirety as follows:

"**13.5** Direct License to Sublicensee Upon Termination of this Agreement.

a) Notice to Sublicensees. In the event of termination of this Agreement prior to expiration of the Term, LICENSEE agrees to provide written notice of termination to each Sublicensee, with a copy to PRF, and shall advise the Sublicensee(s) of the requirements of this Section 13.5 which apply if the Sublicensee desires to receive a direct license from PRF under the terms of its Sublicense (a "Direct License").

b) Submission of Request. LICENSEE or any Sublicensee, as the case may be, may request that, in the event of termination of this Agreement, PRF grant a direct license to a Sublicensee of the Licensed Patents sublicensed by LICENSEE. That request may be submitted during the Term by LICENSEE. In the event of termination of this Agreement, that request may also be submitted by a Sublicensee within [***] days following receipt of notice of termination of this Agreement. Any such request must be submitted in writing, [***].

c) Notice of Determination. If the request is submitted during the Term, PRF shall have [***] days after receipt of the notice [***] to notify LICENSEE in writing of its determination as to whether to agree to grant the Direct License. If the request is submitted following termination of this Agreement, PRF shall have [***] days after receipt of the notice [***] to notify the Sublicensee in writing of that determination.

d) Eligibility of Sublicensee for Direct License. Upon request of Sublicensee, PRF shall grant a Direct License by executing a new agreement with Sublicensee on the terms set forth below, if:

i. Sublicensee was not in material default or breach under the Sublicense as of the date of termination of this Agreement;

ii. LICENSEE has acquiesced in the termination of this Agreement;

iii. LICENSEE and Sublicensee have agreed to terminate the Sublicense upon execution of a new agreement between PRF and Sublicensee for the Direct License;

iv. Sublicensee agrees to enter into a written agreement (the "Direct License Agreement") under which:

a. Sublicensee shall perform substantially the same obligations (including payment obligations) promised by LICENSEE in this Agreement applicable to Sublicensee's field of use and territory, and PRF's obligations are no greater than those promised under this Agreement.

b. The Licensed Patents are directly licensed to such Sublicensee by PRF with the same exclusivity, field of use, territory, diligence requirements, and reporting requirements as contained in the Sublicense.

c. Article 7 (Patent Prosecution) shall provide for PRF to lead patent prosecution and for Sublicensee to reimburse patent costs (including any patent costs outstanding under this Agreement as of the date of its termination) in proportion to the number of Direct License Agreements issued for the Licensed Patents under which Sublicensee is licensed;

e) Provisional Direct License. If PRF agrees to grant a Direct License to a Sublicensee, during the period from termination of this Agreement until execution of the Direct License Agreement, the relevant Sublicensee may practice the Licensed Patents within the scope of its Sublicense as a provisional licensee, provided that the effective date of the Direct License Agreement shall be retroactive to the date on which this Agreement terminates."

14. SCHEDULE B: Commercialization Plan is hereby deleted and replaced with the revised and updated Commercialization Plan attached hereto as Exhibit 1.

15. SCHEDULE E: Development Milestones is hereby amended to [***]. An amended Schedule E is attached hereto as Exhibit 2.

16. Amendment Fee. In consideration for the foregoing amendments, including [***], LICENSEE shall pay PRF a non-refundable fee of [***] ("Amendment Fee") upon execution of this Amendment, The Amendment Fee, or any portion thereof, shall not be credited toward any other obligation, now or in the future, of LICENSEE under the Agreement. For clarity, the right of LICENSEE to [***] is unaffected by this Amendment [***].

17. Capitalized terms not defined herein shall, unless otherwise indicated herein, have the meanings ascribed to such terms in the Agreement.

18. The Parties agree that except for the amendments set forth herein, the terms of the Agreement as revised, modified or amended shall control the rights and obligations of the Parties; provided that to the extent there is any inconsistency between this Amendment and the Agreement (as amended from time to time) or any term or objective of this Amendment would be frustrated or impeded by application of any other term of the Agreement, this Amendment shall control and supersede all inconsistent provisions of the Agreement. This Amendment shall be construed under and governed by the laws of the State of Indiana (without regard to conflict of law rules) and the United States of America.

(Signatures to follow)

IN WITNESS WHEREOF, the Parties have caused this Amendment to be signed by their duly authorized representatives, to be effective as of the date set forth above.

PURDUE RESEARCH FOUNDATION			**NOVOSTEO, INC.**	
X /s/ Brooke L. Beier			**X /s/** Dirk Thye	
Printed Name:	Brooke L Beier, PhD		Printed Name:	Dirk Thye, MD
Title:	Sr. Vice President, Commercialization		Title:	Chief Executive Officer

EXHIBIT 1

Schedule B: Commercialization Plan

Novosteo Commercialization Plan for NOV004

[***]

EXHIBIT 2

Schedule E: Development Milestones

Date/Timeline	Milestone
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

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 September 30, 2022;

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: November 9, 2022

/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, Ted Monohon, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Quince Therapeutics, Inc. for the quarter ended September 30, 2022;

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: November 9, 2022

/s/ Ted Monohon

Ted Monohon

Chief Accounting 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 September 30, 2022 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: November 9, 2022

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 September 30, 2022 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: November 9, 2022

By: /s/ Ted Monohon

Ted Monohon
Chief Accounting Officer
(Principal Financial Officer)