

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)



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

For the quarterly period ended September 30, 2023

OR



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

For the transition period from _____ to
Commission File Number: 001-39617

Aligos Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

82-4724808

(I.R.S. Employer
Identification No.)

**One Corporate Drive, 2nd Floor
South San Francisco, California**

(Address of principal executive offices)

94080

(Zip Code)

Registrant's telephone number, including area code: (800) 466-6059

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value, \$0.0001 per share	ALGS	The Nasdaq Stock Market LLC (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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

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

As of October 31, 2023, the registrant had 74,931,848 shares of common stock, \$0.0001 par value per share, outstanding, comprised of 71,839,510 shares of voting common stock, \$0.0001 par value per share and 3,092,338 shares of non-voting common stock, \$0.0001 par value per share.

Special note regarding forward-looking statements

This Quarterly Report on Form 10-Q contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business, operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and 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 terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “positioned,” “seek,” “should,” “target,” “will,” “would,” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the scope, progress, results and costs of developing our drug candidates or any other future drug candidates, and conducting nonclinical studies and clinical trials, including our ALG-055009, ALG-000184, ALG-097558 and ALG-125755 clinical trials;
- the scope, progress, results and costs related to the research and development of our pipeline;
- the timing of, and costs involved in, obtaining and maintaining regulatory approval for any of our current or future drug candidates, and any related restrictions or limitations;
- our expectations regarding the potential market size and size of the potential patient populations for ALG-055009, ALG-000184, ALG-097558 and ALG-125755, our other drug candidates and any future drug candidates, if approved for commercial use;
- our ability to maintain existing, and establish new, collaborations, licensing or other arrangements and the financial terms of any such agreements;
- our commercialization, marketing and manufacturing capabilities and expectations;
- the rate and degree of market acceptance of our drug candidates, as well as the pricing and reimbursement of our drug candidates, if approved;
- the implementation of our business model and strategic plans for our business, drug candidates and technology, including additional indications for which we may pursue;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our drug candidates, including the projected term of patent protection;
- any lawsuits related to our drug candidates or commenced against us;
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing and our ability to obtain additional capital;
- developments and projections relating to our competitors and our industry, including competing therapies and procedures;
- regulatory and legal developments in the United States and foreign countries;
- the performance of our third-party suppliers and manufacturers;
- our ability to attract and retain key management, scientific and medical personnel;
- our expectations regarding the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012;
- our expectations regarding our ability to obtain, maintain, enforce and defend our intellectual property protection for our drug candidates; and
- other risks and uncertainties, including those listed under the caption “Risk Factors.”

These forward-looking statements are based on management’s current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management’s beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Quarterly Report on Form 10-Q may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the

section titled “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. 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. We undertake no obligation to publicly update or revise any forward-looking statements contained herein for any reason after the date of this report to conform these statements to new information, actual results or changes in our expectations, except as required by applicable law.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

Investors and others should note that we may announce material business and financial information to our investors using our investor relations website, Securities and Exchange Commission, or SEC, filings, webcasts, press releases and conference calls. We use these mediums, including our website, to communicate with the public about our company, our business and other issues. It is possible that the information that we make available may be deemed to be material information. We therefore encourage investors and others interested in our company to review the information that we make available on our website.

Summary of material risks associated with our business

The principal risks and uncertainties affecting our business include the following:

- We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have incurred significant losses since inception. We expect to incur losses for at least the next several years and may never achieve or maintain profitability, which, together with our limited operating history, makes it difficult to assess our future viability.
- We have never generated revenue from product sales and may never be profitable.
- We will require substantial additional financing to achieve our goals, which may not be available on acceptable terms, or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.
- We are early in our development efforts, and our business is dependent on the successful development of our current and future drug candidates. If we are unable to advance our current or future drug candidates through clinical trials, obtain marketing approval and ultimately commercialize any drug candidates we develop, or experience significant delays in doing so, our business will be materially harmed.
- If we fail to comply with the continued listing requirements of the Nasdaq Stock Market LLC (Nasdaq) our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.
- Our current or future drug candidates may cause undesirable side effects or have other properties when used alone or in combination with other approved products or investigational new drugs that could delay or halt their clinical development, prevent their marketing approval, limit their commercial potential or result in significant negative consequences.
- We depend on collaborations with third parties for the development of certain of our potential drug candidates, and we may depend on additional collaborations in the future for the development and commercialization of these or other potential candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these drug candidates.
- We intend to develop our current drug candidates, and expect to develop other future drug candidates, in combination with other therapies, which exposes us to additional risks.
- We face significant competition, and if our competitors develop and market products that are more effective, safer or less expensive than the drug candidates we develop, our commercial opportunities will be negatively impacted.
- If we and our collaborators are unable to obtain, maintain, protect and enforce sufficient patent and other intellectual property protection for our drug candidates and technology, our competitors could develop and commercialize products and technology similar or identical to ours, and we may not be able to compete effectively in our market or successfully commercialize any drug candidates we may develop.

- Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could negatively impact the success of our business.
- We have entered into licensing and collaboration agreements with third parties. If we fail to comply with our obligations in the agreements under which we license intellectual property rights to or from third parties, or these agreements are terminated, or we otherwise experience disruptions to our business relationships with our licensors or licensees, our competitive position, business, financial condition, results of operations and prospects could be harmed.
- We are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

The summary risk factors described above should be read together with the text of the full risk factors below in the section entitled “Risk Factors” and the other information set forth in this Quarterly Report on Form 10-Q, including our consolidated financial statements and the related notes, as well as in other documents that we file with the SEC. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations, and future growth prospects.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

ALIGOS THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	September 30, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 70,429	\$ 81,347
Restricted cash	74	115
Short-term investments	-	44,480
Other current assets	4,140	7,603
Total current assets	<u>74,643</u>	<u>133,545</u>
Operating lease right-of-use assets	6,940	7,698
Property and equipment, net	3,646	4,816
Other assets	623	634
Total assets	<u>\$ 85,852</u>	<u>\$ 146,693</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,941	\$ 4,737
Accrued liabilities	12,322	16,039
Operating lease liabilities, current	3,197	3,035
Finance lease liabilities, current	58	108
Deferred revenue from customers, current	1,857	467
Deferred revenue from collaborations, current	2,093	8,743
Total current liabilities	<u>22,468</u>	<u>33,129</u>
Operating lease liabilities, net of current portion	8,329	9,201
Finance lease liabilities, net of current portion	188	230
Deferred revenue from customers, net of current portion	-	233
Long term liability	46	-
Total liabilities	<u>31,031</u>	<u>42,793</u>
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred Stock, \$0.0001 par value; 10,000,000 shares authorized as of September 30, 2023 (unaudited) and December 31, 2022, respectively; no shares issued and outstanding as of September 30, 2023 (unaudited) and December 31, 2022, respectively.	-	-
Common stock, \$0.0001 par value; 320,000,000 shares authorized as of September 30, 2023 (unaudited) and December 31, 2022, respectively; 43,502,582 and 42,922,980 shares issued and outstanding as of September 30, 2023 (unaudited) and December 31, 2022, respectively.	4	4
Additional paid-in capital	513,225	502,613
Accumulated deficit	(458,905)	(399,118)
Accumulated other comprehensive income	497	401
Total stockholders' equity	<u>54,821</u>	<u>103,900</u>
Total liabilities and stockholders' equity	<u>\$ 85,852</u>	<u>\$ 146,693</u>

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

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue from collaborations	\$ 2,154	\$ 4,106	\$ 7,329	\$ 10,370
Revenue from customers	1,085	—	5,519	—
Operating expenses:				
Research and development	15,867	17,791	50,783	65,977
General and administrative	6,443	5,263	24,195	19,291
Total operating expenses	22,310	23,054	74,978	85,268
Loss from operations	(19,071)	(18,948)	(62,130)	(74,898)
Interest and other income, net	1,059	284	3,168	795
Loss before income tax expense	(18,012)	(18,664)	(58,962)	(74,103)
Income tax benefit (expense)	(29)	43	(825)	(57)
Net loss	(18,041)	(18,621)	(59,787)	(74,160)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities	—	109	96	(293)
Other comprehensive income (loss)	—	109	96	(293)
Comprehensive loss	\$ (18,041)	\$ (18,512)	\$ (59,691)	\$ (74,453)
Net loss per share, basic and diluted	\$ (0.41)	\$ (0.44)	\$ (1.38)	\$ (1.74)
Weighted average shares of common stock, basic and diluted	43,496,975	42,761,928	43,209,656	42,647,732

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

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(Unaudited)

(In thousands, except share and per share data)

	Three Months Ended September 30, 2023						
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity	
	Shares	Amount					
Balance as of June 30, 2023	43,502,582	\$ 4	\$ 509,998	\$ (440,864)	\$ 497	\$ 69,635	
Issuance of common stock upon exercise of stock options	-	-	-	-	-	-	
Issuance of common stock related to ESPP purchase	-	-	-	-	-	-	
Stock-based compensation expense related to employee stock awards	-	-	2,883	-	-	2,883	
Stock-based compensation expense related to employee stock purchases	-	-	326	-	-	326	
Vesting of early exercised common stock options	-	-	18	-	-	18	
Other comprehensive loss	-	-	-	-	-	-	
Net loss	-	-	-	(18,041)	-	(18,041)	
Balance as of September 30, 2023	<u>43,502,582</u>	<u>\$ 4</u>	<u>\$ 513,225</u>	<u>\$ (458,905)</u>	<u>\$ 497</u>	<u>\$ 54,821</u>	

	Nine Months Ended September 30, 2023						
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity	
	Shares	Amount					
Balance as of December 31, 2022	42,922,980	\$ 4	\$ 502,613	\$ (399,118)	\$ 401	\$ 103,900	
Issuance of common stock upon exercise of stock options	17,109	-	23	-	-	23	
Issuance of common stock related to ESPP purchase	562,493	-	461	-	-	461	
Stock-based compensation expense related to employee stock awards	-	-	9,361	-	-	9,361	
Stock-based compensation expense related to employee stock purchases	-	-	708	-	-	708	
Vesting of early exercised common stock options	-	-	59	-	-	59	
Other comprehensive income	-	-	-	-	96	96	
Net loss	-	-	-	(59,787)	-	(59,787)	
Balance as of September 30, 2023	<u>43,502,582</u>	<u>\$ 4</u>	<u>\$ 513,225</u>	<u>\$ (458,905)</u>	<u>\$ 497</u>	<u>\$ 54,821</u>	

Three Months Ended September 30, 2022						
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balance as of June 30, 2022	42,808,288	\$ 4	\$ 495,538	\$ (358,611)	\$ 50	\$ 136,981
Issuance of common stock upon exercise of stock options	7,305	-	9	-	-	9
Issuance of common stock related to ESPP purchase	-	-	-	-	-	-
Stock-based compensation expense related to employee stock awards	-	-	3,272	-	-	3,272
Stock-based compensation expense related to employee stock purchases	-	-	219	-	-	219
Vesting of early exercised common stock options	-	-	44	-	-	44
Other comprehensive income	-	-	-	-	109	109
Net loss	-	-	-	(18,621)	-	(18,621)
Balance as of September 30, 2022	<u>42,815,593</u>	<u>\$ 4</u>	<u>\$ 499,082</u>	<u>\$ (377,232)</u>	<u>\$ 159</u>	<u>\$ 122,013</u>

Nine Months Ended September 30, 2022						
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2021	42,690,229	\$ 4	\$ 487,347	\$ (303,072)	\$ 452	\$ 184,731
Issuance of common stock upon exercise of stock options	12,896	-	20	-	-	20
Issuance of common stock related to ESPP purchase	112,468	-	111	-	-	111
Stock-based compensation expense related to employee stock awards	-	-	10,306	-	-	10,306
Stock-based compensation expense related to employee stock purchases	-	-	1,110	-	-	1,110
Vesting of early exercised common stock options	-	-	188	-	-	188
Other comprehensive loss	-	-	-	-	(293)	(293)
Net loss	-	-	-	(74,160)	-	(74,160)
Balance as of September 30, 2022	<u>42,815,593</u>	<u>\$ 4</u>	<u>\$ 499,082</u>	<u>\$ (377,232)</u>	<u>\$ 159</u>	<u>\$ 122,013</u>

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

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)
(In thousands)

	<u>Nine Months Ended September 30,</u>	
	<u>2023</u>	<u>2022</u>
Cash flows from operating activities:		
Net loss	\$ (59,787)	\$ (74,160)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accretion of discount on investments	(424)	(84)
Amortization of right of use assets	1,129	994
Impairment of right of use assets	724	-
Loss on disposal of assets	17	-
Depreciation expense	1,165	1,784
Stock-based compensation including ESPP	10,069	11,277
Changes in operating assets and liabilities:		
Other assets	3,472	6,167
Right of use assets	-	(278)
Accounts payable	(1,796)	(84)
Accrued liabilities	(3,657)	(11,528)
Operating lease liabilities	(1,805)	(1,334)
Other liabilities	46	-
Deferred revenue from collaborations	(6,650)	4,640
Deferred revenue from customers	1,158	-
Net cash and cash equivalents used in operating activities	<u>(56,339)</u>	<u>(62,606)</u>
Cash flows from investing activities:		
Activities in available-for-sale investments:		
Maturities of investments	45,011	42,695
Purchase of short-term investments	(11)	(79,740)
Purchases of property and equipment	(12)	(852)
Net cash and cash equivalents provided by (used in) investing activities	<u>44,988</u>	<u>(37,897)</u>
Cash flows from financing activities:		
Payments on finance lease	(92)	(88)
Proceeds from the ESPP purchase	461	111
Proceeds from the exercise of common stock option	23	20
Net cash and cash equivalents provided by financing activities	<u>392</u>	<u>43</u>
Net decrease in cash, cash equivalents, and restricted cash	<u>(10,959)</u>	<u>(100,460)</u>
Cash, cash equivalents, and restricted cash, beginning of period	81,462	186,980
Cash, cash equivalents, and restricted cash, end of period	<u>\$ 70,503</u>	<u>\$ 86,520</u>

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

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2023	2022
Reconciliation to amounts on the consolidated balance sheet:		
Cash and cash equivalents	\$ 70,429	\$ 86,440
Restricted cash	74	80
Total cash, cash equivalents, and restricted cash	<u>\$ 70,503</u>	<u>\$ 86,520</u>
Supplemental disclosures of noncash financing and investing activities:		
Mark to market adjustment for available-for-sale investments	\$ 96	\$ (293)
Acquisition of right of use asset through operating lease obligation	\$ 1,094	\$ -
Vesting of early exercised options	\$ 59	\$ 188

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

ALIGOS THERAPEUTICS, INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization

Description of business

Aligos Therapeutics, Inc. (Aligos-US) was incorporated in the state of Delaware on February 5, 2018 (inception). On September 10, 2018, the Company formed Aligos Belgium BVBA (Aligos-Belgium), a limited liability company organized under the laws of Belgium. On March 30, 2020, the Company formed as a wholly owned subsidiary, Aligos Australia Pty LTD (Aligos-Australia), a proprietary limited company. On May 18, 2021, the Company formed as a wholly owned subsidiary, Aligos Therapeutics (Shanghai) Co. Ltd. (Aligos-Shanghai) and together with Aligos-US, Aligos-Belgium, and Aligos-Australia being the “Company” or “Aligos”.

Aligos is a clinical-stage biopharmaceutical company developing novel therapeutics to address unmet medical needs in viral and liver diseases, including for non-alcoholic steatohepatitis (NASH), coronaviruses and chronic hepatitis B.

The Company is devoting substantially all of its efforts to the research and development of its drug candidates. The Company has not generated any product revenue to date. The Company is also subject to a number of risks similar to other companies in the biotechnology industry, including the uncertainty of success of its nonclinical studies and clinical trials, regulatory approval of drug candidates, uncertainty of market acceptance of products, competition from substitute products and larger companies, the need to obtain additional financing, compliance with government regulations, protection of proprietary technology, dependence on third-parties, product liability, and dependence on key individuals.

Liquidity

The Company has incurred losses and negative cash flows from operations since its inception. As of September 30, 2023 and December 31, 2022, the Company had an accumulated deficit of \$458.9 million and \$399.1 million, respectively. Management expects to continue to incur additional substantial losses in the foreseeable future as a result of expanded research and development activities.

As of September 30, 2023, the Company has unrestricted cash, cash equivalents and investments of approximately \$70.4 million which is available to fund future operations. The Company expects to continue to spend substantial amounts to continue the nonclinical and clinical development of its current and future programs. If the Company is able to gain marketing approval for drug candidates that are being developed, it will require significant additional amounts of cash in order to launch and commercialize such drug candidates. In addition, other unanticipated costs may arise. Because the design and outcome of the Company’s planned and anticipated clinical trials is highly uncertain, the Company cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any drug candidate the Company may develop.

The Company expects to finance its cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. In addition, the Company may seek additional capital to take advantage of favorable market conditions or strategic opportunities even if the Company believes it has sufficient funds for its current or future operating plans. Based on the Company's research and development plans, the Company expects its existing unrestricted cash, cash equivalents and investments, will enable it to fund its operations for at least 12 months following the date the condensed consolidated financial statements are issued. However, the Company's operating plan may change as a result of many factors currently unknown, and the Company may need to seek additional funds sooner than planned. Moreover, it is particularly difficult to estimate with certainty the Company's future expenses given the dynamic nature of its business and the macro-economic environment generally.

The Company's ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond its control. For example, the current inflationary economic environment, the COVID-19 pandemic and rising interest rates have resulted in a disruption of global financial markets. If the disruption persists or deepens, the Company could be unable to access additional capital, which could negatively affect its ability to consummate certain corporate development transactions or other important, beneficial or opportunistic investments. If additional funds are not available to the Company when needed, on terms that are acceptable to the Company, or at all, the Company may be required to: delay, limit, reduce or terminate nonclinical studies, clinical trials or other research and development activities or eliminate one or more of its development programs altogether; or delay, limit, reduce or terminate its efforts to establish manufacturing and sales and marketing capabilities or other activities that may be necessary to commercialize any future approved products, or reduce the Company's flexibility in developing or maintaining its sales and marketing strategy.

Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company deposits its cash in financial institutions that it believes have high credit quality and has not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships. The Company has always maintained a dual banking system to limit its credit and liquidity risk.

2. Summary of significant accounting policies

Basis of presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) and applicable rules and regulations of the Securities and Exchange Commission (SEC) regarding interim financial reporting. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. Any reference in these notes to applicable accounting guidance is meant to refer to the authoritative U.S. GAAP included in the Accounting Standards Codification (ASC), and Accounting Standards Update (ASU) issued by the Financial Accounting Standards Board (FASB).

The condensed consolidated balance sheet as of December 31, 2022 included herein was derived from the audited consolidated financial statements as of that date but does not include all of the information and notes required by U.S. GAAP for complete financial statements. Certain information and note disclosures normally included in the financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to requirements for interim financial statements. As such, the information included in this Quarterly Report on Form 10-Q should be read in conjunction with the audited consolidated financial statements and the related notes thereto as of and for the year ended December 31, 2022, included in the Company's Annual Report on Form 10-K filed with the SEC on March 9, 2023.

Unaudited interim financial information

The accompanying consolidated balance sheet as of September 30, 2023, the consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2023 and 2022, the consolidated statements of stockholders' equity for the three and nine months ended September 30, 2023 and 2022, and the consolidated statements of cash flows for the nine months ended September 30, 2023 and 2022 are unaudited. The unaudited consolidated interim financial statements have been prepared on the same basis as the audited annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's consolidated financial position as of September 30, 2023 and the consolidated results of its operations and cash flows for the three and nine months ended September 30, 2023 and 2022. The consolidated financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2023 and 2022 are unaudited. The consolidated results for the three and nine months ended September 30, 2023 are not necessarily indicative of results to be expected for the year ending December 31, 2023, any other interim periods, or any future year or period.

Significant accounting policies and estimates

Accounting for Government Grants

In 2022, the Company was awarded a grant of \$1.1 million by the National Institute of Health (NIH) for research to target coronaviruses. The grant is for multiple years with the amount updated after each year of progress through 2025, subject to the annual reapplication and approval by the NIH. In 2023, the approved grant awarded was an additional \$1.4 million.

In 2023, the Company was awarded a contract of \$8.5 million by the National Institute of Allergies and Infectious Diseases (NIAID) for research to target coronaviruses. This contract is for 2 years.

U.S. GAAP does not contain authoritative accounting standards for grants or contracts provided by governmental entities to a for-profit entity. Absent authoritative accounting standards, interpretative guidance issued and commonly applied by financial statement preparers allows for the selection of accounting policies amongst acceptable alternatives. The Company determined it most appropriate to account for grants by analogy to International Accounting Standards 20 (“IAS 20”), *Accounting for Government Grants and Disclosure of Government Assistance*. Under this model, reimbursements the Company receives from the U.S. government for qualifying expenditures under the NIH grant will be recognized in earnings as a reduction to Research and development expense when there is reasonable assurance that the Company will receive the grant. IAS 20 does not define “reasonable assurance”; however, based on certain interpretations, it is analogous to “probable” as defined in FASB ASC 450-20-20 under U.S. GAAP, which is the definition the Company has applied. The grants and contracts will be recognized in earnings as a reduction of the related expenses.

Impairment of Right of Use Assets

In accordance with ASC 360, Property, Plant and Equipment, management reviews the Company’s right of use assets for impairment annually or whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. Events relating to recoverability may include significant unfavorable changes in business conditions, recurring losses, or a forecasted inability to achieve break-even operating results over an extended period. The Company determines the extent to which an asset may be impaired based upon its expectation of the asset’s future usability, as well as on a reasonable assurance that the future cash flows associated with the asset will be in excess of its carrying amount. If the total of the expected undiscounted future cash flows is less than the carrying amount of the asset, a loss is recognized for the difference between fair value and the carrying value of the asset. During the three months ended June 30, 2023, the Company vacated certain leased office space and as a result, the Company took an impairment charge against right of use assets of \$0.7 million, recorded in the Consolidated Statements of Operations and Comprehensive Loss. No further impairments were made in the three months ended September 30, 2023.

No other material changes have been made to the Company’s significant accounting policies disclosed in Note 2, Summary of significant accounting policies, in its Annual Report on Form 10-K, filed on March 9, 2023, for the year ended December 31, 2022.

Recently issued accounting standards

From time to time, new accounting pronouncements are issued by FASB that the Company adopts as of the specified effective date. The Company qualifies as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012 and has the option to not “opt out” of the extended transition related to complying with new or revised accounting standards. This means that when a standard is issued or revised and it has different application dates for public and nonpublic companies, the Company has the option to adopt the new or revised standard at the time nonpublic companies adopt the new or revised standard and can do so until such time that the Company either (i) irrevocably elects to “opt out” of such extended transition period or (ii) no longer qualifies as an emerging growth company.

The Company has considered all recent accounting pronouncements issued, but not yet effective, and does not expect any to have a material effect on the Company’s condensed consolidated financial statements other than those discussed in its Annual Report on Form 10-K, filed on March 9, 2023, for the year ended December 31, 2022.

3. Property and equipment

The components of property and equipment as of September 30, 2023 and December 31, 2022 were as follows (in thousands):

	September 30, 2023	December 31, 2022
Leasehold improvements	\$ 6,101	\$ 6,087
Lab equipment	6,188	6,179
Computer equipment	1,050	1,052
Furniture and office equipment	739	739
Vehicles	296	305
Asset under construction	4	22
Total, at cost	14,378	14,384
Accumulated depreciation	(10,732)	(9,568)
Total, net	\$ 3,646	\$ 4,816

Depreciation expense was \$0.3 million and \$1.2 million for the three and nine months ended September 30, 2023, and \$0.5 million and \$1.8 million for the three and nine months ended September 30, 2022, respectively. Finance leases are also included in property and equipment as vehicles and lab equipment on the condensed consolidated balance sheets.

4. Investments

As of September 30, 2023 and December 31, 2022, amortized cost, gross unrealized gains and losses, and estimated fair values of total fixed-maturity securities were as follows (in thousands):

	September 30, 2023			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Available-for-sale securities:				
U.S. Treasury bonds	\$ -	\$ -	\$ -	\$ -
	December 31, 2022			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Available-for-sale securities:				
U.S. Treasury bonds	\$ 44,576	\$ -	\$ (96)	\$ 44,480

Changes in fair value are related to changes in market interest rates. The Company expects to collect all contractual principal and interest payments.

The following is a summary of maturities of securities available-for-sale as of September 30, 2023 (in thousands):

	Available-for-sale	
	Amortized Cost	Estimated Fair Value
Amounts maturing in:		
One year or less	\$ -	\$ -
Total investments	\$ -	\$ -

The Company recorded interest income of \$1.0 million and \$2.7 million for the three and nine months ended September 30, 2023, and \$0.5 million and \$0.8 million for the three and nine months ended September 30, 2022, respectively, as a component of interest and other income, net on the Company's condensed consolidated statement of operations and comprehensive loss.

5. Accrued liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Accrued compensation	\$ 4,083	\$ 6,297
Accrued payables	6,973	8,203
Liability for early exercised stock options	7	66
Other	1,259	1,473
Total	<u>\$ 12,322</u>	<u>\$ 16,039</u>

As of September 30, 2023, there remains a \$0.1 million accrual, included within Accrued Compensation noted above, for the workforce reduction announced in February 2023, which is expected to be fully utilized by the end of 2023.

6. Stock-based compensation

Stock options

During the three and nine months ended September 30, 2023, the Company's stock option compensation expense was approximately \$2.9 million and \$9.4 million, respectively, and during the three and nine months ended September 30, 2022, the Company's stock option compensation expense was approximately \$3.3 million and \$10.2 million, respectively. There was no recognized tax benefit in either of the periods. As of September 30, 2023, the unamortized expense balance was \$19.0 million, to be amortized over a weighted average period of 2.13 years.

Stock option activity during the nine months ended September 30, 2023 is as follows:

	Shares subject to options	Weighted- average exercise price	Weighted- average remaining contractual term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of January 1, 2023	9,840,127	\$ 7.49	8.28	\$ —
Granted	2,151,160	\$ 1.19		
Exercised	(17,109)	\$ 1.34		
Cancelled	(842,236)	\$ 7.36		
Outstanding as of September 30, 2023	<u>11,131,942</u>	\$ 6.29	7.85	\$ —
Options vested and expected to vest as of September 30, 2023	11,131,027	\$ 6.29	7.85	\$ —
Options vested and exercisable as of September 30, 2023	5,471,525	\$ 8.28	7.04	\$ —

The weighted-average grant date fair value of options granted during the three and nine months ended September 30, 2023 was \$0.59 and \$0.83 per share, respectively, and during the three and nine months ended September 30, 2022 was \$0.98 and \$1.81 per share, respectively.

Restricted stock units

During the three and nine months ended September 30, 2023, the Company recorded \$2 thousand and \$2 thousand stock-based compensation expense related to restricted stock units newly granted in the three months ended September 30, 2023. During the three and nine months ended September 30, 2022, the Company recorded total stock-based compensation expense related to restricted stock awards of \$4 thousand and \$95 thousand. As of September 30, 2023, the unamortized expense balance was \$0.1 million, to be amortized over a weighted average period of 3.8 years.

Restricted stock activity during the nine months ended September 30, 2023 is as follows:

	Number of Awards	Weighted- Average Grant Date Fair Value	Aggregate Fair Value (in thousands)
Issued and unvested as of January 1, 2023	—	\$ -	\$ -
Restricted stock awards granted	134,120	\$ 0.84	\$ 101
Restricted stock awards vested	—	\$ -	\$ -
Issued and unvested as of September 30, 2023	<u>134,120</u>	<u>\$ 0.84</u>	<u>\$ 101</u>

During the nine months ended September 30, 2023 and 2022, the Company did not issue shares of common stock, upon exercise of unvested stock options or purchases for unvested restricted stock awards. As of September 30, 2023 and December 31, 2022, there were 1,975 and 28,711 shares of Common Stock held by employees subject to repurchase at an aggregate price of approximately \$0.0 million and \$0.1 million, respectively. A corresponding liability was recorded and included in accrued expenses on the condensed consolidated balance sheet as of September 30, 2023 and December 31, 2022, respectively.

Employee stock purchase plan

During the three and nine months ended September 30, 2023, the Company recorded total stock-based compensation expense related to the employee stock purchase plan of \$0.3 million and \$0.7 million, respectively. During the three and nine months ended September 30, 2022, the Company recorded total stock-based compensation expense related to the employee stock purchase plan of \$0.2 million and \$1.0 million. During the three and nine months ended September 30, 2023 and 2022, 0 and 562,493, and 0 and 112,468, purchases of awards under this plan have been made, respectively.

Stock-based compensation expense was allocated as follows for the three and nine months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	\$ 1,585	\$ 1,949	\$ 5,328	\$ 6,155
General and administrative	1,624	1,542	4,741	5,122
Total	<u>\$ 3,209</u>	<u>\$ 3,491</u>	<u>\$ 10,069</u>	<u>\$ 11,277</u>

7. Fair value

Certain assets and liabilities of the Company are carried at fair value under U.S. GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

Level 1 — Quoted prices in active markets for identical assets or liabilities.

Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3 — Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The following tables present the fair value of the Company's financial instruments that are measured or disclosed at fair value on a recurring basis (in thousands):

	Fair Value Measurements as of September 30, 2023		
	Level 1	Level 2	Level 3
Assets:			
Cash equivalents	\$ 70,429	\$ -	\$ -
U.S. Treasury bonds	-	-	-
	<u>\$ 70,429</u>	<u>\$ -</u>	<u>\$ -</u>

	Fair Value Measurements as of December 31, 2022		
	Level 1	Level 2	Level 3
Assets:			
Cash equivalents	\$ 81,347	\$ -	\$ -
U.S. Treasury bonds	44,480	-	-
	<u>\$ 125,827</u>	<u>\$ -</u>	<u>\$ -</u>

8. License and collaboration agreements

Agreement with Emory University (Emory)

In June 2018, the Company entered into a license agreement with Emory (the Emory License Agreement), pursuant to which Emory granted the Company a worldwide, sublicensable license under certain of its intellectual property rights to make, have made, develop, use, offer to sell, sell, import and export products containing certain compounds relating to Emory's hepatitis B virus capsid assembly modulator technology, for all therapeutic and prophylactic uses. Such license is initially exclusive with respect to specified licensed patents owned by Emory and non-exclusive with respect to certain of Emory's specified know-how. In June 2022, the license to such patents became non-exclusive with respect to all fields except for the treatment and prevention of HBV; however, the Company may select up to six compounds which will maintain exclusivity with respect to all therapeutic and prophylactic uses. With respect to all other compounds that are enabled by the licensed patents, those which are jointly invented by the Company and Emory or inventors in the Schinazi laboratory, or which are disclosed in a specified licensed patent, are licensed to the Company exclusively including as to Emory; whereas all other such compounds are licensed to the Company non-exclusively. Under the terms of the Emory License Agreement, the Company is obligated to use commercially reasonable efforts to bring licensed products to market in accordance with a mutually agreed upon development plan. Unless terminated earlier by either party in accordance with the provisions thereof, the Emory License Agreement shall continue until the expiration of the last-to-expire of the patents licensed to the Company thereunder.

In June 2020, the Company amended the license agreement with Emory. Pursuant to the amended license agreement, Emory granted the Company additional patent rights to certain compounds targeting the treatment or prevention of HBV. As consideration for the additional rights, the Company made a one-time, non-refundable payment to Emory in the amount of \$0.2 million, with an additional obligation to pay up to a maximum of \$35,000. On the same date, the Company entered into a collaboration agreement with Emory, with the initial research plan pertaining to the synthesis and evaluation of the compounds licensed through the additional patent rights granted in the amended license agreement. The research plan was set to terminate one year from the effective date of June 2020 but the Company exercised its option to extend it for a second year. In June 2022, the research plan terminated. In connection with the research plan, the Company will provide Emory funding up to \$0.3 million per year.

The Company has agreed to pay Emory up to an aggregate of \$125.0 million upon the achievement of specified development, regulatory, and commercial milestones, and all ongoing patent costs. During the three and nine months ended September 30, 2023 and 2022, the Company had no expenses related to milestone payments. The Company also agreed to pay Emory tiered single-digit royalties on worldwide annual net sales of licensed products, on a quarterly basis and calculated on a product-by-product basis. With respect to licensed products containing any of a specified subset of the licensed compounds, such royalties range from a mid-single digit to a high-single digit percentage rate. With respect to licensed products which do not contain such compounds, the royalties span

a range of percentage rates within the mid-single digits if a Phase 1 clinical trial is initiated for the product within three years of the effective date of the Emory License Agreement, and range from a low-single digit to a mid-single digit rate if a Phase 1 clinical trial is initiated more than three years after the effective date. During the three and nine months ended September 30, 2023 and 2022, the Company made no payments associated with royalties and recognized no expense or accruals.

Agreement with Luxna Biotech Co., Ltd. (Luxna)

On December 19, 2018, the Company entered into a license agreement with Luxna, pursuant to which Luxna granted the Company an exclusive, worldwide, sublicensable license under certain of Luxna's intellectual property rights to research, develop, make, have made and commercialize for all therapeutic and prophylactic uses, (i) products containing oligonucleotides targeting the hepatitis B virus genome, (ii) products containing certain oligonucleotides targeting up to three genes which contribute to NASH, which the Company may select at any time during the first eight years of the term, to the extent not licensed to a third party, and (iii) products containing oligonucleotides targeting up to three genes which contribute to hepatocellular carcinoma, which the Company may select at any time during the first three years of the term, which expired in December 2021. As consideration for this agreement, the Company paid an upfront license fee of \$0.6 million.

In April 2020, the Company amended the license agreement with Luxna. Pursuant to the amended license agreement, Luxna granted the Company an exclusive, worldwide license under the licensed patents to research, develop, make, have made and commercialize products containing oligonucleotides targeting three families of viruses: Orthomyxoviridae, Paramyxoviridae, and Coronaviridae (a family which includes SARS-CoV-2). As consideration for the amended license agreement, the Company paid Luxna a one-time non-refundable fee of \$0.2 million in April 2020.

The Company is obligated to make payments to Luxna, in aggregate, totaling up to but no more than \$55.5 million upon the achievement of specified development, regulatory, and commercial milestones. During the three and nine months ended September 30, 2023 and 2022, the Company recognized no expenses related to milestone payments. The Company is also required to pay Luxna a low-single digit royalty percentage on net sale of applicable products, if any. During the three and nine months ended September 30, 2023 and 2022, the Company made no payments associated with royalties.

Agreement with Katholieke Universiteit Leuven (KU Leuven)

On June 25, 2020, the Company entered into a Research, Licensing and Commercialization Agreement (KU Leuven Agreement) with KU Leuven, under which the Company is collaborating with KU Leuven's Rega Institute for Medical Research, as well as its Centre for Drug Design and Discovery, to research and develop potential protease inhibitors for the treatment, diagnosis or prevention of coronaviruses, including of SARS-CoV-2. Unless terminated earlier by either party in accordance with provisions in the agreement, the collaboration period will terminate at the earlier of completion of all collaboration activities or 2.5 years. In connection with the KU Leuven Agreement, KU Leuven and the Company granted each other exclusive cross-licenses to use certain know-how and existing patents of the other party as well as certain joint know-how and joint patents to carry out research and development collaboration activities during the collaboration period. As of December 2022, the original collaboration period has expired. An amendment to the agreement was agreed in July 2023 to include a new collaboration plan. KU Leuven granted to the Company an exclusive (including as to KU Leuven), worldwide license under certain of KU Leuven's know-how and existing patents, and certain joint patents and joint know-how, to manufacture and commercialize the licensed products for the treatment, diagnosis or detection of viral infections in humans. KU Leuven reserved the right to use all KU Leuven know-how, existing KU Leuven patents, joint patents and joint know-how for academic and non-commercial research and teaching purposes. As consideration for this license, the Company is obligated to make payments to KU Leuven, in aggregate, totaling up to but no more than \$30.0 million upon the achievement of certain commercial sales milestones. For each licensed product developed through KU Leuven and the Company's collaborative effort, the Company is obligated to make payments to KU Leuven, in aggregate, totaling up to \$32.0 million upon the achievement of certain development and regulatory milestones. The Company is also required to pay KU Leuven a low-to-mid-single digit royalty percentage, subject to certain adjustments, on net sales of applicable products, if any. The Company is also required to pay a revenue share to KU Leuven should the program be partnered with an external party. Unless terminated earlier by either party, the agreement shall continue until the expiration of the last to expire royalty term, which is the later of the expiration or termination of the last valid patent claim covering the manufacture, use, sale or importation of the licensed product in a particular country or 10 years after the first commercial sale of a licensed product. During the three and nine months ended September 30, 2023, the Company recognized and paid \$2.0 million related to milestone payments due to the first dosing of the first patient in a Phase 1 clinical trial.

Agreements with Merck

In December 2020, the Company and Merck & Co. entered into an exclusive License and Research Collaboration Agreement under which Merck and the Company agreed to apply the Company's oligonucleotide platform technology to discover, research, optimize and develop oligonucleotides directed against a NASH target and up to one additional liver-targeted cardiometabolic and/or

fibrosis target. Under the terms of the agreement, the Company received an upfront payment of \$12 million from Merck. With respect to the collaboration target, the Company will be eligible for up to \$458.0 million in development and commercialization milestones as well as tiered royalties on net sales. These potential payments consist of (i) potential development milestones (such as for the first dosing of an animal specimen in a Good Laboratory Practice toxicology study, and initiation of Phase 1, 2 and 3 clinical trials), (ii) regulatory milestones (such as for marketing authorizations for a product in certain countries) and (iii) sales-based milestones. The Company is primarily responsible for designing, preparing and evaluating the oligonucleotide molecules and delivering optimized lead molecules, and Merck is responsible for subsequent research, clinical development and commercialization efforts.

In January 2022, the Company and Merck entered into an amendment to the exclusive License and Research Collaboration Agreement (the First Amendment, together with the Original Agreement, the Expanded Arrangement). As a result of the First Amendment, the collaboration with Merck was expanded to include the Company's grant of rights to Merck of an early-stage program with respect to a second undisclosed NASH target, on which the Company had previously been working independently. In addition, under this Expanded Arrangement, Merck has the ability to add an additional third target of interest in the cardiometabolic/fibrosis space to the collaboration. This right to add an additional third target expired in January 2023. Under the Expanded Arrangement, the Company received an upfront payment of \$15 million from Merck for the Company's grant of rights to the program directed at a second undisclosed NASH target. With respect to the second target in the collaboration, the Company is eligible to receive up to approximately \$460.0 million in development and commercialization milestones as well as tiered royalties on net sales. These potential payments consist of (i) potential development milestones (such as for the first dosing of an animal specimen in a Good Laboratory Practice toxicology study, and initiation of Phase 1, 2 and 3 clinical trials), (ii) regulatory milestones (such as for marketing authorizations for a product in certain countries) and (iii) sales-based milestones.

In February 2023, Merck provided to the Company written notice of termination for one of the targets in the collaboration.

The Company determined that the Original Agreement and First Amendment fall within the scope of ASC 808, Collaborative Arrangements (ASC 808), due to Merck and the Company being joint active participants, as well as both parties having significant risks and rewards. The Company analogized to ASC 606, Revenue from Contracts with Customers (ASC 606), for the accounting of payments including upfront payments and other milestones. Management of the Company determined that there was one performance obligation for each of the agreements given the deliverables are not distinct. The Company evaluated the performance obligation within each agreement and determined the performance obligations are satisfied over time as Merck jointly owns any collaboration intellectual property that is developed during the research term. Given the nature of the arrangements, the Company believes that the satisfaction of its performance obligations is best measured by the progress of its efforts. As such, the Company has used an input method based on costs incurred to recognize revenue associated with the upfront payments. This assessment is performed separately for each of the Original Agreement and the First Amendment, and the Company recognizes revenue over time based on the costs incurred. The effect of any updates to the estimated overall costs are recorded as a change in estimate. In addition, variable consideration (e.g., milestone payments) were evaluated based on the Company's analysis that the possibility of achieving any of the milestone payments is remote, and therefore determined to be constrained and excluded from the transaction price. Similarly, the Company accounts for the future royalties under the sales-based royalty exception in ASC 606-10-55-65 through 55-65B therefore they are not considered in the transaction price and expected to be recognized when future sales occur since that is expected to occur after the performance obligation has been fully satisfied.

During the three and nine months ended September 30, 2023, the Company recognized \$2.2 million and \$7.3 million, respectively, in revenue from collaborative arrangements related to upfront payments. During the three and nine months ended September 30, 2022, the Company recognized \$4.1 million and \$10.4 million, respectively, in revenue from collaborative arrangements related to upfront payments. During the three and nine months ended September 30, 2023 and 2022, the Company recognized no revenue from collaborative arrangements related to milestone payments. The unrecognized portion of the upfront payments received during the three and nine months ended September 30, 2023 and 2022 is recorded on the consolidated balance sheets as "Deferred revenue from collaborations".

Changes in deferred revenue balances arose as a result of the Company recognizing the following revenue from collaborative arrangements during the periods below (in thousands):

	<u>As of September 30,</u>	
	<u>2023</u>	<u>2022</u>
Deferred revenue from collaborations as of January 1	\$ 8,743	\$ 7,641
Consideration received in the period	\$ 679	\$ 15,010
Revenue from collaborations recognized in the period	\$ (7,329)	\$ (10,370)
Deferred revenue from collaborations as of September 30	<u>\$ 2,093</u>	<u>\$ 12,281</u>

9. Revenue from contracts with customers

Agreement with ADCT

The Company determined that the ADC Therapeutics (ADCT) agreement falls within the scope of ASC 606, Revenue from Contracts with Customers (ASC 606). The agreement did not fall under the ASC 808 guidance due to ADCT and the Company not being joint active participants, nor both parties having significant risks and rewards. Management of the Company determined that there was one performance obligation for the agreements given the deliverables are not distinct. The Company evaluated the performance obligation and determined the performance obligations are satisfied over time. Given the nature of the arrangement, the Company believes that the satisfaction of its performance obligations is best measured by the progress of its efforts. As such, the Company has used an input method based on costs incurred to recognize revenue associated with the upfront payments, and the Company recognizes revenue over time based on the costs incurred. The effect of any updates to the estimated overall costs are recorded as a change in estimate. In addition, variable consideration (e.g., milestone payments) were evaluated based on the Company's analysis that the possibility of achieving any of the milestone payments is remote, and therefore determined to be constrained and excluded from the transaction price. Similarly, the Company accounts for the future royalties under the sales-based royalty exception in ASC 606-10-55-65 through 55-65B therefore they are not considered in the transaction price and expected to be recognized when future sales occur since that is expected to occur after the performance obligation has been fully satisfied.

Agreement with Amoytop

In May 2023, the Company and Amoytop Biotech Co., Ltd (Amoytop) entered into an exclusive Development Agreement and Research Collaboration Agreement with a focus on nucleic acid technology for HBV treatment, with the Company granting to Amoytop an exclusive option to enter into an exclusive license to develop and commercialize such compounds. Under the terms of the agreement, the Company received an upfront payment of \$7.0 million, less withholding taxes of \$1.1 million from Amoytop. With respect to the agreement, the Company will be eligible for up to \$109.0 million in development and commercialization milestones as well as tiered royalties on net sales. These potential payments consist of (i) potential development milestones (such as for the commencement of a Good Laboratory Practice toxicology study for a collaboration compound, approval of IND by regulatory authority, initiation of Phase 2 and 3 clinical trials, and regulatory approval of a licensed product), and (ii) sales-based milestones.

The Company determined that the Amoytop agreement falls within the scope of ASC 606, Revenue from Contracts with Customers (ASC 606). The agreement did not fall under the ASC 808 guidance due to Amoytop and the Company not being joint active participants, and both parties not having significant risks and rewards. Management of the Company determined that there were three performance obligations for the agreement given the deliverables are distinct. The Company evaluated the standalone selling price for each obligation based on available data for similar arrangements. The Company evaluated the performance obligations and determined the provision of R&D services for the collaboration compound performance obligation will be satisfied over time, the research license including data and know-how has been satisfied, and the provision of materials will be satisfied upon delivery. Given the nature of the arrangement, the Company believes that the satisfaction of its performance obligations is best measured by the progress of its efforts as it relates to the performance of the R&D services. As such, the Company has used an input method based on costs incurred to recognize revenue associated with the upfront payments, and the Company recognizes revenue over time based on the costs incurred. The effect of any updates to the estimated overall costs are recorded as a change in estimate. In addition, variable consideration (e.g., milestone payments) were evaluated based on the Company's analysis that the possibility of achieving any of the milestone payments is remote, and therefore determined to be constrained and excluded from the transaction price. Similarly, the Company accounts for the future royalties under the sales-based royalty exception in ASC 606-10-55-65 through 55-65B therefore they are not considered in the transaction price and expected to be recognized when future sales occur since that is expected to occur after the performance obligation has been fully satisfied.

During the three and nine months ended September 30, 2023, the Company recognized \$1.1 million and \$5.5 million, respectively, in revenue from customers related to upfront payments. There was no revenue recognized from customers in the three and nine months ended September 30, 2022. During the three and nine months ended September 30, 2023 and 2022, the Company recognized no revenue from customers related to milestone payments. The unrecognized portion of the upfront payments received during the three and nine months ended September 30, 2023 and 2022 is recorded on the consolidated balance sheets as "Deferred revenue from customers".

Changes in deferred revenue balances arose as a result of the Company recognizing the following revenue from customers during the periods below (in thousands):

	As of September 30,	
	2023	2022
Deferred revenue from customers as of January 1	\$ 700	\$ —
Consideration received in the period	\$ 6,676	\$ —
Revenue from customers recognized in the period	\$ (5,519)	\$ —
Deferred revenue from customers as of September 30	\$ 1,857	\$ —

10. Commitments and contingencies

From time to time, the Company may have certain contingent liabilities, including legal matters that arise in the ordinary course of its business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. Contingent liabilities requiring accrual were appropriately accrued as of September 30, 2023 and December 31, 2022. The Company enters into contracts in the normal course of business that includes arrangements with clinical research organizations, vendors for preclinical research and vendors for manufacturing. These agreements generally allow for cancellation with notice. As of September 30, 2023, the Company had no material non-cancellable purchase commitments.

On March 26, 2022, the Company received notice of a complaint (the Complaint) filed by Janssen Biopharma, LLC (Janssen), which generally concerned an alleged breach by certain of our employees of their obligations to Janssen as prior employees of Janssen by purporting to assign to Aligos various inventions allegedly owned by Janssen. The Complaint was filed on March 9, 2022 in the Superior Court of the State of California, County of San Mateo, against the Company, Lawrence M. Blatt, Chairman, Chief Executive Officer and Director of the Company, and Leonid Beigelman, President and Director of the Company. The Complaint alleges breach of contract by Lawrence M. Blatt and Leonid Beigelman and tortious interference with contract by the Company and seeks declaratory judgment of ownership of certain intellectual property by the Company, among other claims. The Complaint states that Janssen is seeking injunctive relief, assignment of certain intellectual property from us to Janssen and monetary damages.

On August 4, 2022, the Company filed counterclaims against Janssen alleging Janssen has engaged in unfair competition and promissory fraud, and on August 22, 2022, the Company filed its response to the Complaint.

On October 16, 2023, the Company entered into a settlement agreement with Janssen that provides for the resolution of the action brought by Janssen alleging breach of contract by Lawrence M. Blatt, and Leonid Beigelman, and tortious interference with contract by the Company and seeking declaratory judgment of ownership of certain intellectual property by the Company, among other claims. Pursuant to the settlement agreement, Janssen agreed to dismiss the action and released the Company, Dr. Blatt and Dr. Beigelman from the claims alleged. In addition, pursuant to the Settlement Agreement, the Company agreed to dismiss the counterclaims against Janssen alleging unfair competition and promissory fraud and released Janssen from the alleged counterclaims.

11. Income taxes

The Company recorded income tax expense of \$0.0 million and \$0.8 million for the three and nine months ended September 30, 2023, primarily related to the agreement with Amoytop as discussed in footnote 9.

The Company has a history of losses and projects losses for the full year 2023. The Company continues to maintain a full valuation allowance on its net deferred tax assets.

12. Net loss per share

The following table summarizes the computation of basic and diluted net loss per share of the Company (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net loss	\$ (18,041)	\$ (18,621)	\$ (59,787)	\$ (74,160)
Weighted average common stock outstanding, basic and diluted	43,496,975	42,761,928	43,209,656	42,647,732
Net loss per share - basic and diluted	\$ (0.41)	\$ (0.44)	\$ (1.38)	\$ (1.74)

The Company's potentially dilutive securities, which include options to purchase common stock and unvested restricted stock, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of shares of Common Stock outstanding used to calculate both basic and diluted net loss per share is the same. The Company excluded the following potential shares of Common Stock, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Options to purchase common stock	11,131,942	10,082,266	11,131,942	10,082,266
Unvested restricted stock	134,120	-	134,120	-
	<u>11,266,062</u>	<u>10,082,266</u>	<u>11,266,062</u>	<u>10,082,266</u>

13. Subsequent events

In preparing the interim financial statements for the three and nine months ended September 30, 2023, the Company evaluated subsequent events for recognition and measurement purposes during which time the following events has occurred that require disclosure:

PIPE offering

On October 25, 2023, the Company closed its private investment in public equity (PIPE) offering that resulted in gross proceeds of \$92,149,996.41. In the PIPE, the Company issued 31,429,266 shares of its common stock, pre-funded warrants (Pre-Funded Warrants) to purchase up to 81,054,686 shares of its common stock and accompanying common warrants (Common Warrants) to purchase up to 56,241,973 shares of its common stock. The combined price per share of common stock and accompanying Common Warrant is \$0.8193 and the combined price per Pre-Funded Warrant and Common Warrant is \$0.8192.

Each Pre-Funded Warrant has an exercise price of \$0.0001 per share of common stock, is immediately exercisable and does not expire. Each Common Warrant has an exercise price of \$0.7568, is immediately exercisable and will expire in October 2030.

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 together with our condensed consolidated financial statements and related notes and other financial information appearing elsewhere in this Quarterly Report on Form 10-Q. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results could differ materially from these forward-looking statements as a result of many factors, including those discussed in “Risk Factors” and “Special note regarding forward-looking statements.”

Overview

We are a clinical-stage biopharmaceutical company focused on developing novel therapeutics to address unmet medical needs in liver diseases and viral infections, including in the areas of non-alcoholic steatohepatitis (NASH), coronavirus (e.g., SARS-CoV-2 and related infections) and chronic hepatitis B (CHB). We utilize our proprietary small molecule and oligonucleotide platforms to develop pharmacologically optimized drug candidates for use in combination regimens designed to achieve improved treatment outcomes.

Our primary area of focus is NASH, a complex, chronic liver disease where combination regimens may prove beneficial. Our most advanced drug candidate for NASH is ALG-055009, a small molecule thyroid hormone receptor (THR- β) agonist. This drug candidate recently completed evaluation in a Phase 1 study in healthy volunteers (HVs) (oral single ascending doses (SAD)) and subjects with hyperlipidemia (14 oral daily doses). Preliminary data after single doses up to 4 mg and multiple doses up to 1 mg showed that ALG-055009 was well tolerated, had dose proportional pharmacokinetics (PK) with low variability, and demonstrated expected thyromimetic effects (i.e., generally dose proportional increases in sex hormone binding globulin and decreases in various atherogenic lipids and thyroid hormones). In this same study, we have also conducted a relative bioavailability study in HVs where we have shown the Phase 2 gel cap formulation delivers similar exposures (~86%) compared to the Phase 1 liquid formulation, low variability and no evidence of a meaningful food effect. We are presently taking the necessary steps to advance ALG-055009 into a Phase 2 proof of concept study, the design of which is currently being discussed with the FDA (Type D meeting) and also with investigators, including the study’s Principal Investigator, Dr. Stephen Harrison. The study’s preliminary design is as a 12-week randomized, placebo-controlled trial evaluating 3-4 doses of ALG-055009 vs. placebo in approximately 100 subjects with NASH. In addition to collecting safety and PK data, the study will also assess multiple efficacy biomarkers, which include MRI-PDFF and other non-invasive tests previously shown to be impacted by treatment with THR- β agonists. We anticipate submitting to the recently opened IND the final Phase 2 protocol in Q4 of 2023, followed by dosing in subjects beginning in Q1 2024, and anticipate sharing topline safety and efficacy (12 week MRI-PDFF) data in Q4 2024. We believe ALG-055009 has the potential to become a best-in-class THR- β agonist and could play an integral role in future NASH combination regimens based on its favorable PK profile, which could result in uniform exposures and lead to consistent efficacy and safety in a NASH population.

In addition to our small molecule THR- β program, we are also progressing oligonucleotide projects for NASH, including in collaboration with Merck. These programs are currently progressing through preclinical activities.

Our second area of focus is to develop drug candidates with pan-coronavirus antiviral activity, including against Severe Acute Respiratory Syndrome coronavirus 2 (SARS-CoV-2), the virus responsible for COVID-19. In this area of focus, we are using a small molecule approach, where we are exploring coronavirus 3CL protease inhibitors (PIs) in collaboration with Katholieke Universiteit Leuven (KU Leuven), the Center for Innovation and Stimulation of Drug Discovery (CISTIM) and the Centre for Drug Design and Discovery (CD3). Our lead candidate, ALG-097558, is at least 6-fold more potent in cell-based assays against a panel of SARS-CoV-2 variants (including Omicron) than nirmatrelvir and other PIs in clinical development, demonstrates broad pan-coronavirus activity, and, based on emerging clinical data, is not projected to require ritonavir boosting. Evaluation of ALG-097558 in the hamster SARS-CoV-2 infection model has shown that, when dosed prior to infection or up to 24 hours post-infection, the compound caused a significant reduction in the levels of infectious virus in the lungs. ALG-097558 also appeared to better maintain its antiviral activity against certain resistant mutants compared to other PIs in development based on publicly available data. The safety and PK properties of ALG-097558 are currently being assessed in an ongoing Phase 1 study in HVs. To date single doses up to 800 mg have been well tolerated with PK similar to projections. We anticipate initiating multiple dose cohorts beginning in Q4 2023 and expect to share topline data from this study in H1 2024.

Preclinical activities for the ALG-097558 program were partially funded through a grant from the National Institutes of Health (NIH) and the National Institute of Allergy and Infectious Diseases (NIAID) Antiviral Drug Discovery (AViDD) Centers for Pathogens of Pandemic Concern program through the Metropolitan AntiViral Drug Accelerator (MAVDA) consortium. The ALG-097558 program is now also being funded with federal funds from the NIAID, NIH, Department of Health and Human Services, under Contract No. 75N93023C00052, which will partially support the further clinical development of ALG-097558. We expect to receive approximately \$11 million in funds across these two NIH awards and contracts.

Our third area of focus seeks to enhance the rate of functional cure for CHB, which often results in life-threatening conditions such as cirrhosis, end-stage liver disease and, the most common form of liver cancer, hepatocellular carcinoma (HCC). The most widely used treatment for CHB, nucleos(t)ide analogs (NAs), suppress viral replication, but only achieve low rates of functional cure and require life-long administration. To address this, we are developing a portfolio of differentiated drug candidates for CHB,

including a small molecule Capsid Assembly Modulator that results in the production of empty viral capsids (CAM-E) and small molecule inhibitors of the programmed death 1 (ligand) PD-1/PD-L1 interaction.

The initial Phase 1a study in HVs for our CAM-E, ALG-000184, has been completed as has a Phase 1b dose ranging study evaluating the safety, PK and antiviral activity of 10-300 mg doses of ALG-000184 for 28 days among untreated HBV e-antigen (HBeAg) positive/negative CHB subjects. For these studies, ALG-000184 was found to be well tolerated with a favorable PK profile and demonstrated potentially best-in-class HBV DNA and RNA reductions as well as HBsAg reductions in a subset of HBeAg positive subjects receiving 300 mg ALG-000184 (Hou et. al, AASLD 2022). Based on the favorable profile after dosing ≤ 300 mg ALG-000184 x 28 days, additional Phase 1b cohorts are currently ongoing and evaluating the risk-benefit profile of 100-300 mg doses of ALG-000184 \pm entecavir (ETV) therapy for up to 96 weeks in HBeAg positive or negative CHB subjects. Preliminary data have been presented for several of these cohorts (McClure et al, Global Hepatitis Summit, April 2023, Hou et al., EASL 2023) and indicate that ALG-000184 dosed for up to 36 weeks is well tolerated with a favorable PK profile and potentially best-in-class antiviral activity. Specifically, antiviral activity data in subjects dosed with 300 mg ALG-000184 + ETV for up to 36 weeks are available in a cohort (Part 4 Cohort 2) of HBeAg positive subjects with normal/elevated baseline ALT. In this cohort, we observed mean DNA reductions of over 6 \log_{10} IU/mL. Notably, subjects in this cohorts who initially received ETV x 12 weeks had more modest reductions in HBV DNA vs. subjects receiving ALG-000184 + ETV over the same time period. However, these subjects then experienced further reductions in HBV DNA levels once they started receiving the combination and their HBV DNA levels also reached levels exceeding 6 \log_{10} IU/mL, indicating an additive effect of ALG-000184 with ETV. Among the subjects in Part 4 Cohort 2 who were dosed with 300 mg ALG-000184 + ETV, HBsAg levels declined in a majority of subjects by at least 0.4 and 1.0 \log_{10} IU/mL after dosing for 12 and 24 weeks, respectively; the maximum HBsAg decline observed at that time was 2.0 \log_{10} IU/mL at week 36. By comparison, no meaningful change in HBsAg levels was observed in subjects dosed with ETV alone. Dosing of HBeAg positive/negative subjects with ALG-000184 + ETV in ongoing cohorts will continue throughout 2023 and interim safety, PK, and antiviral activity data will be presented at scientific conferences throughout the year, including as a late breaking poster (“Long-term dosing with the capsid assembly modulator ALG-000184 results in multi-log reductions of DNA, RNA, HBsAg, HBeAg, and HBcrAg in untreated HBeAg positive chronic hepatitis B subjects,” to be presented by Dr. MF Yuen, Chair Professor of Gastroenterology and Hepatology, University of Hong Kong), which is to be presented on November 13, 2023 at The Liver Meeting® of the American Association for the Study of Liver Diseases (AASLD).

We are also exploring ways to boost immune responses via small molecule inhibitors of the Programmed Cell Death Ligand 1 (PD-L1) transmembrane protein and its interaction with PD-1. We have rationally designed these T cell activating drug candidates to partition in the liver and thereby potentially mitigate systemic toxicity in an effort to develop better tolerated PD-1/PD-L1 inhibitors for CHB patients. Lead molecules developed to date show similar in vivo efficacy in tumor models to approved PD-1/PD-L1 antibodies. Our small molecule lead compounds also demonstrate greater PD-L1 target occupancy at a lower dose in a humanized PD-L1 subcutaneous tumor model compared to competitor small molecule PD-L1 inhibitors.

For our siRNA drug candidate targeting HBsAg production, ALG-125755, we conducted a Phase 1 study evaluating single doses ranging from 20-200 mg and 50-320 mg in HVs and virologically suppressed HBeAg negative CHB subjects, respectively. In this study, we found that these single doses were well tolerated with a favorable PK profile. With respect to antiviral activity, available data indicate evidence of HBsAg lowering at all 3 dose levels evaluated. We plan to seek additional external funding to further advance this drug candidate in clinical development.

We believe that combination regimens utilizing our portfolio of CHB drug candidates, with or without other mechanisms of action, may lead to higher rates of functional cure.

We have incurred net losses and negative cash flows from operations in each year since our formation in February 2018. Our net losses were \$18.0 million and \$59.8 million for the three and nine months ended September 30, 2023, respectively, and our net losses were \$18.6 million and \$74.2 million for the three and nine months ended September 30, 2022. We have had no revenue from product sales. As of September 30, 2023, we had an accumulated deficit of \$458.9 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses over at least the next several years. Our net operating losses may fluctuate from quarter to quarter and year to year depending primarily on the timing of our clinical trials and nonclinical studies and our other research and development expenses. We have no internal manufacturing capabilities or sales force and outsource a substantial portion of our clinical trial work to third parties.

Components of our results of operations

Operating expenses

Our operating expenses since inception have consisted solely of research and development costs and general and administrative costs.

Research and development expenses

We rely substantially on third parties to conduct our discovery activities, nonclinical studies, clinical trials and manufacturing. We estimate research and development expenses based on estimates of services performed, and rely on third party contractors and vendors to provide us with timely and accurate estimates of expenses of services performed to assist us in these estimates. A portion of our research and development expenses are based on contractual milestones. Research and development costs consist primarily of costs incurred for the identification and development of our drug candidates through our technology platforms, which include:

- salaries, benefits and other employee-related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- costs of outside consultants, including their fees, and related travel expenses;
- costs associated with in-process research and development, including license fees and milestones paid to third-party collaborators for technologies with no alternative use;
- costs related to production of clinical materials, including fees paid to contract manufacturers;
- expenses incurred under agreements with collaborators that perform nonclinical activities;
- costs related to compliance with regulatory requirements; and
- facility costs, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance, and other supplies.

We expense research and development costs as the services are performed or the goods are received. Non-refundable payments for goods or services that will be used for future research and development activities are deferred and capitalized. Such amounts are recognized as an expense as the goods are delivered or the related services are performed until it is no longer expected that the goods will be delivered or the services will be rendered.

Our research and development costs may increase in future periods as we continue to invest in research and development activities and advance our nonclinical and clinical programs through clinical development. The process of conducting nonclinical studies and, eventually, clinical trials necessary to obtain regulatory approval is costly and time consuming, and the successful development of our drug candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or clinical trials or if and to what extent we will generate revenue from the commercialization and sale of any of our drug candidates.

We track direct external research and development expenses on a program-specific basis (steatohepatitis, coronaviruses, chronic hepatitis B and early-stage programs). The following table summarizes these research and development costs, in thousands:

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Direct research and development expenses by development program:				
Non-alcoholic Steatohepatitis program	\$ 1,642	\$ 677	\$ 4,266	\$ 3,448
Coronaviruses program	3,092	1,181	7,361	3,790
Chronic Hepatitis B program	973	444	5,572	15,977
Other early-stage programs	1,741	2,839	4,980	8,597
Total direct research and development expenses	\$ 7,447	\$ 5,141	\$ 22,178	\$ 31,812
Total indirect research and development expenses	8,420	12,649	28,605	34,165
Total research and development expense	\$ 15,867	\$ 17,791	\$ 50,783	\$ 65,977

General and administrative expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, corporate and business development and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs not otherwise classified as research and development costs.

Our general and administrative expenses may increase in the future as we increase our general and administrative personnel headcount to support personnel in research and development and to support our operations generally as we increase our research and development activities and activities related to the potential commercialization of our drug candidates. We may also incur increased expenses associated with operating as a public company, including costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing rules and requirements of the Securities and Exchange Commission (the SEC), director and officer insurance costs, and investor and public relations costs.

Interest and other income, net

Interest and other income, net comprises interest income, net and other income, net. Interest income, net primarily consists of interest earned on our cash, cash equivalents, and investments. Other income, net consists primarily of the change in fair value of our investments and foreign currency gains/losses.

Results of Operations

Comparison of the three and nine months ended September 30, 2023 and 2022

Operating expenses

The following table summarizes our operating expenses for the three and nine months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2023	2022	(\$)	%	2023	2022	(\$)	%
Operating expenses:								
Research and development	\$ 15,867	\$ 17,791	\$ (1,924)	-11 %	\$ 50,783	\$ 65,977	\$ (15,194)	-23 %
General and administrative	6,443	5,263	1,180	22 %	\$ 24,195	\$ 19,291	4,904	25 %
Total operating expenses	<u>\$ 22,310</u>	<u>\$ 23,054</u>	<u>\$ (744)</u>	<u>-3 %</u>	<u>\$ 74,978</u>	<u>\$ 85,268</u>	<u>\$ (10,290)</u>	<u>-12 %</u>

Research and development expenses

Research and development expenses decreased by \$1.9 million during the three months ended September 30, 2023, compared to the same period in 2022. The decrease in the three-month period was primarily due to a \$2.0 million decrease in employee-related costs including a \$0.4 million decrease in stock-based compensation, as well as a \$1.9 million decrease in facility and other expenses. This was partially offset by an increase of \$2.0 million in third-party expenses due to the milestone payment to Katholieke Universiteit Leuven (KU Leuven) under its collaboration agreement related to the coronaviruses and the dosing of the first patient in a Phase 1 clinical trial.

Research and development expenses decreased by \$15.2 million during the nine months ended September 30, 2023, compared to the same period in 2022. The decrease in the nine-month period was due primarily to a decrease of \$12.3 million in third-party expenses mainly related to our discontinued STOPs and ASO programs in 2022, partially offset by increases in our ongoing activities and related expenditures associated with our CAM clinical trial activities and NASH program, as well as the milestone payment to Katholieke Universiteit Leuven (KU Leuven) under its collaboration agreement related to the coronaviruses and the dosing of the first patient in a Phase 1 clinical trial. There was also a decrease of \$3.5 million in depreciation and employee-related costs, of which \$0.6 million related to stock-based compensation, due to reduced headcount. Partially offsetting this, there was an increase of \$0.6 million in other costs including facility expenses due to the right of use asset impairment.

General and administrative expenses

General and administrative expenses increased by \$1.2 million during the three months ended September 30, 2023, compared to the same period in 2022. This was primarily due to a \$1.1 million increase in facility and other expenses, and a \$0.1 million increase in legal and related costs.

General and administrative expenses increased by \$4.9 million during the nine months ended September 30, 2023, compared to the same period in 2022. This was primarily due to an increase of \$6.6 million in legal and related costs. This was partially offset by a decrease of \$1.3 million related to facility and other costs and a decrease of \$0.4 million in employee-related costs.

Interest and other income, net

The following table summarizes our interest and other income, net for the three and nine months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2023	2022	(\$)	%	2023	2022	(\$)	%
Interest income, net	\$ 1,005	\$ 466	\$ 539	116 %	\$ 2,708	\$ 764	\$ 1,944	255 %
Other income (expense), net	54	(182)	236	-130 %	460	31	429	1398 %
Total interest and other income, net	<u>\$ 1,059</u>	<u>\$ 284</u>	<u>\$ 775</u>	<u>273 %</u>	<u>\$ 3,168</u>	<u>\$ 795</u>	<u>\$ 2,373</u>	<u>299 %</u>

Interest income, net increased by \$0.5 million for the three months ended September 30, 2023 compared to the three months ended September 30, 2022, primarily due to a general increase in market interest rates.

Interest income, net increased by \$1.9 million for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022, primarily due to a general increase in market interest rates.

Other income, net increased for the three months ended September 30, 2023 compared to the three months ended September 30, 2022, due primarily to foreign currency exchange gains.

Other income, net increased for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022, due primarily to foreign currency exchange gains.

Liquidity and capital resources

Liquidity

We have incurred net losses since inception. We have not generated any revenue from product sales or any other sources and have incurred significant operating losses. We have not yet commercialized any products and we do not expect to generate revenue from sales of any drug candidates for at least several years, if ever.

Our operations have been financed primarily by net proceeds from the sale and issuance of our convertible preferred stock, net proceeds from our IPO, proceeds from public offerings, and proceeds from private placements of our common stock, warrants and pre-funded warrants, and the issuance of convertible debt.

As of September 30, 2023, we had cash, cash equivalents and investments of \$70.4 million. Additionally, we raised gross proceeds of approximately \$92 million from our private placement in October 2023.

Capital resources

Our primary use of cash is to fund operating expenses, which consist primarily of research and development costs related to our drug candidates and our discovery programs, and to a lesser extent, general and administrative expenditures. We expect our expenses to increase substantially in connection with our ongoing clinical development activities related to our NASH drug candidate ALG-055009, which we have initiated clinical trials, as well as our research and development of our other drug candidates within our coronavirus and CHB programs.

In addition, we incur costs associated with operating as a public company. We expect that our expenses will increase substantially to the extent we:

- conduct our current and future clinical trials, and additional nonclinical studies;
- initiate and continue research and nonclinical and clinical development of other drug candidates;
- seek to identify additional drug candidates;
- pursue marketing approvals for any of our drug candidates that successfully complete clinical trials, if any;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- require the manufacture of larger quantities of our drug candidates for clinical development and potentially commercialization;

- obtain, maintain, expand, protect and enforce our intellectual property portfolio;
- acquire or in-license other drug candidates and technologies;
- hire and retain additional clinical, quality control and scientific personnel;
- achieve milestones triggering payments by us under our current and potential future licensing and/or collaboration agreements;
- build out or expand existing facilities to support our ongoing development activity; and
- add operational, financial and management information systems and personnel, including personnel to support our drug development, any future commercialization efforts and any additional requirement of being a public company.

We believe that our existing cash, cash equivalents and investments will enable us to fund our planned operating expenses and capital expenditure requirements through at least the twelve months from the date of issuing our financial statements. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. Furthermore, we may elect to raise additional capital on an opportunistic basis to fund operations.

Because of the numerous risks and uncertainties associated with our research and development programs and because the extent to which we may enter into collaborations with third parties for development of our drug candidates is unknown, we are unable to estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our drug candidates. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of researching and developing our drug candidates and programs, and of conducting nonclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining marketing approvals for drug candidates we develop if clinical trials are successful;
- the cost of commercialization activities for our current drug candidates, and any future drug candidates we develop, whether alone or in collaboration, including marketing, sales and distribution costs if our current drug candidates or any future drug candidate we develop is approved for sale;
- the cost of manufacturing our current and future drug candidates for clinical trials in preparation for marketing approval and commercialization;
- our ability to establish and maintain strategic licenses or other arrangements and the financial terms of such agreements including milestone payments to our licensors;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- any lawsuits related to our drug candidates or commenced against us;
- the timing, receipt and amount of sales of, or profit share or royalties on, our future products, if any;
- the emergence of competing therapies for hepatological indications and viral diseases and other adverse market developments; and
- any acquisitions or in-licensing of other programs or technologies.

Developing pharmaceutical products, including conducting nonclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval for any drug candidates or generate revenue from the sale of any drug candidate for which we may obtain marketing approval. In addition, our drug candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drugs that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Adequate additional funds may not be available to us on acceptable terms, or at all. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of these securities may include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a common stockholder. Additional debt or preferred equity financing, if available, may involve agreements that include restrictive covenants that may limit our ability to take specific actions, such as

incurring debt, making capital expenditures or declaring dividends, which could adversely constrain our ability to conduct our business, and may require the issuance of warrants, which could potentially dilute your ownership interest.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technology, future revenue streams, research programs, or drug candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or collaborations, strategic alliances or licensing arrangements with third parties when needed, we may be required to delay, limit, reduce and/or terminate our product development programs or any future commercialization efforts or grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves.

Cash flows

The following table summarizes our sources and uses of cash for each of the periods presented (in thousands):

	Nine Months Ended September 30,	
	2023	2022
Net cash used in operating activities	\$ (56,339)	\$ (62,606)
Net cash provided by (used in) investing activities	44,988	(37,897)
Net cash provided by financing activities	392	43
Net decrease in cash, cash equivalents, and restricted cash	<u>\$ (10,959)</u>	<u>\$ (100,460)</u>

Operating activities

During the nine months ended September 30, 2023, operating activities utilized \$56.3 million of cash, primarily resulting from our net loss of \$59.8 million and net changes in operating assets and liabilities of \$9.2 million, partially offset by non-cash charges of \$12.7 million. Net cash used in operating activities resulted in changes in our operating assets and liabilities of \$9.2 million, consisting of a decrease of \$1.8 million in accounts payable, a decrease of \$3.7 million in accrued liabilities, a decrease of \$1.8 million in operating lease liabilities, and a decrease of \$6.7 million in deferred revenue from collaborations, partially offset by a decrease in other assets of \$3.5 million and an increase of \$1.2 million in deferred revenue from customers. The decrease in deferred revenue from collaborations was due to the recognition of revenue from collaborations due to progress towards the completion of the projects. The decrease in accrued liabilities was largely due to reduced manufacturing spend. The decrease in accounts payable is due to the timing of payments to vendors.

During the nine months ended September 30, 2022, operating activities utilized \$62.6 million of cash, primarily resulting from our net loss of \$74.2 million, and net changes in operating assets and liabilities of \$2.4 million, partially offset by non-cash charges of \$14.0 million. Net cash used in operating activities resulted in changes in our operating assets and liabilities of \$2.4 million, consisting of a decrease of \$0.1 million in accounts payable, a decrease of \$11.5 million in accrued liabilities, a decrease of \$1.3 million in operating lease liabilities, and an increase of \$0.3 million in right of use assets, partially offset by an increase of \$4.6 million in deferred revenue from collaborations, and a decrease in other assets of \$6.2 million. The increase in deferred revenue from collaborations was a result of our First Amendment to the License and Research Collaboration Agreement (refer to Note 8 License and collaboration agreements, for details), partially offset by the recognition of revenue from collaborations due to progress towards the completion of the projects. The decrease in accrued liabilities was largely due to charges related to the discontinuation of our ASO and STOPs drug candidates, and payment of the annual bonus in 2022 that was accrued for in 2021.

Investing activities

During the nine months ended September 30, 2023, investing activities provided \$45.0 million of cash, primarily due to \$45.0 million of investment maturities.

During the nine months ended September 30, 2022, investing activities utilized \$37.9 million of cash, primarily for \$79.7 million of investment purchases, and \$0.9 million of property and equipment purchases, partially offset by \$42.7 million of investment maturities.

Financing activities

During the nine months ended September 30, 2023, net cash provided by financing activities was \$392 thousand, consisting primarily of proceeds from the ESPP purchase and from the exercise of stock options, partially offset by payments of our finance leases.

During the nine months ended September 30, 2022, net cash provided by financing activities was \$43 thousand, consisting primarily of proceeds from the purchase of shares in our Employee Stock Purchase Plan, partially offset by payments of our finance leases.

Contractual obligations and commitments

We have no material changes to our contractual obligations and commitments as of September 30, 2023 as disclosed in the contractual obligations and commitment section in our Annual Report on Form 10-K filed with the SEC on March 9, 2023.

Off-balance sheet arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Indemnification agreements

We enter into standard indemnification arrangements in the ordinary course of business. Pursuant to these arrangements, we indemnify, hold harmless and agree to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to its technology. The term of these indemnification agreements is generally perpetual any time after the execution of the agreement. The maximum potential amount of future payments we could be required to make under these arrangements is not determinable. We have never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, we believe the fair value of these agreements is minimal.

Critical accounting policies and use of 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 and the disclosure of assets and liabilities at the date of the consolidated 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.

For a discussion of our critical accounting estimates, see "Management's discussion and analysis of financial condition and results of operations" and the notes to our audited financial statements in our annual report on Form 10-K, filed with the SEC on March 9, 2023 for the year ended December 31, 2022, and the notes to the financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. There have been no material changes to these critical accounting policies and estimates through September 30, 2023 from those discussed in our Form 10-K.

Recently issued and adopted accounting pronouncements

For a description of the expected impact of recently adopted accounting pronouncements, see Note 2. Summary of Significant Accounting Policies in the "Notes to Unaudited Condensed Consolidated Financial Statements" contained in Part I, Item 1 of this report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest rate risk

We are exposed to market risk related to changes in interest rates applicable to our investment portfolio of cash equivalents and short-term investments. As of September 30, 2023, our cash equivalents consisted primarily of money market funds, and our

investments consisted of certificates of deposit available-for-sale securities. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. Should U.S. interest rates decline, interest income would be reduced in future periods for short-term investments which mature and the proceeds of which are reinvested in similar instruments at lower interest rates. Additionally, the fair value of our short-term investments is subject to change as a result of potential changes in market interest rates, including changes resulting from the impact of the COVID-19 pandemic. The potential change in fair value from interest-rate-sensitive instruments has been assessed on a hypothetical 100 basis point adverse movement across all maturities. As of September 30, 2023, we estimate that a hypothetical 100 basis point adverse movement would not result in a material impact on our financial position or results of operations or cash flows. As of September 30, 2023, we had no debt outstanding, besides short-term payables arising in the normal course of business, and are therefore not exposed to interest rate risk with respect to debt.

Foreign currency exchange risk

We have employees and operations, including contracts with third-party vendors, in Europe through our subsidiary Aligos Belgium BVBA. We have similar, but more limited, operations in Australia and China. Though the functional currency in these locations is the U.S. dollar, we remeasure transactions initially recorded in local currencies in these locations, the Euro, Australian dollar and Chinese yuan, respectively, to the U.S. dollars periodically. As such, we are exposed to foreign currency exchange risk as the underlying contracts to pay employees or vendors in these locations are generally denominated in the local currencies. A decline in the value of the U.S. dollar relative to these currencies would increase our cost of doing business in these locations. We are subject to foreign currency transaction gains or losses on our contracts denominated in foreign currencies. To date, foreign currency transaction gains and losses have not been material to our financial statements, and we have not had a formal hedging program with respect to foreign currency. A 10% increase or decrease in current exchange rates would not have a material effect on our financial position or results of operations or cash flows.

Item 4. Controls and Procedures.

We have established disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and is accumulated and communicated to management, including the principal executive officer (our Chief Executive Officer) and principal financial officer (our Chief Financial Officer), to allow timely decisions regarding required disclosure. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of disclosure controls and procedures

Our management has evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures have been designed to provide reasonable assurance of achieving their objectives. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of September 30, 2023, our disclosure controls and procedures were effective.

Changes in internal control over financial reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended September 30, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

As a result of the COVID-19 pandemic, in March 2020, substantially all of our employees began working remotely. Since the availability of COVID-19 vaccines in 2021, almost all of our employees have been fully vaccinated and as a result, we have allowed such employees to return to work subject to certain COVID-19 related protocols and policies we have in place which may be modified from time to time in response to the evolution of the pandemic and any future pandemics/epidemic outbreaks. We have not identified any material changes in our internal control over financial reporting as a result of these changes to the working environment, in part because our internal control over financial reporting was designed to operate in a remote working environment. We are continually monitoring and assessing the COVID-19 situation to determine any potential impacts on the design and operating effectiveness of our internal controls over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings. While the outcome of any such proceedings cannot be predicted with certainty, we are not currently involved in any legal proceedings that we believe are, individually or in the aggregate, material to our business, results of operations or financial condition, except as described below. However, regardless of the outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of associated costs and diversion of management time.

On March 26, 2022, the Company received notice of a complaint (the Complaint) filed by Janssen Biopharma, LLC (Janssen), which generally concerned an alleged breach by certain of our employees of their obligations to Janssen as prior employees of Janssen by purporting to assign to Aligos various inventions allegedly owned by Janssen. The Complaint was filed on March 9, 2022 in the Superior Court of the State of California, County of San Mateo, against the Company, Lawrence M. Blatt, Chairman, Chief Executive Officer and Director of the Company, and Leonid Beigelman, President and Director of the Company. The Complaint alleges breach of contract by Lawrence M. Blatt and Leonid Beigelman and tortious interference with contract by the Company and seeks declaratory judgment of ownership of certain intellectual property by the Company, among other claims. The Complaint states that Janssen is seeking injunctive relief, assignment of certain intellectual property from us to Janssen and monetary damages.

On August 4, 2022, the Company filed counterclaims against Janssen alleging Janssen has engaged in unfair competition and promissory fraud, and on August 22, 2022, the Company filed its response to the Complaint.

On October 16, 2023, the Company entered into a settlement agreement with Janssen that provides for the resolution of the action brought by Janssen alleging breach of contract by Lawrence M. Blatt, and Leonid Beigelman, and tortious interference with contract by the Company and seeking declaratory judgment of ownership of certain intellectual property by the Company, among other claims. Pursuant to the settlement agreement, Janssen agreed to dismiss the action and released the Company, Dr. Blatt and Dr. Beigelman from the claims alleged. In addition, pursuant to the Settlement Agreement, the Company agreed to dismiss the counterclaims against Janssen alleging unfair competition and promissory fraud and released Janssen from the alleged counterclaims.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report on Form 10-Q, including our consolidated financial statements and the related notes and the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” before deciding whether to invest in our common stock. Many of the following risks and uncertainties are, and will be, exacerbated by any worsening of the global business and economic environment that resulted from the coronavirus pandemic (COVID-19). The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and the market value of our common stock.

Risks related to our limited operating history, financial position and need for additional capital

We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have incurred significant losses since inception. We expect to incur losses for at least the next several years and may never achieve or maintain profitability, which, together with our limited operating history, makes it difficult to assess our future viability.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage biopharmaceutical company, and we have only a limited operating history upon which you can evaluate our business and prospects. We currently have no products approved for commercial sale, have not generated any revenue from sales of products and have incurred losses in each year since our inception in February 2018. In addition, we have limited experience as a company and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry.

Since inception, we have incurred significant net losses. Our net losses were \$18.0 million and \$59.8 million for the three and nine months ended September 30, 2023, respectively, and \$96.0 million for the year ended December 31, 2022. As of September 30, 2023, we had a total stockholders’ equity of \$54.8 million. We have funded our operations to date primarily with proceeds from the sale of common stock, preferred stock and convertible notes. To date, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, acquiring and discovering development programs, securing intellectual property rights and conducting discovery, research and development activities for our programs. We have not yet demonstrated our ability to successfully complete any clinical trials, including pivotal clinical trials, obtain marketing approvals, manufacture a

commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Our drug candidates will require substantial additional development time and resources before we will be able to apply for or receive regulatory approvals and, if approved, begin generating revenue from product sales. We may continue to incur significant expenses and operating losses for the foreseeable future.

We have never generated revenue from product sales and may never be profitable.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with our collaboration partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our drug candidates. We do not anticipate generating revenue from product sales for the next several years, if ever. Our ability to generate revenue from product sales depends heavily on our and our current and potential future collaborators' success in:

- completing clinical and nonclinical development of drug candidates and programs and identifying and developing new drug candidates;
- seeking and obtaining marketing approvals for any drug candidates that we develop;
- launching and commercializing drug candidates for which we obtain marketing approval by establishing a sales force, marketing, medical affairs and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
- achieving adequate coverage and reimbursement by third-party payors for drug candidates that we develop;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and the market demand for drug candidates that we develop, if approved;
- obtaining market acceptance of drug candidates that we develop as viable treatment options;
- technological and market developments;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations in such collaborations;
- maintaining, protecting, enforcing and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- defending against third-party interference, infringement or other intellectual property-related claims, if any; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of the drug candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved drug candidate. Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration (the FDA), the European Medicines Agency (the EMA), or other regulatory agencies to perform clinical trials or studies in addition to those that we currently anticipate. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

We will require substantial additional financing to achieve our goals, which may not be available on acceptable terms, or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

Our operations have consumed substantial amounts of cash since our inception. Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities for our initial nonclinical and clinical drug candidates. Nonclinical studies and clinical trials and additional research and development activities will require substantial funds to complete. As of September 30, 2023, we had unrestricted cash, cash equivalents and investments of \$70.4 million. In October 2023, we closed a private placement, which resulted in gross proceeds of approximately \$92 million, before deducting placement agent fees and expenses. We expect to continue to spend substantial amounts to continue the nonclinical and clinical development of our current and future programs. If we are able to gain marketing approval for drug candidates that we develop, we will require significant additional amounts of cash in order to launch and commercialize such drug candidates. In addition, other unanticipated costs may arise. Because the design and outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any drug candidate we develop.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our drug candidates and programs, and of conducting nonclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining marketing approvals for drug candidates we develop if clinical trials are successful;
- the cost of commercialization activities for our current drug candidates, and any future drug candidates we develop, whether alone or in collaboration, including marketing, sales and distribution costs if our current drug candidates or any future drug candidate we develop is approved for sale;
- the cost of manufacturing our current and future drug candidates for clinical trials in preparation for marketing approval and commercialization;
- our ability to establish and maintain strategic licenses or other arrangements and the financial terms of such agreements including milestone payments to our licensors;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- any lawsuits related to our drug candidates or commenced against us;
- the timing, receipt and amount of sales of, or profit share or royalties on, our future products, if any;
- the emergence of competing therapies for hepatological indications and viral diseases and other adverse market developments; and
- any acquisitions or in-licensing of other programs or technologies.

To date, we have primarily financed our operations through the sale of common stock, preferred stock and convertible notes. For example, in November 2021, we filed a Registration Statement on Form S-3 covering the offering of up to \$400.0 million of common stock, preferred stock, debt securities, warrants and units, which was declared effective by the SEC in November 2021 (November 2021 Shelf Registration Statement). In November 2021, we also entered into a sales agreement (November 2021 Sales Agreement), with Jefferies LLC, as sales agent to sell shares of our common stock, from time to time, with aggregate gross sales proceeds of up to \$75.0 million pursuant to the November 2021 Shelf Registration Statement as an “at-the-market” offering under the Securities Act (ATM Offering Program). In October 2023, we completed a private placement of common stock, warrants and pre-funded warrants

We expect to finance our cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. In addition, we may seek additional capital to take advantage of favorable market conditions or strategic opportunities even if we believe we have sufficient funds for our current or future operating plans. Based on our research and development plans, we expect that our existing cash, cash equivalents and investments will enable us to fund our operations for at least 12 months following the date of this report. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. Moreover, it is particularly difficult to estimate with certainty our future expenses given the dynamic nature of our business, the global business and economic environment that resulted from the COVID-19 pandemic and the macro-economic environment generally.

Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. For example, the current inflationary economic environment, the COVID-19 pandemic, and rising interest rates have resulted in a disruption of global financial markets. If the disruption persists or deepens, we could be unable to access additional capital, which could negatively affect our ability to consummate certain corporate development transactions or other important, beneficial or opportunistic investments. If additional funds are not available to us when we need them, on terms that are acceptable to us, or at all, we may be required to:

- delay, limit, reduce or terminate nonclinical studies, clinical trials or other research and development activities or eliminate one or more of our development programs altogether; or
- delay, limit, reduce or terminate our efforts to establish manufacturing and sales and marketing capabilities or other activities that may be necessary to commercialize any future approved products, or reduce our flexibility in developing or maintaining our sales and marketing strategy.

We currently have a shelf registration statement effective and existing ATM Offering Program, however, our ability to raise capital under this registration statement and through the ATM Offering Program may be limited by, among other things, SEC rules and regulations impacting the eligibility of smaller companies to use Form S-3 for primary offerings of securities. Based on our public

float, as of the date of the filing of this Annual Report on Form 10-K, we are only permitted to utilize a shelf registration statement, including the registration statements under which our ATM Offering Programs are operated, subject to Instruction I.B.6 to Form S-3, which is referred to as the “baby shelf” rule. For so long as our public float is less than \$75.0 million, we may not sell more than the equivalent of one-third of our public float during any 12 consecutive months pursuant to the baby shelf rules. Although alternative public and private transaction structures may be available, these may require additional time and cost, may impose operational restrictions on us, and may not be available on attractive terms.

Our operating results may fluctuate significantly, which will make our future results difficult to predict and could cause our results to fall below expectations.

Our quarterly and annual operating results may fluctuate significantly, which will make it difficult for us to predict our future results. These fluctuations may occur due to a variety of factors, many of which are outside of our control and may be difficult to predict, including:

- the timing and cost of, and level of investment in, research, development and commercialization activities, which may change from time to time;
- the timing and status of enrollment for our clinical trials;
- the timing of regulatory approvals, if any, in the United States and internationally;
- the timing of expanding our operational, financial and management systems and personnel, including personnel to support our clinical development, quality control, manufacturing and commercialization efforts and our operations as a public company;
- the cost of manufacturing, as well as building out our supply chain, which may vary depending on the quantity produced, and the terms of any agreements we enter into with third-party suppliers;
- the timing and amount of any milestone, royalty or other payments due under any current or future collaboration or license agreement, including our existing license agreements with Emory University (Emory) and KU Leuven;
- coverage and reimbursement policies with respect to any future approved products, and potential future drugs that compete with our products;
- the timing and cost to establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with current or future collaborators;
- expenditures that we may incur to acquire, develop or commercialize additional products and technologies;
- expenditures that we may incur in any lawsuits related to our drug candidates or commenced against us;
- the level of demand for any future approved products, which may vary significantly over time;
- future accounting pronouncements or changes in accounting principles or our accounting policies; and
- the timing and success or failure of nonclinical studies and clinical trials for our drug candidates or competing drug candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or collaboration partners.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even if we have met any previously publicly stated revenue or earnings guidance we may provide.

If we fail to comply with the continued listing requirements of Nasdaq, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

We must satisfy Nasdaq’s continued listing requirements, including, among other things, a minimum closing bid price of \$1.00 per share and timely filing of all periodic financial reports, or risk delisting, which would have a material adverse effect on our business. In the event we are delisted from Nasdaq, the only established trading market for our common stock would be eliminated, and we

would be forced to list our shares on the OTC Markets or another quotation medium, depending on our ability to meet the specific listing requirements of those quotation systems. As a result, an investor would likely find it more difficult to trade or obtain accurate price quotations for our shares. Delisting would likely also reduce the visibility, liquidity, and value of our common stock, reduce institutional investor interest in our company, and may increase the volatility of our common stock. Delisting could also cause a loss of confidence of potential industry partners, lenders, and employees, which could further harm our business and our future prospects.

On September 5, 2023, we received a letter from Nasdaq indicating that, for the last 30 consecutive business days, the bid price for our common stock had closed below the minimum \$1.00 per share required for continued inclusion on the Nasdaq Global Select Market under the Nasdaq Listing Rules. The notice had no immediate effect on the listing or trading of our common stock.

Under Nasdaq Listing Rule 5810(c)(3)(A), if during the 180 calendar day period following the date of the notice, the closing bid price of our Common Shares is at or above \$1.00 for a minimum of 10 consecutive business days, we would regain compliance with the minimum bid price requirement and our Common Shares would continue to be eligible for listing on the Nasdaq Global Select Market, absent noncompliance with any other requirement for continued listing.

We intend to monitor the closing bid price of our common stock and consider our available options if the closing bid price of our common stock remains below \$1.00 per share. There can be no assurance that we will be able to regain compliance with the minimum bid price requirement during the 180-day compliance period with respect to the minimum bid price requirement, maintain compliance with the other listing requirements, or maintain the listing of our common stock on Nasdaq.

Delisting from the Nasdaq Global Select Market or any Nasdaq market could make trading our common stock more difficult for investors, potentially leading to declines in our share price and liquidity. In addition, without a Nasdaq market listing, stockholders may have a difficult time getting a quote for the sale or purchase of our common stock, the sale or purchase of our common stock would likely be made more difficult and the trading volume and liquidity of our common stock could decline. Delisting from Nasdaq could also result in negative publicity and could also make it more difficult for us to raise additional capital. The absence of such a listing may adversely affect the acceptance of our common stock as currency or the value accorded by other parties. If our common stock is delisted by Nasdaq, our common stock may be eligible to trade on an over-the-counter quotation system, such as the OTCQB market, where an investor may find it more difficult to sell our common stock or obtain accurate quotations as to the market value of our common stock. We cannot assure you that our common stock, if delisted from Nasdaq, will be listed on another national securities exchange or quoted on an over-the-counter quotation system.

Our business could be materially adversely affected by the effects of health pandemics or epidemics and in particular in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations, including the San Francisco Bay Area where our headquarters are located.

Our business could be materially adversely affected by the effects of health pandemics or epidemics. For instance, the outbreak of COVID-19, which the World Health Organization had declared a global pandemic, prompted severe lifestyle and commercial restrictions aimed at reducing the spread of the disease. In March 2020, the San Francisco Bay Area counties issued a joint shelter-in-place order, which was subsequently followed by a California state-wide shelter order, and other state and local governments implemented similar orders which, among other things, directed individuals to shelter at their places of residence, directed businesses and governmental agencies to cease non-essential operations at physical locations, prohibited certain non-essential gatherings, and ordered cessation of non-essential travel. As a result of these developments, we had implemented work-from-home policies for most of our employees until March 2022 when we allowed our employees to return to work at our U.S. facility. Government-imposed quarantines and any future work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions, the potential impact of changing government orders in response to health pandemics or epidemics and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition in the future.

Quarantines, shutdowns and shelter-in-place and similar government orders related to infectious diseases, or the perception that such events, orders or other restrictions on the conduct of business operations could occur, could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. Restrictions resulting from health pandemics or epidemics may at any time disrupt our supply chain and delay or limit our ability to obtain sufficient materials for our drug candidates.

In addition, our current clinical trial and planned clinical trials may be affected by any future public health pandemics or epidemics. Site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the disease, and potential patients may not be able or willing to comply with clinical trial protocols, whether due to quarantines impeding patient movement or interrupting healthcare services, or due to potential patient concerns regarding interactions with medical facilities or staff. Similarly, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to the disease, may be delayed or disrupted, which may adversely impact our clinical trial operations.

In addition, any future significant outbreak of contagious diseases in the human population could similarly adversely affect, the economies and financial markets of many countries, including the United States, resulting in an economic downturn that could suppress demand for our future products. Any of these events could have a material adverse effect on our business, financial condition, results of operations or cash flows.

In addition, a continuing widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could negatively affect our liquidity and ability to progress our operations. In addition, a recession, down-turn, market correction or supply chain disruption resulting from health pandemics or epidemics could materially adversely affect the value of our common stock.

Risks related to product development and regulatory process

We are early in our development efforts, and our business is dependent on the successful development of our current and future drug candidates. If we are unable to advance our current or future drug candidates through clinical trials, obtain marketing approval and ultimately commercialize any drug candidates we develop, or experience significant delays in doing so, our business will be materially harmed.

Our clinical development efforts across our drug candidates are in an early stage. We have initiated clinical trials for our most advanced drug candidates in many countries (e.g., New Zealand, Hong Kong, the United Kingdom). Our other programs are in the discovery or nonclinical development stage. We have invested substantially all of our efforts and financial resources in the identification of targets and nonclinical development of therapeutics to address hepatological indications and viral diseases. However, the biology of these indications and diseases is complex and not completely understood, and our current and future drug candidates may never achieve expected or functional levels of efficacy or achieve an acceptable safety profile. For example, our CHB portfolio previously included our STOPSTM drug candidate, ALG-010133, one of our proprietary s-antigen transport-inhibiting oligonucleotide polymers that was in a Phase 1b dose range finding trial (NCT04485663) evaluating subjects with CHB as well as our proprietary antisense oligonucleotide, ALG-020572, that was in a Phase 1a/1b umbrella study (NCT05001022) and for which dosing in CHB patients were initiated as part of the multiple ascending dose portion of such study. However, in January 2022, we announced we halted further development of ALG-010133 based on data from such trial indicating insufficient antiviral activity to warrant further development of such drug candidate. And, in March 2022, we announced our discontinuation of further development of ALG-020572 due to an unanticipated serious adverse event involving significant increase in alanine aminotransferase (ALT) in one CHB subject and several additional subjects experiencing ALT flares. Finally, for our siRNA drug candidate targeting HBsAg production, ALG-125755, we conducted a Phase 1 study evaluating single doses ranging from 20-200 mg and 50-320 mg in HVs and virologically suppressed HBeAg negative CHB subjects, respectively. In this study, we found that these single doses were well tolerated with a favorable PK profile. With respect to antiviral activity, while available data indicate evidence of HBsAg lowering at all 3 dose levels evaluated, the comparative efficacy of ALG-125755 vs. competitor siRNAs is inconclusive. Because further clinical evaluation of ALG-125755 is not prioritized with current funding, any further advancement of ALG-125755 will require partnership which may not come to fruition.

Our use of clinically validated targets to pursue treatments of these indications and diseases does not guarantee efficacy or safety or necessarily reduce the risk that our current or future drug candidates will not achieve expected or functional levels of efficacy or achieve an acceptable safety profile.

The success of our business, including our ability to finance our company and generate revenue from products in the future, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of the drug candidates we develop, which may never occur. Our current drug candidates, and any future drug candidates we develop, will require additional nonclinical and clinical development, management of clinical, nonclinical and manufacturing activities, marketing approval in the United States and other markets, demonstrating effectiveness to pricing and reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production, building of a commercial organization, and substantial investment and significant marketing efforts before we generate any revenues from product sales.

We are evaluating drug candidates in clinical trials in many countries (e.g., New Zealand, Hong Kong, the United Kingdom). As a company, we have limited experience in preparing, submitting and prosecuting regulatory filings. Specifically, we have not previously submitted a new drug application (NDA) to the FDA or similar approval filings to a comparable foreign regulatory authority for any drug candidate. An NDA or other relevant regulatory filing must include extensive nonclinical and clinical data and supporting information to establish that the drug candidate is safe and effective for each desired indication. The NDA or other comparable regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product. We have had limited interactions with the FDA and cannot be certain how many clinical trials of any of our drug candidates will be required or whether the FDA will agree with the design or implementation of our clinical trials. In addition, we cannot be certain that our current or future drug candidates will be successful in clinical trials such that the information contained in an NDA or

comparable regulatory filing would support approval, and thus we cannot guarantee that any of our drug candidates will receive regulatory approval. Further, even if our current or future drug candidates are successful in clinical trials, such candidates may not receive regulatory approval. If we do not receive regulatory approvals for current or future drug candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market a drug candidate, our revenue will depend, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights, as well as the availability of competitive products, third-party reimbursement and adoption by physicians.

We plan to seek regulatory approval to commercialize our drug candidates both in the United States and in select foreign countries. While the scope of regulatory approval in other countries is generally similar to that in the United States, in order to obtain separate regulatory approval in other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy. Other countries also have their own regulations governing, among other things, clinical trials and commercial sales, as well as pricing and distribution of drugs, and we may be required to expend significant resources to obtain regulatory approval and to comply with ongoing regulations in these jurisdictions.

The success of our current and future drug candidates will depend on many factors, which may include the following:

- sufficiency of our financial and other resources to complete the necessary nonclinical studies and clinical trials, and our ability to raise any additional required capital on acceptable terms, or at all;
- our ability to develop and successfully utilize our drug discovery platforms;
- the timely and successful completion of our nonclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- acceptance of investigational new drug applications (INDs), clinical trial applications (CTAs) and/or similar applications in other jurisdictions for our planned and future clinical trials;
- whether we are required by the FDA or a comparable foreign regulatory agency to conduct additional clinical trials or other studies beyond those planned to support approval of our drug candidates;
- successful enrollment and completion of clinical trials;
- successful data from our clinical program that supports an acceptable risk-benefit profile of our drug candidates in the intended populations;
- receipt and maintenance of marketing approvals from applicable regulatory authorities;
- establishing agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our drug candidates are approved;
- our ability, and the ability of any third parties with whom we contract, to remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices (cGMPs);
- entry into collaborations to further the development of our drug candidates in select indications or geographies;
- obtaining, maintaining and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- enforcing and defending our intellectual property rights and having and successfully executing an intellectual property life cycle management strategy that supports long-term product development and commercialization goals;
- obtaining and maintaining regulatory exclusivity for our drug candidates;
- successfully launching commercial sales of our drug candidates, if approved;
- acceptance of the drug candidate's benefits and uses, if approved, by patients, the medical community and third-party payors;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our drug candidates following approval;
- effectively competing with other therapies; and
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors.

If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully obtain approval of or commercialize the drug candidates we develop, which would materially harm our business. If we do not receive marketing approvals for our current or future drug candidates, we may not be able to continue our operations. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any products. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of products to continue our business.

Nonclinical development is uncertain. Our nonclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize our drug candidates on a timely basis or at all, which would have an adverse effect on our business.

In order to obtain approval from the FDA and other major regulatory agencies in non-U.S. countries to market a new drug candidate, we must demonstrate proof of safety and efficacy in humans. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a drug candidate, we must complete extensive nonclinical studies that support our planned INDs or CTAs in the United States and other countries. At this time, we are evaluating drug candidates in clinical trials in many countries (e.g., New Zealand, Hong Kong, the United Kingdom). The rest of our programs are in nonclinical research or earlier stages of development, including our other chronic hepatitis B (CHB) drug candidates and our coronavirus drug candidates. We cannot be certain of the timely completion or outcome of our nonclinical studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our nonclinical studies will ultimately support further development of our programs. In addition, the FDA may decline to accept the data we obtain from foreign clinical studies in support of an IND or NDA in the United States, which may require us to repeat or conduct additional nonclinical studies or clinical trials that we did not anticipate in the United States. As a result, we cannot be sure that we will be able to submit INDs in the United States, or CTAs or similar applications in other jurisdictions, on the timelines we expect, if at all, and we cannot be sure that submission of INDs, CTAs or similar applications will result in the FDA or other regulatory authorities allowing additional clinical trials to begin.

Conducting nonclinical testing is a complex, lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can take several years or more per program. Delays associated with programs for which we are directly conducting nonclinical studies may cause us to incur additional operating expenses. Moreover, we may be affected by delays associated with the studies of certain programs that are the responsibility of potential future partners, if any, over which we have no control. The commencement and rate of completion of nonclinical studies and clinical trials for a drug candidate may be delayed by many factors, including:

- inability or failure by us or third parties to comply with regulatory requirements, including the requirements of good laboratory practice (GLP);
- inability to generate sufficient nonclinical or other in vivo or in vitro data to support the initiation of clinical studies;
- delays in reaching a consensus with regulatory agencies on study design and obtaining regulatory authorization to commence clinical trials;
- obtaining sufficient quantities of our drug candidates for use in nonclinical studies and clinical trials from third-party suppliers on a timely basis; and
- delays due to other global-scale potentially catastrophic events, including other public health pandemics or epidemics, terrorism, war, and climate changes.

Moreover, even if candidates from our drug programs advance into clinical trials, our development efforts may not be successful, and clinical trials that we conduct or that third parties conduct on our behalf may not demonstrate sufficient safety or efficacy to obtain the requisite regulatory approvals for any drug candidates we develop. Even if we obtain positive results from nonclinical studies or initial clinical trials, we may not achieve the same success in future trials.

The regulatory approval processes of the FDA, the EMA and comparable foreign authorities are lengthy, time-consuming, complex and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA, the EMA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate's clinical development and may vary across jurisdictions. We have

not obtained regulatory approval for any drug candidate and it is possible that none of our current or future drug candidates will ever obtain regulatory approval.

Our current and future drug candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, the EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, the EMA or comparable foreign regulatory authorities that a drug candidate is safe or effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, the EMA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;
- the FDA, the EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or nonclinical studies;
- the data collected from clinical trials of our drug candidates may not be sufficient to support the submission of an NDA to the FDA or other submission or to obtain regulatory approval in the United States, the European Union or elsewhere;
- the FDA, the EMA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, the EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of clinical trial results may result in our failing to obtain regulatory approval to market any drug candidate we develop, which would significantly harm our business, results of operations and prospects. The FDA, the EMA and other comparable foreign authorities have substantial discretion in the approval process, and in determining when or whether regulatory approval will be obtained for any drug candidate that we develop. Even if we believe the data collected from future clinical trials of our drug candidates are promising, such data may not be sufficient to support approval by the FDA, the EMA or any other regulatory authority.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a drug candidate with a label that does not include the labeling claims that we believe are necessary or desirable for the successful commercialization of that drug candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our drug candidates.

We cannot be certain that any of our programs will be successful in clinical trials or receive regulatory approval. Further, drug candidates we develop may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our drug candidates, we may not be able to continue our operations.

Clinical product development involves a lengthy and expensive process, with uncertain outcomes. We may experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current and future drug candidates, which could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our business, financial condition, results of operations and prospects.

To obtain the requisite regulatory approvals to commercialize any of our drug candidates, we must demonstrate through extensive nonclinical studies and clinical trials that our products are safe and effective in humans. Clinical trials are expensive and can take many years to complete, and their outcomes are inherently uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful. For example, in January 2022, we halted further development of ALG-010133. This decision was based on emerging data from the Phase 1 Study ALG-010133-101, that indicated that at the projected efficacious dose (400 mg, estimated to achieve liver exposures $>3 \times EC_{90}$ for HBsAg inhibition) there was no meaningful HBsAg reduction. Furthermore, higher doses levels (maximum feasible dose is 600 mg) that were planned to be evaluated in a subsequent cohort were very unlikely to reach the $1 \log_{10}$ IU/mL HBsAg reduction level that we had previously defined as necessary to advance the program. As another example, in March 2022, we discontinued further development of our ASO drug candidate for CHB, ALG-020572, due to an unanticipated serious adverse event involving significant increase in ALT in one CHB subject and several other subjects experiencing ALT flares in the same study. Finally, for our siRNA drug candidate targeting HBsAg production,

ALG-125755, we conducted a Phase 1 study evaluating single doses ranging from 20-200 mg and 50-320 mg in HVs and virologically suppressed HBeAg negative CHB subjects, respectively. In this study, we found that these single doses were well tolerated with a favorable PK profile. With respect to antiviral activity, while available data indicate evidence of HBsAg lowering at all 3 dose levels evaluated, the comparative efficacy of ALG-125755 vs. competitor siRNAs is inconclusive. Because further clinical evaluation of ALG-125755 is not prioritized with current funding, any further advancement of ALG-125755 will require partnership which may not come to fruition.

We may experience delays in completing our clinical trials and initiating or completing additional clinical trials. We may also experience numerous unforeseen events prior to, during, or as a result of our nonclinical studies or clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the drug candidates we develop, including:

- regulators, Institutional Review Boards (IRBs) or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations (CROs);
- the number of patients required for clinical trials may be larger than we anticipate;
- it may be difficult to enroll a sufficient number of suitable patients, or enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require us to add new clinical trial sites or investigators;
- the supply or quality of materials for drug candidates we develop or other materials necessary to conduct clinical trials may be insufficient or inadequate; and
- we may experience disruptions by man-made or natural disasters or public health pandemics or epidemics or other business interruptions.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or ethics committees of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval of our drug candidates.

Further, we are currently conducting clinical trials in many countries (e.g., New Zealand, Hong Kong, the United Kingdom). We may also in the future conduct clinical trials for these and other drug candidates in other countries and territories which presents additional risks that may delay completion of our clinical trials. These risks include the possibility that we could be required to conduct additional nonclinical studies before initiating any clinical trials, may be unable to enroll and retain patients as a result of differences in healthcare services, research guidelines or cultural customs, or may face additional administrative burdens associated with comparable foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

If we experience termination or delays in the completion of any clinical trial of our drug candidates, the commercial prospects of our drug candidates will be harmed, and our ability to generate product revenues from any of these drug candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do, shorten any periods during which we may have the exclusive right to commercialize our drug candidates, impair our ability to commercialize our drug candidates and harm our business and results of operations.

Specifically, should we experience another pandemic or epidemic outbreak on a similar if not greater scale as the COVID-19 outbreak, the clinical trial sites for our current drug trials, including for ALG-055009, ALG-000184, ALG-097558 and ALG-125755, and future planned trials may be affected due to prioritization of hospital resources toward the outbreak efforts, travel or quarantine restrictions imposed by national, federal, state or local governments, and the inability to access sites for initiation and patient monitoring and enrollment. As a result, patient screening, new patient enrollment, monitoring and data collection may be affected or

delayed. Some of our third-party manufacturers we use for the supply of materials for drug candidates or other materials necessary to manufacture product to conduct clinical trials may be located in countries affected by the outbreak, and, should they experience disruptions such as temporary closures or suspension of services, we would likely experience delays in advancing these trials.

Separately, principal investigators for our clinical trials serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or a regulatory authority concludes that the financial relationship may have affected the interpretation of the clinical trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any applications we submit. Any such delay or rejection could prevent or delay us from commercializing our current or future drug candidates.

Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or could lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates or result in the development of our drug candidates being terminated.

Our pursuit of potential treatments for NASH is at an early stage and we may be unable to produce a therapy that successfully treats NASH. Even if successful, we may be unable to obtain regulatory approval for and successfully commercialize our drug candidates.

We have invested, and will continue to invest, a significant portion of our time and financial resources in the pursuit of a treatment for NASH, including ALG-055009, our THR-b agonist which is currently in a Phase 1 trial. If we cannot successfully develop, obtain regulatory approval for and commercialize our drug candidates for the treatment of NASH, our business may be harmed. The mechanism of action of our NASH drug candidates is complex, and we do not know the degree to which it will translate into a therapeutic benefit, if any, in NASH or any other indication, and we do not know the degree to which the complex mechanism of action may contribute to long-term safety issues or adverse events when our drug candidates are taken for prolonged periods, as is inherent in the treatment of NASH.

In addition, the standards implemented by clinical or regulatory agencies may change at any time and we cannot be certain what efficacy endpoints the FDA or foreign clinical or regulatory agencies may require at the time we plan to conduct clinical trials with respect to NASH or any other applicable indication. Also, if we are able to obtain accelerated approval of our drug candidates based on a liver biopsy endpoint, we may be required to conduct a post-approval clinical outcomes trial to confirm the clinical benefit of the drug candidate; if any such post-approval trial is not successful, we would not be able to continue marketing the product.

If we are successful and any of our drug candidates are approved for the treatment of NASH, our drug candidates will likely compete with products that may be approved for the treatment of NASH prior to our drug candidates and/or that have greater efficacy than our drug candidates, either alone or in combination. Behavioral modifications, such as diet and exercise, can also decrease or eliminate the demand for our potential NASH treatments.

Our pursuit of potential therapies for COVID-19 is at an early stage.

In response to the outbreak of COVID-19, the disease caused by the virus SARS-CoV-2, we are pursuing various potential therapies to address the disease, including our drug candidate ALG-097558, an oral protease inhibitor which we have selected as our drug candidate to move forward into development. Our identification and development of these potential therapies is at an early stage, and we may be unable to produce in a timely manner a therapy that successfully treats the virus or that has broad clinical applicability, if at all.

For example, in June 2020, we entered into a Research, Licensing and Commercialization Agreement with Katholieke Universiteit Leuven (KU Leuven) under which we were collaborating with KU Leuven's Rega Institute for Medical Research, as well as its Centre for Drug Design and Discovery, to research, develop, manufacture and commercialize potential protease inhibitors for the treatment of coronaviruses, including SARS-CoV-2. In July 2023, we amended our license agreement with KU Leuven (as amended, KU Leuven Agreement) to further our collaboration. While ALG-097558 has been selected as our drug candidate to move forward into development, the KU Leuven Agreement may ultimately not result in a therapy that successfully treats SARS-CoV-2. Further, if the KU Leuven Agreement does result in such a therapy, the therapy may not be developed and commercialized in a timely manner, or at all.

We are also committing significant financial resources and personnel to the development of potential therapies for COVID-19, which may cause delays in or otherwise negatively impact our other development programs, despite uncertainties surrounding the longevity and extent of COVID-19 as a global health concern. COVID-19 may be substantially eradicated prior to our development of

a successful therapy or a vaccine may be developed that is highly efficacious and widely adopted, reducing or eliminating the need for therapies to treat the disease. For instance, the Pfizer/BioNTech BNT162b2, the adenovirus type 26 (Ad26) vaccine by Janssen Pharmaceutical Companies of Johnson & Johnson, Moderna mRNA-1273 and Novavax NVX-CoV2373 COVID-19 vaccines have been approved and/or authorized for emergency use and are in the process of being widely administered in various countries throughout the world which could adversely impact the need for our potential COVID-19 therapies. Further, while we hope to develop potential therapies that are effective against other or future coronaviruses, in addition to SARS-CoV-2, we cannot be certain this will be the case. If our potential therapies are not effective against other or future coronaviruses, the value and/or sales potential of our therapies will be reduced or eliminated. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate or against which our potential therapies, if developed, may not be partially or fully effective, and may ultimately prove unsuccessful or unprofitable. Furthermore, there are no assurances that our therapy will be approved for inclusion in government stockpile programs, which may be material to the commercial success of any approved coronavirus-related drug candidate, either in the United States or abroad.

We will also need to enter into manufacturing arrangements in the future in order to create a supply chain for our COVID-19 drug candidates that can adequately support demand. Even if we are successful in developing and manufacturing an effective treatment for COVID-19, the SARS-CoV-2 virus could develop resistance to our treatment, which could affect any long-term demand or sales potential for our potential therapies.

In addition, another party may be successful in producing a more efficacious therapy for COVID-19 or a therapy with a more convenient or preferred route of administration or in producing a therapy in a more timely manner, which may lead to the diversion of funding away from us and toward other companies or lead to decreased demand for our potential therapies. For instance, on December 22, 2021, Pfizer, Inc. received an emergency use authorization from the FDA for Paxlovid, an orally administered SARS-CoV-2 protease inhibitor co-administered with ritonavir. Similarly, Merck (together with Ridgeback Bio), is developing the drug molnupiravir, an oral antiviral drug which has been issued an emergency use authorization by the FDA on December 23, 2021. Several drugs are likely being used off-label for treatment, such as dexamethasone. Several approved drugs are being studied for their utility in reducing the severity of SARS-CoV-2 infections, including Soliris by Alexion Pharmaceuticals Inc., Atea Pharmaceuticals, Inc., Jakafi by Incyte Corporation, and Kevzara by Sanofi S.A./Regeneron Pharmaceuticals, Inc. There are significant efforts by other companies globally to develop both therapeutic and prophylactic drug candidates. These other entities may be more successful at developing, manufacturing or commercializing a therapy for COVID-19, especially given that several of these other organizations are much larger than we are and have access to larger pools of capital, including U.S. government funding, and broader manufacturing infrastructure. The success or failure of other entities, or perceived success or failure, may adversely impact our ability to obtain any future funding for our development and manufacturing efforts or to ultimately commercialize a therapy for COVID-19, if approved.

The regulatory pathways for our drug candidates targeting SARS-CoV-2, the virus that causes COVID-19, are continually evolving, and may result in unexpected or unforeseen challenges.

Our drug candidates targeting SARS-CoV-2, the virus that causes COVID-19, are in the early discovery stages. The speed at which companies and institutions are acting to create and test many therapeutics and vaccines for COVID-19 is unusually rapid and evolving or changing plans or priorities within the FDA, including changes based on new knowledge of COVID-19 and how the disease affects the human body, may significantly affect the regulatory timelines for our COVID-19 drug candidates. Results from our continued development and planned clinical trials may raise new questions and require us to redesign proposed nonclinical studies and clinical trials, including revising proposed endpoints or adding new clinical trial sites or cohorts of subjects, with minimal lead time.

The FDA has the authority to grant an EUA to allow unapproved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when, based on the totality of scientific evidence, there is evidence of effectiveness of the medical product, and there are no adequate, approved, and available alternatives. For instance, the FDA had granted an EUA for each of the COVID-19 vaccines developed by Pfizer/BioNTech, Moderna, and Janssen Pharmaceutical Companies of Johnson & Johnson. In addition, on December 22, 2021, Pfizer, Inc. received an emergency use authorization from the FDA for Paxlovid, an orally administered COVID-19 protease inhibitor. Similarly, Merck (together with Ridgeback Bio), is developing the drug molnupiravir, an oral antiviral drug which similarly has been issued an emergency use authorization by the FDA on December 23, 2021. Depending on the outcomes of our planned nonclinical and initial clinical testing for our proposed COVID-19 therapies, we may seek an EUA for one or more of our drug candidates for use in the ongoing public health emergency, which would permit us to commercialize a drug candidate prior to FDA approval of an NDA. However, commercialization under an EUA is permitted only during the underlying public health emergency (as declared by the Secretary of the Department of Health and Human Services), meaning that once the emergency declaration is terminated, we would be required to obtain NDA approval to continue marketing the product. Furthermore, the FDA may revoke an EUA based on a determination that the product no longer satisfies the criteria for issuance of an EUA - for example, if there is no longer evidence of effectiveness of the product or there are other adequate, approved alternatives. Accordingly, we cannot predict how long, if at all, an EUA for any of our drug candidates may remain in place. Any termination or revocation of an EUA (if any) for one of our drug candidates could adversely impact our business in a variety of

ways, including if one of our COVID-19 drug candidates is not yet approved by the FDA and if we and our manufacturing partners have invested in the supply chain to provide one of our COVID-19 drug candidates under an EUA.

The results of nonclinical studies and early-stage clinical trials may not be predictive of future results.

The results of nonclinical studies may not be predictive of the results of clinical trials, and the results of any early-stage clinical trials we commence may not be predictive of the results of the later-stage clinical trials. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and initial clinical trials. There is a high failure rate for drugs proceeding through clinical trials, and a number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies. There can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our drug candidates. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval of any products. Any such setbacks in our clinical development could have a material adverse effect on our business and operating results.

Interim, “topline” and preliminary data from our clinical trials may differ materially from the final data.

From time to time, we may disclose interim data from our clinical trials, including candidates ALG-055009, ALG-000184, ALG-097558 and ALG-125755. Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more data on existing patients become available. Adverse differences between interim data and final data could significantly harm our business, financial condition, results of operations and prospects. From time to time, we may also publicly disclose preliminary or “topline” data from our clinical trials, 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 topline results that we report may differ from future results of the same clinical trials, or different conclusions or considerations may qualify such topline results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available.

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 the value of our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically a summary of 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 product, drug candidate or our business. If the topline 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, financial condition, operating results and prospects.

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

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial’s primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians’ and patients’ perceptions as to the potential advantages of the drug candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;

- our ability to obtain and maintain patient consents for participation in our clinical trials and, where appropriate, biopsies for future patient enrichment efforts;
- the risk that patients enrolled in clinical trials will not remain in the trial through the completion of evaluation; and
- disruption by man-made or natural disasters, or public health pandemics or epidemics or other business interruptions.

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

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

Changes in methods of drug candidate manufacturing or formulation may result in additional costs or delay.

As drug candidates proceed from nonclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered to optimize results. However, any change could entail additional cost and risks potential delay if the reformulated or otherwise altered drug candidate performs differently than expected or intended, which could require modification to the nonclinical or clinical program. Such changes may also require additional testing, including bridging or comparability testing to demonstrate the validity of clinical data obtained in clinical trials following manufacturing changes, FDA notification or FDA approval.

Moreover, we have not yet manufactured or processed on a commercial scale any of our drug candidates. We may make changes as we work to optimize our manufacturing processes, but we cannot be sure that even minor changes in our processes will result in therapies that are safe and effective or that will be approved for commercial sale.

Our current or future drug candidates may cause undesirable side effects or have other properties when used alone or in combination with other approved products or investigational new drugs that could delay or halt their clinical development, prevent their marketing approval, limit their commercial potential or result in significant negative consequences.

Undesirable or clinically unmanageable side effects from one or more of our drug candidates or potential future products could occur and cause us or regulatory authorities to interrupt, delay or terminate clinical trials, could result in a more restrictive label or could cause the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities. Further, results of our planned clinical trials could reveal unacceptably severe and prevalent side effects or unexpected characteristics.

If unacceptable toxicities or other undesirable side effects arise in the development of any of our current or future drug candidates, we could suspend or terminate our trials, or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of the drug candidate for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial, or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. Inadequately recognizing or managing the potential side effects of our drug candidates could result in patient injury or death. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected drug candidate and may harm our business, financial condition and prospects significantly.

Although our current and future drug candidates will undergo safety testing to the extent possible and, where applicable, under such conditions discussed with regulatory authorities, not all adverse effects of drugs can be predicted or anticipated. Unforeseen side effects could arise either during clinical development or, if such side effects are more rare, after our products have been approved by regulatory authorities and the approved product has been marketed, resulting in the exposure of additional patients. To date, we have not demonstrated that any of our drug candidates are safe in humans, and we cannot predict if ongoing or future clinical trials will do so.

Furthermore, we plan to evaluate our drug candidates in combination with approved and/or experimental therapies. These combinations may have additional or more severe side effects than caused by our drug candidates as monotherapies or may cause side

effects at lower doses. The uncertainty resulting from the use of our drug candidates in combination with other therapies may make it difficult to accurately predict side effects in potential future clinical trials.

If any of our drug candidates receives marketing approval and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could occur, including:

- regulatory authorities may withdraw their approval of the product;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we may be required to implement a Risk Evaluation and Mitigation Strategy (REMS) or create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing events could prevent us from achieving or maintaining market acceptance of the particular drug candidate, if approved, and result in the loss of significant revenue to us, which would adversely affect our business, financial condition, results of operations and prospects. In addition, if one or more of our drug candidates prove to be unsafe, our entire technology platform and pipeline could be affected, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

Even if we complete the necessary nonclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us or any of our future collaboration partners from obtaining approvals for the commercialization of our current drug candidates and any other drug candidate we develop.

Any current or future drug candidates we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a drug candidate will prevent us from commercializing the drug candidate in a given jurisdiction. We have not received approval to market any drug candidates from regulatory authorities in any jurisdiction and it is possible that none of our current or future drug candidates will ever obtain regulatory approval. As an organization, we have no experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive nonclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the drug candidate’s safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any drug candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the drug candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional nonclinical, clinical or other studies. In addition, varying interpretations of the data obtained from nonclinical and clinical testing could delay, limit, or prevent marketing approval of a drug candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining marketing approval or if we fail to obtain marketing approval of any current or future drug candidates we may develop, the commercial prospects for those drug candidates may be harmed, and our ability to generate revenues will be materially impaired.

Even if a current or future drug candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any current or future drug candidate we develop receives marketing approval, whether as a single agent or in combination with other therapies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community, or such participants may prefer existing treatment options such as nucleos(t)ide analogs including tenofovir and entecavir. If the drug candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any drug candidate, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer our products, if approved, for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the ability to obtain sufficient third-party coverage and adequate reimbursement, including with respect to the use of the approved product as a combination therapy;
- adoption of a companion diagnostic and/or complementary diagnostic (if any); and
- the prevalence and severity of any side effects.

Adverse events in our therapeutic areas of focus, including hepatological indications and viral diseases, could damage public perception of our current or future drug candidates and negatively affect our business.

The commercial success of our products will depend in part on public acceptance of our therapeutic areas of focus. Adverse events in clinical trials of our drug candidates, or post-marketing activities, or in clinical trials of others developing similar products or targeting similar indications and the resulting publicity, as well as any other adverse events in our therapeutic areas of focus, including hepatological indications and viral diseases, could result in decreased demand for any product that we may develop. If public perception is influenced by claims that the use of therapies in our therapeutic areas of focus are unsafe, whether related to our therapies or those of our competitors, our products may not be accepted by the general public or the medical community.

Future adverse events in our therapeutic areas of focus or the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for the drug candidates we have developed, are developing and may in the future develop.

Negative developments and negative public opinion of technologies on which we rely may damage public perception of our drug candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our drug candidates.

The clinical and commercial success of our drug candidates will depend in part on public acceptance of the use of technologies for the prevention or treatment of human diseases. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians specializing in our targeted diseases prescribing, and their patients being willing to receive, our drug candidates as treatments in lieu of, or in addition to, existing, more familiar, treatments for which greater clinical data may be available. Any increase in negative perceptions of the technologies that we rely on may result in fewer physicians prescribing our products (if approved) or may reduce the willingness of patients to utilize our products or participate in clinical trials for our drug candidates.

Increased negative public opinion or more restrictive government regulations in response thereto, would have a negative effect on our business, financial condition, results of operations or prospects and may delay or impair the development and commercialization of our drug candidates or demand for such drug candidates. Adverse events in our nonclinical studies or clinical trials or those of our competitors or of academic researchers utilizing similar technologies, even if not ultimately attributable to drug candidates we may discover and develop, and the resulting publicity could result in increased governmental regulation, unfavorable

public perception, potential regulatory delays in the testing or approval of potential drug candidates we may identify and develop, stricter labeling requirements for those drug candidates that are approved, a decrease in demand for any such drug candidates and a suspension or withdrawal of approval by regulatory authorities of our drug candidates.

Even if we receive marketing approval of a drug candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products, if approved.

Any marketing approvals that we receive for any current or future drug candidate may be subject to limitations on the approved indicated uses for which the product may be marketed or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the drug candidate. The FDA may also require a REMS as a condition of approval of any drug candidate, which could include requirements for a Medication Guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk-minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves a drug candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import and export and record keeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration, as well as continued compliance with current Good Manufacturing Practice, or cGMP, and Good Clinical Practice, or GCP, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with any approved candidate, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or product recalls;
- fines, untitled and warning letters, or holds on clinical trials;
- refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications we filed or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of the product; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval of a product. 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 profitability.

Even if we obtain and maintain approval for our drug candidates from the FDA, we may never obtain approval outside the United States, which would limit our market opportunities.

Approval of a drug candidate in the United States by the FDA does not ensure approval of such drug candidate by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries. Sales of our drug candidates outside the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval. Even if the FDA grants marketing approval for a drug candidate, comparable foreign regulatory authorities also must approve the manufacturing and marketing of the drug candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and more onerous than, those in the United States, including additional nonclinical studies or clinical trials. In many countries outside the United States, a drug candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for any drug candidates, if approved, is also subject to approval. Obtaining approval for our drug candidates in the European Union (the EU) from the European Commission following the opinion of the EMA, if we choose to submit a marketing authorization application there, would be a lengthy and expensive process. Even if a drug candidate is approved, the EMA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming additional clinical trials or reporting as conditions of approval. Approval of certain drug candidates outside of the United States, particularly those that target diseases that are more prevalent outside of the United States, will be particularly important to the commercial success of such drug candidates. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our drug candidates in certain countries.

Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. For example, we are conducting our initial clinical trials for ALG-055009, ALG-000184, ALG-097558 and ALG-125755 in many countries (e.g., New Zealand, Hong Kong, the United Kingdom), and plan to conduct additional clinical trials in several other countries and territories within the Asia Pacific and/or Europe and our conduct of the trials must satisfy specific requirements in order for the FDA to accept the data in support of an IND or NDA in the United States. Further, any regulatory approval for our drug candidates may be withdrawn. If we fail to comply with the applicable regulatory requirements, our target market will be reduced and our ability to realize the full market potential of our drug candidates will be harmed and our business, financial condition, results of operations and prospects could be harmed.

Risks associated with our international operations, including seeking and obtaining approval to commercialize our drug candidates in foreign jurisdictions, could harm our business.

We engage in international operations with offices in the United States, Belgium and China and intend to seek approval to market our drug candidates outside of the United States. We may also do so for future drug candidates. We expect that we are or will be subject to additional risks related to these international business markets and relationships, including:

- different regulatory requirements for approval of drug candidates in foreign countries, including challenging processes for marketing biopharmaceutical products;
- reduced protection for and enforcement of intellectual property rights;
- heightened or different data privacy and information security laws, regulations and policies;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- 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;
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires; and
- disruptions resulting from the impact of public health pandemics or epidemics (including, for example, the COVID-19 pandemic).

In addition, there are complex regulatory, tax, labor and other legal requirements imposed by many of the individual countries in which we may operate, with which we will need to comply.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or could otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new products 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.

Relatedly, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates. Any resurgence of the virus or emergence of new variants may lead to further inspectional delays.

Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to events such as the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impair the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

If the market opportunities for our drug candidates are smaller than we believe or any approval we obtain is based on a narrower definition of the patient population, our business may suffer.

We currently focus our product development on novel therapeutics to address unmet needs in hepatological indications and viral diseases. Our eligible patient population, pricing estimates and available coverage and reimbursement may differ significantly from the actual market addressable by our drug candidates. Our estimates 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 our drug candidates, are based on our beliefs and analyses based on a variety of sources, including scientific literature, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of the diseases we are targeting. The number of patients may turn out to be lower than expected, and the potentially addressable patient population for each of our drug candidates may be limited or may not be receptive to treatment with our drug candidates, and new patients may become increasingly difficult to identify or access. Certain potential patients may have or develop a resistance to our potential therapies or otherwise be unable to be treated with our potential therapies for COVID-19, HBV or other viral diseases as a result of their genetic makeup. In addition, the route of administration for our potential therapies could be inconvenient and/or not commercially viable, which could also limit the potential market for our therapies. If the market opportunities for our drug candidates are smaller than we estimate, it could have an adverse effect on our business, financial condition, results of operations and prospects.

For example, we believe NASH to be one of the most prevalent chronic liver diseases worldwide, however, our projections of the number of people who have NASH, as well as the subset of people with the disease who have the potential to benefit from treatment with our drug candidates, are based on our beliefs and estimates. The effort to identify patients with NASH is in early stages, and we cannot accurately predict the number of patients for whom treatment might be possible. NASH is often undiagnosed and may be left undiagnosed for a long time, partly because a definitive diagnosis of NASH is currently based on a histological assessment of a liver biopsy, which impairs the ability to easily identify patients. If improved diagnostic techniques for identifying NASH patients who will benefit from treatment are not developed, our market opportunity may be smaller than we currently anticipate. Further, if government authorities and third-party payors choose to limit coverage and reimbursement of our NASH drug candidate, such as limiting the number of patients' treatment that would be covered and reimbursable, this could result in a smaller market opportunity for our NASH drug candidate than we anticipate.

In addition, the number of people who have HBV, as well as the subset of people with the disease who have the potential to benefit from treatment with our drug candidates, may be reduced due to factors including the genotype or variant of HBV, more widespread use of vaccines or alternative therapies, political roadblocks to approval and/or treatment in certain countries and the virus's development of resistance to our potential treatments after long-term and persistent exposure to antiviral therapy.

We intend to develop our current drug candidates, and expect to develop other future drug candidates, in combination with other therapies, which exposes us to additional risks.

We intend to develop our current drug candidates, and expect to develop other future drug candidates, in combination with one or more therapies, including therapies that we develop and those developed externally. Even if a drug candidate we develop were to receive marketing approval or be commercialized for use in combination with other therapies, we would face the risk that the FDA or similar regulatory authority outside of the United States could revoke approval of the therapy used in combination with our drug candidate or that safety, efficacy, manufacturing or supply issues could arise with these other therapies. Combination therapies are commonly used for the treatment of viral diseases and it is generally believed they will be required for NASH, and we would be subject to similar risks if we develop any of our drug candidates for use in combination with other drugs. This could result in our own products, if approved, being removed from the market or suffering commercially. In addition, we may evaluate our current drug candidates and other future drug candidates in combination with one or more other therapies that may have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the United States. We will not be able to market and sell any drug candidate we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval.

If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with or any of our drug candidate, we may be unable to obtain approval of or market any of our combination treatments.

We face significant competition, and if our competitors develop and market products that are more effective, safer or less expensive than the drug candidates we develop, our commercial opportunities will be negatively impacted.

The life sciences industry is highly competitive. We are currently developing therapies that will compete, if approved, with other products and therapies that currently exist or are being developed. Products we may develop in the future are also likely to face competition from other products and therapies, some of which we may not currently be aware of. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities and other research institutions. Many of our competitors have significantly greater financial, manufacturing, marketing, product development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining marketing approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the drug candidates that we develop obsolete. Further, mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or marketing approval or discovering, developing and commercializing products in our field before we do.

There are a number of companies developing or marketing treatments for CHB, including Roche Holding AG (Roche), Gilead, Bristol-Myers Squibb Company, Arbutus Biopharma Corporation, Dicerna Pharmaceuticals, Inc. (together with Roche), Ionis Pharmaceuticals, Inc. (together with GSK), Arrowhead Pharmaceuticals, Inc. (together with Janssen Pharmaceuticals Company (Janssen)), Vir Biotechnology, Inc. (together with Alnylam Pharmaceuticals, Inc.), Johnson & Johnson, Assembly Biosciences Inc., Enanta Pharmaceuticals, Altimimmune, Inc., GSK, Janssen, Transgene SA, Dynavax Technologies, Inc., Merck and Replicor, Inc. There are also companies developing or marketing treatments or vaccines for COVID-19, including Soliris by Alexion Pharmaceuticals Inc., Atea Pharmaceuticals, Inc. (together with Roche), Jakafi by Incyte Corporation, Kevzara by Sanofi S.A./Regeneron Pharmaceuticals, Inc., Amgen Inc. (together with Adaptive Biotechnologies Corporation), AbCellera Biologics, Inc. (together with Eli Lilly and Company), Vir Biotechnology, Inc. (together with GSK, Biogen Inc. and WuXi Biologics Ltd.), Altimimmune, Inc., AstraZeneca PLC (together with Oxford University), BioNTech SE (together with Pfizer Inc.), GlaxoSmithKline plc (GSK) (together with Sanofi S.A.), Heat Biologics, Inc., Inovio Pharmaceuticals, Inc., Johnson & Johnson, Moderna, Inc., Novavax, Inc., Regeneron Pharmaceuticals Inc., Vaxart, Inc., Enanta Pharmaceuticals, Novartis and Shionogi & Co., Ltd. For example, BioNTech SE (together with Pfizer Inc.), Janssen Pharmaceutical Companies of Johnson & Johnson and Moderna Inc. have developed COVID-19 vaccines that have received authorization for emergency use and/or regulatory approval are being widely administered. In addition, on December 22, 2021, Pfizer, Inc. received an emergency use authorization from the FDA for Paxlovid, an orally administered COVID-19 protease inhibitor. Similarly, Merck (together with Ridgeback Bio) is developing the drug Molnupiravir, an oral antiviral drug which similarly has been issued an emergency use authorization by the FDA on December 23, 2021. The availability of such COVID-19 vaccines and each of Pfizer's and Merck's oral COVID-19 drug may reduce or eliminate the need for our potential COVID therapies to treat the disease and therefore negatively impact the commercial opportunity.

Furthermore, there are companies developing or marketing treatments for NASH, including AbbVie, Inc., AstraZeneca PLC/MedImmune LLC, Bristol-Myers Squibb Company, Eli Lilly and Company, FronThera US Pharmaceuticals LLC, Janssen, Merck, Novartis Pharmaceuticals Corporation (together with Pfizer, Inc.), Novo Nordisk A/S, Pfizer Inc., Roche, Sanofi S.A., Takeda Pharmaceutical Company Limited (together with HemoShear Therapeutics, LLC), 89bio, Inc., Akero Therapeutics, Inc., Cirus Therapeutics, Inc., Enanta Pharmaceuticals, Inc., Galectin Therapeutics Inc., Galmed Pharmaceuticals Ltd., Genfit SA, Gilead, Intercept Pharmaceuticals, Inc., Inventiva Pharma SA, Madrigal Pharmaceuticals, Inc., MediciNova, Inc., NGM Biopharmaceuticals, Inc., Pliant Therapeutics, Inc. (together with Novartis), Terns Pharmaceuticals, Inc. and Viking Therapeutics, Inc.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient, have a broader label, are marketed more effectively, including gaining exclusivity for their competing products on formularies thereby excluding our products from such formularies, are reimbursed or are less expensive than any products that we may develop. Our competitors also may obtain FDA, EMA or other marketing approval for their products more rapidly than we may obtain approval for ours (if at all), which could result in our competitors establishing a strong market position before we are able to enter the market (if ever). Even if the drug candidates we develop achieve marketing approval, they may be priced at a significant premium over competitive products, resulting in reduced competitiveness of our products.

Smaller and other early stage companies may also prove to be significant competitors. In addition, academic research departments and public and private research institutions may be conducting research on compounds that could prove to be competitive.

These third parties compete with us not only in drug candidate development, but also in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring and/or licensing technologies complementary to, or necessary for, our programs.

In addition, the biopharmaceutical industry is characterized by rapid technological change. If we fail to keep pace with technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our drug candidates obsolete, less competitive or not economical, thereby adversely affecting our business, financial condition and results of operations.

If any of our current or future drug candidates obtain regulatory approval, additional competitors could enter the market with generic versions of such products, which may result in a material decline in sales of our competing products.

Under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (the FDCA), a pharmaceutical manufacturer may file an abbreviated new drug application (an ANDA) seeking approval of a generic version of an approved innovator product. Under the Hatch-Waxman Amendments, a manufacturer may also submit an NDA under section 505(b)(2) of the FDCA that references the FDA's prior approval of the innovator product. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. The Hatch-Waxman Amendments also provide for certain periods of regulatory exclusivity, which preclude FDA approval (or in some circumstances, FDA filing and review) 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, product formulation or an approved use of the drug, which would be listed with the product 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 for a product, a generic or 505(b)(2) applicant that seeks to market its product before expiration of the patents must include in their applications what is known as a "Paragraph IV" certification, challenging the validity or enforceability, or claiming non-infringement, of the listed patent or patents. Notice of the certification must be given to the patent owner and NDA holder and if, within 45 days of receiving notice, either the patent owner or NDA holder sues for patent infringement, approval of the ANDA or 505(b)(2) NDA is stayed for up to 30 months.

Accordingly, if any of our future drug candidates are approved, competitors could file ANDAs for generic versions of these products or 505(b)(2) NDAs that reference our products. If there are patents listed for such drug products 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 which, if any, patents in our current portfolio or patents we may obtain in the future will be eligible for listing in the Orange Book, how any generic competitor would address such patents, 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 products and technologies we develop or license, despite expending a significant amount of resources that could have been focused on other areas of our business. 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 product could immediately face generic competition and its sales would likely decline rapidly and materially.

Even if we are able to commercialize any drug candidates, such products may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a drug candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the drug candidate, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the drug candidate in that country, potentially to the point of unviability. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain marketing approval.

Our ability to successfully commercialize any drug candidates, whether as a single agent or in combination, will also depend in part on the extent to which coverage and reimbursement for these drug candidates and related treatments is available from government authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. It is difficult to predict at this time what government authorities and third-party payors may decide with respect to coverage and reimbursement for our programs (if approved).

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities, particularly in the European Union, and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular products and requiring substitutions of generic products and/or biosimilars. Increasingly, third-party payors are scrutinizing the prices charged for drugs. We cannot be sure that coverage will be available for any drug candidate that we commercialize and, if coverage is available, the level of reimbursement. These government authorities and third-party payors are also examining the cost-effectiveness of drugs, in addition to their safety and efficacy. For example, in some countries, we, or any future collaborators, may be required to conduct a clinical trial that compares the cost-effectiveness of our drug to other therapies to obtain reimbursement or pricing approval. Reimbursement may impact the demand for, or the price of, any drug candidate for which we obtain marketing approval. 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.

Further, there may be significant delays in obtaining coverage and reimbursement for newly approved drugs, as the process is time-consuming and costly, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Additionally, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States, which may result in coverage and reimbursement for drug products that differ significantly from payor to payor. 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 not be sufficient to cover our costs and may not be 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. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved drugs that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drugs and our overall financial condition.

We may not be successful in our efforts to identify or discover other drug candidates and may fail to capitalize on programs or drug candidates that may present a greater commercial opportunity or for which there is a greater likelihood of success.

The success of our business depends upon our ability to identify, develop and commercialize drug candidates. If we do not successfully develop and eventually commercialize products, we will face difficulty in obtaining product revenue in future periods, resulting in significant harm to our financial position and adversely affecting our share price. Research programs to identify new drug candidates require substantial technical, financial and human resources, and we may fail to identify potential drug candidates for numerous reasons.

Additionally, because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or drug candidates or for indications that later prove to have greater commercial potential. For example, we are currently focused on the development of our current drug candidates for hepatological indications. In addition, we are pursuing other drug candidates for viral diseases. However, the advancement of these drug candidates may ultimately prove to be unsuccessful or less successful than another program in our pipeline that we might have chosen to pursue on a less aggressive basis. However, due to the significant resources required for the development of our drug candidates, we must focus on specific diseases and disease pathways and decide which drug candidates to pursue and the amount of resources to allocate to each. Our near-term objective is to demonstrate favorable profiles through Phase 1 clinical trials of our drug candidates ALG-055009, ALG-000184, ALG-097558 and ALG-125755. Our estimates regarding the potential market for our drug candidates could be inaccurate and our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular drug candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, any potential decision to delay or terminate development of a drug candidate or program may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. Further, if we do not accurately evaluate the commercial potential for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate. Alternatively, we may allocate internal resources to a drug candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

If any of these events occur, we may be forced to abandon or delay our development efforts with respect to a particular drug candidate or we may fail to develop a potentially successful drug candidate or capitalize on profitable market opportunities, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may seek and fail to obtain fast track or breakthrough therapy designations from the FDA for our current or future drug candidates or priority review designation for any NDA we may submit to the FDA. Even if we are successful, these programs may not lead to a faster development or regulatory review process, and they do not guarantee we will receive approval for any drug candidate. We may also seek to obtain accelerated approval for one or more of our drug candidates but the FDA may disagree that we have met the requirements for such approval.

If a product is intended for the treatment of a serious or life-threatening condition and nonclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for fast track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular drug candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may rescind the fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

We may also seek breakthrough therapy designation for any drug candidate that we develop. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Like fast track designation, breakthrough therapy designation is within the discretion of the FDA. Accordingly, even if we believe a drug candidate we develop meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of breakthrough therapy designation for a drug candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if a drug candidate we develop qualifies as a breakthrough therapy, the FDA may later decide that the drug no longer meets the conditions for qualification and rescind the designation.

Drugs designated as fast track products or breakthrough therapies by the FDA are also eligible for priority review of any NDA submitted for such drug candidates, which could result in FDA action on the NDA in a shorter timeframe than under standard review. In order to grant priority review designation, the FDA must find that the product, if approved, would provide a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious disease or condition. However, priority review does not guarantee approval of the NDA and may not result in a shorter overall review timeline if the FDA has significant questions or additional requests as part of the NDA review.

In addition, the FDA may grant accelerated approval to a product if the FDA determines that it has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. For example, this is currently the case with drugs for the treatment of NASH. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA requires pre-approval of promotional materials for accelerated approval products, once approved. We cannot guarantee that the FDA will conclude that any of our drug candidates has met the criteria to receive accelerated approval, which would require us to conduct additional clinical testing prior to seeking FDA approval. Even if any of our drug candidates received approval through this pathway, the product may fail required post-approval confirmatory clinical trials, and we may be required to remove the product from the market or amend the product label in a way that adversely impacts its marketing.

We may seek Orphan Drug Designation for drug candidates we develop, and we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity.

As part of our business strategy, we may seek Orphan Drug Designation for any drug candidates we develop, and we may be unsuccessful in obtaining such designation. Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Similarly, in the EU, the European Commission grants Orphan Drug Designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an Orphan Drug Designation application. Orphan Drug Designation is intended to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in Europe and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug. In Europe, Orphan Drug Designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor.

Generally, if a drug with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States and ten years in the EU. The EU exclusivity period can be reduced to six years if a drug no longer meets the criteria for Orphan Drug Designation or if the drug is sufficiently profitable such that market exclusivity is no longer justified.

Even if we obtain orphan drug exclusivity for a drug candidate, that exclusivity may not effectively protect the drug candidate from competition because different therapies can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug candidate nor gives the drug candidate any advantage in the regulatory review or approval process. While we may seek Orphan Drug Designation for applicable indications for our current and any future drug candidates, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations.

We may be required to make significant payments under our license agreements with Emory University, KU Leuven, and Luxna Biotech Co., Ltd.

We entered into a License Agreement with Emory in June 2018 (the Emory License Agreement), a Research, Licensing and Commercialization Agreement with KU Leuven in June 2020 and an amendment in July 2023 and a License Agreement with Luxna in December 2018 and an amendment in April 2020 (as amended, the Luxna Agreement). Under the Emory License Agreement, KU Leuven Agreement and Luxna Agreement, we are subject to significant obligations, including milestone payments, royalty payments, and certain other agreed-to costs. For more information regarding our license agreements, please see the section titled “Business—License agreements and collaborations” of our Annual Report on Form 10-K for the year ended December 31, 2022, previously filed with the Securities and Exchange Commission. If these payments become due under the terms of the Emory University License Agreement, the KU Leuven Agreement or the Luxna Agreement, we may not have sufficient funds available to meet our obligations and our development efforts may be materially harmed. Furthermore, if we are forced to raise additional funds, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts, or grant rights to develop and market drug candidates that we would otherwise develop and market ourselves.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of any approved products.

We face an inherent risk of product liability as a result of the clinical testing of drug candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any drug candidate we develop causes or is perceived to cause illness or is 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. 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 commercialization of any approved products. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any approved product;

- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary payments to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- adverse effects to our results of operations and business;
- 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 or at all to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaboration partners.

Insurance coverage is increasingly expensive. We may not be able to maintain insurance, including product liability insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise, if at all. Our product liability insurance policy contains 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 current or future collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Affordable Care Act (the ACA) was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs being covered under Medicare Part D.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, re-examining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. In addition, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers. The American Rescue Plan Act of 2021 was also signed into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, beginning January 1, 2024.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation and regulation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Most recently, on August 16, 2022, the Inflation Reduction Act of 2022 (the IRA), was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in additional pricing pressure or reduced demand for any drug candidate we develop or complementary or companion diagnostics.

Failure to comply with current or future federal, state and foreign laws and regulations and industry standards relating to privacy and data protection laws 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 our partners may be subject to federal, state and foreign data privacy and security laws and regulations. Failure by us or our third-party vendors, collaborators, contractors and consultants to comply with any of these laws and regulations could result in notification obligations or enforcement actions against us, which could result in, among other things, fines, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects. These laws, rules and regulations evolve frequently and their scope may continually change, through new legislation, amendments to existing legislation and changes in enforcement, and may be inconsistent from one jurisdiction to another. The interpretation and application of consumer, health-related and data protection laws in the United States, the EU and elsewhere, are often uncertain, contradictory and in flux. As a result, implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities.

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 (e.g., Section 5 of the Federal Trade Commission Act), which govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our 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 HIPAA, as amended. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information provided to us by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Many states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. Further, we may also be subject to other state laws governing the privacy, processing and protection of personal information. For example, the California Consumer Privacy Act of 2018 (CCPA) went into effect on January 1, 2020. The CCPA, among other things, creates individual privacy rights for California consumers, such as the right to access and delete their personal information, opt-out of certain sales of personal information and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase the frequency of data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. Further, the California Privacy Rights Act (CPRA), which significantly amends the CCPA, generally went into effect on January 1, 2023. The CPRA imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It has also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement, and additional compliance investment and potential business process changes may be required. Similar laws have passed in Virginia, Colorado, Connecticut and Utah, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

We currently operate in countries outside of the United States, including Belgium, Australia and China, where laws may in some cases be more stringent than the requirements in the United States. For example, in Europe, the General Data Protection Regulation (GDPR) went into effect in May 2018 and imposes strict requirements for the collection, storage, use, disclosure, transfer and other processing of the personal data of individuals within the European Economic Area (EEA). The GDPR applies extra-territorially under certain circumstances and imposes stringent requirements on controllers and processors of personal data, including, for example, requirements to obtain consent or other legal bases from individuals to process their personal data, provide robust disclosures to individuals, accommodate a set of individual data rights, provide data security breach notifications, limit retention of personal information and apply enhanced protections to health data and other special categories of personal data. The GDPR also applies to pseudonymized data, which is defined as “the processing of personal data in such a way that the data can no longer be attributed to a specific data subject without the use of additional information,” and imposes additional obligations when we contract with third-party processors in connection with the processing of any personal data. The GDPR provides that EU and EEA member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data, which could limit our ability to use and share personal data, could cause our costs to increase and could harm our financial condition. Failure to comply with the requirements of the GDPR could result in fines of up to €20 million or 4% of the total worldwide annual turnover of our preceding fiscal year, whichever is higher, and other administrative penalties.

Further, from January 1, 2021, we have to comply with the GDPR and also the United Kingdom GDPR (UK GDPR), which, together, with the amended Data Protection Act 2018, retains the GDPR in UK national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover.

The GDPR further prohibits, without an appropriate legal basis, the transfer of personal data to countries outside of the EEA, such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States. For example, in July 2020, the Court of Justice of the EU (CJEU) limited how organizations could lawfully transfer personal data from the EU/EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses (SCCs). In March 2022, the US and EU announced a new regulatory regime intended to replace the invalidated regulations; however, this new EU-US Data Privacy Framework has not been implemented beyond an executive order signed by President Biden on October 7, 2022 on Enhancing Safeguards for United States Signals Intelligence Activities. European court and regulatory decisions subsequent to the CJEU decision of July 16, 2020 have taken a restrictive approach to international data transfers. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Compliance with U.S. and foreign privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or in some cases, impact our or our partners’ ability to operate in certain jurisdictions. Each of these evolving laws can be subject to varying interpretations. Failure to comply with U.S. and foreign data protection laws and regulations could result in government investigations and enforcement actions (which could include civil or criminal penalties), fines, private litigation, and/or adverse publicity and could negatively affect our operating results and business.

Our business and operations may suffer in the event that our information technology systems, or those used by our CROs or other contractors or consultants, fail or suffer security breaches.

Despite the implementation of security measures, our information technology systems and those of our CROs and other contractors and consultants are vulnerable to damage from cyber-attacks, computer hacks, theft, viruses, malicious software, phishing, employee error, denial-of-service attacks, unauthorized access and other security breaches that could jeopardize the performance of our software and computer systems, and could expose us to financial and reputational harm. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we have not to our knowledge experienced any significant 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 or future clinical trials could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on 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 applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the development and commercialization of our future drug candidates could be delayed. Further, our insurance coverage may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

Risks related to reliance on third parties

We depend on collaborations with third parties for the development of certain of our potential drug candidates, and we may depend on additional collaborations in the future for the development and commercialization of these or other potential candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these drug candidates.

We are currently collaborating with third parties to develop certain of our potential drug candidates. For example, we are collaborating with Merck with respect to the discovery, research and development of oligonucleotides against a NASH target. In the future, we may form or seek strategic alliances, joint ventures, or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to drug candidates we develop.

Collaborations involving our current and future drug candidates may pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- 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, products that compete directly or indirectly with our products (if any) or drug candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or may otherwise not perform satisfactorily in carrying out these activities;
- collaborators may not properly prosecute, maintain, enforce or defend our intellectual property rights or may use our 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 litigation, or other intellectual property proceedings;
- collaborators may own or co-own intellectual property covering products that result from our collaboration with them, and in such cases, we may not have the exclusive right to develop, license or commercialize such intellectual property;
- disputes may arise with respect to ownership of any intellectual property developed pursuant to our collaborations;
- disputes may arise between a collaborator or strategic partner and us that cause the delay or termination of the research, development or commercialization of the drug candidate, or that result in costly litigation or arbitration that diverts management attention and resources; and
- if a current or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

As a result, if we enter into additional collaboration agreements and strategic partnerships or license our intellectual property, products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to any drug candidate we develop could delay the development and commercialization of our drug candidates, which would harm our business prospects, financial condition, and results of operations.

We may seek to establish additional collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

The advancement of our drug candidates and development programs and the potential commercialization of our current and future drug candidates will require substantial additional cash to fund expenses. For some of our programs, we may decide to collaborate with other pharmaceutical and biotechnology companies with respect to development and potential commercialization. Any of these relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, divert our management's attention and disrupt our business.

We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for any other collaborations will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the progress of our clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject drug candidate, the costs and complexities of manufacturing and delivering such drug candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative drug candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our drug candidate. Further, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for future drug candidates because they may be deemed to be at too early of a stage of development for collaborative efforts and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

We may also be restricted under future collaboration agreements from entering into additional agreements on certain terms with potential collaborators.

In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

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

If conflicts arise between us and our collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.

If conflicts arise between our academic collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Current or future collaborators or strategic partners may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations.

Our current or future collaborators or strategic partners may preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, or fail to devote sufficient resources to the development and commercialization of products. Furthermore, competing products, either developed by our current or future collaborators or strategic partners or to which our collaborators or strategic partners may have rights, may result in the withdrawal of partner support for our drug candidates. Any of these developments could harm our product development efforts.

We rely on third parties to conduct our ongoing and planned clinical trials and certain of our nonclinical studies for drug candidates we develop. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize the drug candidates we are developing and our business could be substantially harmed.

We do not have the ability to independently conduct certain nonclinical studies and clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, and other third parties, such as CROs, to conduct or otherwise support certain nonclinical studies and clinical trials for our drug candidates, including ALG-055009, ALG-000184, ALG-097558 and ALG-125755, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our nonclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our nonclinical studies or clinical trials, we could be subject to untitled and warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and our CROs are required to comply with regulations and requirements, including GLP and GCP, for conducting, monitoring, recording and reporting the results of nonclinical studies and clinical trials, respectively, to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the EEA and comparable foreign regulatory authorities for any drugs in clinical development. The FDA enforces GLP and GCP requirements through periodic inspections of laboratories conducting studies, clinical trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GLP or GCP, the data generated in our nonclinical studies or clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional nonclinical studies before allowing us to proceed with clinical trials or additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our future nonclinical studies or clinical trials will comply with GLP or GCP, as applicable. In addition, our nonclinical studies and clinical trials must be conducted with drug candidates produced under cGMP regulations. Our failure or the failure of our CROs to comply with these regulations may require us to delay or repeat nonclinical studies or clinical trials, which would delay the marketing approval process and could also subject us to enforcement action. We also are required to register certain ongoing clinical trials and provide certain information, including information relating to the trial's protocol, on a government-sponsored database, ClinicalTrials.gov, within specific timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we intend to design the nonclinical studies and clinical trials for our drug candidates, CROs conduct all of the clinical trials and certain nonclinical studies. As a result, many important aspects of our nonclinical and clinical development, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct future nonclinical studies and clinical trials will also result in less direct control over the management of data developed through nonclinical studies or clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities;
- become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our nonclinical studies or clinical trials and may subject us to unexpected cost increases and/or delays that are beyond our control. If the CROs do not perform nonclinical studies or clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, marketing approval and commercialization of our drug candidates may be delayed, we may not be able to obtain marketing approval and commercialize our drug candidates, or our development program may be materially and irreversibly harmed. If we are unable to rely on nonclinical or clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of any nonclinical studies or clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the nonclinical or clinical data they obtain are

compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, any nonclinical studies or clinical trials such CROs are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing approval for or successfully commercialize our drug candidates. As a result, we believe that our financial results and the commercial prospects for our drug candidates in the subject indication would be harmed, our costs would increase and our ability to generate revenue would be delayed.

We rely on third parties to manufacture nonclinical and clinical drug supplies, and we intend to rely on third parties to produce commercial supplies of any approved product which increases the risk that we will not have sufficient quantities of such drug candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities for the production of nonclinical, clinical or commercial supplies of the drug candidates that we are developing or evaluating in our development programs. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture any of our drug candidates on a nonclinical, clinical or commercial scale. We rely on third parties for supply of our nonclinical and clinical drug supplies (including key starting and intermediate materials), and our strategy is to outsource all manufacturing of our drug candidates and products to third parties. A disruption or termination in the supply of nonclinical or clinical drug supplies due to our reliance on third parties and/or a disruption in the supply chain generally could delay, prevent or impair our development or commercialization efforts.

In order to conduct clinical trials of drug candidates, we will need to have them manufactured in potentially large quantities. Our third-party manufacturers may be unable to successfully increase the manufacturing capacity for any of our clinical drug supplies (including key starting and intermediate materials) in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities and at any other time. For example, ongoing data on the stability of our drug candidates may shorten the expiry of our drug candidates and lead to clinical trial material supply shortages, and potentially clinical trial delays. If these third-party manufacturers 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 infeasible, and regulatory approval or commercial launch of that drug candidate may be delayed or not obtained, which could significantly harm our business.

Our use of new third-party manufacturers increases the risk of delays in production or insufficient supplies of our drug candidates (and the key starting and intermediate materials for such drug candidates) as we transfer our manufacturing technology to these manufacturers and as they gain experience manufacturing our drug candidates (and the key starting and intermediate materials for such drug candidates).

Even after a third-party manufacturer has gained significant experience in manufacturing our drug candidates (or the key starting and intermediate materials for such drug candidates) or even if we believe we have succeeded in optimizing the manufacturing process, there can be no assurance that such manufacturer will produce sufficient quantities of our drug candidates (or the key starting and intermediate materials for such drug candidates) in a timely manner or continuously over time, or at all.

We may be delayed if we need to change the manufacturing process used by a third party. Further, if we change an approved manufacturing process, then we may be delayed if the FDA or a comparable foreign authority needs to review the new manufacturing process before it may be used.

We do not currently have any agreements with third-party manufacturers for long-term commercial supply. In the future, we may be unable to enter into agreements with third-party manufacturers for commercial supplies of any drug candidate that we develop, or may be unable to do so on acceptable terms. Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers entails risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with cGMP requirements or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of drug candidates or products, operating restrictions and/or criminal prosecutions, any of which could significantly and adversely affect supplies of our drug candidates.

Our future drug candidates and any products that we may develop may compete with other drug candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP requirements and that might be capable of manufacturing for us.

If the third parties that we engage to supply any materials or manufacture product for our nonclinical studies and clinical trials should cease to continue to do so for any reason, we likely would experience delays in advancing these studies and trials while we identify and qualify replacement suppliers or manufacturers and we may be unable to obtain replacement supplies on terms that are favorable to us or at all. In addition, if we are not able to obtain adequate supplies of our drug candidates or the substances used to manufacture them, it will be more difficult for us to develop our drug candidates and compete effectively.

Some of our third-party manufacturers which we use for the supply of materials for drug candidates or other materials necessary to manufacture product to conduct clinical trials could experience unexpected disruptions from man-made or natural disasters or public health pandemics or epidemics or other business interruptions which, if they occurred, might result in delays in advancing our clinical development.

Our current and anticipated future dependence upon others for the manufacture of our drug candidates (or the key starting and intermediate materials for such drug candidates) may adversely affect our future profit margins and our ability to develop drug candidates and commercialize any products that receive marketing approval on a timely and competitive basis.

Our future relationships with customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act (the FCA), which may constrain the business or financial arrangements and relationships through which we sell, market and distribute any products for which we obtain marketing approval. In addition, we may be subject to transparency laws by the U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, 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 the Medicare and Medicaid programs or other federal healthcare programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other;
- the federal civil and criminal false claims laws, including the FCA, which prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. 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 FCA;
- HIPAA, which created federal criminal statutes that prohibit 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. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statutes or specific intent to violate them;

- the Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to CMS 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 (including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives) 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 laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and healthcare laws in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that our business arrangements with third parties comply with applicable healthcare laws, as well as responding to investigations by government authorities, can be time- and resource-consuming and can divert management’s attention from the business.

If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal- and state-funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, any of which could harm our ability to operate our business and our financial results. Further, if the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. In addition, the approval and commercialization of any drug candidate we develop outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Risks related to intellectual property

If we and our collaborators are unable to obtain, maintain, protect and enforce sufficient patent and other intellectual property protection for our drug candidates and technology, our competitors could develop and commercialize products and technology similar or identical to ours, and we may not be able to compete effectively in our market or successfully commercialize any drug candidates we may develop.

Our success depends in significant part on our ability and the ability of our current or future collaborators and licensors to obtain, maintain, enforce and defend patents and other intellectual property rights with respect to our drug candidates and technology and to operate our business without infringing, misappropriating, or otherwise violating the intellectual property rights of others. If we and our current or future collaborators and licensors are unable to obtain and maintain sufficient intellectual property protection for our drug candidates or other drug candidates that we may identify, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors and other third parties could develop and commercialize drug candidates similar or identical to ours, and our ability to successfully commercialize our drug candidates and other drug candidates that we may pursue may be impaired. While we own some issued or allowed patents with respect to our programs, including our CHB and NASH programs, we do not own or in-license any issued patents with claims that specifically recite our ALG-125755 or ALG-097558 drug candidates. We can provide no assurance that any of our other current or future patent applications will result in issued patents or that any issued patents will provide us with any competitive advantage. We cannot be certain that there is no invalidating prior art of which we and the patent examiner are unaware or that our interpretation of the relevance of prior art is correct. If a patent or patent application is determined to have an earlier priority date, it may prevent our patent applications from issuing at all or issuing in a form that provides

any competitive advantage for our drug candidates. Failure to obtain additional issued patents could have a material adverse effect on our ability to develop and commercialize our drug candidates. Even if our patent applications do issue as patents, third parties may be able to challenge the validity and enforceability of our patents on a variety of grounds, including that such third party's patents and patent applications have an earlier priority date, and if such challenges are successful, we may be required to obtain one or more licenses from such third parties, or be prohibited from commercializing our drug candidates.

We seek to protect our proprietary positions by, among other things, filing patent applications in the United States and abroad related to our current drug candidates and other drug candidates that we may identify. Obtaining, maintaining, defending and enforcing pharmaceutical patents is costly, time consuming and complex, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, under certain of our license or collaboration agreements, we may not have the right to control the preparation, filing, prosecution and maintenance of patent applications, or to maintain the rights to patents licensed to or from third parties.

We currently are the assignee of a number of U.S. provisional patent applications. U.S. provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of filing one or more of our related provisional patent applications. With regard to such U.S. provisional patent applications, if we do not timely file any non-provisional patent applications, we may lose our priority dates with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. Further, in the event that we do timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents or if such issued patents will provide us with any competitive advantage.

Although we enter into confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Further, we may not be aware of all third-party intellectual property rights potentially relating to our drug candidates. 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 know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

The patent position of pharmaceutical companies generally is highly uncertain, involves complex legal, technological and factual questions and has, in recent years, been the subject of much debate and litigation throughout the world. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. The subject matter claimed in a patent application can be significantly reduced or eliminated before the patent issues, if at all, and its scope can be reinterpreted or narrowed after issuance. Therefore, our pending and future patent applications may not result in patents being issued in relevant jurisdictions that protect our drug candidates, in whole or in part, or that effectively prevent others from commercializing competitive drug candidates, and even if our patent applications issue as patents in relevant jurisdictions, they may not issue in a form that will provide us with any meaningful protection for our drug candidates or technology, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Additionally, our competitors may be able to circumvent our patents by challenging their validity or by developing similar or alternative drug candidates or technologies in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party preissuance submission of prior art to the United States Patent and Trademark Office (the USPTO), or become involved in opposition, derivation, revocation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others, or other proceedings in the USPTO or applicable foreign offices that challenge priority of invention or other features of patentability. An adverse determination in any such submission, proceeding or litigation could result in loss of exclusivity or ability to sell our products free from infringing the patents of third parties, patent claims being narrowed, invalidated or held unenforceable, in whole or in part, and limitation of the scope or duration of the patents directed to our drug candidates, all of which could limit our ability to stop others from using or commercializing similar or identical drug candidates or technology to compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drug candidates or approved products (if any) without infringing third-party patent rights. In addition, if the breadth or strength of the claims of our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates, or could have a material adverse effect on our ability to raise funds necessary to continue our research programs or clinical trials. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

In addition, 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 candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products or technology similar or identical to ours for a meaningful amount of time, or at all. Moreover, some of our licensed patents and owned or licensed patent applications may in the future be co-owned with third parties. If we are unable to obtain exclusive licenses to any such co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

We have entered into licensing and collaboration agreements with third parties. If we fail to comply with our obligations in the agreements under which we license intellectual property rights to or from third parties, or these agreements are terminated, or we otherwise experience disruptions to our business relationships with our licensors or licensees, our competitive position, business, financial condition, results of operations and prospects could be harmed.

In addition to patent and other intellectual property rights we own or co-own, we have licensed, and may in the future license, patent and other intellectual property rights to and from other parties. In particular, we have in-licensed significant intellectual property rights from Emory and Luxna. Licenses may not provide us with exclusive rights to use the applicable intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our drug candidates, products (if approved) and technology in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products or technologies.

In addition, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications or to maintain, defend and enforce the patents that we license to or from third parties, and we may have to rely on our partners to fulfill these responsibilities. For example, under the Luxna Agreement, we obtained a license from Luxna under patents relevant to certain aspects of our HBV programs as well as to various potential therapies, which we are pursuing to address SARS-CoV-2. Although we have review and comment rights regarding prosecution of patents that we license under the Luxna Agreement, Luxna retains ultimate decision-making control with respect to the prosecution of these patents. Additionally, under the Emory License Agreement, we obtained a license from Emory University under patents relevant to certain aspects of our small molecule CHB program. Although we direct prosecution of patents licensed under the Emory License Agreement, we are obligated to consult with Emory University with respect to prosecution of these patents and Emory and its counsel are responsible for making all filings related to such prosecution. Similarly, although we will control the prosecution of jointly developed patents resulting from our collaboration with the Rega Institute for Medical Research and the Centre for Drug Design and Discovery under the KU Leuven Agreement, we are obligated to consult with such parties with respect to prosecution of these patents. Consequently, any such licensed patents and applications may not be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our current or future licensors, licensees or collaborators fail to prepare, file, prosecute, maintain, enforce, and defend licensed patents and other intellectual property rights, such rights may be reduced or eliminated, and our right to develop and commercialize any of our drug candidates or technology that are the subject of such licensed rights could be adversely affected. In addition, 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.

If we fail to comply with our obligations, including the obligation to make various milestone payments and royalty payments, under any of the agreements under which we license intellectual property rights from third parties, such as the Emory License Agreement or Luxna Agreement, the licensor may have the right to terminate the license. Under some of our in-license agreements, as a sublicensee, we may be obligated to comply with applicable requirements, limitations or obligations of our sublicensors to other third parties. For example, the Luxna Agreement includes rights that Luxna in-licensed from Osaka University (Osaka), which are in turn sublicensed to us. Prior to granting such rights to Luxna, Osaka granted certain rights to third parties and therefore the rights we in-license from Luxna are subject to such third-party rights. Although we understand that these rights granted to such third parties are for uses outside the scope of our business, license agreements are complex, subject to multiple interpretations and disputes may arise regarding scope of such licensed rights. Further, under the Luxna Agreement and other in-licenses under which we sublicense certain rights, we rely on Luxna and our other sublicensors to comply with their obligations under their upstream license agreements, where we may have no relationship with the original licensor of such rights. If our sublicensors fail to comply with their obligations under their upstream license agreements, and the upstream license agreements are consequently terminated, such termination may result in the termination of our sublicenses.

If any of our license agreements are terminated, the underlying licensed patents fail to provide the intended exclusivity or we otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business or be prevented from developing and commercializing our drug candidates, and competitors could have the freedom to seek regulatory approval of, and to market, products identical to ours. Termination of these agreements or reduction or

elimination of our rights under these agreements may also result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, or impede, delay or prohibit the further development or commercialization of one or more drug candidates that rely on such agreements. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our drug candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis.

In addition, the research resulting in certain of our owned and in-licensed patent rights and technology may have been funded in part by the U.S. federal or state governments. As a result, the government may have certain rights, including march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for noncommercial purposes. These rights may permit the government to disclose our confidential information to third parties or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, or because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and certain provisions in intellectual property license agreements may be susceptible to multiple interpretations. Disputes may arise between us and our licensing partners regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which technology and processes of one party infringe intellectual property of the other party that are not subject to the licensing agreement;
- rights to sublicense patent and other rights to third parties;
- any diligence obligations with respect to the use of the licensed technology in relation to development and commercialization of our drug candidates, and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property;
- rights to transfer or assign the license; and
- the effects of termination.

The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could harm our business, financial condition, results of operations and prospects. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms or at all, we may be unable to successfully develop and commercialize the affected drug candidates. Moreover, any dispute or disagreement with our licensing partners may result in the delay or termination of the research, development or commercialization of our drug candidates or any future drug candidates, and may result in costly litigation or arbitration that diverts management attention and resources away from our day-to-day activities, which may adversely affect our business, financial conditions, results of operations and prospects.

Furthermore, current and future collaborators or strategic partners may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by our collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of partner support for our drug candidates. Any of these developments could harm our product development efforts.

In addition, if our licensors fail to abide by the terms of the license, if the licensors fail to prevent infringement by third parties or if the licensed patents or other rights are found to be invalid or unenforceable, our business, competitive position, financial condition, results of operations and prospects could be materially harmed. For more information regarding our license agreements, see the section titled “Business—License agreements and collaborations” of our Annual Report on Form 10-K for the year ended December 31, 2022, previously filed with the SEC.

If we are unable to obtain licenses from third parties on commercially reasonable terms or at all, our business could be harmed.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products (if approved), in which case we would be required to obtain a license from these third parties. The licensing of third-party intellectual property rights is a competitive area, and more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. More established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected drug candidates, which could materially harm our business, and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, it may be or become non-exclusive, thereby giving our competitors access to the same technologies licensed to us. For example, under the Emory License Agreement we currently have an exclusive license with respect to certain patents and a non-exclusive license with respect to certain of Emory's specified know-how. In June 2022, the license to such patents became non-exclusive with respect to all fields except for the treatment and prevention of HBV. For more information regarding our license agreements, see the section titled "Business—License agreements and collaborations" of our Annual Report on Form 10-K for the year ended December 31, 2022, previously filed with the SEC. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

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

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

We are aware of certain third-party issued patents and pending patent applications, including those of our competitors, that, if issued with their current claim scope, may be construed to cover our drug candidates, including ALG-055009 and ALG-125755. In the event that any of these patents were asserted against us, we believe that we would have defenses against any such action, including that such patents are not valid. However, if any such patents were to be asserted against us and our defenses to such assertion were unsuccessful and alternative technology was not available or technologically or commercially practical, unless we obtain a license to such patents, we could be liable for damages, which could be significant and include treble damages and attorneys' fees if we are found to willfully infringe such patents, and we could be precluded from commercializing any drug candidates that were ultimately held to infringe such patents.

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

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

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

Depending upon the timing, duration and conditions of any FDA marketing approval of our drug candidates, one or more of our owned or licensed U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act, and similar legislation in the EU and certain other countries. The Hatch-Waxman Act permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims for the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable drug candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and nonclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations and prospects could be materially harmed.

Further, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Orange Book. We may be unable to obtain patents covering our drug candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If one of our drug candidates is approved and a patent covering that drug candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated new drug application filed with the FDA to obtain permission to sell a generic version of such drug candidate. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

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

Filing, prosecuting, maintaining, defending and enforcing patents on our drug candidates in all countries throughout the world would be prohibitively expensive, and consequently our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patents to develop their own products and may export otherwise infringing products to territories where we have patents, but enforcement rights are not as strong as those in the United States. These products 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.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement or protection of patents, trade secrets and other intellectual property, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in

violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

Many foreign countries, including some EU countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of the applicable patents and limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license, which could adversely affect our business, financial condition, results of operations and prospects.

In 2012, the European Patent Package, or EU Patent Package, regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court, or UPC, for litigation involving European patents. The Unitary Patent system and UPC successfully launched on June 1, 2023. Under the UPC, all European patents, including those issued prior to ratification of the European Patent Package, will by default automatically fall under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan-European injunctions. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. Under the EU Patent Package as currently proposed, we will have the right to opt our patents out of the UPC over the first seven years of the court's existence, but doing so may preclude us from realizing the benefits of the new unified court.

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

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

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

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

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

If we were to initiate legal proceedings against a third party to enforce a patent directed to our drug candidates, or one of our future drug candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or insufficient written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO or an equivalent foreign body, even outside the context of litigation. Potential proceedings include reexamination, post-grant review, inter partes review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our technology or any drug candidates that we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent rights directed towards the applicable drug candidates or technology related to the patent rendered invalid or unenforceable. Such a loss of patent rights would materially harm our business, financial condition, results of operations and prospects.

Interference 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. 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 materially harmed if the prevailing party does not offer us a license on commercially reasonable terms.

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.

Some of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or otherwise violating our intellectual property. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims could result in substantial costs and diversion of management resources, which could harm our business. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, or in-license needed technology or other drug candidates. There could also be public announcements of the results of the hearing, motions, or other interim proceedings or developments. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline. Any of the foregoing events could harm our business, financial condition, results of operation and prospects.

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

Our commercial success depends upon our ability to develop, manufacture, market and sell our drug candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. There is considerable intellectual property litigation in the pharmaceutical industry. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our drug candidates and their manufacture and our other technology, including reexamination, interference, post-grant review, inter partes review or derivation proceedings before the USPTO or an equivalent foreign body. Numerous U.S.- and foreign-issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our drug candidates. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit.

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

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

Many of our employees were previously employed at other biotechnology or pharmaceutical companies. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. We may also be subject to claims that patents and applications we have filed to protect inventions made on our behalf by our employees, consultants and advisors, even those related to one or more of our drug candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims.

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

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

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we or our licensors or collaborators may have inventorship disputes arising from conflicting obligations of employees, consultants or others who are involved in developing our drug candidates. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' or collaborators' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors or collaborators 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, intellectual property that is important to our drug candidates. 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. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to any drug candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we license or may own in the future;
- we, or our current or future licensors or collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or our current or future licensors or collaborators might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending owned or licensed patent applications or those that we may own or license in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by 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 products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the intellectual property rights of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent directed to such intellectual property.

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

Risks related to employee matters, managing our growth and other risks related to our business

We are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

We are highly dependent on our management, scientific and medical personnel. The loss of the services of any of them may adversely impact the achievement of our objectives. Any of our executive officers could leave our employment at any time, as all of our employees are “at-will” employees. We currently do not have “key person” insurance on any of our employees.

Recruiting and retaining qualified employees, consultants and advisors for our business, including scientific and technical personnel, also will be critical to our success. Competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies and academic institutions for skilled individuals. In addition, failure to succeed in nonclinical studies, clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or the loss of services of certain executives, significant employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse effect on our business, financial condition, results of operations and prospects.

We currently have no sales organization. If we are unable to establish sales capabilities on our own or through third parties, we may not be able to market and sell any products effectively, if approved, or generate product revenue.

We currently do not have a marketing or sales organization. In order to commercialize any product, if approved, in the United States and foreign jurisdictions, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. In advance of any of our drug candidates receiving regulatory approval, we expect to establish a sales organization with technical expertise and supporting distribution capabilities to commercialize each such drug candidate, which will be expensive and time-consuming. We have no prior experience in the marketing, sale and distribution of pharmaceutical products, and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain, and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our drug candidates. We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our drug candidates. If we are not successful in commercializing products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of September 30, 2023, we had 68 full-time employees, including 52 employees engaged in research and development. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our current drug candidates and any other drug candidate we develop, while complying with our contractual obligations to contractors and other third parties; and
- expanding and enhancing our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to advance development of and, if approved, commercialize our current drug candidates and any other drug candidate we develop will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of marketing, clinical management, and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed or at a reasonable cost, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our nonclinical studies and clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of any current or future drug candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may experience delays or may not be able to successfully implement the tasks necessary to further develop and commercialize our current drug candidates and any future drug candidates we develop and, accordingly, may not achieve our research, development and commercialization goals.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce

hazardous waste products. We cannot eliminate the risk of contamination or injury from these materials, and we generally contract with third parties for the disposal of these materials and wastes. In the event of contamination or injury resulting from our use or third-party disposal of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

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 maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials, and as such we would have to pay the full amount of any resultant liability out of pocket, which could significantly impair our financial condition.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters and other facilities are located in the San Francisco Bay Area, which in the past has experienced both severe earthquakes and wildfires. We are also conducting clinical trials in New Zealand, an area also known for earthquakes. We do not carry earthquake insurance, and as such we would have to pay the full amount of any resultant liability out of pocket, which could significantly impair our financial condition. In addition, earthquakes, wildfires or other natural disasters could severely disrupt our operations. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our enterprise financial systems or manufacturing resource planning and enterprise quality systems, that delayed our clinical trials, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business, results of operations, financial condition and prospects. Furthermore, integral parties in our supply chain are similarly vulnerable to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business.

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

We are exposed to the risk that our employees, independent contractors, vendors, principal investigators, CROs, consultants and collaborators may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and comparable foreign regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our nonclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, 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.

Risks related to our common stock

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for investors.

Our stock price is likely to be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

- the success of our and competitive products or technologies;
- results of clinical trials and nonclinical studies or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to our drug candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license drug candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States and abroad;
- the COVID-19 pandemic or future public health pandemics or epidemics; and
- investors' general perception of us and our business.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their shares at or above the price paid for the shares and may otherwise negatively affect the liquidity of our common stock.

Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming, and could divert our management's attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a further negative effect on the market price of our common stock.

An active trading market for our common stock may not be sustained.

Prior to our initial public offering in October 2020, there was no public market for shares of our common stock and an active trading market for our shares may not be sustained. In the absence of an active trading market for our common stock, investors may not be able to sell their common stock at a price or at the time that they would like to sell.

An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other drug candidates, businesses, or technologies using our shares as consideration.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, investors are not likely to receive any dividends on common stock owned by them for the foreseeable future. Since we do not intend to pay dividends, an investor's ability to receive a return on its investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders purchased it.

We are an emerging growth company and a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the JOBS Act). For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, certain disclosure obligations regarding executive compensation and the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year of our IPO, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenue of at least \$1.235 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed \$700.0 million as of the prior June 30th, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use the extended transition period for any other new or revised accounting standards during the period in which we remain an emerging growth company; however, we may adopt certain new or revised accounting standards early. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

Even after we no longer qualify as an emerging growth company, we may continue to qualify as a smaller reporting company, which would allow us to rely on certain reduced disclosure requirements, such as an exemption from providing selected financial data and executive compensation information. We are also exempt from the requirement to obtain an external audit on the effectiveness of internal control over financial reporting provided in Section 404(b) of the Sarbanes-Oxley Act. These exemptions and reduced disclosures due to our status as a smaller reporting company mean that our auditors do not review our internal controls over financial reporting and may make it harder for investors to analyze our results of operations and financial prospects.

We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions as an emerging growth company and a smaller reporting company. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Our executive officers, directors and their affiliates have significant influence over our company, which will limit an investor's ability to influence corporate matters and could delay or prevent a change in corporate control.

As of September 30, 2023, our executive officers, directors and their affiliates beneficially own, in the aggregate, approximately 51.2% of our outstanding common stock (assuming all shares of non-voting common stock are converted into voting common stock in accordance with the terms of our amended and restated certificate of incorporation). In addition, in our October 2023 private placement, certain of the holders of 5% or more of our capital stock acquired pre-funded warrants to purchase shares of our common stock (which are immediately exercisable and have an exercise price of \$0.0001 per share) and common warrants to purchase shares of our common stock (which are immediately exercisable and have an exercise price of \$0.7568 per share). Until exercised, the shares issuable upon the exercise of the pre-funded warrants and the common warrants are not included in the number of our outstanding shares of common stock. If such holders exercise their warrants, then the shares of our capital stock beneficially owned by our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates would increase significantly. As a result, these stockholders, if they act together, will be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation or sale of all or substantially all of our assets. In addition, this concentration of ownership might adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

The dual class structure of our common stock may limit the ability to influence corporate matters and may limit the visibility with respect to certain transactions.

The dual class structure of our common stock may limit an investor's ability to influence corporate matters. Holders of our common stock are entitled to one vote per share, while holders of our non-voting common stock are not entitled to any votes. Nonetheless, each share of our non-voting common stock may be converted at any time into one share of our common stock at the option of its holder by providing written notice to us, subject to the limitations provided for in our amended and restated certificate of incorporation. Consequently, the exercise by holders of our non-voting common stock of their option to make this conversion will have the effect of increasing the relative voting power of such holders, and correspondingly decreasing the voting power of the holders of our common stock, which may limit an investor's ability to influence corporate matters. As of September 30, 2023, we had 3,092,338 shares of non-voting common stock outstanding. Additionally, stockholders who hold, in the aggregate, more than 10% of our common stock and non-voting common stock, but 10% or less of our common stock, and are not otherwise a company insider, may not be required to report changes in their ownership due to transactions in our non-voting common stock pursuant to Section 16(a) of the Securities Exchange Act of 1934, as amended (the Securities Exchange Act), and may not be subject to the short-swing profit provisions of Section 16(b) of the Exchange Act.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline.

As of September 30, 2023, approximately 12.5 million shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plans are eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

In addition, the holders of approximately 43.5 million of our total common stock and non-voting common stock are entitled to rights with respect to the registration of their shares under the Securities Act described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the market price of our common stock.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), and corresponding provisions of state law, if a corporation undergoes an “ownership change” (generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a rolling three-year period), the corporation’s ability to use its pre-change net operating loss (NOL) carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We performed a Code Section 382 analysis in 2021 and determined there was an ownership change that resulted in Section 382 limitations. The ownership change limited our ability to utilize NOLs against future taxable income but will not result in the expiration of any NOLs. We may have experienced additional ownership changes in the past and may in the future experience ownership changes as a result of changes in our stock ownership (some of which are not in our control). In addition, under current tax law, federal NOL carryforwards generated in periods after December 31, 2017, may be carried forward indefinitely but, in taxable years beginning after December 31, 2020, may only be used to offset 80% of our taxable income. For these reasons, our ability to utilize our NOL carryforwards and other tax attributes to reduce future tax liabilities may be limited.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies, in part, on the research and reports that industry or financial analysts publish about us or our business. If no or few analysts commence coverage of us, the trading price of our stock would likely decrease. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which, in turn, could cause our stock price to decline.

If we fail to implement and maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of Sarbanes-Oxley, our management is required to report upon the effectiveness of our internal control over financial reporting for our fiscal year ended December 31, 2022. When we lose our status as an “emerging growth company,” our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we will need to implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff, all of which will entail additional expense.

We cannot assure you that there will not be material weaknesses in our internal control over financial reporting in the future. Any failure to implement and maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

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

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;

- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66 2/3% of the shares entitled to vote at an election of directors to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by our chief executive officer or, in the absence of a chief executive officer, president or by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

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

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 Delaware General Corporation Law, 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;
- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter and have entered 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 amended and restated certificate of incorporation provides for an exclusive forum in the Court of Chancery of the State of Delaware for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation, our amended and restated bylaws or any action as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; or any action asserting a claim against us that is governed by the internal affairs doctrine. Our amended and restated certificate of incorporation also provides that the federal district courts of the United States of America is 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 have the effect of discouraging lawsuits against our directors and officers. The choice of forum provision requiring that the Court of Chancery of the State of Delaware or the federal district courts of the United States of America be the exclusive forum for certain actions does not apply to suits brought to enforce any liability or duty created by the Exchange Act. Our exclusive forum provision does not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations. Although our amended and restated certificate of incorporation contains the choice of forum provisions described above, it is possible that a court could find that such a provision is inapplicable for a particular claim or action or that such provision is unenforceable.

General risk factors

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

To date, we have primarily financed our operations through the sale of common stock, preferred stock and convertible notes. We will be required to seek additional funding in the future and may do so through public or private equity offerings or debt financings, credit or loan facilities, collaborations or a combination of one or more of these funding sources. If we raise additional funds by issuing equity securities, our stockholders may suffer dilution and the terms of any equity financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Debt financing, if available, is likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our drug candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. Attempting to secure additional financing may also divert our management's attention from our day-to-day activities, which may adversely affect our ability to develop our drug candidates.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets, including due to the current inflationary economic environment and rising interest rates. Adverse developments that affect financial institutions, transactional counterparties, or other third parties, or concerns or rumors about these events, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (SVB) was closed by the California Department of Financial Protection and Innovation, which appointed the U.S. Federal Deposit Insurance Corporation (FDIC) as receiver. Similarly, other institutions have been and may continue to be swept into receivership. We have no borrowing or deposit exposure to directly impacted institutions and have not experienced an adverse impact to our liquidity or to our business operations, financial condition, or results of operations as a result of these recent events. However, uncertainty may remain over liquidity concerns in the broader financial services industry, and there may be unpredictable impacts to our business and our industry.

Further, Russia began a full-scale invasion of Ukraine in February 2022 which is the largest conventional military attack in Europe since World II and has triggered unprecedented sanctions against Russia. While the situation remains highly fluid and the outlook of such war in Ukraine is subject to extraordinary uncertainty, the ongoing war and associated sanctions will likely have a severe impact on the global economy. A severe or prolonged economic downturn, such as the 2008 global financial crisis, and one that could be caused by the war in Ukraine, could result in a variety of risks to our business, including, weakened demand for any drug

candidates we may develop and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or disruptions in the supply chain generally could also strain our suppliers, possibly resulting in supply disruption. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers or other partners may not survive such difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. Furthermore, our stock price may decline due in part to the volatility of the stock market and any general economic downturn.

Our insurance policies are expensive and protect us only from some business risks, which leaves 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, property, umbrella, clinical trials and directors' and officers' insurance. Any additional insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

We also expect that operating as a public company will make it more difficult and more expensive for us to obtain directors' and officers' liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers.

The continuing impact of "Brexit" may have a negative effect on our business.

Following a national referendum and subsequent legislation, the United Kingdom formally withdrew from the European Union, commonly referred to as "Brexit," and ratified a trade and cooperation agreement governing its future relationship with the European Union. Among other things, the agreement, which became effective in 2021, addresses trade, economic arrangements, law enforcement, judicial cooperation and governance. Because the agreement merely sets forth a framework in many respects that requires complex additional bilateral negotiations between the United Kingdom and the European Union, significant uncertainty remains about how the precise terms of the relationship between the parties will differ from the terms before withdrawal.

We cannot yet predict the full implications of Brexit, including whether it will increase our operational costs or otherwise have a negative effect on our business, financial condition or results of operations, which could reduce the price of our common stock.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, violations of which can have serious negative consequences for our business.

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations (collectively, Trade Laws), prohibit, among other matters, companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, and reputational harm, among other consequences. We routinely have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations, and we expect our non-U.S. activities to increase in time. We plan to engage third parties for clinical trials and/or obtain necessary permits, licenses, patent registrations, and other regulatory approvals from such officials, employees and government agencies and affiliates and we may be held liable for any corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

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 rights, if any, could be reduced or eliminated if we fail to comply with these requirements.

Periodic maintenance fees, renewal fees, annuity fees, and various other fees are required to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent. In certain circumstances, we rely on our collaborators or licensors to pay

these fees. The USPTO and various foreign patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar requirements during the patent application and prosecution process. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official communications within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. While an inadvertent lapse can in some cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in irrevocable abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we or our licensors fail to maintain the patents and patent applications covering our drug candidates, our competitors might be able to enter the market with similar or identical products or technology, which would harm our business, financial condition, results of operations and prospects.

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

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. As noted above, some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development collaborations that would help us commercialize our drug candidates, if approved. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

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

We rely on confidential methodologies and processes and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information and to maintain our competitive position. Trade secrets and know-how can be difficult to protect. We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, licensors, collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our drug candidates that we consider proprietary. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary information will be effective.

We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. 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. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

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 registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing 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 collaborators 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. Further, 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 business, financial condition, results of operations and prospects.

We may in the future engage in strategic transactions; such transactions could affect our liquidity, dilute our existing stockholders, increase our expenses and present significant challenges in focus and energy to our management or prove not to be successful.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of intellectual property, products or technologies.

Such potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations, investments and licensings. Any future transactions could result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the acquisition.

Public health pandemics or epidemics, political instability, terrorist attacks, other acts of violence or war, or other unexpected events could materially and adversely impact us.

Public health pandemics or epidemics, political instability, terrorist attacks, other acts of violence or war or other unexpected events could materially interrupt our business operations (or those of the third parties upon whom we depend), cause consumer confidence and spending to decrease or result in increased volatility in the United States and worldwide financial markets and economy. They also could result in or prolong an economic recession in the United States. Any of these occurrences could materially and adversely affect us.

Current or future litigation or administrative proceedings could have a material adverse effect on our business, our financial condition and our results of operations.

We may be involved in legal proceedings, administrative proceedings, claims, and other litigation that arise in the ordinary course of business. Unfavorable outcomes or developments relating to proceedings to which we are a party or transactions involving our current or future drug candidates, such as judgments for monetary damages, injunctions, or denial or revocation of permits, could have a material adverse effect on our business, our financial condition, and our results of operations. In addition, settlement of claims could adversely affect our financial condition and our results of operations.

We incur significantly increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we incur significant legal, accounting and other expenses that we did not previously incur as a private company. We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Dodd-Frank Act) was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as “say on pay” and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of the IPO. We intend to take advantage of this legislation, but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, results of operations and prospects. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services (if approved). For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

We may experience fluctuations in our tax obligations and effective tax rate, which could materially and adversely affect our results of operations.

We are subject to U.S. federal and state income taxes and taxes in certain other non-U.S. jurisdictions. Tax laws, regulations and administrative practices in various jurisdictions may be subject to significant change, with or without advance notice, due to economic, political and other conditions, and significant judgment is required in evaluating and estimating our provision and accruals for these taxes. There are many transactions that occur during the ordinary course of business for which the ultimate tax determination is uncertain. Our effective tax rates could be affected by numerous factors, such as changes in tax, accounting and other laws, regulations, administrative practices, principles and interpretations, the outcome of current and future tax audits, examinations, or administrative appeals, changes in the mix and level of earnings in a given taxing jurisdiction or changes in our ownership or capital structures.

Our current shares outstanding and resulting market valuation do not reflect shares of our common stock issuable upon the exercise of pre-funded warrants and common warrants that are exercisable at the discretion of the holders of such warrants. If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. For example, in October 2023, we closed a private placement which included the sale of pre-funded warrants and common warrants to purchase shares of our common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution, such dilutive impact may be difficult to compute, and our stock price may decline.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our operating results could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. If our assumptions change or if actual circumstances differ from our assumptions, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.***Unregistered sales of equity securities***

None.

Use of proceeds from our IPO

On October 15, 2020, our registration statement on Form S-1 (File No. 333-249077) relating to our IPO of Common Stock became effective. The IPO closed on October 20, 2020 at which time we issued 10,000,000 shares of common stock at a public offering price of \$15.00 per share. We received net proceeds from the IPO of approximately \$135.4 million, after deducting the underwriting discounts and commissions of \$10.5 million and expenses of \$4.1 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to our affiliates. On November 5, 2020 the underwriters of the IPO partially exercised their over-allotment option by purchasing an additional 1,150,000 shares from us at the IPO price, resulting in an additional \$16.0 million in net proceeds after deducting the underwriting discounts and commissions. J.P. Morgan Securities LLC, Jefferies LLC, Piper Sandler & Co. acted as joint book-running managers for the offering.

There has been no material change in the planned use of proceeds from the IPO from that described in the prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on October 19, 2020.

Issuer purchasers of equity securities

None.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference			Provided Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation.	8-K	10/20/2020	3.1	
3.2	Amended and Restated Bylaws.	8-K	10/20/2020	3.2	
4.1	Reference is made to Exhibits 3.1 and 3.2 .				
4.2	Form of Common Stock Certificate.	S-1/A	10/9/2020	4.2	
4.3	Form of Common Warrant Agreement.	8-K	10/25/2023	4.2	
4.4	Form of Pre-Funded Warrant Agreement.	8-K	10/25/2023	4.1	
10.1	Form of Securities Purchase Agreement.	8-K	10/25/2023	10.1	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				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	The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 has been formatted in Inline XBRL.				X

* The certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q, are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Aligos Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURES

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

ALIGOS THERAPEUTICS, INC.

Date: November 2, 2023

By: _____
/s/ Lawrence Blatt
Lawrence Blatt
Chairman and Chief Executive Officer

Date: November 2, 2023

By: _____
/s/ Lesley Ann Calhoun
Lesley Ann Calhoun
Chief Financial Officer

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Lawrence Blatt, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aligos Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 2023

By: _____ /s/ Lawrence Blatt

Lawrence Blatt
Chairman and Chief Executive Officer

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Lesley Ann Calhoun, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Aligos Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 2023

By: _____ /s/ Lesley Ann Calhoun

**Lesley Ann Calhoun
Chief Financial Officer**

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Aligos Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 2, 2023

By: _____ /s/ Lawrence Blatt
Lawrence Blatt
Chairman and Chief Executive Officer

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Aligos Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 2, 2023

By: _____ /s/ Lesley Ann Calhoun

Lesley Ann Calhoun
Chief Financial Officer
