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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2023
or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to_____
Commission File Number: 001-32587

ALTIMMUNE, INC.

(Exact name of registrant as specified in its charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**20-2726770** **(I.R.S. Employer Identification No.)**
910 Clopper Road, Suite 201S, Gaithersburg, MD **(Address of principal executive offices)**	**20878** **(Zip Code)**

Registrant's telephone number, including area code

(240) 654-1450

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	ALT	The NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☐ No ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of voting and non-voting common equity held by non-affiliates, based upon the closing price of the registrant's common stock on the NASDAQ Global Market on June 30, 2023, was approximately $184.4 million.

As of March 22, 2024, there were 70,895,286 shares of the registrant's common stock, $0.0001 par value per share, outstanding.

ALTIMMUNE, INC.

ANNUAL REPORT ON FORM 10-K

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Forward-looking statements

This Annual Report on Form 10-K for the year ended December 31, 2023 (this "Annual Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the Private Securities Litigation Reform Act of 1995. Written or oral statements that constitute forward-looking statements may be made by us or on our behalf. Words such as "expect," "anticipate," "intend," "plan," "believe," "estimate," "may," "will," "should," "could," "target," "strategy," "intend," "project," "guidance," "likely," "usually," "potential," or the negative of these words or variations of such words, similar expressions, or comparable terminology are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. There are a number of important risks and uncertainties that could cause our actual results to differ materially from those indicated by forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate, and management's beliefs and assumptions. These statements are not guarantees of future performance and involve certain risks, uncertainties and assumptions that are difficult to predict and may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by any forward-looking statements. These risks, uncertainties and other factors include, but are not limited to, risks associated with the following:

- our ability to develop and commercialize our current and future product candidates;
- our ability to expand our pipeline of product candidates and the success of future product candidate advancements, including the success of future preclinical studies and clinical trials, and our ability to commercialize our products;
- the reliability of the results of the clinical trials relating to human safety and possible adverse effects resulting from the administration of our product candidates;
- our ability to obtain potential regulatory approvals on the timelines anticipated, or at all;
- our ability to obtain additional patents or extend existing patents on the timelines anticipated, or at all;
- our ability to identify and consummate potential future strategic partnerships or business combinations;
- our expectations regarding the potential market size and the size of the patient populations for our product candidates, if approved for commercial use;
- our anticipated financial or operational results;
- our ability to obtain additional capital resources;
- risks related to the conflict in Israel and the Gaza Strip and the conflict in Ukraine on the global economy, including causing or contributing to global supply chain disruption, price fluctuations, including increased costs for raw materials, and other significant economic effects;
- breaches of data privacy, or disruptions in our information technology systems;
- our ability to continue to satisfy the listing requirements of the NASDAQ Global Market ("NASDAQ"); and
- risks detailed under the caption "Risk Factors" in this Annual Report and in our other reports filed with the U.S. Securities and Exchange Commission ("SEC"), from time to time hereafter.

We have based the forward-looking statements included in this Annual Report on information available to us on the date of this annual report. Except as required by law we undertake no obligation to revise or update any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised to consult any additional disclosures that we may make in reports that we, in the future, may file with the SEC, including annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K.

All forward-looking statements included herein are expressly qualified in their entirety by the foregoing cautionary statements. Unless otherwise indicated, the information in this Annual Report is as of December 31, 2023.

Note regarding trademarks

"Altimmune," our logo and other trademarks, trade names or service marks of the Company appearing in this Annual Report, including, NasoVAX, HepTcell, EuPort, Densigen and RespirVec are the property of the Company. The other trademarks, trade names and service marks appearing in this Annual Report are the property of their respective owners. We do not intend our use or display of other companies' trademarks, trade names or service marks to imply an endorsement or sponsorship of us by such companies, or any relationship with such companies. Solely for convenience, trademarks and trade names referred to in this Annual Report may appear without the ® or TM symbol.

Summary of Risk Factors

The risk factors detailed in Item 1A entitled "Risk Factors" in this Annual Report on Form 10-K are the risks that we believe are material to our investors and a reader should carefully consider them. Those risks are not all of the risks we face and other factors not presently known to us or that we currently believe are immaterial may also affect our business if they occur. The following is a summary of the risk factors detailed in Item 1A:

Risks Related to Our Business, Financing Requirements, Product Development and Clinical Trials

- we have incurred significant losses since our founding and anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability
- our profitability depends on our ability to develop and commercialize our current and future product candidates
- our ability to raise capital may be limited by applicable laws and regulations
- we may encounter substantial delays in our clinical trials, or our clinical trials may fail to demonstrate the safety and efficacy of our product candidates to the satisfaction of applicable regulatory authorities
- we may find it difficult to enroll patients in our clinical trials, which could delay or prevent clinical trials of our product candidates
- it may be difficult to predict the time and cost of product development for our product candidates, and unforeseen problems may prevent further development or approval of our product candidates
- we rely, and expect to continue to rely, on third parties to conduct preclinical studies and clinical trials for our product candidates, and if they do not properly and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for our product candidates
- we face substantial competition from other pharmaceutical and biotechnology companies, which may result in others discovering, developing or commercializing products before, or more successfully, than we do
- we are heavily dependent on the success of our leading product candidate, pemvidutide. If we ultimately are unable to develop, obtain regulatory approval for or commercialize pemvidutide, or any other product candidate, our business will be substantially harmed
- labor shortages and constraints in the supply chain could adversely affect our results of operations
- our overall performance depends in part on worldwide economic conditions and uncertainties

Risks Related to the Regulatory Approval Process

- our product candidates have undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential
- our ability and the timeline to obtain required regulatory approvals, including in non-U.S. jurisdictions
- the expense and uncertainty of the marketing approval process and ongoing regulatory review if our product candidates ever receive regulatory approval

Risks Related to Our Intellectual Property

- the cost and difficulty of protecting our proprietary rights and the potential that our intellectual property rights do not adequately protect our product candidates

- our ability to protect our intellectual property rights throughout the world
- the adequacy of our patent terms to protect our competitive position on our products for an adequate amount of time
- third-party claims of intellectual property infringement or misappropriation, including circumstances involving our employees, independent contractors or consultants

Risks Related to Commercialization of the Company's Product Candidates

- our ability to attain significant market acceptance of our product candidates, if approved, among physicians, patients, third-party payers and others in the medical community
- our reliance on third parties to manufacture our product candidates and related materials for our products, if approved, as well as our clinical trials and preclinical studies
- our reliance on third parties to obtain regulatory approvals for a manufacturing facility for our products and if approved, to manufacture our products in sufficient quantities to meet commercial demand the ability of our contract manufacturers to manufacture any such product to the specifications and the quantities that are needed along the timelines that are specified
- our ability to identify and consummate potential future strategic partnerships or business combinations

Risks Related to Reimbursement and Government Regulation

- our ability to obtain coverage and reimbursement in certain market segments for our product candidates, if they are approved
- the imposition of price controls
- our ability to comply with multiple substantial federal and state health care and other laws, and the complexity of our regulatory compliance obligations
- the unknown impact of recent health care reform legislation and other changes in the health care industry and in health care spending

Risks Related to our Securities

- the volatility of the trading price of our common stock and substantial price fluctuations on heavy volume

PART I

Item 1. Business

Overview

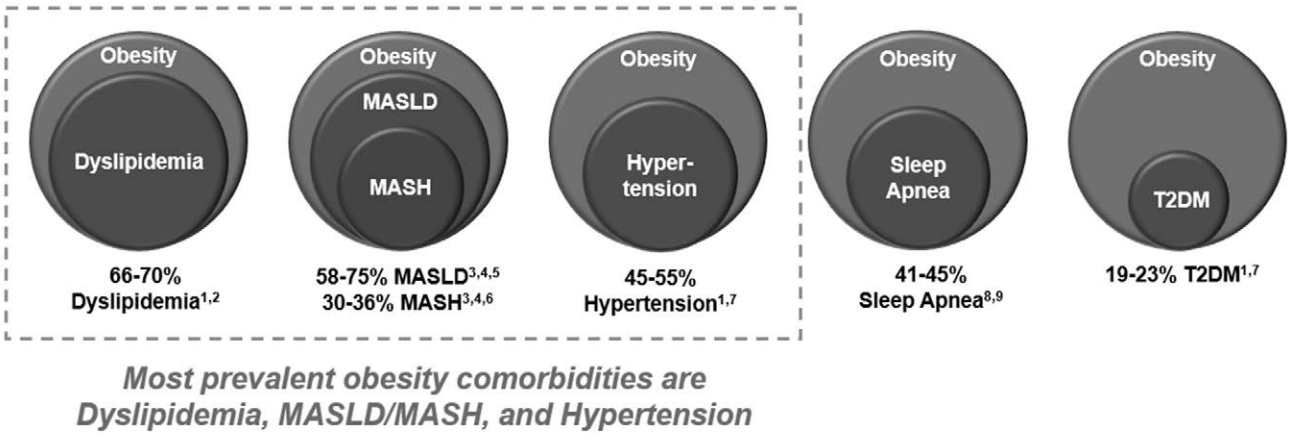
Altimmune, Inc. is a clinical stage biopharmaceutical company focused on developing treatments for obesity and liver diseases. Our lead product candidate, pemvidutide (formerly known as ALT-801), is a GLP-1/glucagon dual receptor agonist that is being developed for the treatment of obesity and metabolic dysfunction-associated steatohepatitis ("MASH"), previously termed non-alcoholic steatohepatitis ("NASH"). Except where the context indicates otherwise, references to "we," "us," "our," "Altimmune" or the "Company" refer to the company and its subsidiaries.

Pemvidutide

We completed an acquisition in July 2019 of all of the equity interests of Spitfire Pharma, Inc. ("Spitfire"). Spitfire was a privately held, preclinical pharmaceutical company with the primary asset being pemvidutide, a novel peptide-based GLP-1/glucagon dual receptor agonist product candidate designed to treat obesity and the metabolic dysfunction that causes MASH.

Obesity is a significant burden to the global healthcare systems and is implicated in two-thirds of the leading causes of death from non-communicable diseases worldwide. Some of the leading risk factors or co-morbidities of obesity include high low density lipoprotein cholesterol ("LDL-C") and other serum lipids, high liver fat content, high total cholesterol, hypertension, type 2 diabetes, ischemic heart disease, cerebrovascular events, gallbladder disease, osteoarthritis, sleep apnea and breathing problems, certain cancers and MASH. According to the Center for Disease Control and Prevention, the estimated annual medical cost of obesity in the U.S. was nearly $173.0 billion in 2019 dollars. Globally, the market size for weight loss alone was $2.4 billion in 2022 and is estimated that it will reach $54.0 billion by 2030. Previous approaches to the treatment of obesity were associated with safety concerns, limiting the success of those approaches; however, the new class of incretin-based therapeutics has demonstrated both substantial weight loss and beneficial cardiovascular effects in clinical outcome studies.

U.S. prevalence of obesity comorbidities



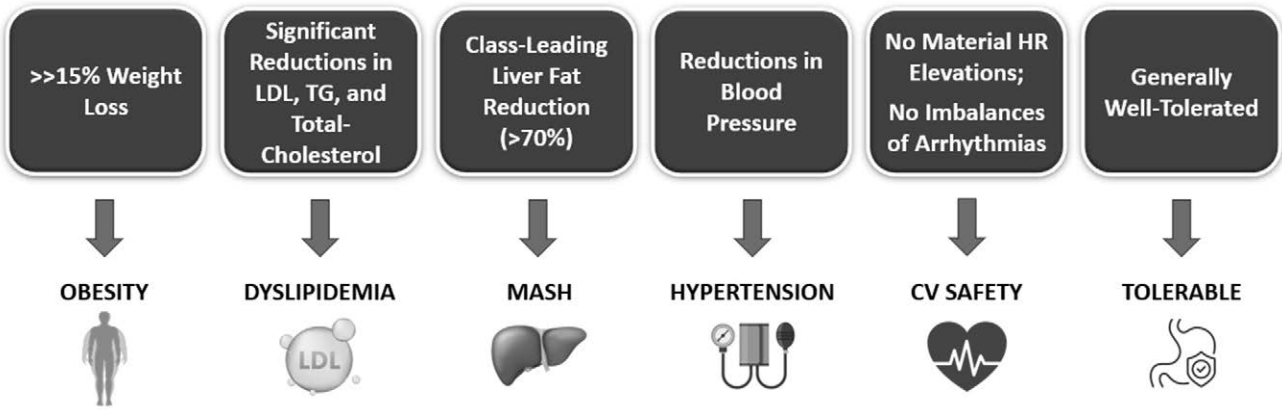
1) Bays, Harold, et. al. (2013) Obesity, adiposity, and dyslipidemia: A consensus statement from the National Lipid Association. Journal of Clinical Lipidology 7(4):304–383.
2) Lim Y, Boster J. Obesity and Comorbid Conditions. [Updated 2023 Feb 8]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; https://www.ncbi.nlm.nih.gov/books/NBK574535/
3) Quek, Jingxuan, et. al. (2023) Global prevalence of non-alcoholic fatty liver disease and non-alcoholic steatohepatitis in the overweight and obese population:. The Lancet Gastroenterology & Hepatology 8(1):20-30.
4) Vernon, G, et. al. (2011) Systematic review: the epidemiology and natural history of non-alcoholic fatty liver disease and non-alcoholic steatohepatitis in adults. Aliment Pharmacol Ther 34:274–285.
5) Le, Michael, et. al. (2022) 2019 Global NAFLD Prevalence: A Systematic Review and Meta-analysis. Clinical Gastroenterology and Hepatology 2022:20:2809–2817
6) Dufour, Jean-François, et. al. (2021) The global epidemiology of nonalcoholic steatohepatitis (NASH) and associated risk factors–A targeted literature review. Endocrine and Metabolic Science 3.
7) Pantalone KM, et al. Prevalence and recognition of obesity and its associated comorbidities. BMJ Open 2017;7:e017583. doi:10.1136/ bmjopen-2017-017583
8) Romero-Corral, Abel, et. al. (2010) Interactions Between Obesity and Obstructive Sleep Apnea. Chest 137(3): 711-719.
9) Garvey JF, Pengo MF, Drakatos P, Kent BD. Epidemiological aspects of obstructive sleep apnea. J Thorac Dis 2015;7(5):920-929.

MASH involves multiple metabolic pathways leading to the abnormal accumulation of liver fat, toxic lipid metabolites, and inflammation, leading to fibrosis and increased risk of death due to cardiovascular disease and to liver

failure. MASLD, the fatty liver precursor to MASH, is present in up to 75% of patients with obesity, and up to 20% of MASLD patients progress to MASH. We believe the treatment of obesity is a cornerstone of treating MASH and the principal morbidities of MASH. In addition, clinical evidence from recent trials of potential MASH products indicates that reduction in liver fat may play an important role in the resolution of liver inflammation and improvement in liver fibrosis. We believe that combining a reduction in liver fat content with weight loss could be the optimal approach for treating MASH.

Pemvidutide's dual agonist mechanism of action is designed to combine the activity of GLP-1 for the reduction of appetite and inflammation, with the activity of glucagon, including increased energy expenditure, adipose browning and mobilization of the liver fat through lipolysis and reduction of lipid synthesis. Pemvidutide incorporates a proprietary side chain, referred to as the EuPort domain, which is designed to enhance pharmacokinetics for gastrointestinal tolerability and permit weekly dosing. As observed in a well-established preclinical model of obesity and MASH, pemvidutide is capable of inducing significant weight loss with concomitant decreases in liver fat content, inflammation and fibrosis. In a first-in-human, randomized, placebo-controlled, single-ascending and multiple-ascending dose study of pemvidutide in overweight and obese volunteers, at 12 weeks, we observed significant reductions in body weight and serum lipids, including LDL-C. In November 2023, we announced topline results from our 48-week MOMENTUM Phase 2 trial of pemvidutide in 391 subjects with obesity or overweight with at least one co-morbidity and without diabetes. We observed robust reductions in body weight and serum lipids and improvements in blood pressure without imbalances in cardiac events, arrhythmias or clinically meaningful increases in heart rate.

Pemvidutide Target Profile



In addition, pemvidutide demonstrated improved metabolic function and pleiotropic effects in preclinical testing across multiple metabolic pathways involved in MASH. In these studies, by using RNA sequencing, we also observed suppression of genes associated with steatosis, inflammation and stellate cell fibrosis. Additionally, in Phase 1b trials of pemvidutide in subjects with MASLD, we observed profound rapid decreases and normalization in liver fat content and significant reductions in body weight and serum alanine aminotransferase ("ALT") at both 12 weeks and 24 weeks of treatment. We believe that pemvidutide is one of the only MASH candidates currently in development that combines rapid effects on liver fat reduction and liver inflammation with significant weight loss.

Regulatory Basis for Clinical Trials of Pemvidutide

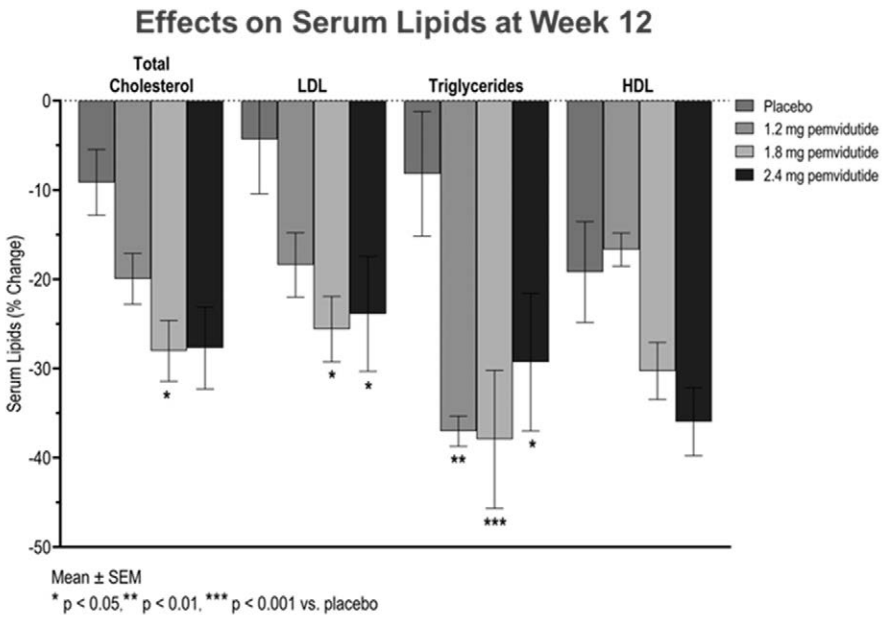
On November 9, 2020, we announced that we received clearance from the Human Research and Ethics Committee and filed a Clinical Trial Notification with the Australian regulatory authority prior to commencing our first-in-human trial of pemvidutide. On September 28, 2021, we announced that we received clearance of our Investigational New Drug ("IND") Application in MASH from the U.S. Food and Drug Administration ("FDA") prior to commencing our Phase 1b trial of pemvidutide in MASLD. On January 23, 2022, we further announced that we received clearance of our IND application from the FDA prior to commencing our 48-week MOMENTUM Phase 2 trial of pemvidutide in obesity. On October 24, 2023, the FDA granted fast track designation to pemvidutide for the treatment of MASH.

Phase 1 Clinical Trial Results – Obesity

In September 2021, we announced the completion of a 12-week Phase 1 clinical trial of pemvidutide in Australia under a clinical trial application. The trial was a first-in-human, randomized, placebo-controlled, single-ascending and multiple-ascending dose ("MAD") study in non-diabetic overweight and obese volunteers. The endpoints of the Phase 1 trial were to assess the safety, tolerability and pharmacokinetics of pemvidutide, with primary readouts on safety, pharmacokinetics and weight loss. Additional readouts included metabolic and lipid profiles, cardiovascular measures and glucose homeostasis. At 12 weeks, subjects receiving pemvidutide showed mean weight losses of 4.9%, 10.3% and 9.0% at the 1.2 mg, 1.8 mg and 2.4 mg doses, respectively, while the placebo group experienced a mean weight loss of 1.6%, and in the absence of caloric restriction or lifestyle modification. Weight loss occurred rapidly and consistently over 12 weeks.

Summary of 12-week MAD weight loss findings					
Characteristic		**Treatment**			
		1.2mg (n=7)	**1.8mg (n=9)**	**2.4mg (n=11)**	**Pooled Placebo (n=7)**
Baseline demographics					
Age, years	Mean (SD)	27.7 (10.5)	32.0 (10.7)	31.4 (11.7)	35.3 (12.4)
Body weight (kg)	Mean (SD)	90.5 (15.4)	86.4 (12.9)	91.9 (15.1)	87.6 (14.3)
BMI (kg/m^2)	Mean (SD)	30.0 (3.9)	30.1 (3.9)	31.8 (2.9)	31.0 (4.3)
Results					
Weight loss (kg)	Mean (SD)	-4.7 (3.0)	-8.8 (3.0)	-8.4 (2.8)	-1.5 (3.0)
Weight loss (%)	Mean (SD)	-4.9 (2.9) %	-10.3 (3.4) %**	-9.0 (3.3) %*	-1.6 (3.0) %
*p < .01, **p < .005, compared to placebo					

The 1.8 mg dose cohort experienced the highest weight loss, with 100% of the subjects losing at least 5% of body weight and 55% of subjects losing at least 10% of body weight. The amounts of weight loss at the 1.8 mg and 2.4 mg doses were similar given the sample size and overlapping confidence intervals. No correlation was found between the magnitude of weight loss and either age or baseline body mass index ("BMI"). Favorable or statistically significant trends were observed in secondary measures, including reductions in systolic and diastolic blood pressure, serum lipids and HOMA-IR (a measure of insulin resistance). As seen in the table below, the effect on serum lipids was particularly striking and in the 1.8mg dose, included a greater than 25% decrease in LDL-C, which is known to increase the risk of cardiovascular disease, as well as significant decreases in total cholesterol and triglycerides. In addition, a rise in serum ketone bodies and a fall in serum tripalmitin was observed, consistent with the stimulatory effects of glucagon on hepatic beta-oxidation of lipids and suppressive effects of pemvidutide on triglyceride synthesis, respectively.



Side effects in this trial were mild to moderate, with no serious or severe treatment-emergent adverse events reported. No discontinuations due to adverse events were reported.

Summary of 12-week MAD safety findings				
Characteristic	**Treatment**			
	1.2mg (n=7)	**1.8mg (n=9)**	**2.4mg (n=11)**	**Pooled Placebo (n=7)**
Discontinuations due to adverse events (n)	0	0	0	0
Early withdrawal (n)	1	0	2	2
Gastrointestinal adverse events				
Nausea				
Mild	14.3%	55.6%	45.5%	14.3%
Moderate	14.3%	11.1%	45.5%	0%
Vomiting				
Mild	14.3%	11.1%	45.5%	14.3%
Moderate	0%	11.1%	27.3%	0%
Diarrhea				
Mild	0%	0%	18.2%	0%
Moderate	0%	0%	0%	0%
Constipation				
Mild	0%	11.1%	18.2%	0%
Moderate	0%	11.1%	9.1%	0%
Other adverse events (n)	0	2	1	0

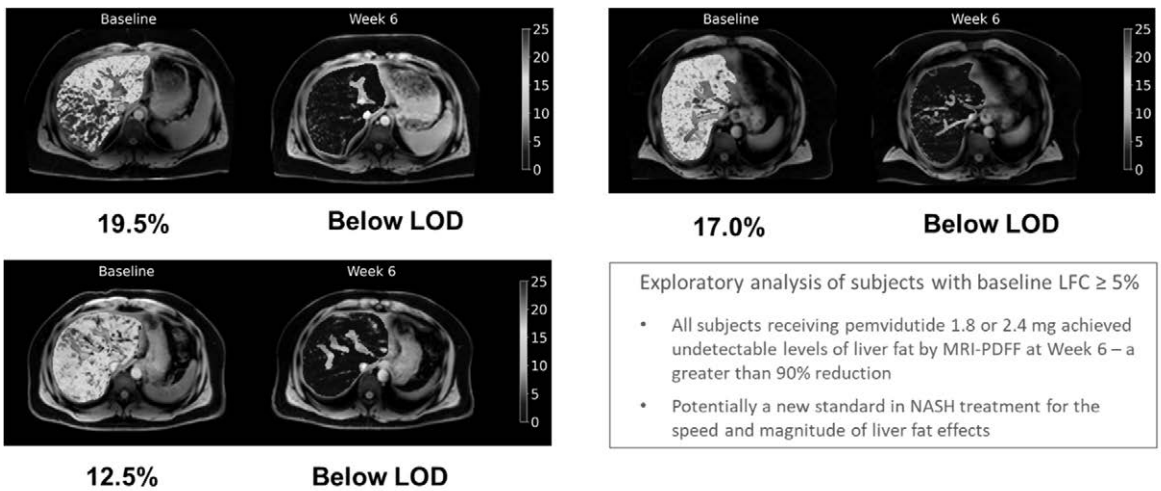
Unlike the majority of other clinical trials with agents within the GLP-1 class, including dual agonists and tri-agonists, dose titration, a gradual increasing of dose within a subject over a period of weeks to months to improve tolerability, was not used in the pemvidutide trial. Even without that dose titration, the symptoms experienced by subjects who received pemvidutide 1.2 mg and 1.8 mg were predominantly mild, did not require treatment and were consistent with known effects of GLP-1-based therapies. Tolerability was observed to decrease at the highest dose level. One subject receiving placebo and one subject receiving pemvidutide 1.8 mg had a 3 to 5-fold elevation in ALT levels over baseline that resolved rapidly after a pause in dosing. In this trial, no perturbations of glucose control, as assessed by fasting glucose

and hemoglobin A1c ("HbA1c"), were observed in subjects with obesity/overweight with pre-diabetes; in fact, a reduction of insulin resistance was observed, as expected when significant weight loss is experienced.

Phase 1 Clinical Trial Results – Liver Fat Content

Although the trial inclusion criteria for the MAD study did not pre-specify a minimum liver fat content ("LFC"), the trial did enroll a number of subjects with measurable LFC as determined by magnetic resonance imaging – proton density fat fraction ("MRI-PDFF"). A post-hoc analysis of the trial data through 6 weeks showed that 8 subjects had hepatic steatosis, defined as liver fat content greater than or equal to 5% at baseline (LFC range from 5.5% to 19.5% in these 8 subjects). LFC fell below the limit of detection ("LOD"), or less than 1.5%, within 6 weeks of treatment in all subjects with steatosis receiving the 1.8 mg or 2.4 mg dose of pemvidutide, representing on average a greater than 90% reduction in the liver fat content (see chart below). These findings reinforce the results from preclinical studies of pemvidutide, in which we observed statistically greater reductions in liver fat than an equivalent dose of semaglutide. We believe these findings support the potential combined beneficial effects of weight loss and glucagon agonism on liver fat content.

Images of Representative MRI-PDFF Images at Baseline and Week 6



The table below displays the changes in liver fat content at Week 6 compared to baseline in the 8 subjects with steatosis at baseline:

Treatment Group	Weight Loss (%) at Week 6	MRI-PDFF					
		Baseline	Week 6	Absolute Δ at Week 6 (%)		Relative Δ at Week 6 (%)	
				Individual	Mean	Individual	Mean
Placebo	0.5	5.2	3.7	1.5	1.5	28.8	28.8
pemvidutide 1.2 mg	1.0	19.1	14.0	5.10	6.50	26.7	48.2
	5.1	11.2	3.4	7.80		69.6	
pemvidutide 1.8 mg	4.4	12.4	< LOD	11.65	11.65	94.0	94.0
pemvidutide 2.4 mg	3.7	17.0	< LOD	16.25	11.50	95.6	91.9
	4.9	5.5	< LOD	4.75		86.4	
	3.1	7.0	< LOD	6.25		89.3	
	4.7	19.5	< LOD	18.75		96.2	
LOD (limit of detection) = 1.5%; for absolute and relative Δ, values < LOD are set at 0.75%							

Clinical Trial Results – 12-week Phase 1b (MASLD)

In September 2022, we announced the topline results from our 12-week Phase 1b clinical trial of pemvidutide in subjects with MASLD. The trial was a double-blind, placebo-controlled study. Subjects were randomized 1:1:1:1 to 1.2 mg, 1.8 mg, 2.4 mg pemvidutide or placebo administered weekly for 12 weeks. No dose titration was used with the 1.2 mg or 1.8 mg dose, while a short 4-week dose titration was employed at the 2.4 mg dose. The primary efficacy endpoint was the percent (%) reduction in LFC from baseline, and the key secondary efficacy endpoint was the % weight loss from baseline, both at 12 weeks of treatment. This MASLD trial was conducted without the adjunctive diet and exercise interventions that would have been the standard for obesity trials.

Ninety-four (94) subjects were randomized and treated at 13 sites across the U.S. Mean BMI at baseline was approximately 36 kg/m^2 and mean LFC, as measured by MRI-PDFF, was approximately 22%. Twenty-seven (29%) subjects had type 2 diabetes at baseline, and approximately 75% of study subjects were of Hispanic ethnicity. The table below details the baseline study demographics.

Characteristic		Treatment			
		Placebo (n = 24)	**1.2 mg (n=23)**	**1.8 mg (n=23)**	**2.4 mg (n=24)**
Age, years	Mean (SD)	47.9 (14)	48.6 (11)	50.3 (9)	48.8 (8)
Sex	Female, n (%)	14 (58.3%)	9 (39.1%)	12 (52.2%)	15 (62.5%)
Race	White, n (%)	21 (87.5%)	21 (91.3%)	20 (87.0%)	24 (100%)
	Other, n (%)	3 (12.5%)	2 (8.7%)	3 (13.0%)	0 (0.0%)
Ethnicity	Hispanic, n (%)	14 (58.3%)	20 (87.0%)	19 (82.6%)	18 (75.0%)
	Non-Hispanic, n (%)	10 (41.7%)	3 (13.0%)	4 (17.4%)	6 (25.0%)
BMI, kg/m^2	Mean (SD)	36.9 (4.7)	36.3 (5.6)	35.4 (3.9)	35.3 (5.0)
Body weight, kg	Mean (SD)	105.1 (20.8)	102.4 (14.6)	98.9 (19.7)	98.2 (18.9)
Diabetes status	T2D, n (%)	6 (25.0%)	7 (30.4%)	7 (30.4%)	7 (33.3%)
LFC, %	Mean (SD)	23.8 (9.2)	21.6 (7.3)	21.8 (8.0)	20.2 (7.0)

The trial met its primary endpoint in all pemvidutide treatment groups. As seen in the table below showing reduction in LFC as measured by MRI-PDFF in all subjects, at the 1.8 mg dose (with and without diabetes), pemvidutide achieved a mean reduction of liver fat content of 68.5%, with 94.4% of subjects achieving a 30% reduction in liver fat, 72.2% achieving a 50% reduction in liver fat, and 55.6% of subjects achieving normalization of liver fat, defined as liver fat fraction of 5% or less.

Endpoint		Treatment			
		Placebo (n = 24)	**1.2 mg (n=20)**	**1.8 mg (n=18)**	**2.4 mg (n=20)**
Absolute reduction, %	Mean (SE)	0.2 (1.7)	8.9 (1.8)**	14.7 (1.7)**	11.3 (2.0)**
Relative reduction, %	Mean (SE)	4.4 (8.7)	46.6 (8.1)**	68.5 (9.7)**	57.1 (8.0)**
30% reduction	n (%)	1 (4.2%)	13 (65.0%)**	17 (94.4%)**	17 (85.0%)**
50% reduction	n (%)	0 (0.0%)	8 (40.0%)**	13 (72.2%)**	14 (70.0%)**
Normalization (≤ 5% LFC)	n (%)	0 (0.0%)	4 (20.0%)*	10 (55.6%)**	10 (50.0%)**

*p < .05, **p<.001 compared to placebo

In addition, as shown in the below table, mean serum ALT levels declined in all subjects, and in subjects with baseline serum ALT above 30 IU/L, levels declined more than 17 IU/L at all dose levels and 27.0 IU/L in the 2.4 mg dose cohort.

Endpoint	Treatment			
	Placebo	**1.2 mg**	**1.8 mg**	**2.4 mg**
ALT, change from baseline, IU/L, LSM (SE)	**n = 24**	**n = 23**	**n = 23**	**n = 24**
	-6.2 (2.8)	-11.2 (3.1)	-13.8 (3.0)*	-13.6 (3.2)*
ALT, change from baseline, IU/L, LSM (SE), baseline ≥ 30 IU/L	**n = 15**	**n = 10**	**n = 15**	**n = 12**
	-12.6 (4.1)	-17.8 (4.8)	-20.8 (4.2)	-27.0 (4.8)*

*p < .05

The trial also met its key secondary endpoint of weight loss in all pemvidutide treatment groups. As portrayed in the following table, employing an efficacy estimand, mean weight losses of 4.9% (placebo-adjusted 4.7%) in subjects without diabetes and 4.4% in subjects with diabetes (placebo-adjusted 3.9%) were achieved at the 1.8 and 2.4 mg doses, respectively.

Population		**Treatment**			
		Placebo (n = 24)	**1.2 mg (n=23)**	**1.8 mg (n=23)**	**2.4 mg (n=24)**
No diabetes, (% change)	LSM (SE)	-0.2 (0.7)	-3.4** (0.8)	-4.9** (0.8)	-3.5** (0.8)
Diabetes, (% change)	LSM (SE)	-0.5 (1.3)	-3.3* (1.1)	-3.8* (1.2)	-4.4* (1.3)
All subjects (% change)	LSM (SE)	-0.2 (0.7)	-3.4** (0.7)	-4.3** (0.7)	-3.7** (0.7)

LSM least square mean; *p < .05, **p<.001 compared to placebo

Pemvidutide was reported to be generally well tolerated. Gastrointestinal events comprised the majority of the adverse events ("AEs"). Even without dose titration, the symptoms experienced by subjects were predominantly mild and transient in nature, consistent with known GLP-1 class effects. No serious or severe AEs were reported. Two subjects treated with pemvidutide discontinued treatment due to AEs [1 (4.3%) at 1.8 mg and 1 (4.2%) at 2.4 mg], both secondary to gastrointestinal intolerability. No clinically significant ALT elevations (defined as an increase to 3-fold or greater the upper limit of normal) were observed. Glycemic control was unaffected, with no clinically meaningful changes in HbA1c or fasting glucose. Clinically meaningful reductions in systolic blood pressure were observed, along with the 2 to 3 beats per minute increase in heart rate typical for GLP-1 class of drugs. The table below summarizes the safety findings.

Characteristic		**Treatment**			
		Placebo (n = 24)	**1.2 mg (n=23)**	**1.8 mg (n=23)**	**2.4 mg (n=24)**
Severe AEs	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Serious AEs ("SAE"s)	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
AEs leading to treatment discontinuation	n (%)	0 (0.0%)	0 (0.0%)	1 (4.3%)	1 (4.2%)
Nausea	Mild, n (%)	3 (12.5%)	3 (13.0%)	6 (26.1%)	6 (25.0%)
	Mod, n (%)	0 (0.0%)	1 (4.3%)	6 (26.1%)	3 (12.5%)
Vomiting	Mild, n (%)	0 (0.0%)	3 (13.0%)	2 (8.7%)	2 (8.3%)
	Mod, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Diarrhea	Mild, n (%)	4 (16.7%)	3 (13.0%)	5 (21.7%)	1 (4.2%)
	Mod, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Constipation	Mild, n (%)	0 (0.0%)	3 (13.0%)	4 (17.4%)	1 (4.2%)
	Mod, n (%)	0 (0.0%)	1 (4.3%)	0 (0.0%)	0 (0.0%)

Clinical Trial Results – 24-week Phase 1b extension (MASLD)

In December 2022, we announced the topline results from our 24-week (12-week extension) Phase 1b clinical trial of pemvidutide in subjects with MASLD. Sixty-six (66) of the 83 subjects who completed the initial 12-week Phase 1b MASLD trial consented to participate in this 12-week extension trial to receive a total of 24 weeks of treatment, and

64 subjects were enrolled. The trial was conducted without adjunctive diet and exercise interventions and the double-blinding of the trial was maintained during the extension study. The same endpoints as the 12-week parent MASLD trial were employed, with a primary efficacy endpoint of percent (%) reduction in liver fat content; key secondary endpoints were reduction in liver inflammation, as measured by serum ALT levels and corrected T1 ("cT1"), and percent weight loss.

The population of the 12-week extension trial had similar baseline characteristics as the population of the parent, 12-week Phase 1b MASLD trial. At baseline, across all treatment groups, mean BMI was 36.7 kg/m^2 and mean LFC, as measured by MRI-PDFF, was 22.2%. Type 2 diabetes was present in 26.6% of subjects and 73.4% of study subjects were of Hispanic ethnicity.

The trial met its primary endpoint in all pemvidutide treatment groups. At the 1.8 mg and 2.4 mg doses, subjects receiving pemvidutide achieved mean relative reductions of liver fat content of 75.2% and 76.4%, respectively; 92.3% and 100% of subjects at the 1.8 mg and 2.4 mg doses, respectively, achieved a 30% reduction in liver fat, 84.6% and 72.7% of subjects, respectively, achieved a 50% reduction in liver fat, and 53.8% and 45.5% of subjects, respectively, achieved normalization of liver fat content to below 5%. As in the 12-week Phase 1b MASLD trial, statistically significant declines in mean serum ALT levels were observed in all pemvidutide-treated subjects, and in subjects with baseline serum ALT ≥30 IU/L, ALT levels declined at least 17 IU/L at all pemvidutide dose levels. In a subset of subjects evaluated for cT1 response, 75.0% and 100% of subjects receiving 1.8 mg or 2.4 mg pemvidutide, respectively, achieved an 80 millisecond (ms) decrease in cT1 relaxation time. cT1 is an MRI-based quantitative metric for assessing a composite of liver inflammation and fibrosis. Elevated cT1 relaxation times have been associated with increased risk of major adverse cardiac events ("MACE") and major adverse liver outcomes ("MALO"), and an 80 ms reduction has been associated with a 2-point reduction of NAFLD Activity Score ("NAS").

The trial also met its key secondary endpoint of weight loss in all pemvidutide treatment groups. Employing an efficacy estimand, mean weight losses of 7.2% (placebo-adjusted 6.0%) in subjects without diabetes and 6.2% (placebo-adjusted 4.8%) in all subjects were achieved at the 1.8 mg dose. A summary of the key primary and secondary efficacy findings is below:

Endpoint	**Treatment**			
	Placebo	**1.2 mg**	**1.8 mg**	**2.4 mg**
Primary Endpoint—Liver Fat Content	**n = 18**	**n = 14**	**n = 13**	**n = 11**
Liver fat reduction, absolute, % change, LSM (SE)	1.6 (0.8)	11.2 (2.3) ***	17.0 (2.4) ***	15.6 (2.1) ***
Liver fat reduction, relative, % change, LSM (SE)	14.0 (3.8)	56.3 (11.6) ***	75.2 (8.1) ***	76.4 (5.9) ***
Proportion of subjects with 30% reduction, (%)	5.6	76.9 ****	92.3 ****	100.0 ****
Proportion of subjects with 50% reduction, (%)	0.0	61.5 ***	84.6 ****	72.7 ****
Proportion of subjects with normalization, (%)	0.0	30.8 *	53.8 ***	45.5 **
Secondary Endpoint—Markers of Inflammation				
ALT, change from baseline, IU/L, LSM (SE)	**n = 19**	**n = 16**	**n = 15**	**n = 14**
	-2.2 (2.5)	-13.3 (3.7) **	-13.7 (5.1) **	-15.2 (5.8) **
ALT, change from baseline, IU/L, LSM (SE), baseline ≥ 30 IU/	**n = 13**	**n = 7**	**n = 10**	**n = 9**
	-3.1 (3.5)	-17.0 (7.6) *	-17.7 (7.2) *	-20.6 (9.8) *
Proportion of subjects with cT1 response, (%)	**n = 6**	**n = 7**	**n = 4**	**n = 2**
	0.0	85.7 **	75.0 *	100.0 *
Secondary Endpoint—Weight Loss				
Weight loss, no diabetes, (% change), LSM (SE)	**n = 14**	**n = 13**	**n = 9**	**n = 11**
	1.2 (0.7)	5.2 (1.7) **	7.2 (1.1) ***	5.8 (1.6) **
Weight loss, diabetes, (% change), LSM (SE) †	**n = 5**	**n = 3**	**n = 6**	**n = 3**
	3.4 (2.1)	4.3 (1.9)	5.3 (2.7)	3.5 (2.5)
Weight loss, all subjects, (% change), LSM (SE	**n = 19**	**n = 16**	**n = 15**	**n = 14**
	1.4 (0.7)	5.1 (1.4) **	6.2 (1.3) ***	5.2 (1.4) **

Normalization of liver fat defined as ≤ 5%; cT1 response define as an 80 ms change from baseline; LSM, least square mean
† High variability due to the small numbers of diabetic subjects (n = 5, 3, 6, 3 in respective treatment groups)
* p < .05; ** p < 0.01, *** p < 0.001, ****p < 0.0001 compared with placebo

Pemvidutide was generally well tolerated. A total of three serious or severe AEs were reported, each unrelated to study drug administration (chest pain post-elective cardiac stent placement; Salmonella infection; and hypertension greater than three weeks after the completion of treatment). Three AEs led to treatment discontinuation, one being the Salmonella infection, and mild (Grade 1) instances of abdominal pain AEs in two subjects, one (6.3%) at the 1.2 mg dose and one (6.7%) at the 1.8 mg dose. As expected, gastrointestinal events comprised the majority of AEs and were predominantly mild in nature. No clinically significant ALT elevations were observed. Meaningful reductions in systolic blood pressure were observed, and increases in heart rate, typical of the incretin class of agents, were minimal at 0 to 4 beats per minute and independent of dose. Below is a summary of the safety findings:

Characteristic		**Treatment**			
		Placebo (n = 19)	**1.2 mg (n=16)**	**1.8 mg (n=15)**	**2.4 mg (n=14)**
Serious or severe AEs	n (%)	1 (5.3%)	1 (6.3%)	1 (6.7%)	0 (0.0 %)
AEs leading to treatment discontinuation	n (%)	0 (0.0%)	2 (12.5%)	1 (6.7%)	0 (0.0 %)
Nausea	Mild, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)
	Moderate, n (%)	0 (0.0%)	0 (0.0%)	3 (20.0%)	0 (0.0%)
Vomiting	Mild, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Moderate, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Diarrhea	Mild, n (%)	1 (5.3%)	0 (0.0%)	1 (6.7%)	0 (0.0%)
	Moderate, n (%)	0 (0.0%)	1 (6.3%)	0 (0.0%)	0 (0.0%)
Constipation	Mild, n (%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	0 (0.0%)
	Moderate, n (%)	1 (5.3%)	1 (6.3%)	0 (0.0%)	0 (0.0%)
Systolic Blood Pressure, mm Hg, LSM (SE)		-2.3 (2.8)	-10.1 (4.2) *	-5.5 (3.7)	-12.0 (3.5) *
Diastolic Blood Pressure, mm Hg, LSM (SE)		-2.5 (1.5)	-2.9 (2.6)	-4.0 (3.7)	-3.8 (2.8)
Heart Rate, mmHg, LSM (SE)		-1.0 (1.7)	3.7 (1.8)	0.5 (2.8)	-0.1 (1.8)

*$p < .05$ compared with placebo.

As detailed in the table below, glycemic control was maintained in subjects with diabetes, all pemvidutide groups demonstrating trends toward improvements in fasting glucose and either maintaining or demonstrating trends toward improvement in HbA1c over the 24 weeks of treatment:

Characteristic	**Treatment**			
	Placebo	**1.2 mg**	**1.8 mg**	**2.4 mg**
Non-diabetes	**n = 14**	**n = 13**	**n = 9**	**n = 11**
Fasting glucose				
Baseline, mg/dL, mean (SD)	96.2 (12.4)	99.4 (11.9)	96.0 (12.4)	99.3 (13.6)
Week 24, mg/dL, mean (SD)	93.3 (12.1)	99.1 (13.1)	96.9 (12.5)	98.4 (24.5)
HbA1c				
Baseline, %, mean (SD)	5.8 (0.2)	5.7 (0.3)	5.7 (0.2)	5.5 (0.4)
Week 24, %, mean (SD)	5.7 (0.3)	5.8 (0.3)	5.8 (0.3)	5.6 (0.3)
Diabetes	**n = 5**	**n = 3**	**n = 6**	**n = 3**
Fasting glucose				
Baseline, mg/dL, mean (SD)	111.5 (19.2)	132.1 (28.2)	120.2 (37.1)	147.4 (40.4)
Week 24, mg/dL, mean (SD)	109.4 (14.8)	123.4 (50.8)	109.0 (13.1)	75.5 (29.0)
HbA1c				
Baseline, %, mean (SD)	6.1 (0.6)	7.8 (1.4	6.4 (0.5)	6.8 (1.3)
Week 24, %, mean (SD)	6.4 (1.1)	7.4 (2.3	6.4 (0.3)	6.3 (1.3)

Phase 1b Trial – 12-Week Type 2 Diabetes Safety Trial

In March 2023, we announced topline results from a 12-week Phase 1b safety trial of pemvidutide, which evaluated the safety profile of pemvidutide in subjects with overweight or obesity and type 2 diabetes. The trial was comprised of 54 subjects randomized 1:1:1:1 to 1.2 mg, 1.8 mg, 2.4 mg pemvidutide or placebo administered weekly for 12 weeks. No caloric restrictions or lifestyle interventions were employed. Subjects were required to be 18-65 years of age with BMI $\geq$ 28 kg/m^2 and type 2 diabetes on a stable regimen of diet and exercise, metformin with absent or mild GI symptoms, or SGLT-2 therapy for at least 3 months.

Subjects receiving pemvidutide achieved mean weight losses of 4.4%, 6.1% and 7.7% at the 1.2 mg, 1.8 mg, and 2.4 mg doses, respectively, over 12 weeks of treatment, with the placebo group experiencing a mean weight gain of 0.8% (efficacy estimand using MMRM analysis). Below is a summary of the efficacy findings:

Body weight		**Placebo (n=14)**	**1.2 mg (n=14)**	**1.8 mg (n=13)**	**2.4 mg (n=13)**
Δ Body weight, all subjects	%, LSM (SE)[1]	+0.8 (0.7)	-4.4 (1.1)***	-6.1 (1.6)***	-7.7 (1.4)***

[1] MMRM (mixed model for repeated measures), *** $p < 0.001$ compared with placebo

Glucose homeostasis was maintained throughout the 12 weeks of treatment, with no significant changes in fasting glucose or HbA1c and no hyperglycemic AEs. No SAEs were observed in patients treated with pemvidutide. Rates of GI AEs were low, and there were no AEs leading to study discontinuation. Below is a summary of the safety findings:

		Placebo (n=14)	1.2 mg (n=14)	1.8 mg (n=13)	2.4 mg (n=13)
Glycemic Control					
Fasting glucose					
Baseline, mg/dL	mean (SD)	140.9 (41.6)	132.6 (25.0)	124.9 (31.0)	128.2 (22.8)
Week 24, mg/dL	mean (SD)	140.4 (45.4)	132.0 (32.8)	126.2 (15.7)	140.6 (28.7)
HbA1c					
Baseline, %	mean (SD)	6.6 (1.3)	6.5 (1.0)	6.6 (0.7)	6.9 (0.7)
Week 24, %	mean (SD)	7.0 (1.4)	6.5 (0.5)	6.7 (0.8)	7.0 (0.6)
Adverse events (AEs)					
Serious AEs	n (%)	1 (7.1%)[2]	0 (0.0%)	0 (0.0%)	0 (0.0%)
Discontinuations due to AE	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hyperglycemia AEs	n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Gastrointestinal AEs					
Nausea AEs	Mild, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (15.4%)
	Moderate, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)
Vomiting AEs	Mild, n (%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	1 (7.7%)
	Moderate, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Diarrhea AEs	Mild, n (%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)
	Moderate, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Constipation AEs	Mild, n (%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	2 (15.4%)
	Moderate, n (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

[2] Cervical radiculopathy

MOMENTUM Phase 2 Obesity Trial – 48-Week Analysis

On November 30, 2023, we announced topline results from our 48-week MOMENTUM Phase 2 obesity trial of pemvidutide. The trial enrolled 391 subjects with obesity or overweight with at least one co-morbidity and without diabetes. Subjects were randomized 1:1:1:1 to 1.2 mg, 1.8 mg, 2.4 mg pemvidutide or placebo administered weekly for 48 weeks in conjunction with diet and exercise. The 1.2 mg and 1.8 mg doses were administered without dose titration, while a short 4-week titration period was employed for the 2.4 mg dose. Unlike other obesity studies with GLP-1 based agents, dose-reduction was not allowed. At baseline, subjects had a mean age of approximately 50 years, mean BMI of approximately 37 kg/m^2 and mean body weight of approximately 104 kg. Approximately 75% of subjects were female.

At Week 48, subjects receiving pemvidutide achieved mean weight losses of 10.3%, 11.2%, 15.6% at the 1.2 mg, 1.8 mg, and 2.4 mg doses, respectively, compared to weight loss of 2.2% for placebo. A near-linear trajectory of continued weight loss was observed on the 2.4 mg dose at the end of treatment. Over 50% of subjects achieved at least 15% weight loss and over 30% of subjects achieved at least 20% weight loss on the 2.4 mg dose. As in prior clinical trials, pemvidutide resulted in robust reductions in serum lipids and improvements in blood pressure without imbalances in cardiac events, arrhythmias or clinically meaningful increases in heart rate. Glucose homeostasis was maintained, with no significant changes in fasting glucose or HbA1c. Below is a summary of the efficacy findings:

Primary Endpoint: Body weight		**Placebo (N=97)**	**1.2 mg (N=98)**	**1.8 mg (N=99)**	**2.4 mg (N=97)**
Δ Body weight, all subjects	%, LSM (SE)[1]	-2.2 (1.4)	-10.3 (1.4)***	-11.2 (1.4)***	-15.6 (1.4)***

Responder Analyses		**Placebo (N=51)**	**1.2 mg (N=70)**	**1.8 mg (N=63)**	**2.4 mg (N=56)**
% Subjects w/ ≥5% weight loss	%[2]	17.6%	68.6%****	76.2%****	83.9%****
% Subjects w/ ≥10% weight loss		3.9%	42.9%****	49.2%****	71.4%****
% Subjects w/ ≥15% weight loss		2.0%	21.4%**	28.6%***	51.8%****
% Subjects w/ ≥20% weight loss		2.0%	10.0%	9.5%	32.1%****

Secondary Endpoints		**Placebo (N=50)**	**1.2 mg (N=69)**	**1.8 mg (N=58)**	**2.4 mg (N=55)**
Δ Total cholesterol	%, LSM (SE)[3]	-2.8 (2.0)	-11.6 (1.7)**	-13.1 (1.9)***	-15.1 (2.0)***
Δ LDL cholesterol		-2.8 (4.1)	-6.2 (3.5)	-11.2 (3.8)	-9.9 (3.9)
Δ Triglycerides		+7.3 (4.6)	-21.7 (3.9)***	-22.3 (4.3)***	-34.9 (4.4)***

Blood Pressure and Heart Rate		**Placebo (N=97)**	**1.2 mg (N=98)**	**1.8 mg (N=99)**	**2.4 mg (N=97)**
Δ Systolic BP	mm Hg, LSM (SE)[1]	+3.5 (2.3)	-2.3 (2.2)	-1.6 (2.2)	-4.6 (2.3)
Δ Diastolic BP		+1.8 (1.4)	-2.1 (1.3)	-1.0 (1.3)	-2.9 (1.4)
Δ Heart rate	bpm, LSM (SE)[1]	-1.4 (1.6)	0.1 (1.5)	3.1 (1.5)	2.5 (1.6)

[1]MMRM, [2]CMH (Cochran Mantel Haenszel), [3]ANCOVA (analysis of covariance)

*p < .05; ** p < 0.05, *** p < 0.001, ****p < 0.0001 compared with placebo

More subjects receiving pemvidutide stayed on study compared to those receiving placebo, with 74.1% of pemvidutide subjects completing the trial compared to 61.9% of placebo subjects. Nausea and vomiting comprised the majority of AEs, which were predominantly mild to moderate in severity. Only one subject experienced a drug-related SAE, a case of vomiting at the 2.4 mg dose. Rates of AEs leading to treatment discontinuation were 6.2% in subjects receiving placebo and 5.1%, 19.2%, and 19.6% in subjects receiving 1.2 mg, 1.8 mg and 2.4 mg of pemvidutide, respectively. Study discontinuations related to study drug occurred in 2.1% of placebo subjects and 4.1%, 16.2% and 15.5% in subjects receiving 1.2 mg, 1.8 mg and 2.4 mg of pemvidutide, respectively, with most discontinuations due to AEs in the pemvidutide groups occurring in the first 16 weeks of treatment. No AEs of special interest or MACE were observed, and there were low rates of cardiac AEs, including arrhythmias, with no imbalance across pemvidutide or placebo groups. Below is a summary of the safety findings:

Adverse events (AEs)		Placebo (N=97)	1.2 mg (N=98)	1.8 mg (N=99)	2.4 mg (N=97)
SAEs related to study drug	N (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.0%)[4]
All AEs leading to discontinuation	N (%)	6 (6.2%)	5 (5.1%)	19 (19.2%)	19 (19.6%)
Drug-related AEs leading to discontinuation	N (%)	2 (2.1%)	4 (4.1%)	16 (16.2%)	15 (15.5%)
Gastrointestinal AEs—mainly mild to moderate					
Nausea	N (%)	11 (11.3%)	25 (25.5%)	59 (59.6%)	50 (51.5%)
Vomiting	N (%)	3 (3.1%)	6 (6.1%)	27 (27.3%)	27 (27.8%)
Diarrhea	N (%)	5 (5.2%)	8 (8.2%)	10 (10.1%)	18 (18.6%)
Constipation	N (%)	8 (8.2%)	17 (17.3%)	13 (13.1%)	22 (22.7%)
MACE	N (%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cardiac AEs including arrhythmias	N (%)	4 (4.1%)	3 (3.1%)	4 (4.0%)	3 (3.1%)

[4] Vomiting

Summary of Glycemic Control		Placebo (N=50)	1.2 mg (N=68)	1.8 mg (N=58)	2.4 mg (N=55)
Fasting glucose					
Baseline, mg/dL	mean (SE)	95.5 (1.5)	99.4 (1.4)	101.6 (1.4)	101.5 (1.6)
Week 48, mg/dL	mean (SE)	95.2 (1.5)	98.6 (1.7)	100.6 (1.6)	99.4 (2.0)
HbA1c					
Baseline, %	mean (SE)	5.6 (0.0)	5.5 (0.0)	5.5 (0.1)	5.6 (0.0)
Week 48, %	mean (SE)	5.5 (0.0)	5.5 (0.0)	5.6 (0.1)	5.5 (0.1)

Clinical Development Plan

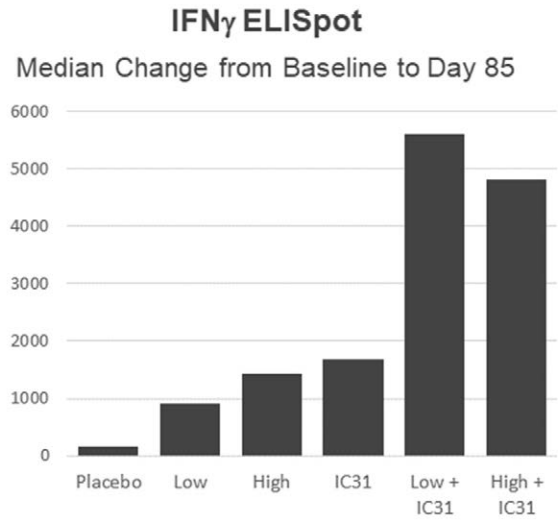
In August 2023 we initiated a 48-week Phase 2b trial, IMPACT, to evaluate the safety and efficacy of pemvidutide in subjects with MASH. The biopsy-driven trial is expected to enroll approximately 190 subjects with and without diabetes randomized 1:2:2 to receive 1.2 mg, 1.8 mg pemvidutide or placebo weekly for 48 weeks. The key efficacy endpoints are MASH resolution and fibrosis improvement after 24 weeks of treatment, with subjects to be followed for an additional 24 weeks to a total of 48 weeks for assessment of safety and additional biomarker responses. Top-line 24-week results from this trial are expected in the first quarter of 2025.

HepTcell

HepTcell is an immunotherapeutic product candidate for patients chronically infected with the hepatitis B virus ("HBV"). Approximately 300 million people worldwide live with chronic HBV infection, including approximately 2.4 million in the United States. Chronic HBV infection can lead to serious complications, including cirrhosis and liver cancer. Approximately 820,000 people die per year worldwide due to cirrhosis and liver cancer. Current antivirals prevent disease progression but rarely clear chronic infection. HepTcell is designed to drive CD4+ and CD8+ T-cell responses against all HBV genotypes in patients of all ethnic backgrounds. Stimulating T-cell responses in chronically infected HBV patients has been challenging because chronic infection with HBV strongly suppresses T-cell immunity directed against the virus. HepTcell focuses the T cell response on discrete, highly conserved regions of the HBV proteome. We believe our approach allows HepTcell to break immune tolerance by activating T-cells against critical viral sequences with decreased probability of immune escape due to viral mutation. HepTcell is based on our synthetic peptide technology platform and is given by intramuscular injection. In 2018, we completed a Phase 1 trial in the United Kingdom and South Korea in adult patients with chronic HBV. The HepTcell Phase 1 trial was a double-blinded, placebo-controlled, randomized, dose-escalation

study that enrolled 61 subjects with chronic HBV who were HBeAg-negative and well-controlled on licensed antivirals. A total of 41 patients received one of two dose levels of HepTcell, with and without IC31®, a depot-forming TLR9 adjuvant developed by Valneva SE, while 20 control patients received either IC31® alone or placebo. Patients received three injections 28 days apart and were followed for six months after the final dose. All dose combinations were generally well-tolerated and met the primary endpoint of safety. In the two adjuvanted HepTcell arms, T-cell responses against HBV markedly increased over baseline compared to placebo.

The chart below presents the immunogenicity against hepatitis B epitopes that was demonstrated in our Phase 1 clinical trial:



We initiated a Phase 2 trial during the fourth quarter of 2020 in the United States, Canada, Europe and Asia that is a double-blind, randomized, placebo-controlled study of 80 adult patients with HBeAg-negative inactive CHB and HBsAg ≤ 200 IU/mL Patients with approximately low HBsAg are more likely to mount effective T cell responses against HBV than those with higher levels. The rationale for the study design is based in our understanding that HepTcell could be used in combination with newer, direct acting agents that may be more effective than the current nucleosides analogs in reducing HBsAg to this level. Accordingly, selection of patients with HBsAg levels ≤ 200 IU/mL may mimic the eventual combination of HepTcell with the newer antiviral drugs in development. HepTcell was being administered in six doses at the low dose level of HepTcell plus IC31® at 4-week intervals for 24 weeks, and patients will be followed for one year to evaluate safety and durability of response. The primary efficacy endpoint is virological response, defined as a 1-log reduction in HBsAg levels from baseline or HBsAg clearance at 24 weeks. Secondary efficacy endpoints include reactivation of anti-HBV T cell responses and other assessments of virologic response. Enrollment in this trial was completed in April 2023.

On March 27, 2024, we announced that the overall response in the Phase 2 trial was deemed to be insufficient to warrant further advancement in clinical trials. As a result, we have stopped any further development related to HepTcell.

Our Strategy

Key elements of our strategy include the following:

- Strategically partner or out-license certain product candidates at later stages of development to focus our efforts on early to mid-stage product development;

- In-license or acquire complementary metabolic or immunotherapeutic technologies and product candidates that are either synergistic or complementary to our capabilities to expand our pipeline; and

- Apply our EuPort platform technologies to design and develop treatments for obesity, MASH and other metabolic diseases.

Our Technology Platforms

Certain product candidates are based on our proprietary platform technologies as described below:

EuPort-based Peptide Technology

EuPort is a platform technology that comprises a hydrophobic domain (e.g., substituted or unsubstituted alkyl chain) and a hydrophilic group (e.g., saccharide) conjugated to a non-terminal amino acid of the peptide. The technology, on which pemvidutide is based, allows the peptide to bind extensively to albumin, an abundant protein in the blood, slowing the elimination of the peptide and increasing its serum half-life, allowing for weekly instead of daily dosing, for example. EuPort technology may also slow the entry of the peptide into the circulation following subcutaneous injection which may lead to improvements in tolerability, cardiovascular risk and other characteristics of the peptide as have been observed with pemvidutide. We have license rights to develop oxynomodulin (GLP1/glucagon dual receptor agonist)-based peptide therapeutics based on EuPort technology for any indication.

Key aspects of our EuPort technology, supported by findings in our preclinical studies and clinical trials, include its potential to:

- increase the serum half-life of the peptide allowing for extended dosing intervals; and

- slow the entry of the peptide into the circulation, decreasing the Cmax (maximal concentration) increasing the Tmax (time to maximal concentration) of the peptide, and potentially improving the tolerability of the peptide and preventing the increases in heart rate that have been observed with other agents.

Synthetic Peptide Technology - Densigen

Densigen is our synthetic fluorocarbon peptide technology platform. HepTcell, an immunotherapeutic developed using our Densigen platform, is designed to activate T-cells to generate a cytotoxic immune response against intracellular pathogens. This synthetic peptide technology is based on peptides of 30 – 40 amino acids that comprise a high density of CD4 and CD8 T-cell epitopes selected to focus the T-cell response on highly conserved targets and allow diverse populations to respond to the product candidate. Densigen technology is protected by patents owned by us.

Key aspects of our Densigen technology, supported by findings in our preclinical studies and clinical trials, include its potential to:

- elicit responses across multiple targets for the disease;

- direct an immune response precisely to specific antigen sites, thereby avoiding more reactive but less effective sites present in the full-length protein; and

- prompt a stronger immune response than naked peptides due to depot effect caused by attaching a biologically inert fluorocarbon chain to each peptide.

Competition

The biopharmaceutical industry is intensely competitive and is characterized by rapid technological progress. In general, competition among pharmaceutical products is based in part on product efficacy, safety, reliability, availability, price and patent position. An important factor is the relative timing of the market introduction of our products and our competitors' products. Accordingly, the speed with which we can develop products, complete the clinical trials and approval processes and supply commercial quantities of the products to the market is an important competitive factor. Our competitive position also depends upon our ability to show differentiation with a product that is either more efficacious, particularly in the relevant target populations, offers a better safety or tolerability profile, is less expensive or quicker to manufacture, or represents a combination of these advantages. We also depend upon our ability to attract and retain

qualified personnel, obtain patent protection or otherwise develop proprietary products or processes and secure sufficient capital resources for the often substantial period between technological conception and commercial sale.

Large and established companies such as Eli Lilly, Roche through its acquisition of Carmot and D&D Pharma, Novo Nordisk, Pfizer, AstraZeneca, Amgen, Boehringer Ingelheim and Merck, among others, compete in the same market as our product candidates. These companies compete with us with their greater experience and resources to support their research and development efforts, conduct testing and clinical trials, obtain regulatory approvals to market products, manufacture such products on a broad scale and market approved products. These companies also compete with us by having 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 have 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 products that we develop obsolete. We also face competition from smaller companies who, like us, rely on investors to fund research and development and compete for co-development and licensing opportunities from large and established pharmaceutical companies.

We face competition for pemvidutide, our dual GLP-1/glucagon dual agonist for the treatment of obesity and MASH. For obesity, we face competition from companies such as Novo Nordisk, whose GLP-1 agonist, brand named Wegovy, or compound name semaglutide, was approved for weight loss in June 2021. Other companies with potentially competitive products or product candidates, include Eli Lilly with GLP-1/glucose-dependent insulinotropic polypeptide receptor ("GIP") dual agonists, including Zepbound, or compound name tirzepatide, approved for obesity in November 2023; Boehringer Ingelheim, AstraZeneca, Innovent Biologics/Eli Lilly, and Roche through its acquisition of Carmot and D&D Pharma, with GLP-1/glucagon receptor dual agonists; Hanmi Pharmaceutical and Eli Lilly with GLP-1/glucagon/GIP triple agonists; Amgen with its GLP-1 agonist/GIP antagonist antibody; and Novo Nordisk with Amylin and Amylin-GLP-1 combination candidates. Other companies have been developing oral candidates for the treatment of obesity with GLP-1 monoagonist or GLP-1/GIP dual receptor agonists including Pfizer, Lilly, Structure Therapeutics, AstraZeneca through its acquisition of Eccogene and Roche through its acquisition of Carmot. In addition, Novo Nordisk has an FDA-approved oral GLP-1 therapy, Rybelsus or compound name semaglutide. We face competition in MASH from companies such as Madrigal Pharmaceuticals, Terns, Aligos and Viking Therapeutics, which are developing orally administered, thyroid hormone receptor ("THR") β-selective agonist; Akero Therapeutics, 89Bio, Novo Nordisk and Boston Pharmaceuticals, which are developing fibroblast growth factor 21 ("FGF-21") analogs; Novo Nordisk, which is developing a GLP-1 agonist; Merck/Hanmi Pharmaceutical, which is developing a GLP-1/glucagon dual agonist, Eli Lilly, which is developing a GLP-1/GIP dual agonist, Inventiva, which is developing a pan-peroxisome proliferator-activated receptor ("PPAR") agonist; Sagimet which is developing a fatty acid synthetase inhibitor, HEC Pharma which is developing a GLP-1/FGF-21dual agonist; and Pfizer and Eli Lilly, which are developing small molecule GLP-1 agonists. In addition, many other small companies are developing other new technologies directed towards obesity or MASH.

Intellectual Property

We generally seek patent protection for our technology and product candidates in the United States and abroad. The patent coverage available to biotechnology companies is generally uncertain because it involves complex legal and factual considerations. Our success will depend, in part, on whether we can:

- obtain patents to protect our own technologies and product candidates;
- obtain licenses to use the technologies of third parties, which may be protected by patents;
- protect our trade secrets and know-how; and
- operate without infringing the intellectual property and proprietary rights of others.

We have relied upon certain proprietary trade secrets, know-how and continuing technological advances to develop a competitive position. In efforts to maintain confidentiality and ownership of trade secrets, proprietary information and developments, all of our employees are required to execute agreements regarding confidentiality and assign to us all rights to any inventions and processes they develop while they are employed by us. We may in the future

use license agreements to access external products and technologies as well as to convey our own intellectual property to others. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets.

Patent Rights Related to our EuPort Platform Technology

EuPort Technology — In-Licensed from Mederis Diabetes, LLC

Pursuant to a license agreement between the Company and Mederis Diabetes, LLC ("Mederis") (the "Mederis IP License Agreement"), we are the exclusive licensee of patent rights owned by Mederis to develop and commercialize surfactant functionalized ("EuPort domain") incretin-based peptide therapeutics, including (GLP-1-glucagon)/oxyntomodulin, and variants thereof, including pemvidutide, for any indication, and Mederis has certain patent rights granted back to it for the use of the EuPort technology outside of the Company's exclusive field of incretin-based peptide therapeutics. The EuPort domain comprises a hydrophobic domain (e.g., substituted or unsubstituted alkyl chain) and a hydrophilic group (e.g., saccharide) conjugated to a non-terminal amino acid of the peptide. Patents under Mederis IP License Agreement have been granted in the United States, Japan and Korea, and applications are pending in the United States, Japan as well as other commercially relevant jurisdictions. The claims are directed to peptides (at least four amino acids in length), including peptides that bind receptors for glucagon and/or GLP-1, conjugated to an alkyl saccharide surfactant, including an alkyl glycoside surfactant. The patents and, if issued, the patent(s) resulting from the pending application(s) have an expiration date of no earlier than May 2032, not giving effect to any potential extensions and assuming payment of all associated fees. Patents subject to the Mederis IP License Agreement have also been granted in the United States, Canada, Europe, Korea, Australia, Israel and Japan, and applications are pending in the United States, Europe, Japan, China and other commercially relevant jurisdictions, wherein the claims are directed to specific GLP-1 and/or glucagon peptides conjugated to the EuPort domain. The patents and, if issued, the patent(s) resulting from the pending application(s) have an expiration date of no earlier than May 2035.

Patent Rights Related to our Densigen Platform Technology

Fluorocarbon Antigen Delivery Vectors

We are developing a fluorocarbon antigen construct platform technology. Our patents covering this technology are issued in the United States, China, Japan and certain European countries, including the United Kingdom, Germany and France. Additional patents are issued in other commercially relevant jurisdictions and an application is pending in the United States. The claims are directed to the fluorocarbon linked antigen construct, compositions comprising the construct and methods of using the construct to stimulate an immune response. The patents and, if issued, the patent(s) resulting from the pending patent applications, are expected to have an expiration date no earlier than April 2025, not giving effect to any potential extensions and assuming payment of all associated fees.

Formulation of Antigen Delivery Vectors — Manufacturing Process for the Final Formulation of the Antigen Delivery Vectors

We are developing a manufacturing process for solubilizing certain fluorocarbon peptides and final lyophilized compositions thereof that are soluble in an aqueous solution, for which we have patents issued in the United States, Europe, Korea and Japan as well as other commercially relevant jurisdictions, and a patent application pending in the United States. The claims are directed to methods of solubilizing certain fluorocarbon antigen peptides using acetic acid formulations and manufactured lyophilized compositions thereof that are soluble in an aqueous solution. The patents and, if issued, the patent(s) resulting from the pending patent applications, are expected to have an expiration date no earlier than December 2031, not giving effect to any potential extensions and assuming payment of all associated fees.

Patent Rights Related to our Product Candidates

Pemvidutide, Dual GLP-1/Glucagon Dual Agonist for Obesity and MASH

We are the exclusive licensee of patent rights owned by Mederis to develop and commercialize surfactant functionalized (GLP-1-glucagon)/oxyntomodulin-based peptide therapeutics, and variants thereof, including pemvidutide, for any use including the treatment of obesity, metabolic syndrome, insulin resistance, diabetes and cardiovascular disease.

Patents under the Mederis IP License Agreement have been granted in the United States, Europe, Japan, Australia and Mexico with pending applications in the United States, Europe, Japan and Korea, as well as other commercially relevant jurisdictions. The claims are directed to GLP-1/glucagon dual agonist peptides conjugated to a surfactant and their use to treat metabolic syndrome, obesity and other related diseases. The patents and, if issued, the patent(s) resulting from the pending application(s) have an expiration date of no earlier than May 2032 and extending to May 2035, not giving effect to any potential extensions and assuming payment of all associated fees. Use of pemvidutide for treating MASH or MASLD (referred to as NASH or NAFLD in the patent and patent applications) is further covered by, and subject to the Mederis IP License Agreement, with a granted patent in the United States, and pending applications in the United States, Europe, Japan and other commercially relevant jurisdictions. The patents and, if issued, the patent(s) resulting from the pending patent applications, are expected to have an expiration date of no earlier than January 2039, not giving effect to any potential extensions and assuming payment of all associated fees.

Use of pemvidutide in methods with improved tolerability, dosing and therapeutic regimens is further covered in pending applications in the United States, Europe, Japan and Korea, as well as other commercially relevant jurisdictions, which are owned by us and not subject to the Mederis IP License Agreement. The claims are directed to liquid formulations and the use of pemvidutide in a therapeutic dosing regimen with improved tolerability. If issued, the patent(s) resulting from the pending application(s) have an expiration date of no earlier than February 2041 not giving effect to any potential extensions and assuming payment of all associated fees.

Use of pemvidutide in methods for inducing weight loss is further covered in pending applications in the United States, Europe, Japan and Korea, as well as other commercially relevant jurisdictions owned by us and not subject to the Mederis IP License Agreement. The claims are directed to the use of pemvidutide in a therapeutic dosing regimen for chronic weight management. If issued, the patent(s) resulting from the pending application(s) have an expiration date of no earlier than December 2041, not giving effect to any potential extensions and assuming payment of all associated fees.

Use of pemvidutide in methods for reducing body weight in a human with fatty liver disease is further covered in United States patent application and corresponding international (PCT) patent application owned by us and not subject to the Mederis IP License Agreement, and from which we expect to file National Phase patent applications in commercially relevant jurisdictions. The claims are directed to the use of pemvidutide in methods for reducing body weight in a human with MASH or MASLD (referred to as NASH or NAFLD in the patent and patent applications), with or without also having type II diabetes. If issued, the patent(s) resulting from the pending application(s) have an expiration date of no earlier than September 2043, not giving effect to any potential extensions and assuming payment of all associated fees.

Use of pemvidutide in methods for reducing the risk of cardiovascular (CV) disease is further covered in a United States patent application and corresponding international (PCT) patent application owned by us and not subject to the Mederis IP License Agreement, and from which we expect to file National Phase patent applications in commercially relevant jurisdictions. The claims are directed to the use of pemvidutide in methods for reducing the risk of cardiovascular (CV) disease in a human with or without also having type 2 diabetes. If issued, the patent(s) resulting from the pending application(s) have an expiration date of no earlier than November 2043, not giving effect to any potential extensions and assuming payment of all associated fees.

HepTcell, Chronic Hepatitis B Immunotherapy

We have issued patents for HBV immunotherapy technology directed to compositions comprising fluorocarbon constructs with specific peptide HBV antigen sequences in the United States, Europe, Japan and Korea, and pending applications in the United States, Europe, Japan and China, as well as other commercially relevant jurisdictions. The claims are directed to HBV antigen peptide sequences comprising T-cell epitopes linked to fluorocarbon chains and compositions comprising a combination of HBV antigen peptide sequences. The patents, and if issued, the patent(s) resulting from the pending patent applications, are expected to have an expiration date no earlier than December 2033, not giving effect to any potential extensions and assuming payment of all associated fees. HepTcell is also covered by the patents and patent applications relating to our Densigen platform technology.

Use of HepTcell for treating patients with chronic HBV infection is further covered by a pending United States provisional patent application, from which we expect to file United States and international (PCT) patent applications. The claims are directed to treating patients with chronic HBV infection characterized with low hepatitis B surface antigen

("HBsAg"). If issued, the patent(s) resulting from the pending patent application(s) are expected to have an expiration date no earlier than December 2044, not giving effect to any potential extensions and assuming payment of all associated fees.

United States Government Regulation

The FDA regulates drugs and biological products under the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), the Public Health Service Act ("PHS Act"), the regulations under Titles 21 and 42 of the Code of Federal Regulations (21 CFR and 42 CFR), as well as other federal, state and local statutes and regulations. The FD&C Act and the PHS Act and their corresponding regulations govern, among other things, the testing, research, manufacturing, approval, safety, efficacy, labeling, packaging, storage, record keeping, distribution, import, export, reporting, sale, advertising and other promotional practices involving drugs and biological products. An IND application must be in effect before clinical testing of drugs and biological products can begin. FDA approval must be obtained before drugs and biological products can be marketed. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources, and each process may take several years to complete, although certain expedited programs potentially applicable to our product candidates, such as FDA fast track designation for certain new drugs with the potential to address unmet medical needs for certain serious or life-threatening conditions, may potentially expedite development and/or approval processes. Certain federal incentive programs are also potentially applicable to our product candidates, such as for "orphan drugs" that treat rare conditions. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all, and we may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our product candidates. In addition, the FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application of the products. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval. In addition, our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could adversely affect our ability to commercialize our product candidates.

Drug and Biological Products Development Process

The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies according to applicable good laboratory practices ("GLP"), applicable requirements for the humane use of laboratory animals, such as the Animal Welfare Act or other applicable regulations;

- submission to the FDA of an application for an IND which must become effective before human clinical trials may begin;

- obtaining approval by an independent Institutional Review Board ("IRB") at each clinical site before a clinical trial may be initiated at that site;

- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices ("GCP") and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed product for its intended use;

- submission to the FDA of a new drug application ("NDA") or biologics license application ("BLA") for marketing approval that includes substantial evidence of safety, purity and potency from results of clinical trials, as well as the results of preclinical testing, detailed information about the chemistry, manufacturing and controls, and proposed labeling and packaging for the product candidate;

- review of the product candidate by an FDA advisory committee, if applicable;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product candidate is produced to assess compliance with cGMP and to confirm that the facilities, methods and controls are adequate to assure the product candidate's identity, strength, quality and purity;

- satisfactory completion of potential FDA audits of the preclinical study and clinical trial sites that generated the data in support of the NDA or BLA; and

- FDA review and approval, or licensure, of the NDA or BLA, including agreement on post-marketing commitments, if applicable.

Before testing any drug or biological product candidate in humans, the product candidate enters the preclinical study stage. Preclinical studies include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of certain preclinical studies must comply with federal regulations and requirements including GLP and the Animal Welfare Act.

The clinical trial sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical trial protocol, to the FDA as part of the IND. Some preclinical studies may continue even after the IND is submitted. The FDA requires a 30-day waiting period after the filing of each IND before clinical trials may begin. The FDA may also place the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Even after the IND has gone into effect and clinical testing has begun, the FDA may impose a partial or complete clinical hold on clinical trials due to safety concerns or non-compliance. A partial clinical hold can limit a trial, for example, to certain doses or for a certain length of time or to a certain number of subjects. A complete clinical hold order issued by the FDA would delay a proposed clinical study or suspend an ongoing study until all outstanding concerns have been adequately addressed and the FDA has notified the company that clinical investigations may proceed or resume. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once the trials have begun, issues will not arise that suspend or terminate such studies.

Clinical trials involve the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events ("AEs") should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND during applicable phases of development. Clinical trials must be conducted and monitored in accordance with the FDA's regulations and GCP requirements, which establish standards for conducting, recording data from, and reporting the results of clinical trials, with the goals of assuring that the data and results are credible and accurate and that study participants' rights, safety, and well-being are protected. GCP requirements include the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials, not only from the investigational product itself but also from any required procedures or study visits to be conducted during the trial, are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1*. The drug or biological product is initially introduced into a small group of healthy human subjects (e.g., 10 to 20 volunteers) and tested for safety and to develop detailed profiles of its pharmacological and pharmacokinetic actions, determine side effects associated with increasing doses, and, if possible, gain early evidence of effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

- *Phase 2*. The drug or biological product is evaluated in a larger but limited patient population (e.g., a few hundred patients with the disease or conduction under study) to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

- *Phase 3*. These clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency and safety in an expanded patient population (e.g., several hundred to several thousand patients) at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit profile of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected AEs, any findings from other studies, tests in laboratory animals or in vitro testing and other sources that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within 7 calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biological product has been associated with unexpected serious harm to patients.

In limited circumstances, FDA also permits the administration of investigational small molecule drug or biological products to patients under its expanded access regulatory authorities. Under the FDA's expanded access authority, patients who are not able to participate in a clinical trial may be eligible for accessing investigational products, including through individual compassionate or emergency use in concert with their requesting physician.

Concurrent with clinical trials, companies usually complete additional animal studies, develop additional information about the physical characteristics of the drug or biological product candidate and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHS Act emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Certain FDA programs are available to facilitate and expedite the development and review of new drugs intended to address unmet needs in the treatment of serious or life-threatening conditions. These expedited programs include fast track designation, breakthrough therapy designation, priority review and accelerated approval. Each of these programs has its own features and qualifying criteria. A sponsor must submit a request for fast track designation, breakthrough therapy designation, or priority review, which may or may not be granted by the FDA. For fast track and breakthrough therapy designations, FDA may later decide the product no longer meets the conditions for designation and may rescind the designation. For accelerated approval, a sponsor generally discusses the possibility of accelerated approval with the FDA during development, and the FDA may or may not agree that accelerated approval is an appropriate pathway for a particular drug. Some of these expedited programs could potentially apply to our product candidates, although this cannot be assured, and we do not currently have any products with expedited program designations.

The sponsor of a clinical trial or the sponsor's designated responsible party may be required to register certain information about the trial and disclose certain results on government or independent registry websites, such as ClinicalTrials.gov. Additionally, a manufacturer of an investigational drug for a serious disease or condition is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational drug. This requirement applies on the earlier of the first initiation of a Phase 2 or Phase 3 trial of the investigational drug or, as applicable, 15 days after the drug receives a designation as a breakthrough therapy, fast track product, or regenerative medicine advanced therapy.

Review and Approval Processes

After the completion of clinical trials of a drug or biological product candidate, the FDA's approval of an NDA or BLA must be obtained before commercial marketing of the product may begin. The NDA or BLA must include results of product development, laboratory and animal studies, human studies, information on the manufacture and composition of the product, proposed labeling and other relevant information. In addition, under the Pediatric Research Equity Act, as amended, an NDA or BLA or supplement to an NDA or BLA generally must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers depending on the designated pathway for submission. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the NDA or BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act ("PDUFA"), as amended, each NDA or BLA must be accompanied by a significant application fee. PDUFA also imposes an annual prescription drug product program fee for biologics. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business.

Following submission of the application, the FDA reviews the NDA or BLA to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any NDA or BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the NDA or BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the NDA or BLA. FDA performance goals generally provide for action on an NDA or BLA within 10 months of the 60-day filing date, which would be within 12 months of its submission. That deadline can be extended under certain circumstances, including by the FDA's requests for additional information. The targeted action date can also be shortened to 6 months of the 60-day filing date, or 8 months after submission, for products that are granted priority review designation because they are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. The FDA reviews the NDA or BLA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure the product's identity, safety, quality, potency and purity. The FDA may refer applications for drugs or biological products that are novel or that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

During the NDA or BLA review process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy ("REMS") is necessary to assure the safe use of the drug or biological product. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS; the FDA will not approve the NDA or BLA without a REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products.

Before approving an NDA or BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the NDA or BLA unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required

specifications. Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND study requirements and GCP requirements. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the NDA or BLA does not satisfy its regulatory criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than how we interpret the same data. If the agency decides not to approve the NDA or BLA in its present form, the FDA will issue a complete response letter that usually describes all of the specific deficiencies in the NDA or BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes; or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant may take for the FDA to reconsider the application. If a complete response letter is issued, the applicant may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the complete response letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a REMS, or otherwise limit the scope of any approval. In addition, the FDA may require post-marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized. Post-approval modifications to a drug product, such as changes in indications, labeling or manufacturing processes or facilities, may require development and submission of additional information or data in a new or supplemental NDA or BLA, which would also require prior FDA approval.

Post-Approval Requirements

After regulatory approval of a product is obtained, products are subject to extensive continuing regulation and post-approval requirements. For example, as a condition of approval of an NDA or BLA, the FDA may require post-marketing testing and surveillance to monitor the product's safety or efficacy. In addition, holders of an approved NDA or BLA are required to keep extensive records, submit annual reports, report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information, and comply with requirements concerning advertising and promotional labeling for their products. Also, quality control and manufacturing procedures must continue to conform to cGMP regulations and practices, as well as the manufacturing conditions of approval set forth in the NDA or BLA. Drug manufacturers and their subcontractors and those supplying products, ingredients, and components are required to register their establishments with the FDA and certain state agencies, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes certain procedural, substantive and recordkeeping requirements. Manufacturers and other parties involved in the drug supply chain for prescription drug products also must comply with product tracking and tracing requirements and notify the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. If, after receiving approval, a company makes a material change in manufacturing equipment, location, or process (all of which are, to some degree, incorporated in the NDA or BLA), additional regulatory review and approval may be required.

Future FDA inspections may identify cGMP compliance issues at manufacturer facilities or at the facilities of third-party suppliers that may disrupt production or distribution or require substantial resources to correct and prevent recurrence of any deficiencies, and could result in fines or penalties by regulatory authorities. In addition, discovery of problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA or BLA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action, including warning letters, fines, injunctions, civil penalties, license revocations, seizure, total or partial suspension of production or criminal penalties, any of which could delay or prohibit further marketing. Newly discovered or developed safety or efficacy data may require changes to a product's approved labeling, including the addition of new warnings and contraindications.

Certain U.S. Regulatory Incentives and Other Programs

Marketing Exclusivity and Patent Term Restoration

The Drug Price Competition and Patent Term Restoration Act of 1984, also referred to as the Hatch-Waxman Amendments, established certain periods of marketing exclusivity for new drugs approved by the FDA, including a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application ("ANDA") or a 505(b)(2) NDA submitted by another applicant for such drug where the applicant does not own or have a right of reference to the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The Hatch-Waxman Amendment also established a three-year period of marketing exclusivity for an NDA, 505(b)(2) NDA, or supplement to an NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application (e.g., new indications, dosages or strengths of an approved drug). This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the active ingredient for other conditions of use.

For biological products, the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") created an abbreviated regulatory approval pathway in the United States for biological products that are found to be "biosimilar" to (and in some instances "interchangeable" with) a biological "reference product" previously licensed under an NDA or BLA. This abbreviated approval pathway is intended to permit a biosimilar to come to market more quickly and less expensively by relying to some extent on the data generated by the reference product's sponsor and the FDA's previous review and approval of the reference product. Under the BPCIA, a biosimilar sponsor's ability to seek or obtain approval through the abbreviated pathway is limited by periods of exclusivity granted by the FDA to the holder of the reference product's NDA or BLA. In general, no biosimilar application may be accepted by the FDA for review until 4 years after the date the reference product was first licensed by the FDA, and no biosimilar application, once accepted, may receive final approval until 12 years after the reference product was first licensed by the FDA.

Although we would expect to be granted this 12-year period of exclusivity for our applicable product candidates, if approved, this period of reference product market exclusivity applies only to the biosimilar pathway and will not, for example, provide protection against any biological product for a similar indication that achieves FDA approval under a traditional NDA or BLA based on the sponsor's own research data. There is also risk that the 12-year period of biological reference product exclusivity could be shortened due to congressional action, or that the FDA will not consider our product candidates, if they are approved, to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Once approved, biosimilars likely would compete with, and in some circumstances may be deemed under the law to be interchangeable with, the previously approved reference product. The extent to which a biosimilar, once approved, would be substituted for any one of our product candidates, if approved, in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. Given this uncertainty, there is risk that, if approved, a biosimilar competitor to one of our products could have an adverse impact on our business. In particular, a biosimilar could be significantly less costly to bring to market and priced significantly lower than our product, if approved by the FDA.

Additionally, products approved under an NDA or BLA may qualify for the restoration of a portion of the patent term lost during product development and FDA review of the application, if approval of the application is the first permitted commercial marketing of a drug containing the active ingredient. The patent term restoration period is generally one-half the time between the effective date of the IND or the date of patent grant (whichever is later) and the date of submission of the NDA or BLA, plus the time between the date of submission of the NDA or BLA and the date of FDA approval of the product. The maximum period of restoration is five years, and the patent cannot be extended to more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The USPTO, in consultation with the FDA, reviews and approves the application for patent term restoration.

Pediatric Exclusivity

Drugs and biological products, such as our product candidates, may be eligible for pediatric exclusivity, an incentive intended to encourage medical product research for children. Pediatric exclusivity, if granted, may add six months to certain patents or regulatory exclusivity periods applicable to an approved drug and six months to regulatory exclusivity periods applicable to an approved biological product. This additional six months of exclusivity may be granted based on the completion of one or more pediatric trials in response to a Written Request from the FDA. It is possible, but not assured, that certain of our current or future product candidates may be targeted to pediatric populations.

Orphan Drug Designation

The FDA may grant orphan drug designation to drugs intended to treat a "rare disease or condition" that affects fewer than 200,000 individuals in the United States, or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such a disease or condition will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation can provide opportunities for grant funding toward clinical trial costs, tax advantages and FDA user fee exemptions. In addition, if a product that has an orphan drug designation subsequently receives FDA approval for the indication for which it has such designation, the product may be entitled to orphan drug exclusivity, which means the FDA would not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. It is possible, but not assured, that certain of our current or future product candidates may target rare diseases or conditions.

U.S. Regulations Affecting Health Care Companies

Pharmaceutical manufacturers with products that are reimbursed by U.S. federally funded health care programs such as Medicare and Medicaid are subject to so-called fraud and abuse laws including false claims and anti-kickback laws.

The federal Anti-Kickback Law prohibits anyone from, among other things, knowingly and willingly, directly or indirectly, soliciting, receiving, offering, or paying any remuneration with the intent of (or in return for) generating referrals of individuals or purchases, leases, orders, or arranging for the purchase, lease, or order of any healthcare item or service reimbursable by federal health care programs like Medicare and Medicaid. Courts have interpreted this law very broadly, including by holding that a violation has occurred if one purpose of the remuneration is to generate referrals even if there are other lawful purposes. Moreover, liability under the Anti-Kickback Law may be established without proving actual knowledge of the law or specific intent to violate. There are statutory exceptions and regulatory safe harbors that protect certain arrangements from prosecution or administrative sanctions, but the exceptions and safe harbors are drawn narrowly. The fact that an arrangement does not fall within a safe harbor does not necessarily render the conduct illegal under the Anti-Kickback Law, but the arrangement may be subject to scrutiny based on the facts and circumstances. Practices that involve remuneration to those who prescribe, purchase, or recommend pharmaceutical products, including certain discounts, or engaging such individuals as consultants, advisors and speakers, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor. Moreover, there are no safe harbors for many common practices, such as educational and research grants, charitable donations, product support and patient assistance programs. Violations of the Anti-Kickback Law may be punished by civil and criminal penalties, damages, fines, or exclusion from participation in federal health care programs like Medicare and Medicaid. Many states have enacted similar laws, some of which apply regardless of payer.

The Federal civil False Claims Act ("FCA") prohibits any person from, among other things, knowingly presenting or causing to be presented a false or fraudulent claim for payment of government funds, 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, or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay or transmit money or property to the government. The FCA is commonly enforced against those who submit allegedly false Medicare or Medicaid claims, as well as those who induce or assist others to submit a false claim. "False claims" can result not only from non-compliance with the express requirements of applicable governmental reimbursement programs, such as Medicaid or Medicare, but also from non-compliance with other laws, such as the Anti-Kickback Law or laws that require

quality care in service delivery. Actions under the FCA may be brought by the government or by whistleblowers referred to as "relators," who may initiate an action in the name of the government and the individual and may share in any monetary recovery. Violations of the FCA can result in treble damages, mandatory per claim penalties, and exclusion from participation in federal health care programs. Most states have adopted similar state false claims laws, some of which are broader than the FCA, and these state laws have their own penalties which may be in addition to FCA penalties.

The Health Care Reform Law significantly strengthened the FCA and federal Anti-Kickback Law provisions, which could lead to the possibility of increased whistleblower or relator suits, and among other things, made clear that a federal Anti-Kickback Law violation can be a basis for federal FCA liability. The bringing of any FCA or other enforcement investigation or action, even if unsuccessful, could require us to devote resources to investigate and defend the action, as well as result in reputational harm. Failure to comply with fraud and abuse laws could result in significant civil and criminal penalties and costs, including the loss of licenses and the ability to participate in federal and state health care programs, and could have a material adverse effect on our business. In addition, many of these laws are vague, subject to modification, and are subject to evolving interpretation by prosecutorial and regulatory authorities, increasing the risk of noncompliance. We cannot predict whether changes in applicable law, or interpretation of laws, or changes in our services or marketing practices in response to changes in applicable law or interpretation of laws, could have a material adverse effect on our business.

In addition to the above, several other laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. Some state laws restrict whether and when pharmaceutical companies may provide meals to health care professionals or engage in other marketing-related activities; some states require certain compliance program elements and disclosures; and certain states and cities require identification or licensing of sales representatives.

For example, the federal Health Insurance Portability and Accountability Act of 1996, and its implementing regulations (collectively, "HIPAA"), prohibits 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 payer (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 Anti-Kickback Law, a person or entity can be found guilty of violating the HIPAA fraud statute without actual knowledge of the statute or specific intent to violate it. Violations of HIPAA fraud provisions may result in criminal, civil and administrative penalties, fines and damages, including exclusion from participation in federal healthcare programs.

Privacy Laws

In the U.S., we may be subject to data privacy and security laws and regulations by both the federal government and the states in which we conduct our business. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. Numerous federal and state laws and regulations, including state data breach notification laws, health information and/or genetic privacy laws and federal and state consumer protection laws (e.g., Section 5 of the FTC Act, HIPPA and the California Consumer Privacy Act ("CCPA")), govern the collection, use, disclosure, and protection of health-related and other personal information. Many of these laws differ from each other in significant ways and may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another, thus complicating compliance efforts. Compliance with these laws is difficult, constantly evolving, and time consuming. Federal regulators, state attorneys general, and plaintiffs' attorneys, including class action attorneys, have been and will likely continue to be active in this space. Any failure or perceived failure by us to comply with such laws may result in governmental enforcement actions, litigation, fines and penalties and/or adverse publicity, and could have an adverse effect on our reputation and business.

The CCPA, for example establishes certain requirements for data use and sharing transparency, and provides California residents certain rights concerning their personal data. In November 2020, California voters approved the California Privacy Rights Act ("CPRA") which introduced significant amendments to the CCPA and established and funded a dedicated California privacy regulator, the California Privacy Protection Agency. The amendments introduced

by the CPRA became effective on January 1, 2023, and it is not yet fully clear how the CCPA and CPRA will be enforced and interpreted. The effects of the CCPA and CPRA are potentially significant and may require us to modify our data collection or processing practices and policies and to incur substantial costs and expenses in an effort to comply. Certain other states have passed legislation similar to the CCPA, which will provide individuals with new privacy rights and increase the privacy and security obligations of entities handling certain personal data of such individuals. For example, in March 2021, Virginia enacted the Consumer Data Protection Act which became effective on January 1, 2023. In July 2021, Colorado passed the Colorado Privacy Act, which will become effective on July 1, 2023. Additionally, in March 2022, Utah enacted the Utah Consumer Privacy Act, which will become effective on December 31, 2023. Also, in May 2022, Connecticut signed the Connecticut Data Privacy Act into law, which will become effective on July 1, 2023.

A number of additional states have proposed bills for comprehensive privacy legislation, and it is possible that certain of these bills will pass. The existence of new comprehensive privacy laws in different states in the country, if enacted, could add additional complexity, variation in requirements, restrictions and potential legal risk. Such new laws could also require additional investment of resources in compliance programs, impact strategies regarding and the availability of personal data, and would result in increased compliance costs and/or changes in business practices and policies.

On the federal level, HIPAA imposes requirements relating to the privacy, security and transmission of individually identifiable health information. We may obtain health information from third parties, such as research institutions, that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA other than with respect to providing certain employee benefits, we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Outside of the U.S., the legislative and regulatory landscape for privacy and data security continues to become more comprehensive. There has been increased attention to privacy and data security issues that could potentially affect our business, including as a result of the General Data Protection Regulation in the EU and the U.K. and data protection laws in the U.K. The EU GDPR (and the regulation as incorporated in U.K. law) imposes fines of up to EUR 20 million (£17.5 million) or 4% of the annual global revenue of a noncompliant company, for non-compliance. In addition, laws and regulations enacted in the U.S., Europe, Asia and Latin America increases potential enforcement and litigation activity.

If we, our agents, or our third-party partners fail to comply or are alleged to have failed to comply with these or other applicable data protection and privacy laws and regulations, or if we were to experience a data breach involving personal information, we could be subject to government enforcement actions or private lawsuits. Any associated claims, inquiries, or investigations or other government actions could lead to unfavorable outcomes that have a material impact on our business including through significant penalties or fines, monetary judgments or settlements including criminal and civil liability for us and our officers and directors, increased compliance costs, delays or impediments in the development of new products, negative publicity, increased operating costs, diversion of management time and attention, or other remedies that harm our business, including orders that we modify or cease existing business practices.

U.S. Health Care Reform Law

Our financial prospects could be affected by changes in health care spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations, or judicial decisions, or new interpretations of existing laws, regulations, or decisions, related to, among other things, health care availability, or the method of delivery of or payment for health care products and services could negatively impact our business, operations and financial condition.

For example, in the United States there is significant interest in promoting health care reform, as evidenced by the enactment in the United States of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "Health Care Reform Law"). The Health Care Reform Law substantially changed the way health care is financed by both governmental and commercial payers and significantly impacts the pharmaceutical industry. The Health Care Reform Law contains provisions that may reduce the profitability of drug products, including, for example, by increasing the minimum rebates owed by manufacturers under the Medicaid Drug Rebate Program, extending the rebate program to individuals enrolled in Medicaid managed care plans, addressing

a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and imposing certain annual fees based on pharmaceutical companies' share of sales to federal health care programs.

The Health Care Reform Law established and provided significant funding for a new Patient-Centered Outcomes Research Institute to coordinate and fund comparative effectiveness research. While the stated intent of comparative effectiveness research is to develop information to guide providers to the most efficacious therapies, outcomes of comparative effectiveness research could influence the reimbursement or coverage for therapies that are determined to be less cost effective than others. Should any of our products be approved for sale, but then determined to be less cost effective than alternative therapies, the levels of reimbursement for these products, or the willingness to reimburse at all, could be impacted, which could materially impact our financial results.

Certain provisions of the Health Care Reform Law have been subject to judicial challenges, as well as efforts to repeal, replace or otherwise modify them or to alter their interpretation or implementation. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017, eliminated the tax-based payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, as amended, commonly referred to as the "individual mandate," effective January 1, 2019. Further, the Bipartisan Budget Act of 2018 among other things, amended the Medicare statute, effective January 1, 2019, to reduce the coverage gap in most Medicare prescription drug plans, commonly known as the "donut hole," by raising the manufacturer discount under the Medicare Part D coverage gap discount program to 70%. Additional legislative changes, regulatory changes and judicial challenges related to the Health Care Reform Law remain possible, but the nature and extent of such potential changes or challenges are uncertain at this time. It is unclear how the Health Care Reform Law, its implementation, efforts to repeal, replace or otherwise modify, or invalidate, the Health Care Reform Law, or portions thereof, and other health care reform measures that may be adopted in the future will affect our business. Another provision of the Health Care Reform Law, generally referred to as the Physician Payments Sunshine Act or Open Payments Program, 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 direct or indirect payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held in the company by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations have been extended to include transfers of value made to certain non-physician providers such as physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives. CMS publishes information from these reports on a publicly available website. Our compliance with these rules may also impose additional costs and may impact our relationships with physicians, teaching hospitals and the other non-physician health care providers.

In addition, other legislative changes have been proposed and adopted since the Health Care Reform Law was enacted. For example, the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012, among other things led to aggregate reductions in Medicare payments for all items and services, including prescription drugs and biologics, to service providers of, on average, 2% per fiscal year beginning April 1, 2013, and, due to subsequent legislation, will continue until 2030 (with the exception of a temporary suspension that lasted from May 1, 2020, through March 31, 2022 due to the COVID-19 pandemic). Following the suspension, a 1% payment reduction began April 1, 2022 and remained through June 30, 2022, The 2% payment reduction resumed on July 1, 2022. To offset the temporary suspension during the COVID-19 pandemic, in 2030, the sequestration will be 2.25% for the first half of the year, and 3% in the second half of the year. As another example, for calendar quarters beginning January 1, 2022, manufacturers will be required to report the average sales price for certain drugs under the Medicare program regardless of whether we participate in the Medicaid Drug Rebate Program. Previously, such reporting was only required for manufacturers that participated in that program. Starting in 2023, manufacturers must pay refunds to Medicare for single source drugs or biologicals, or biosimilar biological products, reimbursed under Medicare Part B and packaged in single-dose containers or single-use packages, for units of discarded drug reimbursed by Medicare Part B in excess of 10% of total allowed charges under Medicare Part B for that drug. Manufacturers that fail to pay refunds could be subject to civil monetary penalties of 125% of the refund amount.

The Inflation Reduction Act ("IRA") was signed into law in August 2022. The IRA includes several provisions that will impact our business to varying degrees, including provisions that create a $2,000 out-of-pocket cap for Medicare Part D beneficiaries, impose new mandatory discounts from manufacturers under Medicare Part D, allow the U.S.

government to negotiate Medicare Part B and Part D pricing for certain high-cost single-source drugs and biologics without generic or biosimilar competition, and require companies to pay rebates to Medicare for drug prices that increase faster than inflation. The IRA provides a five-year temporary increase in Medicare Part B payment for certain qualifying biosimilars, and it also delays the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. The effect of IRA on our business and the healthcare industry in general is not yet known.

Additional legislative changes, regulatory changes or guidance could be adopted, which may impact the marketing approvals and reimbursement for our product candidates.

Further, there has been increasing legislative, regulatory and enforcement interest in the United States with respect to drug pricing practices. There have been several Congressional inquiries and proposed and enacted federal and state legislation and regulatory initiatives designed to, among other things, bring more transparency to product pricing, evaluate the relationship between pricing and manufacturer patient programs, and reform government healthcare program reimbursement methodologies for drug products. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020.

It is possible that the Health Care Reform Law, as currently enacted or may be amended or otherwise modified in the future, as well as other health care reform measures that may be adopted in the future, may result in additional reductions in Medicare payment and other health care financing, more rigorous coverage criteria, and new payment methodologies and in additional downward pressure on coverage and payment and the price that we receive for any approved product. For example, under the IRA, Congress has enacted a program that allows Medicare to negotiate pricing for certain single-source drugs and biologics under Medicare Parts B and D. The IRA also imposes Medicare Part B and Part D inflation-based rebates, under which manufacturers owe additional rebates if the average sales price of a drug increases faster than the pace of inflation, based on a statutory reference period. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. These continuing health care reform initiatives may adversely affect:

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

Congress also could enact additional changes that affect our overall rebate liability and the information we report to the government as part of price reporting calculations. In addition, Congress could enact a drug price negotiation program under which the prices for certain high Medicare spend single source drugs would be capped by reference to the non-federal average manufacturer price. This or any other legislative change could impact the market conditions for our products. We further expect continued scrutiny on government price reporting and pricing more generally from Congress, agencies, and other bodies.

Coverage and Reimbursement

In the United States and markets in other countries, patients generally rely on third-party payers to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payers is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payers, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payers is

essential for most patients to be able to afford treatments such as gene therapy products. Sales of these or other product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payers. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines may be made by CMS. CMS decides whether and to what extent certain new medicines will be covered and reimbursed under Medicare and private payers tend to follow CMS to a substantial degree.

Environmental Regulations

We are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential federal, state or local regulations. These and other laws govern our use, handling and disposal of various biological and chemical substances used in, and waste generated by our operations. Our research and development involve the controlled use of hazardous materials, chemicals and viruses. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources. Additionally, for formulations containing controlled substances, we are subject to Drug Enforcement Act regulations.

Pricing Regulations

There have been a number of federal and state legislative changes made over the last few years regarding the pricing of pharmaceutical and biological products, government control and other changes to the health care system of the United States. Concerns about drug pricing continue to be expressed by members of Congress and prior presidential administrations. It is uncertain how such legislative changes will be adopted or what actions federal, state or private payers for medical goods and services may take in response to such legislation. We cannot predict the effect such health care changes will have on our business, and no assurance can be given that any such reforms will not have a material adverse effect.

Non-U.S. Government Regulations

European Drug Development

Our products will also be subject to extensive regulatory requirements in the European Union ("EU"). As in the United States, medicinal products can only be marketed if a marketing authorization from the competent regulatory agencies has been obtained. See "European Marketing Authorization" below.

In the EU, the new Clinical Trials Regulation 536/2014 has been applicable since January 31. 2022. The Clinical Trials Regulation repealed and replaced the Clinical Trials Directive, and introduced a complete overhaul of the existing regulation of clinical trials for medicinal products in the EU, including a new coordinated procedure for authorization of clinical trials that will be conducted in multiple EU Member States, and increased obligations on sponsors to publish clinical trial results. The transitory provisions of the new Clinical Trials Regulation provide that ongoing clinical trials previously authorized under the Clinical Trials Directive can remain under the Directive, or they can transition to the Regulation. By January 31, 2025, when all ongoing clinical trials must have transitioned to the new Regulation. The new Regulation is directly applicable in all Member States (and so does not require national implementing legislation in each Member State) and aims at simplifying and streamlining the approval of clinical studies in the EU. The main characteristics of the new Regulation include: a streamlined application procedure via a single-entry point through the Clinical Trials

Information System, or CTIS; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts (Part I contains scientific and medicinal product documentation and Part II contains the national and patient-level documentation). Part I is assessed by a coordinated review by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Concerned Member States) of a draft report prepared by a Reference Member State. Part II is assessed separately by each Concerned Member State. Strict deadlines have also been established for the assessment of clinical trial applications.

Similar to the FDA, the European Medicines Agency's Committee for Medicinal Products for Human Use ("CHMP") has adopted ICH S6 as a guideline governing preclinical testing of biologics. Sponsors usually must conduct pharmacodynamic ("PD") studies, such as *in vitro* binding assays and *in vivo* studies that assess the product's pharmacologic activity and define its mechanism of action. Biologics typically undergo single- and repeat-dose toxicity studies using relevant species. Safety pharmacology studies, which evaluate the product's functional effects on major body systems and specific organs, and local tolerance testing can be done separately or subsumed in toxicity testing. Sponsors also usually conduct single- and multiple-dose pharmacokinetic ("PK") and/or toxicokinetic studies to assess absorption, disposition, exposure and clearance (in particular, antibody-mediated clearance), and explore dose-response relationships. This information is used to predict margins of safety for human studies. Immunogenicity testing might include screening and mechanistic studies.

Good Clinical Practices and Other Considerations for Clinical Trials

Clinical trials of medical products (including biologics) must comply with GCP, as described in Directive 2005/28/EC on Good Clinical Practice and the ICH E6 guideline, which the CHMP has adopted. The Directive and guideline describe general governing principles for clinical trials. The rights, safety and well-being of trial subjects must prevail over the interests of science and society. Investigators must obtain freely given informed consent from every trial subject before each subject is enrolled. Clinical trial information must be handled, recorded and stored with respect for relevant confidentiality and privacy rules. Trials must comply with the ethical principles of the World Medical Association's Declaration of Helsinki. Specific GCP guidelines apply to trials of advanced therapy medicinal products (i.e. gene therapy, somatic-cell therapy and tissue-engineered medicines). These guidelines regulate issues such as the donation, procurement and testing of human tissues and cells; the implementation of a traceability system; and specific rules on safety reporting and long-term follow-up. Under the Clinical Trials Regulation, special requirements apply to clinical trials conducted on minors and other persons not able to give informed legal consent. These requirements are intended to preserve the dignity of the trial subjects, confirm that the benefits of the trial outweigh the risks and ensure that subjects' representatives give consent with as much involvement of the subject as possible. CHMP has also issued a guideline on quality requirements during the clinical trial period for investigational medicinal products containing biological or biotechnology-derived substances. The guideline describes quality documentation that should be submitted to the competent authority as part of the sponsor's investigational medicinal product dossier ("IMPD"). The IMPD should include, among other things, (i) an adequate description of the process and process controls, including a flow chart of all successive steps and details of in-process testing and (ii) a description and justification of "any reprocessing during manufacture of the drug substance." The guideline also recognizes that sponsors will improve and optimize their manufacturing processes during clinical development and describes the steps sponsors should take following these changes. Specifically, the sponsor must compare the quality attributes of the pre- and post-change biological active substances and relevant intermediates and conduct a comparability exercise where necessary. For first-in-human clinical trials, sponsors should use product representative of the material used during the non-clinical testing phase. Finally, with regard to characterization, the guideline requires details on the biological activity to be provided, recognizing that the extent of characterization data will further increase in later phases.

Study Design Considerations

General regulatory guidance on study design applies to biologics as well as small molecule medicines. According to the guidance, there is a "close, but variable correlation" between phase of development and type of study, but one type of trial can occur in several different phases. The guidance therefore identifies the most typical kind of study for each phase.

Phase 1 usually involves the initial introduction of the investigational product into human subjects, and studies in this phase usually have non-therapeutic objectives. Specifically, Phase 1 studies typically investigate initial safety and tolerability, PK, PD and/or drug activity, to preliminarily determine the potential therapeutic benefit of a medicine. Phase 1 studies may be conducted in healthy volunteers or certain types of patients. If the medicine has significant potential toxicity (e.g., cytotoxic products), the trial will usually be conducted in patients.

The most typical Phase 2 study is a therapeutic exploratory study that explores efficacy in narrowly defined, relatively homogenous groups of patients. Initially, studies may use a variety of designs (e.g., concurrent controls and comparisons with baseline status). Subsequent Phase 2 trials usually are randomized and concurrently controlled, allowing for evaluation of the medicine's safety and efficacy for a particular indication. A major goal of this phase is to determine the dose(s) for Phase 3 trials.

Phase 3 typically involves therapeutic confirmatory studies that are designed to verify the preliminary evidence obtained in Phase 2 and to provide a sufficient basis for marketing authorization. Phase 3 studies may also further explore the dose response relationship, or explore the drug's use in wider populations, in different stages of disease, or in combination with another drug. With regard to medicines administered for long periods, extended exposure trials ordinarily occur during Phase 3, although the sponsor may start them in Phase 2.

To ensure that clinical trials in all three phases of development will be adequate to support a marketing authorization application ("MAA"), sponsors should design these trials with the MAA requirements in mind. Certain biologics products need to comply with the requirements set out in Part III of the Annex I to Directive 2003/63/EC (which amends the core EU medicines legislation, Directive 2001/83/EC), and advanced therapy medicinal products need to comply with the requirements described in Part IV.

Consultation with the European Medicines Agency

A sponsor may obtain, from the EMA, scientific advice regarding the development of a medicinal product. Although this advice does not bind the EMA and is not binding for purposes of a future MAA, it can be useful to guide developers generally in performing the appropriate preclinical and clinical tests for the product, or on more specific aspects such as guiding revisions to a clinical trial protocol. EMA's remarks will only address scientific issues and will generally focus on matters such as the selection of endpoints and comparator, the duration of treatment or follow-up and the design of pivotal studies. Advice also might address a sponsor's proposal to deviate from a CHMP guideline. If the applicant decides not to follow the EMA's advice, it should justify this decision in its MAA. EMA guidance details the procedures for requesting scientific advice. The fact that an applicant requests advice from EMA does not preclude it from also seeking advice from national competent authorities or from foreign regulators, such as the FDA. The process of obtaining advice from the national competent authorities is often less formal than requesting advice from the EMA, and such advice can prove helpful. Consequently, seeking such advice is a common choice among applicants. Generally, the parallel scientific procedure (a program shred by the EMA and FDA) is available for "important breakthrough drugs," that is, products that the EMA and FDA have identified as falling within therapeutic areas of overlapping interest (e.g., oncology products, vaccines and blood products). The goal of these meetings is to provide clarity regarding the regulatory requirements of each region and the reasons for any differences between them. A sponsor requesting parallel scientific advice should authorize the agencies to exchange all information about the product, including trade secrets. After the parallel scientific advice procedure, each agency will provide its own independent advice on the questions at issue. There is no guarantee of harmonized advice or identical regulatory decisions on the approvability of the product.

European Marketing Authorization

In the European Economic Area ("EEA"), which includes the 27 member states of the EU plus Norway, Iceland and Liechtenstein, medicinal products can only be placed on the market after the grant of a marketing authorization. The MAA is based on the results of pharmaceutical tests, preclinical tests and clinical trials conducted on the medicinal product in question. There are two types of marketing authorizations:

- The centralized marketing authorization, which is issued by the European Commission through the centralized procedure, based on the opinion of the CHMP and which is valid throughout the entire territory of the EEA. The centralized procedure is mandatory for certain types of drugs, such as medicinal products

derived from biotechnology processes (such as genetic engineering), orphan medicinal products, advanced-therapy medicinal products and medicinal products containing new active substances indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. . The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU. . To find out whether a product can be evaluated via the centralized procedure, applicants should always submit an eligibility request to the EMA, including by a justification of eligibility for evaluation under the centralized procedure.

- National marketing authorizations, which are issued by the competent authorities of the member states of the EEA and only cover their respective territory, are available for drugs not falling within the mandatory scope of the centralized procedure. Where a drug has already been authorized for marketing in a member state of the EEA, this National marketing authorization can be recognized in other member states through the Mutual Recognition Procedure. If the drug has not received a National marketing authorization in any member state at the time of application, it can be approved by multiple member states in parallel through the Decentralized Procedure.

Under the above described procedures, before granting the marketing authorization, the EMA or the competent authorities of the member states of the EEA make an assessment of the risk-benefit balance of the drug on the basis of scientific criteria concerning its quality, safety and efficacy.

The Marketing Authorization Application: Contents and Approval Standard

Many biologics fall under the scope of the centralized procedure, which, as mentioned above, is mandatory for medicines developed through biotechnological methods, such as recombinant DNA technology; controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes, including transformed mammalian cells; and hybridoma and mAb methods. Gene therapy and cell therapy products are also subject to the centralized procedure as advanced therapy medicinal products. Nonetheless, some biologics are still approved at the member state level. For example, certain types of vaccines do not fall within the mandatory scope of the centralized procedure (although they may be eligible for the centralized procedure in the interest of public health). The EMA has published a guideline intended to harmonize the quality aspects to be included in summaries of product characteristics and patient information leaflets for human vaccines.

With respect to the centralized procedure, the approval standards for biotechnology products are the same as for chemically synthesized medicines. Both types of products must be safe and effective and have appropriate quality. Because of their special characteristics, however, biotechnology products must comply with several additional dossier requirements. For example, the applicant must thoroughly describe the manufacturing process and must: (i) provide information on the origin and history of the starting materials; (ii) demonstrate that the active substance complies with specific measures for preventing the transmission of animal and human spongiform encephalopathies; (iii) if cell banks are used, demonstrate that cell characteristics remain unchanged at the passage level for production (and beyond); (iv) provide information as to whether there are adventitious agents in seed materials, cell banks, pools of serum or plasma, and all other materials of biological origin, and, if it is not possible to avoid the presence of potentially pathogenic adventitious agents, show that further processing ensures elimination or inactivation of the agents; (v) if possible, base vaccine production on a seed lot system and established cell banks; (vi) in case of medicines derived from human blood or plasma, describe the origin, criteria and procedures for the collection, transportation and storage of the starting material; and (vii) describe the manufacturing facilities and equipment. Other special rules apply certain types of biological medicines. For example, for plasma-derived medicinal products, the applicant must provide an information dossier, the Plasma Master File. MAAs for vaccines other than for influenza need to contain a Vaccine Antigen Master File. Special rules also apply to advanced therapy medicinal products, including gene therapies, somatic cell therapies and tissue-engineered products.

Data and Market Exclusivity in the European Union

In the EU, new chemical entities (including both small molecules and biological medicinal products), sometimes referred to as new active substances, qualify for eight years of data exclusivity upon marketing authorization and an

additional two years of market exclusivity. This data exclusivity if granted, prevents generic or biosimilar applicants from referencing the innovator's pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization, for a period of eight years from the date on which the reference product was first authorized in the EU. After such eight year period, a generic or biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed for two years. The overall ten-year period may be extended to a maximum of 11 years if, during the period of data exclusivity, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if an innovative medicinal product gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained a marketing authorization based on an application with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Orphan Designation in the European Union

The European Commission is also able to grant orphan designation in respect of medicinal products. To qualify the medicinal product must be intended for the diagnosis, prevention or treatment of (i) a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in the EU or (ii) a life-threatening, seriously debilitating or serious and chronic condition in the EU where without incentives it is unlikely that the marketing of the medicinal product in the EU would generate sufficient return to justify the necessary investment in its development. Further, no satisfactory method of diagnosis, prevention or treatment of the condition in question must exist in the EU or, if such method exists, the medicinal product must be of significant benefit to those affected by that condition.

Orphan medicinal products still remain subject to the same regulatory approval process, albeit that they are always assessed through the centralized procedure. Effective September 19, 2018, sponsors applying for orphan designation must use EMA's secure online IRIS platform. However, sponsors of orphan medicinal products are eligible to benefit from a number of incentives offered, including certain assistance with development of the medicinal product, reduced fees for MAAs and protection from market competition once the medicinal product is authorized, as described below.

Where a marketing authorization in respect of an orphan medicinal product is granted, the European Commission, EMA and the competent authorities of the EU member states shall not, for a period of ten years, accept another application for a marketing authorization or grant a marketing authorization or accept an application to extend an existing authorization, for the same therapeutic indication, in respect of a similar medicinal product, unless: (i) the holder of the marketing authorization for the original orphan medicinal product has given its consent to the second applicant; (ii) the holder of the marketing authorization for the original orphan medicinal product is unable to supply sufficient quantities of the medicinal product; or (iii) the second applicant can establish the second medicinal is safer, more effective or otherwise clinically superior than the authorized orphan product. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication.

Other government regulation in the European Union and United Kingdom

The EU and the EU member states and the U.K. have extensive laws and regulations relating to a variety of other topics that would be of relevance for us if we are active in the EU and U.K., including but not limited to laws and regulations regarding data privacy, drug pricing and reimbursement, advertising and interactions with healthcare professionals.

Other Jurisdictions

In addition to regulations in the United States and the EU, we may be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our product. As the United Kingdom is no longer a member state of the EU, this may also apply to the United Kingdom. Whether or not we obtain FDA approval for a product, we must obtain approval from comparable regulatory authorities in foreign countries before we can commence clinical trials in such countries and the approval of the regulators of foreign countries before we may market products in such countries. The approval process and requirements governing the conduct of clinical

trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Acceptance of Foreign Clinical Trials in the United States and the European Union

The FDA has issued regulations governing its acceptance of foreign clinical data not conducted under an IND to support IND applications or marketing authorizations, such as BLAs. FDA may accept a well-designed, well-conducted, non-IND foreign study as support for an IND or marketing application if the study was conducted in accordance with GCP and if FDA is able to validate the data from the study through an onsite inspection, if necessary. Where a marketing application is based solely on foreign data, additional requirements apply, including a demonstration that the foreign data are applicable to the U.S. population and U.S. medical practice.

EU Directive 2001/83/EC allows for clinical trials conducted outside the EU to be taken into consideration during the review of a marketing authorization in the EU if such trials have been designed, implemented and reported based on principles equivalent to those of the Clinical Trials Regulation, including with regard to good clinical practice and ethical principles. Moreover, they should comply with the ethical principles outlined in the Declaration of Helsinki. The applicant must submit a statement declaring such compliance as part of the marketing authorization. In December 2008 and April 2012, the EMA published a strategy paper on the acceptance of data from foreign clinical trials conducted in "third countries," particularly those outside the "'traditional' Western European and North American research areas." According to the 2008 strategy paper, there is a "growing concern both among regulators and in public debate about how well these trials are conducted from an ethical and scientific/organizational standpoint." The EMA has called for increased cooperation between international regulatory authorities involved in the supervision of clinical trials and has put forth other proposals to address these issues.

Manufacturing and Source of Supply

We do not have any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical studies and clinical trials, as well as for commercial manufacture if our product candidates receive marketing approval. To date, we have obtained materials for clinical trials and non-clinical studies from third-party manufacturers who are suppliers to us. We intend to identify and qualify additional contract manufacturers to provide commercial scale manufacturing prior to submission of an NDA or BLA to the FDA.

Employees and Human Capital Management

As of December 31, 2023, we had 59 full-time employees, 22 of whom hold M.D. or Ph.D. degrees and 37 of whom hold other advanced degrees. Of our total workforce, 39 are engaged primarily in research and development activities and 20 are engaged primarily in executive, finance and accounting, and administrative functions. As of December 31, 2023, 57 employees are located in the United States and 2 employees in the United Kingdom. Of our employees, 53% are female and 47% are male. None of our employees are represented by labor unions or covered by collective bargaining agreements.

Corporate Culture

Our values – compliance, collaboration, integrity and high performance – are built on the foundation that the employees we hire and the way we treat one another promote creativity, innovation and productivity, which spur our success. This culture depends in large part on our ability to attract, retain and develop a diverse population of talents and high-performing employees at all levels of our organization. Providing market competitive pay and benefit programs, opportunities to participate in the success they help create, while engaging employees in important dialogue regarding organization performance, we create a culture of inclusion in which all colleagues have the opportunity to thrive. The success of our business is fundamentally connected to the well-being of our employees.

Compensation and Benefits Program

Our compensation program is designed to attract and reward talented individuals who possess the skills necessary to support our business objectives, assist in the achievement of our strategic goals and create long-term value for our

stockholders. We provide all of our employees with what we consider to be a very competitive mix of compensation and insurance benefits, as well as participation in our equity programs.

Hybrid Culture

In the second quarter of 2020, we made the decision to move to a hybrid workplace model, which means that certain of our employees have the option to be 100% remote, work full-time in our office, or have the flexibility to work between office and remotely. This move provides our employees with continued flexibility to work in person, remotely or in a hybrid model.

Available Information

Our stock is traded on the Nasdaq Global Market ("NASDAQ") under the symbol "ALT". Our principal executive offices located at 910 Clopper Road, Suite 201S, Gaithersburg, Maryland 20878. Our telephone number is (240) 654-1450, and our Internet website is www.altimmune.com and our investor relations website is located under the "Investors" tab. The information on, or that can be accessed through, our website is not part of this Annual Report and is not incorporated by reference herein.

We make available our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K, and amendments to these reports, free of charge through our website (www.altimmune.com) as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the SEC. We also make available on our website reports filed by our executive officers and Directors on Forms 3, 4, and 5 regarding their ownership of our securities. Our Code of Business Conduct and Ethics, and any amendments to our Code of Business Conduct and Ethics, are also available on our website under the "Investors" tab.

The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at www.sec.gov.

Item 1A. Risk Factors

In addition to the other information included in this Annual Report, the following risk factors should be carefully considered when evaluating an investment in us. These risk factors and other uncertainties may cause our actual future results or performance to differ materially from any future results or performance expressed or implied in the forward-looking statements contained in this report and in other public statements we make. In addition, because of these risks and uncertainties, as well as other variables affecting our operating results, our past financial performance is not necessarily indicative of future performance. See "Forward-Looking statements" in Item 1 of this Annual Report.

Risks Related to Our Business, Financing Requirements, Product Development and Clinical Trials

We have incurred significant losses since our founding and anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We are a clinical-stage biotechnology company and have not yet generated revenues from product sales. To date, substantially all of our revenues have been derived from past grants and contracts with governmental agencies. We have incurred net losses in most periods since our inception, including a net loss of $88.4 million and $84.7 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we have an accumulated deficit of $466.3 million. To date, we have not received regulatory approvals for any products or generated any revenues from the sale of products, and we do not expect to generate any product revenues in the foreseeable future. We do not know whether or when we will generate product revenues or become profitable.

We have devoted most of our financial resources to research and development, including preclinical and clinical development of our product candidates. We have not completed pivotal clinical trials for any product candidate. Our leading product candidates remain in early-stage clinical development, and it may be several years, if ever, before we have a product candidate ready for commercialization. Even if we obtain regulatory approval to market a product candidate, our future revenues will depend upon the size of any markets in which our product candidates have received approval, our ability to achieve sufficient market acceptance, reimbursement from third-party payers and other factors.

The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

Our profitability depends on our ability to develop and commercialize our current and future product candidates.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates, forming strategic partnerships and alliances with third parties and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, we may never generate revenues that are significant enough to achieve profitability. If some or all of our product candidates do not prove to be safe, pure and efficacious, then we may have to abandon those product candidates altogether and we will be unable to generate revenues from sales of such products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase significantly if and as we:

- continue our clinical trials for our product candidates;
- initiate additional preclinical studies, clinical trials or other studies or trials for our other product candidates;
- manufacture material for clinical trials and, if any product candidate is approved for marketing, for commercial sale;

- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- seek to discover and develop additional product candidates;
- acquire or in-license other product candidates and technologies;
- make royalty, milestone or other payments under any in-license agreements;
- form strategic partnerships and/or make additional acquisitions;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel; and
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the FDA or other regulatory authorities to perform studies in addition to those currently expected, if there are any delays in completing our clinical trials or the development of any of our product candidates, or if we choose to perform additional studies for marketing purposes our expenses could increase.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations.

Future conditions might require us to make substantial write-downs in our assets, which would adversely affect our balance sheet and results of operations.

We review our long-lived tangible and intangible assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. We also test our indefinite-lived intangible assets for impairment at least annually in the fourth quarter, or when events or changes in the business environment indicate that the carrying value of the reporting unit may exceed its fair value. The preliminary data from the HepTcell Phase 2 trial indicates that the results are not sufficient to warrant moving forward with this product candidate. As a result, we recorded non-cash impairment charges of $12.4 million for an acquired In-Process Research and Development asset in connection with the discontinuation of our product candidate HepTcell. This and other significant write-downs of our long-lived assets in the future could adversely affect our balance sheet and results of operations.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed would force us to delay, limit, reduce or terminate our product development or commercialization efforts.

We do not expect to generate revenue from product sales, licensing fees, royalties, milestones, contract research or other sources in an amount sufficient to fully fund our operations for the foreseeable future, if ever. Therefore, we will use our existing cash resources, and will require additional funds to maintain our operations, continue our research and development programs, commence future preclinical studies and clinical trials, seek regulatory approvals and manufacture and market our products. As of December 31, 2023, our cash, cash equivalents, restricted cash and short-term investments were $197.9 million. Based on our current operating plan, we believe that our existing cash will be sufficient to fund our projected operating expenses and capital expenditure requirements for at least a twelve-month period from the issuance date of our December 31, 2023 financial statements. However, we do not expect that these funds will be sufficient to enable us to complete the clinical trials needed to seek marketing approval or commercialize any of our product candidates.

Furthermore, our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned.

We believe that we will continue to expend substantial resources for the foreseeable future developing our product candidates. These expenditures will include costs associated with research and development, maintaining our intellectual property estate, potentially acquiring new technologies, obtaining regulatory approvals and manufacturing products, forming partnerships and strategic alliances, as well as marketing and selling products approved for sale, if any. In addition, other unanticipated costs may arise. Because the 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 our product candidates.

Our future capital requirements depend on many factors, including:

- the progress, results and costs of our clinical trials for our leading product candidates;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates;
- the amount of funding that we receive from other non-dilutive funding sources;
- the number and development requirements of other product candidates that we pursue;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates if clinical trials are successful and the outcome of regulatory review of our product candidates;
- our ability to contract with third-party manufacturing facilities for adequate supply and to establish processes that meet regulatory requirements for commercialization;
- the cost and timing of future commercialization activities for our products, if any of our product candidates are approved for marketing, including product manufacturing, marketing, sales and distribution costs;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements; and
- the costs involved in preparing, filing and prosecuting patent applications, and maintaining, defending and enforcing our intellectual property rights, including litigation costs and the outcome of such litigation.

We may also seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us when needed, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our product candidates or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

Our ability to raise capital may be limited by applicable laws and regulations.

Using a shelf registration statement on Form S-3 to raise additional capital generally takes less time and is less expensive than other means, such as conducting an offering under a Form S-1 registration statement. However, our ability to raise capital using a shelf registration statement may be limited by, among other things, SEC rules and regulations. Under SEC rules and regulations, if our public float (the market value of our common stock held by non-affiliates) is less than $75.0 million, then the aggregate market value of securities sold by us or on our behalf under our Form S-3 in any 12-month period is limited to an aggregate of one-third of our public float. While our public float is currently more than $75.0 million, we have been subject to this limitation in the past and we may be subject to it again in the future. If our

ability to utilize a Form S-3 registration statement for a primary offering of our securities is limited to one-third of our public float, we may conduct such an offering pursuant to an exemption from registration under the Securities Act or under a Form S-1 registration statement, and we would expect either of those alternatives to increase the cost of raising additional capital relative to utilizing a Form S-3 registration statement.

Our ability to timely raise sufficient additional capital also may be limited by NASDAQ's stockholder approval requirements for transactions involving the issuance of our common stock or securities convertible into our common stock. For instance, NASDAQ requires that we obtain stockholder approval of any transaction involving the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than the greater of book or market value, which (together with sales by our officers, directors and principal stockholders) equals 20% or more of our then outstanding common stock, unless the transaction is considered a "public offering" by NASDAQ. In addition, certain prior sales by us may be aggregated with any offering we may propose in the future, further limiting the amount we could raise in any future offering without stockholder approval. NASDAQ also requires that we obtain stockholder approval if the issuance or potential issuance of additional shares will be considered by NASDAQ to result in a change of control of our company.

Obtaining stockholder approval is a costly and time-consuming process. If we are required to obtain stockholder approval for a potential transaction, we would expect to spend substantial additional money and resources. In addition, seeking stockholder approval would delay our receipt of otherwise available capital or alter the terms of the transaction, which may materially and adversely affect our ability to execute our business strategy, and there is no guarantee our stockholders ultimately would approve a proposed transaction.

Raising additional capital may cause dilution to stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates on unfavorable terms.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, and license and development agreements through strategic partnerships with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt or preferred stock financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, issuing additional equity, making capital expenditures or declaring dividends. If we raise additional funds through strategic partnerships with third parties, we may have to relinquish valuable rights to our technologies or product candidates, future revenue streams, research programs or product candidates, or otherwise grant licenses on terms that are not favorable. If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for our leading product candidates or our preclinical product candidates, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our product candidates are in an early stage of development, there is a high risk of failure, and we may never succeed in developing marketable products or generating product revenue.

Our preclinical and clinical results are not necessarily predictive of the final results of our ongoing or future clinical trials. Success in preclinical studies may not be predictive of similar results in humans during clinical trials, and successful results from early or small clinical trials of a product candidate may not be replicated in later and larger clinical trials.

Clinical trials are expensive, time consuming and uncertain as to outcome, and we cannot guarantee that any of these activities will be successful. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet our clinical endpoints with statistical significance or if there are safety concerns or adverse events associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for our product candidates, or we may determine to suspend development of or abandon specific product candidates. For example, we suspended the development of a Densigen platform-based product candidate, Flunisyn, which was being developed as a T-cell vaccine for the treatment of influenza, in favor of NasoVAX. Clinical trials with this product candidate showed that it was generally well-tolerated and able to induce robust T-cell responses

against the viral sequences represented, but a comparison of the entire study population in later-stage clinical trials showed no statistical differences between the vaccinated and placebo groups for several measures of protection.

In addition, we can offer no assurances that we have correctly estimated the resources or personnel necessary to seek partners, co-developers or acquirers for our programs. If a larger workforce or one with a different skillset is ultimately required to maintain these operations, we may be unable to maximize our existing programs.

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

From time to time, we publish interim data, including interim top-line results or preliminary results from our clinical trials. Any interim data and other results from our clinical trials may materially change as more patient data become available. Preliminary or top-line results also remain subject to audit, validation and verification procedures that may result in the final data being materially different from the interim and preliminary data we previously published. As a result, interim and preliminary data may not be predictive of final results and should be viewed with caution until the final data are available. We may also arrive at different conclusions, or considerations may qualify such results, once we have received and fully evaluated additional data. Differences between preliminary or interim data and final data could adversely affect our business.

The manufacture of our product candidates is complex and we may encounter difficulties in production, particularly with respect to acquisition of materials, process development or scaling-up of our manufacturing capabilities.

The manufacture of our product candidates is complex, highly regulated and subject to multiple risks. The complex processes associated with the manufacture of our product candidates expose us to various manufacturing challenges and risks, which may include delays in manufacturing our product candidates, limits on our ability to increase manufacturing capacity, and the potential for product failure and product variation that may interfere with our clinical development plans and add additional costs. It is possible that we will make changes to our manufacturing process at various points during product development or commercialization for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate, or other reasons. Such changes can be costly and carry the risk that they will not achieve their intended objectives, or these changes could cause our product candidates to perform differently and affect the results of current or future clinical trials, or the performance of a commercialized product. In some circumstances, changes in the manufacturing process may require us to perform analytical or clinical comparability studies and to collect additional data prior to undertaking more advanced clinical trials, and such studies may introduce additional costs or delays to the program. We may be required to collect additional clinical data from any modified process prior to obtaining marketing approval for the product candidate produced with such modified process. If clinical data are not ultimately comparable to that seen in the earlier trials in terms of safety or efficacy, we may be required to make further changes to our process and/or undertake additional clinical testing, either of which could significantly delay the clinical development or commercialization of the associated product candidate.

Compliance with cGMP requirements and other quality or regulatory issues may arise with our current or any future contract manufacturing organizations ("CMOs"). Furthermore, ongoing stability studies subsequent to manufacture must be periodically conducted to demonstrate that each of our product candidates do not undergo unacceptable deterioration over its shelf life. If issues affecting the quality of our product candidates or those of our CMOs are discovered, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the issue. To the extent any adversely affected material is being used in an ongoing clinical trial, the FDA could impose a clinical hold on our trial to investigate and remedy the quality issue. We cannot assure that any manufactured product or product candidate will not suffer a loss in stability or that other issues relating to the manufacture of our product candidates will not occur in the future.

Additionally, our CMOs may experience manufacturing difficulties due to resource constraints, including manufacturing capacity, material constraints, or as a result of labor disputes or unstable political environments. If our CMOs were to encounter any of these difficulties, our ability to provide our product candidate to patients in clinical trials, or to provide product for treatment of patients once approved, would be jeopardized.

We may encounter substantial delays in our clinical trials, or our clinical trials may fail to demonstrate the safety and efficacy of our product candidates to the satisfaction of applicable regulatory authorities.

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

- delays or failure in reaching a consensus with regulatory agencies on trial design;
- delays or failure in reaching agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites;
- delays or failure in obtaining required approvals from the IRB or other similar committees or bodies at each clinical trial site;
- imposition of a clinical hold by regulatory agencies for any reason, including safety concerns raised by other clinical trials of similar product candidates that may reflect an unacceptable risk with the patient population, technology platform, product stability or after an inspection of clinical operations or trial sites;
- failure to perform clinical trials in accordance with the FDA's GCP or applicable regulatory guidelines in other relevant countries;
- delays or failure in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites, including as a result of supply chain delays in obtaining materials for the manufacture of our clinical trial materials;
- the number of patients required for our clinical trials may be larger than we anticipate, enrollment in our clinical trials may be slower than we anticipate or participants may withdraw from our clinical trials, fail to complete dosing or fail to return for post-treatment follow-up at higher rates than we anticipate, any of which could result in significant delay;
- withdrawal of clinical trial sites from our clinical trials, including as a result of changing standards of care or the ineligibility of a site to participate;
- occurrence of serious adverse events in clinical trials that are associated with the product candidate that are viewed to outweigh its potential benefits;
- our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators or funders may require us, to conduct additional preclinical testing or clinical trials or to abandon projects that we expected to be promising;
- our third-party contractors (such as CROs, product manufacturers, or investigators) may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;
- fraudulent activity by a clinical researcher, if discovered, could preclude the submission of clinical data prepared by that researcher, lead to the suspension or substantive scientific review or one or more of our marketing applications by regulatory agencies;
- the cost of our clinical trials may be greater than we anticipate;
- additional trials may be necessary, including trials to analyze different dose strengths or dosing schemes;

- the regulatory requirements for product approval may not be explicit, may evolve over time and may diverge by jurisdiction;

- evolution in the standard of care that require amendments to ongoing clinical trials and/or the conduct of additional preclinical studies or clinical trials; or

- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

We, the FDA, other regulatory authorities outside the United States, or an IRB may suspend a clinical trial at any time for various reasons, including if it appears that the clinical trial is exposing participants to unacceptable health risks or if the FDA or one or more other regulatory authorities outside the United States find deficiencies in our IND or similar application outside the United States or the conduct of the trial. Delays, including delays caused by the above factors, can be costly and could negatively affect our ability to complete a clinical trial. For example, we have had delays in previous clinical trials, including those conducted for NasoVAX, as a result of clinical holds imposed by the FDA or other regulatory authorities and requests for additional or new information on vaccine product testing in connection with an IND submitted to the FDA. We have previously experienced multiple failures during the manufacturing of clinical materials for use in a NasoVAX Phase 2 clinical trial.

We cannot give any assurance that we will be able to resolve any future clinical holds imposed by the FDA or other regulatory authorities outside of the United States, or any delay caused by manufacturing failures or other factors described above or any other factors, on a timely basis or at all. If we are not able to successfully initiate and complete clinical trials, we will not be able to obtain regulatory approval and will not be able to commercialize our product candidates.

Even if our clinical trials are successfully completed as planned, the results may not support approval of our product candidates under the laws and regulations of the FDA or other regulatory authorities outside the United States. The clinical trial process may fail to demonstrate that our product candidates are both safe and effective for their intended uses. Pre-clinical and clinical data and analyses are often able to be interpreted in different ways. Even if we view our results favorably, if a regulatory authority has a different view, we may still fail to obtain regulatory approval of our product candidates. This, in turn, would significantly adversely affect our business prospects.

We may find it difficult to enroll patients in our clinical trials, which could delay or prevent clinical trials of our product candidates.

Identifying and qualifying subjects to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit subjects to participate in testing our product candidates. If subjects are unwilling to participate in our trials due to restrictions on travel or healthcare institution policies, negative publicity from adverse events in the biotechnology industries, public perception of vaccine safety issues or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting subjects, conducting studies and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether.

We may not be able to identify, recruit and enroll a sufficient number of subjects, or those with required or desired characteristics to achieve diversity in a trial, to complete our clinical trials in a timely manner. Subject enrollment is affected by several factors, including:

- severity of the disease under investigation;

- design of the trial protocol;

- size of the patient population;

- eligibility criteria for the trial in question;

- perceived risks and benefits of the product candidate being tested;
- willingness or availability of subjects to participate in our clinical trials;
- proximity and availability of clinical trial sites for prospective subjects;
- our ability to recruit clinical trial investigators with appropriate competencies and experience;
- availability of competing vaccines and/or therapies and related clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- our ability to obtain and maintain subject consents;
- patient referral practices of physicians; and
- ability to monitor subjects adequately during and after treatment.

We may not be able to initiate or continue clinical trials if we cannot enroll a sufficient number of eligible subjects to participate in the clinical trials required by regulatory agencies.

Even if we enroll a sufficient number of eligible subjects to initiate our clinical trials, we may be unable to maintain participation of these subjects throughout the course of the clinical trial as required by the clinical trial protocol, in which event we may be unable to use the research results from those subjects. For example, we may face difficulties in identifying patient populations with active disease to enroll in clinical trials of HepTcell in patients with chronic HBV. Other clinical trials involving patients with active HBV have sometimes faced difficulties in working with these patient populations, which may include significant numbers of individuals with difficulties with treatment compliance, such as active drug users. While we are developing strategies to address this issue, there is no guarantee that these strategies will prove successful.

If we have difficulty enrolling and maintaining the enrollment of a sufficient number of subjects to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business.

It may be difficult to predict the time and cost of product development for our product candidates, and unforeseen problems may prevent further development or approval of our product candidates.

Because our product candidates involve novel therapeutic approaches, it may be difficult to predict the time and cost of product development. For example, the Densigen platform involves synthetic peptide T-cell vaccines and the EuPort platform involves a novel peptide-based dual GLP-1/glucagon receptor agonist. Unforeseen problems with our approaches to vaccines and therapies may prevent further development or approval of our product candidates. Because of the novelty of our approaches, there may be unknown safety risks associated with the vaccines and therapies that we develop or the clinical endpoints that we establish in trials may not be generally accepted by regulatory agencies, which may therefore require us to perform large field studies to demonstrate efficacy. There can be no assurance that any development problems we may experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be solved.

In addition, novel vaccine adjuvants, which are included in HepTcell, our product candidate based on the Densigen technology, may pose an increased safety risk to patients. Adjuvants are compounds that are added to vaccine antigens to enhance the activation and improve immune response and efficacy of vaccines. Development of vaccines with novel adjuvants requires evaluation in larger numbers of patients prior to approval than would be typical for therapeutic drugs. Guidelines for evaluation of vaccines with novel adjuvants have been established by the FDA and other regulatory bodies and expert committees. Any vaccine, because of the presence of an adjuvant, may have side effects considered to pose too great a risk to patients to warrant approval of the vaccine. Traditionally, regulatory authorities have required extensive study of novel adjuvants because vaccines typically get administered to healthy populations, in particular infants, children and the elderly, rather than in people with disease. As a result, although it is anticipated that HepTcell is intended

for the treatment of patients suffering from a disease, regulatory agencies such as the FDA may nevertheless require us to conduct extensive safety testing prior to approval to demonstrate a low risk of rare and severe adverse events caused by our product candidates that include novel vaccine adjuvants.

If approved, the novel mechanism of action of the vaccines may adversely affect physician and patient perception and acceptance of our products. Public perception of vaccine safety issues, including adoption of novel vaccine mechanisms of action, may adversely influence willingness of subjects to participate in clinical trials, or if approved, to prescribe and receive novel vaccines. For example, GSK pulled from the market an approved vaccine to prevent Lyme disease (Lymerix) in February 2002 after anecdotal evidence of joint pain resulted in subjects' unwillingness to receive the vaccine. The FDA found no evidence that the vaccine caused a safety risk; however, GSK pulled the vaccine due to low sales resulting from the negative public perception associated with the reports on joint pain.

We rely, and expect to continue to rely, on third parties to conduct preclinical studies and clinical trials for our product candidates, and if they do not properly and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for our product candidates.

We rely, and expect to continue to rely, on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators to assist in managing, monitoring and otherwise carrying out our clinical trials. We compete with many other companies for the resources of these third parties. The third parties on whom we rely generally may terminate their engagements at any time and causing us to enter into alternative arrangements would delay development and commercialization of our product candidates.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, the FDA and foreign regulatory authorities require compliance with applicable law, regulations and standards, including GCP, for designing, conducting, monitoring, recording, analyzing and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials complies with GCP requirements. Although we rely on third parties to conduct our clinical trials, we are responsible for ensuring that each of these clinical trials is conducted in accordance with applicable law, regulations and standards, including our general investigational plan and protocol.

Furthermore, if these third parties do not successfully carry out their duties under their agreements, if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to clinical trial protocols or to regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, then the clinical trials of our product candidates may not meet regulatory requirements. If clinical trials do not meet regulatory requirements or if these third parties need to be replaced, then preclinical development activities or clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidates on a timely basis or at all.

Any third parties conducting aspects of our preclinical studies or clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether they devote sufficient time and resources to our preclinical studies and clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they cannot perform their contractual duties or obligations due to the impacts of public health crises on their operations or at the sites they are overseeing, if they need to be replaced or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons, our development timelines, including clinical development timelines, may be extended, delayed or terminated and we may not be able to complete development of, receive regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third parties terminates, we may not be able to enter into arrangements with alternative third parties or to do so on commercially reasonable terms. Switching or adding additional third-party service providers involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new third-party service provider begins work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines.

We face substantial competition from other pharmaceutical and biotechnology companies, which may result in others discovering, developing or commercializing products before, or more successfully, than we do.

The development and commercialization of new drug products is highly competitive. Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the design, development and commercialization of our product candidates. Our objective is to design, develop and commercialize new products with superior efficacy, convenience, tolerability and safety. In many cases, the products that we intend to commercialize, if successfully commercialized, will compete with existing market-leading products.

Many of our potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products.

Large and established companies such as Eli Lilly, Roche, Novo Nordisk, Pfizer, AstraZeneca, Amgen, Boehringer Ingelheim and Merck, among others, compete in the same market as our product candidates. These companies compete with us with their greater experience and resources to support their research and development efforts, conduct testing and clinical trials, obtain regulatory approvals to market products, manufacture such products on a broad scale and market approved products. These companies also compete with us by having 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 have 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 products that we develop obsolete. We also face competition from smaller companies who, like us, rely on investors to fund research and development and compete for co-development and licensing opportunities from large and established pharmaceutical companies.

We face competition for pemvidutide, our dual GLP-1/glucagon dual agonist for the treatment of obesity and MASH. For obesity, we face competition from companies such as Novo Nordisk, whose GLP-1 agonist, brand named Wegovy, or compound name semaglutide, was approved for weight loss in June 2021. Other companies with potentially competitive products or product candidates, include Eli Lilly with GLP-1/glucose-dependent insulinotropic polypeptide receptor ("GIP") dual agonists, including Zepbound, or compound name tirzepatide, approved for obesity in November 2023; Boehringer Ingelheim, AstraZeneca, Innovent Biologics/Eli Lilly, and Roche through its acquisition of Carmot and D&D Pharma, with GLP-1/glucagon receptor dual agonists; Hanmi Pharmaceutical and Eli Lilly with GLP-1/glucagon/GIP triple agonists; Amgen with its GLP-1 agonist/GIP antagonist antibody; and Novo Nordisk with Amylin and Amylin-GLP-1 combination candidates. Other companies have been developing oral candidates for the treatment of obesity with GLP-1 monoagonist or GLP-1/GIP dual receptor agonists including Pfizer, Lilly, Structure Therapeutics, AstraZeneca through its acquisition of Eccogene and Roche through its acquisition of Carmot. In addition, Novo Nordisk has an FDA-approved oral GLP-1 therapy, Rybelsus or compound name semaglutide. We face competition in MASH from companies such as Madrigal Pharmaceuticals, Terns, Aligos and Viking Therapeutics, which are developing orally administered, thyroid hormone receptor ("THR") β-selective agonist; Akero Therapeutics, 89Bio, Novo Nordisk and Boston Pharmaceuticals, which are developing fibroblast growth factor 21 ("FGF-21") analogs; Novo Nordisk, which is developing a GLP-1 agonist; Merck/Hanmi Pharmaceutical, which is developing a GLP-1/glucagon dual agonist, Eli Lilly, which is developing a GLP-1/GIP dual agonist, Inventiva, which is developing a pan-peroxisome proliferator-activated receptor ("PPAR") agonist; Sagimet which is developing a fatty acid synthetase inhibitor, HEC Pharma which is developing a GLP-1/FGF-21dual agonist; and Pfizer and Eli Lilly, which are developing small molecule GLP-1 agonists. In addition, many other small companies are developing other new technologies directed towards obesity or MASH.

As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA approval or discovering, developing and commercializing products before we do. In addition, any new product that we develop that

competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. If we are not able to compete effectively against potential competitors, our business will not grow, and our financial condition and operations will suffer.

We are heavily dependent on the success of our leading product candidate, pemvidutide. If we ultimately are unable to develop, obtain regulatory approval for or commercialize pemvidutide, or any other product candidate, our business will be substantially harmed.

We currently have no products approved for commercial distribution. Our business strategy is to build a pipeline of product candidates using our proprietary platforms, including our leading product candidate, pemvidutide, and to progress the product candidate through clinical development for the treatment of different types of diseases. We may not be able to develop products that are safe and effective for all or any of the indications that we target. Even if we are successful in building a product pipeline, the potential product candidates that we identify may not be suitable for clinical development for a number of reasons, including causing harmful side effects or demonstrating other characteristics that indicate a low likelihood of receiving marketing approval or achieving market acceptance. If our methods of identifying potential product candidates fail to produce a pipeline of potentially viable product candidates, then our success as a business will be dependent on the success of fewer potential product candidates, which introduces risks to our business model and potential limitations to any success we may achieve.

Because we have limited financial and managerial resources, we must focus on a limited number of research programs and product candidates and on specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future discovery and preclinical development programs and product candidates for specific indications may not yield any commercially viable products. Furthermore, until such time as we are able to build a broader product candidate pipeline, if ever, any adverse developments with respect to our leading product candidate, pemvidutide, would have a more significant adverse effect on our overall business than if we maintained a broader portfolio of product candidates.

If we fail to establish and maintain strategic partnerships related to pemvidutide, we will bear all of the risk and costs related to its development which could negatively affect the development of pemvidutide and materially affect our business and financial condition.

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

If any current or future product 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 payers, and others in the medical community. The degree of market acceptance of any product 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 ability to obtain sufficient third-party coverage and adequate reimbursement, including with respect to the use of the approved product as a combination therapy;
- the cost of treatment in relation to alternative treatments, including generic products;

- the extent and strength of our third-party manufacturer and supplier support;
- the extent and strength of marketing and distribution support;
- any limitations or warnings contained in a product's approved labeling;
- any distribution and use restrictions imposed by the FDA or other regulatory authorities outside the United States or that are part of a REMS or voluntary risk management plan; and
- the prevalence and severity of any side effects, including the tolerability and effect on comorbidities relative to alternative treatments.

For example, even if our products have been approved by the FDA, physicians and patients may not immediately be receptive to them and may be slow to adopt them. If our products do not achieve an adequate level of acceptance among physicians, patients and third-party payers, we may not generate meaningful revenues and we may not become profitable.

We may not be able to comply with the requirements of foreign jurisdictions in conducting trials within the United Kingdom, European Union ("EU") or any other foreign country.

We have in the past conducted clinical trials in the U.S. and other countries; and future clinical trials may be conducted in other foreign jurisdictions. Our ability to successfully initiate, enroll and complete a clinical trial in any other foreign country is subject to numerous risks unique to conducting business in foreign countries, including:

- difficulty in establishing or managing relationships with CROs and physicians;
- different standards for the approval and conduct of clinical trials;
- our inability to locate qualified local consultants, physicians and partners; and
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of the conduct of clinical trials, pharmaceutical and biotechnology products and treatment.

If we fail to successfully meet requirements for the conduct of clinical trials outside of the United States, we may be delayed in obtaining, or be unable to obtain, regulatory approval for our product candidates in the United States or in countries outside of the United States.

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop our products, conduct our clinical trials and commercialize our product candidates.

We are highly dependent on members of our senior management, including Dr. Vipin Garg, our President and Chief Executive Officer, Richard Eisenstadt, our Chief Financial Officer, Dr. Scott Harris, our Chief Medical Officer, Dr. M. Scot Roberts, our Chief Scientific Officer and Raymond Jordt, our Chief Business Officer. Although we have entered into employment agreements with each of these members of senior management and key employees, the loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development, commercialization and business development objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities

and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than the Company and may have commitments under consulting or advisory contracts with other entities that may limit their availability to the Company. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

A pandemic, epidemic or outbreak of an infectious disease in the United States such as the COVID-19 pandemic may adversely affect our business.

Our global operations expose us to risks associated with public health crises and epidemics/pandemics, such as COVID-19. Such risks include significant volatility, uncertainty and worldwide economic disruption which resulted in an economic slowdown of potentially extended duration. Similar events in the future could impact our operations, including the potential interruption of our clinical trial activities, regulatory reviews and our supply chain. For example, future outbreaks of infectious disease, such as COVID 19, and any future variants or subvariants that may emerge, may delay preclinical testing and enrollment in our clinical trials due to prioritization of laboratory and hospital resources toward the outbreak or other factors, and some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay our ability to conduct clinical trials or release clinical trial results and could delay our ability to obtain regulatory approval and commercialize our product candidates.

The spread of an infectious disease, including COVID 19, its subvariants and other SARS-CoV-2 viruses, may affect the operations of key governmental agencies, such as the FDA, which may delay the development of our product candidates or also result in the inability of our suppliers to deliver components or raw materials on a timely basis or at all. In addition, hospitals may reduce staffing and reduce or postpone certain treatments in response to the spread of an infectious disease. Third parties and CROs on which we rely may also reduce staffing which could impact our ability to continue preclinical testing and clinical trials on expected timeframes. Such events may result in a period of business disruption, and in reduced operations, or doctors and medical providers may be unwilling to participate in our clinical trials, any of which could materially affect our business, financial condition and results of operations.

In response to COVID 19 related government and public health directives and orders, we implemented and continue to maintain work-from-home and hybrid policies for certain employees. The effects of these policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines and could negatively impact our business, operating results and financial condition.

In addition, the trading prices for our common stock and other biopharmaceutical companies may be highly volatile as a result of a pandemic, epidemic or the spread of infectious disease. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. A significant outbreak of infectious disease could result in a widespread health crisis that could adversely affect the economies and financial markets worldwide, resulting in an economic downturn that could impact our business, financial condition and results of operations.

Labor shortages and constraints in the supply chain could adversely affect our results of operations.

A number of factors may adversely affect the labor force available to us or increase labor costs, including high employment levels, federal unemployment subsidies, increased wages offered by other employers, vaccine mandates and other government regulations and our responses thereto. As more employers offer remote work, we may have more difficulty recruiting for jobs that require on-site attendance. If we are unable to hire and retain employees capable of performing at a high-level, our business could be adversely affected. A sustained labor shortage, lack of skilled labor, or increased turnover within our employee base, caused by a pandemic, epidemic or the spread of infectious disease or as a result of general macroeconomic factors, could have a material adverse impact on our business and operating results.

In addition, recent developments in the national and worldwide supply chain slowdown, including as a result of the conflict in Israel and the Gaza Strip, and the conflict in Ukraine, have resulted in increased cost and reduced supply for supplies and materials. It is impossible to predict how long this supply chain slowdown will last or how much it will impact our business operations, but it is likely that our costs will increase for supplies.

Our overall performance depends in part on worldwide economic conditions and uncertainties.

Global inflation rates have increased to levels not seen in several decades, which may result in increases in our operating costs, including our labor costs, constrained credit and liquidity, reduced government spending and volatility in financial markets which may adversely affect the Company's business and financial condition. Additionally, the upcoming 2024 U.S. Presidential election could cause additional legal, political and economic uncertainty. The Federal Reserve and other international government agencies have raised, and may again raise, interest rates in response to concerns over inflation risk. Increases in interest rates on credit and debt that would increase the cost of any borrowing that we may make from time to time and could impact our ability to access the capital markets.

Our acquisitions may expose us to unknown liabilities.

Because we have historically acquired all the outstanding shares of most of our acquired companies, our investment in those companies are or will be subject to all of their liabilities other than their respective debts which we paid or will pay at the time of the acquisitions. If there are unknown liabilities or other obligations, our business could be materially affected. We may also experience issues relating to internal controls over financial reporting, issues that could affect our ability to comply with the Sarbanes-Oxley Act, tax examinations by the IRS or state tax authorities, or issues that could affect our ability to comply with other applicable laws.

Tax laws could change.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws resulting from legislative, administrative or judicial decisions may have adverse tax consequences on our business, cash flow, financial condition or results of operations or to a holder of our common stock. Shareholders should consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

We may not be able to utilize a significant portion of our net operating loss carryforwards, which could harm our results of operations.

We had U.S. federal and state net operating loss carryforwards of approximately $152.7 million and $143.3 million, respectively, as of December 31, 2023, of which a portion of the federal and state amount of $7.1 million and $143.3 million, respectively, has a 20-year carry forward period that will expire at various dates beginning in 2024. Under current law, the remaining federal amount of $145.6 million has an indefinite life and generally may not be carried back to prior taxable years. For net operating losses arising in taxable years beginning after December 31, 2017, we are permitted a net operating loss deduction that is limited to 80% of our taxable income in such year. The net operating loss carryforwards are subject to a 382-limitation related to ownership changes. Under Section 382 of the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its net operating losses ("NOLs"), to offset U.S. federal and state taxable income. For these purposes, an ownership change generally occurs in the event of a cumulative change in ownership of the Company of more than 50% within any three-year period. We have reviewed our stock ownership for any ownership changes as defined under IRC Section 382 from January 1, 2021 through November 3, 2023 and determined that the ownership change was less than 50% during that period. Our existing NOLs are subject to limitations arising from previous ownership changes impacting the timing and amount, and the impact of such changes is reflected in the NOL amounts disclosed above. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change. Accordingly, we may not be able to utilize a material portion of our NOLs and this could harm our future operating results by effectively increasing our future tax obligations.

As of December 31, 2023, we have recorded a valuation allowance of $83.0 million against our net deferred tax asset.

Risks Related to the Regulatory Approval Process

We cannot guarantee how long it will take regulatory agencies to review our applications for product candidates, and we may fail to obtain the necessary regulatory approvals to market our product candidates. If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, research, testing, manufacture, safety, efficacy, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and foreign jurisdictions. Failure to obtain marketing approval for our product candidates will prevent us from commercializing them in those markets.

We have not received approval from regulatory authorities to market any product candidate in any jurisdiction, and it is possible that neither our current product candidates nor any product candidates that we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us to commence product sales.

We expect to rely on third-party CROs and consultants to assist in filing and supporting the applications necessary to gain marketing approvals. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication of each of our product candidates to establish the product candidates' safety and efficacy for such indications. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, regulatory authorities.

The pathway to regulatory approvals is time consuming and unpredictable, involves substantial costs and consumes management time and attention. It is not possible to predict the timing or success of obtaining regulatory approvals with any degree of certainty, and as a result, it is difficult to forecast our future financial results or prospects. Any unexpected development in the regulatory approval process, including delays or denials of regulatory approvals or significant modifications to our product candidates required by our regulators, could materially and adversely affect our business, results of operations and financial condition, and could substantially harm our stock price.

To obtain marketing approval, United States laws require:

- controlled research and human clinical testing;
- establishment of the safety and efficacy of the product for each use sought;
- government review and approval of a submission containing, among other things, manufacturing, preclinical and clinical data; and
- compliance with cGMP regulations.

The process of reviewing and approving a drug is time-consuming, unpredictable, and dependent on a variety of factors outside of our control. The FDA and corresponding regulatory authorities in other jurisdictions have a significant amount of discretion in deciding whether or not to approve a marketing application. Our product candidates could fail to receive regulatory approval from the FDA or comparable regulatory authorities outside the United States for several reasons, including:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that our candidate is safe and effective for the proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- failure to demonstrate that the product candidate's benefits outweigh its risks;

- disagreement with our interpretation of preclinical or clinical data; and
- inadequacies in the manufacturing facilities or processes of third-party manufacturers.

The FDA or a comparable regulatory authority outside the United States may require us to conduct additional preclinical and clinical testing, which may delay or prevent approval and our commercialization plans or cause us to abandon the development program. Further, any approval we receive may be for fewer or more limited indications than we request, may not include labeling claims necessary for successful commercialization of the product candidate, or may be contingent upon our conducting costly post-marketing clinical trials. Any of these scenarios could materially harm the commercial prospects of a product candidate, and our operations will be adversely affected.

Our product candidates may cause undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential.

Significant adverse events caused by our product candidates or even competing products in development that utilize a common mechanism of action could cause us, an IRB or ethics committee, and/or regulatory authorities to interrupt, delay or halt clinical trials and could result in clinical trial challenges such as difficulties in patient recruitment, retention, and adherence, the denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. Serious adverse events deemed to be caused by our product candidates could have a material adverse effect on the development of our product candidates and our business as a whole. The most common adverse events observed in clinical trials for product candidates developed using the Densigen platform include injection site reactions, headache, malaise and fatigue.

Our understanding of the relationship between our product candidates and these events, as well as our understanding of adverse events reported in future clinical trials of other product candidates, may change as we gather more information, and additional unexpected adverse events may be observed. In addition, the side effect profile of pharmaceutical drugs cannot be fully established based on preapproval clinical trials involving a limited number of patients. Routine review and analysis of post-marketing safety surveillance and clinical trials will provide additional information, for example, potential evidence of rare, population-specific or long-term adverse reactions, and may adversely affect the commercialization of the product, and even lead to the suspension or revocation of product marketing authorization.

If we or others identify undesirable side effects caused by our product candidates either before or after receipt of marketing approval, a number of potentially significant negative consequences could result, including:

- our clinical trials may be put on hold;
- we may be unable to obtain regulatory approval for our product candidates;
- regulatory authorities may withdraw approvals of our products;
- regulatory authorities may require additional warnings on the label;
- a medication guide outlining the risks of such side effects for distribution to patients may be required;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining marketing approvals for and market acceptance of our product candidates and could have a material adverse effect on our business and financial results.

Fast track designation by the FDA may not lead to a faster development or regulatory review or approval process, and does not assure FDA approval of any product candidates that we may develop.

FDA's fast track program is intended to expedite the development of certain qualifying products intended for the treatment of serious diseases and conditions. If a product candidate is intended for the treatment of a serious or life threatening condition and preclinical or clinical data demonstrate the product's potential to address an unmet medical need for this condition, the sponsor may apply for FDA fast track designation. In October 2023, we announced that the FDA granted fast track designation to our clinical program investigating pemvidutide for the treatment of MASH. Even with fast track designation, we may not experience a faster development process, review or approval for pemvidutide compared to conventional FDA procedures, and fast track designation does not ensure that a product candidate will receive marketing approval at all. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

If we fail to obtain regulatory approval in non-U.S. jurisdictions, we will not be able to market our products in those jurisdictions. Receiving and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in receiving or maintaining regulatory approval of our product candidates in other jurisdictions.

We intend to market certain of our product candidates, if approved, in the United Kingdom and other international markets, in addition to the United States. Such marketing will require separate regulatory approvals in each market and compliance with numerous and varying regulatory requirements. The approval procedures vary among countries and may involve requirements for additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. In addition, in many countries outside the United States, such as certain countries of the European Union, a vaccine or therapeutic must be approved for reimbursement, including the price that can be charged, before it can be approved for sale in that country. In these countries, pricing discussions with governmental authorities can take considerable time after the receipt of marketing approval for a product, and additional clinical research may be required to enable comparison of the cost effectiveness of our product candidate to other available alternatives. Approval by the FDA does not ensure approval 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 or by the FDA. However, the failure to obtain approval in one jurisdiction may compromise our ability to obtain approval elsewhere. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all.

Even if we receive regulatory approval for our product candidates, such products will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and other restrictions, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to conditions of approval. We may also be required to conduct post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product potentially over many years. If the FDA or other regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion and recordkeeping 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, registration, as well as continued compliance with cGMP, and compliance with cGMP and GCP for any clinical trials that we conduct post-approval. Manufacturers and manufacturers' facilities are also required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations and applicable product tracking and tracing requirements. Any such restrictions may result in significant additional expense or could limit sales of the approved product. If we, or any of the third parties on which we rely, fail to meet those requirements, the FDA or comparable regulatory authorities outside the United States could initiate enforcement action. Other consequences include the issuance of fines, warning letters, untitled letters or holds on clinical trials, product seizure or detention or refusal to permit the import or export of our product candidates, and permanent injunctions and consent decrees, including the imposition of civil or criminal penalties, among other consequences, that could significantly impair our ability to successfully commercialize a given product.

Later discovery of previously unknown problems with an approved product, including adverse events of unanticipated severity or frequency, or with manufacturing operations or processes, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines or warning letters, or clinical holds on clinical trials involving related product candidates;
- refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications submitted by us or suspension or revocation of product license approvals;
- product seizure or detention or refusal to permit the import or export of products; and
- injunctions or the imposition of civil, criminal and/or administrative penalties, damages, monetary fines, disgorgement, exclusion from participation in governmental reimbursement programs, such as Medicare, Medicaid and other federal health care programs and curtailment or restructuring of our operations.

In addition, applicable regulatory policies of governmental authorities, such as the FDA, may change and additional government regulations may be enacted that could affect any regulatory approval that we may receive for our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or not able to maintain regulatory compliance, we may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

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

Any current or future product candidate 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, import, export 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 product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we may seek to develop in the future will ever obtain regulatory approval. 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 preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and effectiveness. 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 product 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 product 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 preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. 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 approval or if we fail to obtain approval of any current or future product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired.

If the FDA or comparable foreign regulatory authorities approve generic or biosimilar versions of any of our products that receive marketing approval, or if we do not obtain the exclusivity periods for our approved products that we hope to achieve, the sales of our products could be adversely affected.

If and when approved, our product candidates may face competition from ANDA or 505(b)(2) product candidates referencing our drug product and from biosimilars product candidates referencing our biological product. Certain ANDAs, and certain biosimilar products that are deemed under applicable laws to be "interchangeable with" our biological product, once approved, may be substituted for our product candidates, subject to applicable state laws.

We may also be subject to competition from biosimilar products in the EU. To date, many biosimilar products have been authorized by the European Commission, after application at EMA for a centralized marketing authorization. As in the United States the regulatory approval pathway for biosimilar products in the EU is abbreviated. A biosimilar sponsor must however still provide all of the preclinical and clinical data required to demonstrate the similarity of their product with the reference product. The level of data required is assessed on a case-by-case basis, but it will be less than that required for an original biological product. The pathway is more complex than the abridged procedure that may be followed to obtain authorization of a generic version of a non-biological product, but it would still allow the biosimilar product to be brought to market more quickly and less expensively than our original product. That said, in the EU, applications for marketing authorizations in relation to biosimilar products are subject to the same data and market exclusivity rules that apply to generic non-biologic products so no biosimilar product can be approved or placed on the market during the period such exclusivity applies to our product. Marketing authorization of a biosimilar product in the EU does not guarantee that the biosimilar product may be substituted for the reference product. Interchangeability of a biosimilar product with the reference product is not assessed by the EMA but this determination is left to each of the member states. We cannot know at this stage the extent to which any biosimilar product would be interchangeable with our reference product, and this may vary between member states.

We may pursue pediatric exclusivity for one or more of our product candidates but may not succeed in obtaining it. There is also a risk that a competitor may achieve pediatric exclusivity that would delay any potential approvals of our product candidates. In the United States, the FDA has the authority to award additional exclusivity for approved products where the sponsor conducts specified testing on pediatric or adolescent populations upon the written request of the FDA. If granted, pediatric exclusivity may add six months to certain patents or regulatory exclusivity periods for an approved drug, and to regulatory exclusivity periods for an approved biological product. In the EU, pediatric studies are also incentivized by the reward of additional exclusivity. Pediatric Investigation Plans ("PIPs") must be agreed with the Pediatric Committee of the EMA, unless a waiver or deferral applies with respect to the product. Where an application for a marketing authorization is submitted in respect of a medicinal product designated as an orphan medicinal product and that application contains the results of studies conducted in compliance with an approved PIP, market exclusivity for that orphan medicinal product may be extended by two years. Where an application for a marketing authorization is submitted in respect of a medicinal product that is not designated as an orphan medicinal product and that application contains the results of studies conducted in compliance with an approved PIP, it may be possible to obtain a six month extension of a supplementary protection certificate extending patent protection for a medicinal product.

Orphan drug designation presents yet another regulatory incentive that may be available to us and our competitors. The FDA may grant orphan drug designation to products intended to treat a "rare disease or condition" that affects fewer than 200,000 individuals in the United States, or affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug. Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation can provide opportunities for grant funding towards clinical trial costs, tax advantages and FDA user fee exemptions. In addition, if a product that has an orphan drug designation subsequently receives FDA approval for the indication for which it has such designation, the

product may be entitled to orphan drug exclusivity, which means the FDA would not approve any other application to market the same drug for a period of seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity.

In the European Union, orphan drug status offers similar but not identical benefits as those in the United States. We may pursue orphan drug designation for one or more of our product candidates but obtaining such designation cannot be assured. Even if we obtain orphan drug exclusivity, competitors may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Additionally, should a competitor receive orphan drug designation for a product to treat the same disease and same indication as one of our product candidates, there is a risk that the FDA or a comparable European regulatory body could delay approving our product candidate.

Risks Related to Our Intellectual Property

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If our patent position and other intellectual property rights do not adequately protect our product candidates, others could compete against us (including directly), which could materially harm our business, results of operations and financial condition.

We rely upon a combination of patents, patent applications, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates, platform technology and know-how. The patent position of biotechnology companies is generally uncertain, because it involves complex legal and factual considerations. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology patents. In addition, some countries do not grant patent claims directed to methods of treating humans, and in these countries patent protection may not be available at all to protect our product candidates. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in other countries.

The patent prosecution process is expensive and time consuming, and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties, making us reliant on our licensors, licensees or collaborators. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of the Company's business. If our current or future licensors, licensees or collaborators fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be lost or impaired. If our licensors, licensees or collaborators are not fully cooperative or disagree with the Company as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

If patent applications we hold or have in-licensed with respect to our product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us. We and our licensors have filed several patent applications covering aspects of our product candidates. We cannot offer any assurance about which, if any, patents will issue, the breadth of any such patents or whether any issued patents will be found invalid or unenforceable or will be successfully challenged by third parties.

Patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued. We cannot be certain that our licensors were the first to satisfy the requirements necessary to secure patent rights relating to any particular invention. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be initiated by such third party, or by the USPTO itself, to determine who was the first to invent any of the subject matter covered by the patent claims of our patent applications.

Even if patents do successfully issue and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Any successful challenge to our patents or patent applications, or to any other patents or patent applications owned by or

licensed to us, could deprive us of the rights necessary to prevent competition from third parties, which may impair the commercial success of any product candidate that we may develop. There is no assurance that all potentially relevant prior art relating to our patents and patent applications or those of our licensors has been found, and prior art that we have not identified could be used by a third party to invalidate a patent or prevent a patent from issuing from a pending patent application. Furthermore, even if they are unchallenged, our patents and patent applications, or those of our licensors, may not adequately protect our technology, provide exclusivity for our product candidates, prevent others from designing around our patents with similar products, or prevent others from operating in jurisdictions in which we did not pursue patent protection. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

Any loss of, or failure to obtain, patent protection could have a material adverse impact on our business. We may be unable to prevent competitors from entering the market with a product that is similar to or the same as our products.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States 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 patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

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

Patents have a limited lifespan. In most countries, including the United States, the natural expiration of a patent is 20 years from the date that the application for the patent is filed. In some cases, the term of a U.S. patent is shortened by a terminal disclaimer that reduces its term to that of an earlier-expiring patent. Various extensions of patent term may be available in particular countries; however, in all circumstances the life of a patent, and the protection it affords, has a limited term. If we encounter delays in obtaining regulatory approvals, the period of time during which we could market a product under patent protection could be reduced. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. Such possible extensions include those permitted under the Drug Price Competition and Patent Term Restoration Act of 1984 in the United States, which permits a patent term extension of up to five years to cover an FDA-approved product. The actual length of the extension will depend on the amount of patent term lost while the product was in clinical trials. However, the applicable authorities, including the USPTO and FDA in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available and may refuse to grant extensions to our patents, or may grant more limited extensions than we request, or may not grant regulatory exclusivity. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data, and then may be able to launch their product earlier than might otherwise be the case.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary to enforce or defend our intellectual property rights, to protect our trade secrets and/or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Such litigation can be expensive and time consuming, which could divert management resources and harm our business and financial results. Many of our current and potential competitors have the ability to dedicate substantially greater resources to litigate intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property.

Patent assertion, including initiating litigation, increases the likelihood that the accused third party will seek to narrow or invalidate our asserted patent. The scope and validity of our asserted patent may be challenged in a variety of post-grant proceedings before the USPTO and foreign patent offices. In addition, in an infringement proceeding, a court may decide that our asserted patent is invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding or other legal proceeding could therefore put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. 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.

Third-party claims of intellectual property infringement or misappropriation may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates, and to use our or our licensors' proprietary technologies without infringing the patents and proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing and may develop our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. We may not have identified all U.S. and foreign patents or published patent applications that affect our business either by blocking our ability to commercialize our product candidates or by covering similar technologies that affect our market.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims, for example, to materials, formulations, methods of manufacture, methods of analysis and/or methods for treatment related to the use or manufacture of our product candidates.

In some cases, we may have failed to identify such relevant third-party patents or patent applications. For example, patent applications filed before November 29, 2000 and certain patent applications filed after that date that will not be filed outside the United States remain confidential until issued as patents. Except for the preceding exceptions, patent applications in the United States and elsewhere are generally published only after a waiting period of approximately 18 months after the earliest filing. Therefore, patent applications covering our platform technology or our product candidates could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies or product candidates and/or the use, analysis and/or manufacture of our product candidates.

If any third-party patents are held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture, methods of analysis and/or methods for treatment, the holders of any such patents may be awarded monetary damages, obtain injunctive or other equitable relief, or both. An award of monetary damages may be substantial and may include treble damages and attorneys' fees for willful infringement. An award of injunctive relief could block our ability to develop and commercialize the applicable product candidate until such patent expired or unless we obtain a license. Such licenses may not be available on acceptable terms, if at all. Even if we were able to obtain a license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be forced to redesign an infringing product, prevented from commercializing a product, or

forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business.

We may face a claim of misappropriation if a third party believes that we inappropriately obtained and used trade secrets of such third party. If we are found to have misappropriated a third party's trade secrets, we may be prevented from further using such trade secrets, limiting our ability to develop our product candidates, and we may be required to pay damages.

During the course of any patent or other intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our product candidates, platform technology or intellectual property could be diminished. Accordingly, the market price of our common stock may decline. In addition, the uncertainties associated with litigation could have an adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development partnerships that would help us bring our product candidates to market.

We may be subject to claims that our employees, independent contractors or consultants have wrongfully used or disclosed alleged trade secrets of their former employers, or our employees may challenge the inventorship of our patents.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these individuals, including members of our senior management, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we use reasonable efforts to ensure that our employees, independent contractors and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party.

We may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. In addition, we may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

We have in-licensed a portion of our intellectual property, and, if we fail to comply with our obligations under these arrangements, we could lose such intellectual property rights or owe damages to the licensor of such intellectual property.

We are a party to a number of license agreements that are important to our business, and we may enter into additional license agreements in the future. Certain of our in-licensed intellectual property covers, or may cover, EuPort technology, and certain of our product candidates including pemvidutide. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other of our obligations. If there is any conflict, dispute, disagreement or issue of non-performance between the Company and our licensing partners regarding our rights or obligations under the license agreements, including any such conflict, dispute or disagreement arising from our failure to satisfy payment obligations under any such agreement, we may owe damages, our licensor may have a right to terminate the affected license, and our ability to utilize the affected intellectual property in

our product discovery and development efforts and our ability to enter into collaboration or marketing agreements for an affected product candidate may be adversely affected.

We may need to license certain intellectual property from third parties, and such licenses may not be available on commercially reasonable terms or at all.

A third party may hold intellectual property, including patent rights, that is important or necessary to the development or commercialization of our product candidates. If the patented or proprietary technology of third parties is necessary for us to commercialize our product candidates, we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms or at all, which could materially harm our business.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of proprietary information.

In addition to the protection afforded by patents, we rely on confidentiality agreements to protect trade secrets and proprietary know-how that may not be patentable or that we may elect not to patent, processes for which patents are difficult to enforce and any other elements of our technology and development processes that involve proprietary know-how, information or technology that is not covered by patents. In particular, we seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, outside scientific advisors, contractors and collaborators. These agreements require that all confidential information developed by the individual or made known to the individual by the Company during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. We also enter into agreements with our employees that provide that any inventions conceived by the individual in the course of rendering services to the Company shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. Although we use reasonable efforts to protect our know-how, our employees, consultants, contractors or outside scientific advisors might intentionally or inadvertently disclose our know-how or other proprietary information to competitors. In addition, competitors may otherwise gain access to our know-how or independently develop substantially equivalent information and techniques.

Enforcing a claim that a third party illegally obtained and is using any of our know-how is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States sometimes are less willing than U.S. courts to protect know-how. Misappropriation or unauthorized disclosure of our know-how could impair our competitive position and may have a material adverse effect on our business.

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, declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to those of the Company's, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. For example, we have experienced threatened or actual opposition for two trademarks that we were pursuing. We decided to discontinue our use of one of those trademarks, and the other matter was resolved on favorable terms. Although these matters have been resolved on terms that did not materially harm the Company, we may become subject to other trademark challenges in the future. If we are unable to establish long-term 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.

Risks Related to Commercialization of the Company's Product Candidates

Our future commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, third-party payers and others in the medical community.

Even if we obtain marketing approval for our product candidates, or any other product candidates that we may develop or acquire in the future, the product may not gain market acceptance among physicians, third-party payers, patients and others in the medical community. Market acceptance of any approved products depends on a number of other factors, including:

- the efficacy and safety of the product, as demonstrated in clinical trials;
- the clinical indications for which the product is approved and the label approved by regulatory authorities for use with the product, including any warnings that may be required on the label;
- acceptance by physicians and patients of the product as a safe and effective treatment and the willingness of the target patient population to try new vaccines and/or therapies and of physicians to prescribe new vaccines and/or therapies;
- the cost, safety and efficacy of treatment in relation to alternative treatments;
- the availability of adequate course and reimbursement by third-party payers and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse side effects;
- the effectiveness of our sales and marketing efforts; and
- the restrictions on the use of our products together with other medications, if any.

Market acceptance is critical to our ability to generate significant revenue. Any product candidate, if approved and commercialized, may be accepted in only limited capacities or not at all. If any approved products are not accepted by the market to the extent that we expect, we may not be able to generate significant revenue and our business would suffer.

We rely on, and expect to continue to rely on, third parties to manufacture our product candidates and related materials for our products, if approved, as well as for our clinical trials and preclinical studies, and these third parties may not perform satisfactorily.

We do not have any manufacturing facilities or personnel, and we rely on, and expect to continue to rely on, third-party manufacturers and suppliers to manufacture and supply vaccines, drug substance and drug product for our preclinical studies and clinical trials, and on related materials, such as HBV products and pemvidutide. We rely on a small number of third-party manufacturers and suppliers to manufacture and supply bulk drug substance and drug product and fill finished vaccines for our initial clinical trials. This reliance on a small number of third parties increases the risk that we will not have sufficient quantities of our product candidates or other products needed for our preclinical studies and clinical trials, or that such quantities will be manufactured for us at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

Any of these third parties that we rely upon may terminate their engagement with us at any time. If we need to enter into alternative arrangements, it could delay our product development activities. In addition, our reliance on these third parties for manufacturing activities will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations regarding manufacturing.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the product candidates ourself, including:

- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- reduced control as a result of using third-party manufacturers for all aspects of manufacturing activities, including regulatory compliance and quality assurance. We do not have control over third party manufacturers' compliance with these regulations and standards, but we may ultimately be responsible for any of their failures;
- delays as a result of manufacturing problems or re-prioritization of projects at a third-party manufacturer;
- our third-party manufacturers might be unable to formulate and manufacture our product candidates in the volume and of the quality required to meet our clinical and commercial needs, if any;
- termination or non-renewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how or infringement of third-party intellectual property rights by our contract manufacturers; and
- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy or change in ownership of the manufacturer or supplier.

Any of these events could lead to preclinical study and clinical trial delays or failure to obtain regulatory approval or affect our ability to successfully commercialize future products. Some of these events could be the basis for FDA or other regulatory authority action, including clinical holds, fines, injunctions, civil penalties, license revocations, recall, seizure, total or partial suspension of production, or criminal penalties.

In addition, our product candidates involve technically complex manufacturing processes, and even slight deviations at any point in the production process may lead to production failures and may cause the production of our product candidates to be disrupted, potentially for extended periods of time. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original contract manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. Furthermore, a contract manufacturer may possess technology related to the manufacture of our product candidate that such contract manufacturer owns independently. This would increase our reliance on such contract manufacturer or require us to obtain a license from such contract manufacturer in order to have another contract manufacturer manufacture our product candidates.

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

In addition, if we are required to change contract manufacturers for any reason, we will be required to verify that the new contract manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new contract manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

Our third-party manufacturers may be subject to damage or interruption from, among other things, fire, natural or man-made disaster, power loss, telecommunications failure, unauthorized entry, computer viruses, denial-of-service attacks, acts of terrorism, human error, vandalism or sabotage, financial insolvency, bankruptcy and similar events.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We have limited arrangements in place for redundant supply or a second source for bulk drug substance. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers, and it may prove very difficult and time consuming to identify potential alternative manufacturers who could manufacture our product candidates. Accordingly, we may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

If we are unable to manufacture our products in sufficient quantities, or at sufficient yields, or are unable to obtain regulatory approvals for a manufacturing facility for our products, we may experience delays in product development, clinical trials, regulatory approval and commercial distribution.

Completion of our clinical trials and commercialization of our product candidates require access to, or development of, facilities to manufacture our product candidates at sufficient yields and at commercial scale, and this manufacturing involves a complicated process with which we have limited experience. Even if clinical trials are successful, we still may be unable to commercialize a product due to difficulties in obtaining regulatory approval for our engineering processes or problems in scaling that process to commercial production. We have no experience manufacturing, or managing third parties in manufacturing, any of our product candidates in the volumes that will be necessary to support large-scale clinical trials or commercial sales. Efforts to establish these capabilities may not meet initial expectations as to scheduling, scale-up, reproducibility, yield, purity, cost, potency or quality.

We expect to rely on third parties for the manufacture of clinical and, if approved for marketing, commercial quantities of our product candidates. These third-party manufacturers must also receive FDA or other applicable governmental authority approval before they can produce clinical material or commercial products. Our products may be in competition with other products for access to these facilities and may be subject to delays in manufacture if third parties give other products greater priority. We may not be able to enter into any necessary third-party manufacturing arrangements on acceptable terms, or on a timely basis. In addition, we may have to enter into technical transfer agreements and share our know-how with the third-party manufacturers, which can be time consuming and may result in delays.

Our contract manufacturing organizations may encounter technical or scientific issues related to development or manufacturing that we may be unable to resolve in a timely manner or with available funds. If we or our manufacturing partners are unable to scale the manufacturing process to produce commercial quantities of our product candidates, or our manufacturing partners do not pass required regulatory pre-approval inspections, our commercialization efforts may be adversely affected.

Our reliance on contract manufacturers may adversely affect our operations or result in unforeseen delays or other problems beyond our control. Because of contractual restraints and the limited number of third-party manufacturers with the expertise, required regulatory approvals and facilities to manufacture our products on a commercial scale, replacement of a manufacturer may be expensive and time consuming and may cause interruptions in the production of our product candidates. A third-party manufacturer may also encounter difficulties in production. These problems may include:

- difficulties with production costs, scale-up and yields;
- unavailability of raw materials and supplies;
- insufficient quality control and assurance;

- shortages of qualified personnel;
- failure to comply with strictly enforced federal, state and foreign regulations that vary in each country where product might be sold; and
- lack of capital funding.

Any delay or interruption in the manufacture of our products could have a material adverse effect on our business, financial condition, results of operations and cash flows.

If we are unable to establish sales, marketing and distribution capabilities, we may not be successful in commercializing our product candidates if they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product for which we obtain marketing approval, and for which we decide to independently commercialize, we will need to establish a sales and marketing organization.

In the future, we may build a focused sales and marketing infrastructure to market or co-promote some of our product candidates in the United States and in Europe, if and when they are approved. There are risks involved with our establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians;
- the lack of adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance our product candidates through clinical trials and commercialization, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for the Company. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate

additional management, administrative and, if necessary, sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our business.

We may not be successful in establishing and maintaining strategic partnerships, which could adversely affect our ability to develop and commercialize products.

A key part of our strategy is to seek strategic partnerships in the future, including potentially with major biotechnology or pharmaceutical companies for late-stage development and commercialization of our product candidates. We face significant competition in seeking appropriate partners for our product candidates, and the negotiation process is time consuming and complex. In order for the Company to successfully partner our product candidates, potential partners must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other products available for licensing from other companies. Even if we are successful in our efforts to establish strategic partnerships, the terms that we agree upon may not be favorable to the Company, and we may not be able to maintain such strategic partnerships if, for example, development or approval of a product is delayed or sales of an approved product are disappointing. Any delay in entering into strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

In addition, any future partnerships we may enter into pose a number of risks, including that our partners may breach their agreements with the Company, and we may not be able to adequately protect our rights under these agreements. Furthermore, prospective partners will likely negotiate for certain rights to control decisions regarding the development and commercialization of our product candidates, if approved, and may not conduct those activities in the same manner as we would.

If we fail to establish and maintain strategic partnerships related to our product candidates, including pemvidutide, we will bear all of the risk and costs related to the development of any such product candidate, and we may need to seek additional financing, hire additional employees and otherwise develop expertise which we do not have and for which we have not budgeted. This could negatively affect the development of any unpartnered product candidate and materially affect our business and financial condition.

We may acquire other businesses, form joint ventures or make investments in other companies or technologies that could negatively affect our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of assets or licenses of assets, including preclinical, clinical or commercial stage products or product candidates, businesses, strategic alliances, joint ventures and collaborations, to expand our existing technologies and operations.

In the future, we may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in the incurrence of debt, contingent liabilities or future write-offs of intangible assets or goodwill, any of which could have a negative impact on our cash flows, financial condition and results of operations. Integration of an acquired company also may disrupt ongoing operations and require management resources that we would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could harm our financial condition and results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, license, strategic alliance or joint venture.

To finance such a transaction, we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for these activities through public or private financings or through the issuance of debt. Additional funds may not be available on terms that are favorable to the Company, or at all, and any debt financing may involve covenants limiting or restricting our ability to take certain actions.

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

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product 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 and 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 our product candidates.

Even a 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 product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigations;
- a diversion of management's time and the Company's resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize any product candidates that we may develop; and
- a decline in our stock price.

Failure to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry worldwide product liability insurance covering our clinical trials in the amount of $10.0 million in the aggregate. Although we maintain product liability insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will 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.

A breakdown in our information technology systems could result in a significant disruption to our business.

Our operations and those of our business partners, such as CROs, vendors and others that manage sensitive data, are highly dependent on information technology systems, including Internet-based systems, which may be vulnerable to damage or interruption from, among other things, computer viruses, computer hackers, phishing attacks, ransomware, malware, social engineering, malicious code, employee theft, fraud, misconduct or misuse, denial-of-service attacks, sophisticated nation-state and nation-state-supported actors, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures, breakdown, wrongful intrusions, data breaches and malicious attack. Information security risks have generally increased in recent years. Our systems, and those of our third-party providers, are potentially vulnerable to data security breaches or cyberattack, whether by employees or others, which may expose sensitive data to unauthorized persons. A data security breach or compromise could lead to the loss of trade secrets or other intellectual property, the value of which may be contingent upon maintaining our confidentiality, or could lead to

the public exposure of personal information (including sensitive personal medical information) of clinical trial participants, our employees and others, or adversely impact the conduct of scientific research and clinical trials, including the submission of research results to support marketing authorizations. This could require us to expend significant efforts and resources or incur significant expense to eliminate these problems and address related security concerns. In addition, procedures and safeguards must continually evolve to meet new data security challenges, and enhancing protections, and conducting investigations and remediation, may impose additional costs on the Company. If we or our third-party providers were to experience a cybersecurity compromise or breach or other security incident, suffer a breakdown in our systems, storage, distribution or tracing, we could experience significant disruptions affecting our business, supply chain interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary, personal or confidential information, and reputational harm which could negatively impact our relationship with our customers, partners, vendors and other third parties, and fines and penalties resulting from claims against us by private parties and/or governmental agencies.

Risks Related to Reimbursement and Government Regulation

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if they are approved, which could make it difficult for us to sell our products profitably.

Market acceptance and sales of any approved products will depend significantly on the availability of adequate coverage and reimbursement from third-party payers and may be affected by existing and future health care reform measures. Third-party payers, such as government health care programs, and private health insurers and health plans, decide which drugs they will provide coverage for and establish reimbursement levels. Coverage and reimbursement decisions by a third-party payer may depend upon a number of factors, including the third-party payer's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Third-party payers, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling health care costs. Coverage and reimbursement can vary significantly from payer to payer. As a result, obtaining coverage and reimbursement approval for any approved product from each government and other third-party payer may require us to provide supporting scientific, clinical and cost-effectiveness data for the use of such products to each payer separately, with no assurance that we will be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for any of our product candidates, and we cannot be sure that coverage determinations or reimbursement amounts will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize certain of our products, even if they are approved by the FDA or other regulatory authorities. In addition, in the United States third-party payers are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. As a result, significant uncertainty exists as to whether and how much third-party payers will reimburse patients for their use of newly approved drugs, which in turn will put pressure on the pricing of drugs.

Price controls may be imposed, which may adversely affect our future profitability.

In international markets, reimbursement and health care payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some countries, particularly member states of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a

product. In addition, there can be considerable pressure by governments and other stakeholders on coverage, prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce revenues. In some countries, additional clinical research may be required to enable comparison of the cost-effectiveness of our product candidates, if they are approved, to other available products in order to obtain or maintain coverage, reimbursement or pricing approval. Publication of discounts by third-party payers or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. In the United States, concerns about drug pricing have been expressed by members of Congress and presidential administrations. There can be no assurance that our product candidates, if approved, will be considered cost-effective by third-party payers, that an adequate level of reimbursement will be available or that the third-party payers' reimbursement policies will not adversely affect our ability to sell our products profitably. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

We are subject to multiple and substantial federal and state health care and other laws, and the complexity of our regulatory compliance obligations is likely to increase in the event our product candidates are commercialized.

Our business operations and activities may be directly or indirectly subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal FCA, and their implementing regulations. If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as proposed and future sales, marketing and education programs.

In addition, we may be subject to patient privacy regulation by the federal government and state governments in which we conduct our business. In addition to the Anti-Kickback Statute, FCA and Physician Payments Sunshine Act and their implementing regulations, the laws that may affect our ability to operate include, but are not limited to:

- HIPAA, which created additional 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 payer (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 Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it.

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- federal government price reporting laws that require the calculation and reporting of complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts, on any of our product candidates that may be approved for marketing (participation in these programs and compliance with the applicable requirements may also subject us to potentially significant discounts on our products and increased infrastructure costs, and potentially limit our ability to offer certain marketplace discounts);

- the FCPA, which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals), and anti-bribery laws and related laws, and laws pertaining to the accuracy of our internal books and records, which have been the focus of increasing enforcement activity in recent years; and

- state law equivalents of each of the above federal laws, such as anti-kickback, false claims, consumer protection and unfair competition laws, which may apply to our business practices, including but not limited

to, research, distribution, sales-and-marketing arrangements as well as submitting claims involving health care items or services reimbursed by any third-party payer, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to health care providers; state laws that require drug manufacturers to file reports with states regarding marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to health care professionals and entities (compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships, which could potentially have a negative effect on our business and/or increase enforcement scrutiny of the Company's activities); and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, with differing effects.

In addition, the regulatory approval and commercialization of any of our product candidates outside the United States will also subject us to foreign equivalents of the health care laws mentioned above, among other foreign laws, as well as compliance with the codes of practice of certain associations within such countries (for example, the Association of the British Pharmaceutical Industry (ABPI) in the United Kingdom).

Efforts to help ensure that our business arrangements will comply with applicable health care laws and codes of practice may involve substantial costs. We have adopted policies and practices that are designed to help ensure that the Company, our employees, officers, agents, intermediaries and other third parties comply with applicable laws, but it is not always possible to assure compliance with applicable requirements, and the precautions we take to achieve compliance may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other health care laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to the Company, we may be subject to penalties, including, without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal and state health care programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring 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.

The impact of recent health care reform legislation and other changes in the health care industry and in health care spending on the Company is currently unknown and may adversely affect our business model.

Our financial prospects could be affected by changes in health care spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations, or judicial decisions, or new interpretations of existing laws, regulations, or decisions, related to, among other things, health care availability, or the method of delivery of or payment for health care products and services could negatively impact our business, operations and financial condition.

For example, in the United States there is significant interest in promoting health care reform, as evidenced by the enactment in the United States of the Affordable Care Act of 2010 (the "Health Care Reform Law"). The Health Care Reform Law substantially changed the way health care is financed by both governmental and commercial payers and significantly impacts the pharmaceutical industry. The Health Care Reform Law contains provisions that may reduce the profitability of drug products, including, for example, by increasing the minimum rebates owed by manufacturers under the Medicaid Drug Rebate Program, extending the rebate program to individuals enrolled in Medicaid managed care plans, addressing a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and imposing certain annual fees based on pharmaceutical companies' share of sales to federal health care programs.

The Health Care Reform Law established and provided significant funding for a new Patient-Centered Outcomes Research Institute to coordinate and fund comparative effectiveness research. While the stated intent of comparative

effectiveness research is to develop information to guide providers to the most efficacious therapies, outcomes of comparative effectiveness research could influence the reimbursement or coverage for therapies that are determined to be less cost effective than others. Should any of our products be approved for sale, but then determined to be less cost effective than alternative therapies, the levels of reimbursement for these products, or the willingness to reimburse at all, could be impacted, which could materially impact our financial results.

Certain provisions of the Health Care Reform Law have been subject to judicial challenges, as well as efforts to repeal, replace or otherwise modify them or to alter their interpretation or implementation. For example, the Tax Cuts and Jobs Act of 2017, eliminated the tax-based payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, as amended, commonly referred to as the "individual mandate," effective January 1, 2019. Further, the Bipartisan Budget Act of 2018 among other things, amended the Medicare statute, effective January 1, 2019, to reduce the coverage gap in most Medicare prescription drug plans, commonly known as the "donut hole," by raising the manufacturer discount under the Medicare Part D coverage gap discount program from 50% to 70%. Additional legislative changes, regulatory changes and judicial challenges related to the Health Care Reform Law remain possible. It is unclear how the Health Care Reform Law and its implementation, as well as efforts to repeal, replace or otherwise modify, or invalidate, the Health Care Reform Law, or portions thereof, will affect our business. We cannot predict what affect further changes to the Health Care Reform Law would have on our business, especially including under the Biden administration.

In addition, other legislative changes have been proposed and adopted since the Health Care Reform Law was enacted. For example, the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012, among other things, created measures for spending reductions by Congress that include aggregate reductions of Medicare payments to providers of on average 2% per fiscal year, which remain in effect through 2032. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation. The U.S. American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our drug candidates for which we may obtain regulatory approval or the frequency with which any such drug candidate is prescribed or used.

Additional legislative changes, regulatory changes or guidance could be adopted, which may impact the marketing approvals and reimbursement for our product candidates. For example, on July 9, 2021, President Biden issued an executive order directing the FDA to, among other things, continue to clarify and improve the approval framework for biosimilars, including the standards for interchangeability of biological products, facilitate the development and approval of biosimilar and interchangeable products, clarify existing requirements and procedures related to the review and submission of BLAs, and identify and address any efforts to impede biosimilar competition.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs. The Inflation Reduction Act of 2022 (IRA), for example, includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby eliminating the so-called coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D; allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of

the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

Further, there has been increasing legislative, regulatory and enforcement interest in the United States with respect to drug pricing practices. There have been several Congressional inquiries and proposed and enacted federal and state legislation and regulatory initiatives designed to, among other things, bring more transparency to product pricing, evaluate the relationship between pricing and manufacturer patient programs, and reform government healthcare program reimbursement methodologies for drug products.

It is possible that the Health Care Reform Law, as currently enacted or may be amended or otherwise modified in the future, as well as other health care reform measures that may be adopted in the future, may result in additional reductions in Medicare payment and other health care financing, more rigorous coverage criteria, and new payment methodologies and in additional downward pressure on coverage and payment and the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from commercial payers. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. These continuing health care reform initiatives may adversely affect:

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

Certain business practices associated with the commercialization of pharmaceutical products are subject to scrutiny by regulatory authorities, as well as to lawsuits brought by private citizens under federal and state laws. Failure to comply with applicable law or an adverse decision in lawsuits may result in adverse consequences to the Company.

The laws that would govern our conduct in the United States upon the commercialization of our product candidates are enforceable by criminal, civil and administrative penalties. Violations of laws such as the Anti-Kickback Statute and FCA, the FD&C Act, or any regulations promulgated under their authority, may result in jail sentences, fines or exclusion from federal and state programs, as may be determined by Medicare, Medicaid, the Department of Defense, other regulatory authorities and the courts. There can be no assurance that our activities will not come under the scrutiny of regulators and other government authorities or that our practices will not be found to violate applicable laws, rules and regulations or prompt lawsuits by private citizen "relators" under federal or state false claims laws. In the United States, among the laws that may affect our ability to operate and market our products include, but are not limited to:

- The federal Anti-Kickback Statute prohibits, among other activities, any person from knowingly and willfully, directly or indirectly soliciting, receiving, offering or paying any remuneration with the intent of (or in return for) generating referrals of individuals or purchases, orders or recommendations for services or items reimbursable by federal health care programs like Medicare and Medicaid. Courts have interpreted this law very broadly, including by holding that a violation has occurred if even one purpose of the remuneration is to generate referrals, even if there are other lawful purposes. Moreover, liability under the Anti-Kickback Statute may be established without proving actual knowledge of the law or specific intent to violate. There are statutory exceptions and regulatory safe harbors that protect certain arrangements from prosecution or administrative sanctions, but the exceptions and safe harbors are drawn narrowly. The fact that an arrangement does not fall within a safe harbor does not necessarily render the conduct illegal under the Anti-Kickback Statute, but the arrangement may be subject to scrutiny based on the facts and circumstances. Practices that involve remuneration to those who prescribe, purchase, or recommend pharmaceutical products, including certain discounts, or engaging such individuals as consultants, advisors and speakers, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor. Moreover, there are

no safe harbors for many common practices, such as educational and research grants, charitable donations, product support and patient assistance programs. Violations of the Anti-Kickback Statute may be punished by civil and criminal penalties, damages, fines, or exclusion from participation in federal health care programs like Medicare and Medicaid. In addition, the government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA.

- The FCA prohibits any person from, among other things, knowingly presenting or causing to be presented a false or fraudulent claim for payment of government funds, or making, or causing to be made, a false statement material to a false or fraudulent claim, or knowingly concealing or knowingly and improperly avoiding, or decreasing, an obligation to pay or transmit money or property to the government. The FCA is commonly used to sue those who submit allegedly false Medicare or Medicaid claims, as well as those who induce or assist others to submit a false claim. "False claims" can result not only from non-compliance with the express requirements of applicable governmental reimbursement programs, such as Medicare or Medicaid, but also from non-compliance with other laws, such as the Anti-Kickback Law, FDA laws on off-label promotion, or laws that require quality care in service delivery. Actions under the FCA may be brought by the government or by whistleblowers referred to as relators, who may initiate an action in the name of the government and may share in any monetary recovery. Violations of the FCA can result in treble damages, mandatory per claim penalties, and exclusion from participation in federal health care programs.

- HIPAA created additional 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 payer (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 Anti-Kickback Law, a person or entity can be found guilty of violating the HIPAA fraud statute without actual knowledge of the statute or specific intent to violate it.

- The Physician Payments Sunshine Act, implemented as the Open Payments program, imposes reporting requirements for pharmaceutical, biologic, and device manufacturers regarding payments or other transfers of value made to physicians, teaching hospitals, and other healthcare providers, including investment interests in such manufacturers held by physicians and their immediate family members during the preceding calendar year. Annual reporting of such transfers of value by manufacturers has increased scrutiny of the financial relationships between industry and the physicians, teaching hospitals and other healthcare providers. Failure to submit required annual information may result in civil monetary penalties, which may increase significantly for "knowing failures."

- Analogous state laws and regulations, including anti-kickback and false claims laws, which apply to items and services reimbursed under Medicaid or, in several states, regardless of the payer, including private payers. Some state laws require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual health care providers in those states. Some of these states also prohibit certain marketing related activities including the provision of gifts, meals, or other items to certain health care providers. Some states restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs. Some states require the posting of information relating to clinical studies and their outcomes. Other states and cities require identification or licensing of sales representatives. In addition, several states require pharmaceutical companies to implement compliance programs or marketing codes of conduct.

- The FD&C Act and comparable foreign laws, in addition to prohibiting the promotion of the safety or effectiveness of product candidates not yet approved for commercialization, an act known as pre-approval promotion, also generally restrict companies from promoting approved products for indications other than those indications for which a product is approved, which is also referred to as off-label use. This means, for example, that we may not make claims about the use of our products, should they be approved for sale,

outside of their approved indications, and we may not proactively discuss or provide information regarding any of their off-label uses subject to very specific and limited exceptions. If we or our business partners fail to comply with applicable laws and regulations governing off-label uses of our product candidates, if approved, then we could be subject to administrative or judicially imposed sanctions, including, but not limited to: (i) enforcement proceedings by regulatory agencies; (ii) reduced demand for our products; and (iii) civil or criminal sanctions. Furthermore, actions under the FCA have recently been brought against companies for allegedly promoting off-label uses of drugs, because such promotion induces the use and subsequent claims for reimbursement under Medicare and other federal programs. Similar actions for off-label promotion have been initiated by several states for Medicaid fraud.

The bringing of any FCA or other enforcement investigation or action, even if unsuccessful, could require us to devote resources to investigate and defend the action, as well as result in reputational harm. Failure to comply with the fraud and abuse laws could result in significant civil and criminal penalties and costs, including the loss of licenses and the ability to participate in federal and state health care programs, and could have a material adverse effect on our business. In addition, many of these laws are vague, subject to modification, and subject to evolving interpretation by prosecutorial and regulatory authorities, increasing the risk of noncompliance. We cannot predict whether changes in applicable law, or interpretation of laws, or changes in our services or marketing practices in response to changes in applicable law or interpretation of laws could have a material adverse effect on our business.

If our product candidates are commercialized, then we would also be required to report detailed and complex pricing information, net of included discounts, rebates and other concessions, to CMS for the purpose of calculating national reimbursement levels, certain federal prices and certain federal and state rebate obligations, and we would need to develop the expertise, as well as the systems for collecting and reporting this data accurately to CMS and have instituted a compliance program to assure that the information collected is complete in all respects. Companies that fail to accurately report this kind of pricing information to the U.S. government could be subject to fines and other sanctions (including potential FCA liability) that could adversely affect their business.

We must comply with data privacy and security laws and regulations, and failure to comply with these laws and regulations could expose us to significant liabilities.

We must operate in compliance with various data privacy and security regulations in the United States by both the federal government and the states in which we conduct our business, as well as in other jurisdictions outside of the United States, such as the U.K., the European Economic Area ("EEA") and Asia, where we conduct clinical trials. Our operations entail the collection, use, disclosure, transfer, and processing of sensitive and personal information. Further, our operations extend to commercial partnerships and third-party processors, each of which may be governed by their distinct privacy regulations and cybersecurity laws. These laws are continually evolving and subject to varying interpretations, which requires us to periodically update policies and procedures to maintain compliance.

In the U.S., we may be subject to data privacy and security laws and regulations by both the federal government and the states in which we conduct our business, including, for example, state data breach notification laws, state health information and/or genetic privacy laws and federal and state consumer protection laws (e.g., Section 5 of the FTC Act and the California Consumer Privacy Act ("CCPA")), which, govern the collection, use, disclosure, and protection of health-related and other personal information. Many of these laws and regulations differ from each other in significant ways and the impact of such laws may vary, thus potentially complicating compliance efforts. Compliance with these laws is difficult, constantly evolving, and time consuming, thus we may be required to incur substantial costs and expenses in order to comply with them. Federal regulators, state attorneys general, and plaintiffs' attorneys, including class action attorneys, have been and will likely continue to be active in this space.

HIPAA, for example, imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information. Failure to comply with these laws and regulations can result in substantial penalties and other liabilities. We may obtain health information from third parties, such as research institutions, that are subject to privacy and security requirements under HIPAA. Although we are not directly subject to HIPAA other than with respect to providing certain employee benefits, we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

The CCPA, for example, establishes data privacy rights for individuals located in California and imposes certain requirements for how businesses can collect and use personal data about them. The California Privacy Rights Act, or CPRA, significantly modified the CCPA and imposes additional obligations on covered businesses, including by expanding consumers' rights with respect to their personal data and establishes a state agency vested with the authority to enforce the CCPA. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Other states, such as Virginia, Colorado, Utah Connecticut, Texas, Oregon, Tennessee, Delaware and Iowa have recently passed or enacted similar, comprehensive privacy and data protection legislation. Many state privacy and data protection laws differ from each other in significant ways, and it is not yet fully clear how such laws will be enforced and interpreted. The obligations to comply with the CCPA and other evolving legislation may require us, among other things, to update our notices and develop new processes internally and with our partners.

In Europe, the collection and use of personal information, including health data, is governed by the EU's General Data Protection Regulation and the United Kingdom's implementation of the same (collectively, the "GDPR"). The GDPR is wide-ranging in scope and imposes numerous requirements on covered companies, including requirements related to individual notice regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR. Noncompliance can result in penalties of up to the greater of EUR 20 million, or 4% of annual global company revenues. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR.

While we expect to have substantially compliant programs and controls in place to comply with the GDPR requirements, our compliance with the regulation is likely to impose additional costs on us and we cannot predict whether the interpretations of the requirements, or changes in our practices in response to new requirements or interpretations of the requirements could have a material adverse effect on our business. There is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. Any investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical collaboration partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national clients or pharmaceutical partners to do business with us due to the potential risk of exposure as a result of the current and future data protection obligations imposed on them by certain data protection authorities in interpretation of European privacy and data protection laws, including the GDPR. Such clients or partners may view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to continue their relationship with us. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations and prospects, and we may be required to incur substantial costs and expenses in an effort to comply with our legal and regulatory obligations.

While data generally flows freely between the U.K. and the EEA and vice versa as a result of adequacy decisions and regulations, to enable the transfer of personal data outside of the EEA or the UK, adequate safeguards must be implemented in compliance with the GDPR. On June 4, 2021, the European Commission issued new forms of standard contractual clauses ("SCCs") for data transfers from controllers or processors in the EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EEA (and not subject to the GDPR). As of December 27, 2022 the new SCCs replace the SCCs that were adopted previously under the EU Data Protection Directive. The UK is not subject to the European Commission's new SCCs, and instead it has published the UK International Data Transfer Agreement ("IDTA") and the International Data Transfer Addendum to the new SCCs ("Addendum"), which enable transfers from the UK. For new transfers, the IDTA (or SCCs and Addendum) must be in place, and such measures must be in place for all existing transfers from the UK from March 21, 2024. Companies relying on SCCs or the IDTA to govern transfers of personal data to third countries will also need to assess whether the data importer can ensure sufficient guarantees for safeguarding the personal data under GDPR, including an analysis of the laws in the recipient's country. When conducting restricted data transfers, including to the U.S., under the EU GDPR and UK GDPR (i.e., the UK's post-Brexit transposition of the GDPR), we must ensure these safeguards are in place.

We are subject to extensive government regulatory compliance and ethics oversight, and we will need to develop more extensive compliance and ethics policies in the future.

Our business is subject to extensive government regulation and ethics oversight, which will become more complex and extensive if we succeed in commercializing products. We have enacted various compliance policies and procedures that govern our business practices as appropriate for a company in our stage of development. These policies and procedures are implemented through education, training and monitoring of our employees, distributors and suppliers. However, our adoption and enforcement of these various policies and procedures does not ensure that we will avoid investigation or the imposition of penalties by applicable government agencies.

In addition, to enhance compliance with applicable health care laws and mitigate potential liability in the event of non-compliance, regulatory authorities, such as OIG, of the HHS have recommended the adoption and implementation of a comprehensive health care compliance program that generally contains the elements of an effective compliance and ethics program described in Section 8B2.1 of the U.S. Sentencing Commission Guidelines Manual. Increasing numbers of U.S.-based pharmaceutical companies have such programs. Although we believe our existing compliance policies and procedures are adequate for our current operations, these policies and procedures would not be considered a comprehensive health care compliance program consistent with the HHS OIG's recommendations. Depending upon the nature of our future operations, we anticipate developing a more extensive compliance program in the future.

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

We are exposed to the risk of fraudulent or other illegal activity by our employees, independent contractors, principal investigators, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws of the FDA and similar foreign regulatory bodies; fails to comply with manufacturing standards we have established, or with federal, state and foreign health care fraud and abuse laws and regulations; fails to report financial information or data accurately, including to our regulators, such as the FDA and similar foreign regulatory bodies; or fails to disclose unauthorized activities to the Company. In particular, the promotion, sale and marketing of health care items and services, as well as certain business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent misconduct, including fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and, structuring and commissions, certain customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. We have adopted a Code of Business Conduct and Ethics Policy and other policies and practices that are designed to help ensure that the Company, our employees, officers, agents, intermediaries and other third parties comply with applicable laws, but it is not always possible to identify and deter such misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against the Company, and in some cases regardless of the merits of those actions, those actions could have a significant impact on our business, including the costs of investigation, settlement arrangements, imposition of civil, criminal and administrative penalties (such as additional reporting requirements and oversight if we become subject to Corporate Integrity Agreements and other arrangements, damages, monetary fines, disgorgement, imprisonment, and possible exclusion from participation in Medicare, Medicaid and other federal health care programs), contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We must comply with environmental laws and regulations, and failure to comply with these laws and regulations could expose us to significant liabilities.

We use hazardous chemicals and biological materials in certain aspects of our business and are subject to a variety of federal, state and local laws and regulations governing the use, generation, manufacture, distribution, storage, handling, treatment and disposal of these materials. We cannot eliminate the risk of accidental injury or contamination from the use, manufacture, distribution, storage, handling, treatment or disposal of hazardous materials. In the event of contamination

or injury, or failure to comply with environmental, occupational health and safety and export control laws and regulations, we could be held liable for any resulting damages and any such liability could exceed our assets and resources. In addition, we may be required to pay damages or civil judgments related to third-party claims, for which we are uninsured, including those relating to personal injury (including exposure to hazardous chemicals and biological materials), product quality issues, property damage or contribution to remedial obligations.

Risks Related to our Securities

The trading price of our common stock has been volatile with substantial price fluctuations on heavy volume, which could result in substantial losses for purchasers of our common stock and existing stockholders.

Our stock price has been and, in the future, may be subject to substantial volatility. For example, on September 13, 2018 we amended our Amended and Restated Certificate of Incorporation to effect a reverse stock split at a ratio 1-for-30 (the "Reverse Stock Split"). The Reverse Stock Split was effective on September 13, 2018, and our shares of common stock commenced trading on NASDAQ on a post-Reverse Stock Split basis on September 14, 2018. The volatility of our stock price has increased since we effected the Reverse Stock Split. Since our common stock began trading on a post-Reverse Stock Split basis on September 14, 2018 and through December 31, 2023, our stock has traded in a range with a low of $1.51 and a high of $36.25.

Furthermore, 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. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- announcements relating to development, regulatory approvals or commercialization of our product candidates or those of competitors;
- results of clinical trials of our product candidates or those of our competitors;
- announcements by us or our competitors of significant strategic partnerships or collaborations or terminations of such arrangements;
- actual or anticipated variations in our operating results and whether we have achieved key business targets;
- sales of our common stock, including sales by our directors and officers or specific stockholders;
- changes in, or our failure to meet, financial estimates by us or by any securities analysts who might cover our stock;
- changes in securities analysts' buy and/or sell recommendations;
- general economic, political, or stock market conditions;
- conditions or trends in our industry;
- changes in laws or other regulatory actions affecting us or our industry;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- capital commitments;
- investors' general perception of our company, our business, and our prospects;

- disputes concerning our intellectual property or other proprietary rights; and
- recruitment or departure of key personnel.

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

Future sales and issuances of our common stock or rights to purchase common stock could result in substantial dilution to the percentage ownership of our stockholders.

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell common stock or other securities convertible into or exchanged for our common stock in one or more transactions, and in a manner we determine from time to time and at prices that may not be the same as the price per share paid by other investors, and dilution to our stockholders could result. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by other investors. New investors could also receive rights, preferences and privileges senior to those of existing holders of our common stock. In addition, in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock, we may be required to proportionally adjust the conversion price, exercise price or number of shares issuable upon exercise of our outstanding warrants.

If we do not meet the continued listing standards of NASDAQ our common stock could be delisted from trading, which could limit investors' ability to make transactions in our common stock and subject us to additional trading restrictions.

Our common stock is listed on NASDAQ, a national securities exchange, which imposes continued listing requirements with respect to listed shares. If we fail to satisfy the continued listing standards, including with respect to the maintenance of a minimum share price, or if NASDAQ in its discretion, determines that a condition exists that makes further dealings of our Company on the exchange unwarranted, NASDAQ may issue a non-compliance letter or initiate delisting proceedings.

If our securities are delisted from trading on the NASDAQ exchange, our securities could be quoted on the OTCQB or on the Pink Open Market. As a result, we could face significant adverse consequences including:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage for us; and
- a decreased ability to issue additional securities (including pursuant to short-form registration statements on Form S-3) or obtain additional financing in the future.

Shares that we may issue in the future in connection with certain capital-raising transactions and shares available for future issuance upon exercise of warrants and options could dilute our stockholders and depress the market price of our common stock.

The issuance or even the expected issuance of a large number of shares of our common stock upon purchase, conversion or exercise of the securities described above could depress the market price of our stock and the issuance of such shares will dilute the stock ownership of our existing stockholders. Shares that we may issue in the future in connection with certain capital-raising transactions and shares available for future issuance upon exercise of warrants and options could dilute our stockholders and depress the market price of our common stock and result in the adjustment of the conversion terms of our existing securities.

We can give no assurances that we will ever again pay dividends.

Altimmune has never paid any dividends on our common stock. While subject to periodic review, our current policy is to retain all earnings, if any, primarily to finance our future growth or ability to consummate strategic transactions, such as a merger or other business combination. We make no assurances that we will ever pay future dividends, cash or otherwise. Whether we pay any dividends in the future will depend on our financial condition, results of operations, and other factors that we will consider.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Governance

As part of its oversight role, the Audit Committee of our Board is responsible for overseeing cybersecurity risk exposure as well as management's actions to identify, assess, mitigate and remediate cybersecurity threats. The Audit Committee receives regular reports, on a quarterly basis, from our Chief Financial Officer and Senior Director of Information Technology regarding our cybersecurity risk programs. Our Chief Financial Officer also provides quarterly updates to the Board that include a summary of our cybersecurity risk programs to enable discussion of cybersecurity risk management at the Board level. The Audit Committee annually reviews and recommends our information security policy and program to the Board. The Audit Committee is composed of members with financial expertise as well as one member with a cybersecurity oversight certification.

Our Chief Financial Officer has overall responsibility for our cybersecurity and has over 20 years of experience managing information technology, or IT, departments at biotechnology and pharmaceutical companies. Our Senior Director of Information Technology is responsible for the development and implementation of IT department controls, policies, infrastructure, and day-to-day operations, in addition to managing security risk, evaluating safeguards and recommending security improvements, and has over seven years of experience managing IT departments for a biotechnology company. We utilize third-party vendors to help strengthen our information security risk management by conducting evaluations of our security controls on at least a quarterly basis.

Risk Management and Strategy

Our cybersecurity risk management program is comprised of the following components:

- Identifying assets at risk from cybersecurity threats and taking mitigation measures including the implementation of data backup, recovery and restore procedures to ensure business continuity, as well as through IT controls, policies and infrastructure.

- Identifying potential cybersecurity threats that could disrupt our IT systems, cause a data breach or compromise data security by implementing the following protective measures: patching and updating systems and applications, monitoring our email systems, endpoint protection, Domain Name System (DNS) filtering, Security Information and Event Management, and Multi-Factor Authentication (MFA).

- Conducting periodic assessment of protections to prevent or mitigate cybersecurity threats.

- Retaining of third parties to periodically assess our cybersecurity management program, provide cybersecurity training, perform phishing tests, gap analysis and penetration tests, advise on business continuity plans, and to provide additional support in the event of a cybersecurity incident.

The Chief Financial Officer and Senior Director of Information Technology work with other groups in the Company to understand the severity of the potential consequences of a cybersecurity incident and to make decisions about how to prioritize mitigation and other initiatives based on, among other things, materiality to the business. All employees and contractors receive cybersecurity training, and we plan to implement additional annual training for all employees and

contractors. All trainings are intended to raise awareness of cybersecurity threats in order to reduce our vulnerability as well as to encourage consideration of cybersecurity risks across functions.

Item 2. Properties

Our principal executive offices are located in Gaithersburg, Maryland, where we occupy approximately 19,699 square feet of laboratory and office space. For additional information, see Note 5 to our consolidated financial statements. Management believes that these facilities are suitable and adequate to meet our anticipated needs.

Item 3. Legal Proceedings

We are not currently subject to any material legal proceedings. From time to time, we may be involved in various legal proceedings or investigations, which could be costly and impose a significant burden on management and employees. The results of any current or future litigation cannot be predicted with certainty, and regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock trades on the NASDAQ Global Market under the symbol "ALT".

Holders

As of March 22, 2024, we had 181 record holders of our common stock. The number of record holders is based on the actual number of holders registered on the books of our transfer agent and does not reflect holders of shares in "street name" or persons, partnerships, associations, corporations or other entities identified in security position listings maintained by depository trust companies.

Dividends

Other than the special dividend immediately prior to the Mergers, we have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not expect to pay any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors the board of directors deems relevant, and subject to the restrictions contained in any future financing instruments.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is contained in Part III, Item 12 of this Annual Report under the heading Equity Compensation Plans and is incorporated herein by reference.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchases

None.

Item 6. [Reserved]

Item 7. 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 consolidated financial statements and related notes appearing elsewhere in this Annual Report. Some of the information contained in this discussion and analysis contains forward-looking statements that involve substantial risks and uncertainties. See "Forward-looking statements" in Part I of this Annual Report and the section entitled "Risk Factors" in Part I, Item 1A of this Annual Report for a discussion of certain factors that could cause actual results or events to differ materially from the forward-looking statements that we make.

Overview

Altimmune, Inc. is a clinical stage biopharmaceutical company focused on developing treatments for obesity and liver diseases. Our lead product candidate, pemvidutide (formerly known as ALT-801), is a GLP-1/glucagon dual receptor agonist that is being developed for the treatment of obesity and metabolic dysfunction-associated steatohepatitis ("MASH"), previously termed non-alcoholic steatohepatitis ("NASH"). Except where the context indicates otherwise, references to "we," "us," "our," "Altimmune" or the "Company" refer to the company and its subsidiaries.

Fiscal Year 2023 Business Update

On October 24, 2023, the U.S. Food and Drug Administration ("FDA") granted fast track designation pemvidutide for the treatment of MASH.

Pemvidutide – IMPACT trial

On August 1, 2023 we announced that we enrolled the first subject in the Phase 2b trial, IMPACT, to evaluate the safety and efficacy of pemvidutide in subjects with MASH. The biopsy-driven trial is expected to enroll approximately 190 subjects with and without diabetes randomized 1:2:2 to receive 1.2 mg, 1.8 mg pemvidutide or placebo weekly for 48 weeks. The key efficacy endpoints are MASH resolution and fibrosis improvement after 24 weeks of treatment, with subjects to be followed for an additional 24 weeks to a total of 48 weeks for assessment of safety and additional biomarker responses. Top-line 24-week results from this trial are expected in the first quarter of 2025.

Pemvidutide – MOMENTUM trial

48-Week Analysis

On November 30, 2023, we announced topline results from our 48-week MOMENTUM Phase 2 obesity trial of pemvidutide. The trial enrolled 391 subjects with obesity or overweight with at least one co-morbidity and without diabetes. Subjects were randomized 1:1:1:1 to 1.2 mg, 1.8 mg, 2.4 mg pemvidutide or placebo administered weekly for 48 weeks in conjunction with diet and exercise. The 1.2 mg and 1.8 mg doses were administered without dose titration, while a short 4-week titration period was employed for the 2.4 mg dose. Unlike other obesity studies with GLP-1 based agents, dose-reduction was not allowed. At baseline, subjects had a mean age of approximately 50 years, mean body mass index ("BMI") of approximately 37 kg/m^2 and mean body weight of approximately 104 kg. Approximately 75% of subjects were female. See *Item 1. Business* of this Annual Report for detailed discussion of the data readout.

12-Week Type 2 Diabetes Safety Trial

In March 2023, we announced the topline results from a 12-week Phase 1b safety trial of pemvidutide, which was conducted to evaluate the safety profile of pemvidutide in subjects with overweight or obesity and type 2 diabetes. The trial was comprised of 54 subjects randomized 1:1:1:1 to 1.2 mg, 1.8 mg, 2.4 mg pemvidutide or placebo administered weekly for 12 weeks. See *Item 1. Business* of this Annual Report for detailed discussion of the data readout.

HepTcell

On April 11, 2023, we announced the completion of enrollment in our Phase 2 clinical trial of HepTcell, an immunotherapeutic for the treatment of chronic hepatitis B ("CHB").

The multicenter clinical trial, which is being conducted at 26 sites in North America, Europe and Southeast Asia, enrolled approximately 80 subjects with inactive CHB and low levels of hepatitis B surface antigen ("HBsAg"). Subjects were randomized 1:1 to HepTcell or placebo. The primary endpoint of the trial is clinical response, defined as a 1-log or greater reduction or clearance in HBsAg. Secondary endpoints include changes in the levels of hepatitis B virus ("HBV") DNA, pre-genomic RNA and other markers of virologic response.

On March 27, 2024, we announced that the overall response in the Phase 2 trial was deemed to be insufficient to warrant further advancement in clinical trials. As a result, we have stopped any further development related to HepTcell.

Financial Operations Overview

The consolidated financial information presented below includes the accounts of Altimmune, Inc., Altimmune UK, Ltd, Spitfire Pharma, LLC. and Altimmune AU Pty, Ltd. All intercompany accounts and transactions have been eliminated in consolidation.

Revenue

We have not generated any revenue from the sale of any products to date. Our revenue has historically consisted primarily of government and foundation grants and contracts that supported our efforts on specific research projects. These grants and contracts generally provided for reimbursement of approved costs as those costs were incurred by us. Research grants and contracts and the related accounts receivable were recognized as earned when reimbursable expenses were incurred and the performance obligation was complete. Payments received in advance of services being provided were recorded as deferred revenue. We are closing out one such contract and any revenue reported during the year ended December 31, 2023 was for indirect rate adjustments.

Research and development expenses

Research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- expenses incurred under agreements with contract research organizations ("CROs") and investigative sites that conduct our clinical trials;
- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense;
- costs associated with preclinical and clinical activities and regulatory operations, including the cost of acquiring, developing and manufacturing clinical trial materials; and
- depreciation and other expenses, which include direct and allocated expenses for insurance, consultants, legal fees and other supplies.

Research and development costs are expensed as incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors, CROs and clinical sites.

We cannot determine with certainty the duration and completion costs of the current or future clinical trials of our product candidates or if, when or to what extent we will generate sales from the commercialization of any of our product candidates if they receive regulatory approval. The successful development of our product candidates is highly uncertain and may never result in approved products. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

- scope, rate of enrollment and expense of our ongoing, as well as any additional, clinical trials, and other research and development activities;
- significant and potentially changing government regulation; and

- the timing and receipt of regulatory approvals, if any.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA, or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, we could be required to expend significant additional financial resources and time on the completion of clinical development. Additionally, we may conduct additional trials in support of sales and marketing of our product candidates.

We plan to increase our research and development expenses for the foreseeable future as we continue the development of clinical and preclinical candidates. Our current active and planned research and development activities include the following:

- completion of data analysis of a Phase 2 clinical trial for pemvidutide in obesity;
- conduct of a Phase 2 clinical trial for pemvidutide in MASH;
- conduct of clinical trials and nonclinical safety studies for pemvidutide;
- completion of a Phase 2 clinical trial for HepTcell; and
- manufacture of clinical trial materials in support of our clinical trials.

A significant portion of our research and development efforts have been related to the development of pemvidutide and HepTcell. The development of HepTcell was discontinued on March 27, 2024. We do not allocate personnel-related costs, costs associated with our general research platform improvements, depreciation or other indirect costs to specific programs.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel, including stock-based compensation and travel expenses for our employees in executive, operational, finance and human resource functions. Other general and administrative expenses include insurance expenses, facility-related costs and professional fees for directors, accounting and legal services, and expenses associated with obtaining and maintaining our intellectual property.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development activities. We also anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and the SEC requirements, director and officer insurance, investor relations costs and other costs associated with being a public company. Additionally, if and when we believe a regulatory approval of the first product candidate appears likely, we anticipate an increase in staffing and related expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidates.

Results of Operations

Comparison of years ended December 31, 2023 and December 31, 2022 (in thousands):

	Year Ended December 31,			
	2023	2022	Increase (Decrease)	
Revenue	$ 426	$ (68)	$ 494	726 %
Operating expenses:				
Research and development	65,799	70,538	(4,739)	(7)%
General and administrative	18,137	17,134	1,003	6 %
Impairment loss on intangible asset	12,419	—	12,419	100 %
Total operating expenses	96,355	87,672	8,683	10 %
Loss from operations	(95,929)	(87,740)	(8,189)	9 %
Other income (expense):				
Interest expense	(35)	(8)	(27)	338 %
Interest income	7,351	2,870	4,481	156 %
Other income (expense), net	166	(32)	198	619 %
Total other income (expense), net	7,482	2,830	4,652	164 %
Net loss before income taxes	(88,447)	(84,910)	(3,537)	4 %
Income tax expense (benefit)	—	(197)	197	(100)%
Net loss	$ (88,447)	$ (84,713)	$ (3,734)	4 %

Revenue

We have not generated any revenues from the sale of any products to date. Our revenue has historically consisted primarily of government and foundation grants and contracts that supported our efforts on specific research projects. We are closing out one such contract and any revenue reported during the years ended December 31, 2023 and 2022 were for indirect rate adjustments.

Research and development expenses

Research and development expenses for the years ended December 31, 2023 and 2022 consisted primarily of expenses related to product candidate development. Research and development expenses for the years ended December 31, 2023 and 2022 are summarized as follows:

	Year Ended December 31,			
Product candidates	2023	2022	Increase (Decrease)	
Pemvidutide	$ 35,768	$ 46,928	$ (11,160)	(24)%
HepTcell	6,616	7,524	(908)	(12)%
Non-project costs	23,415	16,086	7,329	46 %
Total research and development expenses	$ 65,799	$ 70,538	$ (4,739)	(7)%

The decrease in research and development expenses for pemvidutide was primarily due to a $13.7 million reduction in expenses associated with the metabolic dysfunction-associated steatotic liver disease ("MASLD"), previously termed non-alcoholic fatty liver disease ("NAFLD"), trials, a $6.8 million reduction in expenses associated with Phase 1 safety trials, all of which were ongoing during the year ended December 31, 2022, and which were substantially completed by March 31, 2023 and a $1.7 million reduction in expense associated with the MOMENTUM Phase 2 trial in obesity, which had commenced and was fully enrolled in the year ended December 31, 2022, but completed its in-life portion by September 30, 2023 and wound down in the year ended December 31, 2023. The decrease in these research and development expenses were partially offset by an $8.3 million increase related to the ramp up of the IMPACT Phase 2b

trial in MASH, and a $2.8 million increase in net manufacturing expenses for production of Good Manufacturing Practice ("GMP") drug substance materials.

The decrease in research and development expenses for HepTcell was primarily due to the winddown and completion of the in-life portion of the Phase 2 trial in 2023.

The increase in other non-project specific research and development expenses was primarily due to $3.3 million for labor related costs, $1.9 million in stock compensation, $1.0 million for electronic document management system ("EDMS") implementation and service costs and $0.3 million for consultants.

General and administrative expenses

General and administrative expenses increased by $1.0 million, or 6%, during the year ended December 31, 2023 as compared to the year ended December 31, 2022. The increased expense is primarily due to a $0.6 million increase in stock compensation and $0.3 million increase in other labor-related expenses.

Impairment loss on intangible asset

Impairment loss on intangible asset of $12.4 million reported during the year ended December 31, 2023 represents a non-cash impairment charge recorded for the in-process research and development ("IPR&D") asset associated with HepTcell (See *Note 2. Summary of Significant Accounting Policies*). There were no impairment charges reported during the year ended December 31, 2022.

Total other income (expense), net

Total other income (expense), net increased by $4.7 million during the year ended December 31, 2023 as compared to the year ended December 31, 2022, primarily due to a $4.5 million increase in interest income earned on our cash equivalents and short-term investments and $0.2 million increase in gain from foreign currency exchange.

Income tax benefit

We recorded an income tax benefit of $0.2 million related to interest received and receivable on income tax refunds during the year ended December 31, 2022. Other than the income tax benefit related to interest, we did not record an income tax benefit in the years ended December 31, 2023 and 2022 due to a full valuation allowance.

Liquidity and Capital Resources

Overview

Our primary sources of cash for the year ended December 31, 2023 were from equity transactions, interest and dividends from our money market funds and short-term investments, and proceeds from maturity of our short-term investments. Our cash, cash equivalents, restricted cash and short-term investments were $197.9 million as of December 31, 2023. We believe, based on the operating cash requirements and capital expenditures expected for 2024 and 2025, our cash on hand as of December 31, 2023, together with expected cash receipts from our income tax refunds and research and development incentives, are sufficient to fund operations for at least a twelve-month period from the issuance date of our December 31, 2023 consolidated financial statements.

We have not generated any revenues from the sale of any products to date, and there is no assurance of any future revenues from product sales. We have incurred significant losses since we commenced operations. As of December 31, 2023, we had an accumulated deficit of $466.3 million. In addition, we have not generated positive cash flows from operations. We have had to rely on a variety of financing sources, including the issuance of debt and equity securities. As capital resources are consumed to fund our research and development activities, we may require additional capital beyond our currently anticipated amounts. In order to address our capital needs, including our planned clinical trials, we must continue to actively pursue additional equity or debt financing, government funding, and monetization of our existing programs through partnership arrangements or sales to third parties.

Sources of Liquidity

Shelf Registrations

On February 28, 2023, we filed a shelf registration statement on Form S-3ASR, which was declared effective immediately. This shelf registration allows us to offer and sell any amount of our common stock, preferred stock, debt securities, warrants, rights and units (the "2023 Shelf") for a period of three years from effectiveness or until such determination that we no longer qualify as a well-known seasoned issuer.

At-the-Market Offerings

On February 28, 2023, we entered an Equity Distribution Agreement (the "2023 Agreement") with Evercore Group L.L.C., JMP Securities LLC and B. Riley Securities, Inc., serving as sales agents, with respect to an at-the-market offerings program under which we may offer and sell, from time to time at our sole discretion, shares of our common stock, having an aggregate offering price of up to $150.0 million. During the year ended December 31, 2023, we sold 20,454,516 shares of common stock under the 2023 Agreement resulting in approximately $86.6 million in net proceeds, and as of December 31, 2023, $60.6 million remained available to be sold under the 2023 Shelf.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2023 and 2022:

	Year Ended December 31,		
(in thousands)	**2023**	**2022**	**Increase (Decrease)**
Net cash provided by (used in):			
Operating activities	$ (75,810)	$ (62,586)	$ (13,224)
Investing activities	13,732	(73,399)	87,131
Financing activities	86,105	56,781	29,324
Net increase (decrease) in cash and cash equivalents and restricted cash	$ 24,027	$ (79,204)	$ 103,231

Operating Activities

Net cash used in operating activities was $75.8 million for the year ended December 31, 2023 compared to $62.6 million during the year ended December 31, 2022. Our sources of cash provided by operations during the year ended December 31, 2023 was primarily cash receipts of research and development incentive credits. The primary uses of cash from our operating activities include payments for labor and labor-related costs, professional fees, research and development costs associated with our clinical trials and other general corporate expenditures. The increase in cash used in operating activities of $13.2 million was due to a $22.4 million change in working capital accounts, partially offset by a $9.2 million decrease in net loss as adjusted for noncash items.

Investing Activities

Net cash provided by investing activities was $13.7 million for the year ended December 31, 2023 compared to $73.4 million net cash used during the year ended December 31, 2022. The net cash provided by investing activities during the year ended December 31, 2023 was primarily due to $102.4 million proceeds from sale and maturities of short-term investments, partially offset by $88.6 million purchase of short-term investments. The net cash used in investing activities during the year ended December 31, 2022 was primarily due to $73.3 million purchase of short-term investments.

Financing Activities

Net cash provided by financing activities was $86.1 million for the year ended December 31, 2023 compared to $56.8 million during the year ended December 31, 2022. The net cash provided by financing activities during the year ended December 31, 2023 was primarily the result of the receipt of $86.6 million in net proceeds from the issuance of common stock from our at-the-market offerings program and $0.2 million in proceeds from our employee stock purchase

plan, partially offset by a $0.5 million payment for tax withholding obligations related to share-based compensation. The net cash provided by financing activities during the year ended December 31, 2022 was primarily the result of the receipt of $56.2 million in proceeds from the issuance of common stock from our at-the-market offerings program, $0.9 million in proceeds from exercise of stock options and $0.2 million in proceeds from employee stock purchase plan, partially offset by $0.5 million payment for tax withholding obligations related to share-based compensation.

Capital Resources

We have financed our operations to date principally through our equity offerings and proceeds from issuances of our preferred stock, common stock and warrants. As of December 31, 2023, we had $197.9 million of cash, cash equivalents, restricted cash and short-term investments. Accordingly, management believes that we have sufficient capital to fund our plan of operations for at least a twelve-month period from the issuance date of our December 31, 2023 consolidated financial statements. However, in order to address our capital needs in the long-term, including our planned clinical trials, we must continue to actively pursue additional equity or debt financing, government funding and monetization of our existing programs through partnership arrangements or sales to third parties.

Critical Accounting 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. The preparation of our consolidated financial statements requires us to make judgments and estimates that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates, if any, will be reflected in the consolidated financial statements prospectively from the date of change in estimates.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this Annual Report, we believe the following accounting policies used in the preparation of our consolidated financial statements require the most significant judgments and estimates.

Impairment of Indefinite-lived Intangible Assets

We evaluate our indefinite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying value of such assets may not be recoverable in accordance with the guidance in Financial Accounting Standards Board ("FASB") Accounting Standard Codification Topic 350, Intangibles—Goodwill and Other ("ASC 350").

We had one IPR&D asset, HepTcell, that we acquired in 2015. This candidate was a viral pathogen immunotherapy product for the treatment of chronic HBV. Since 2020, we have been conducting a Phase 2 clinical trial. However, the preliminary data from this trial that management analyzed in December 2023, indicates that the results are not sufficient to warrant moving forward with this product candidate. As a result, we expect to stop all further development related to HepTcell and do not anticipate that there would be any third-party interest in the asset. This decision rendered the probability of success, which is one of the key inputs in the fair value measurement of this asset, to be effectively zero or close to zero. With no alternative use nor any anticipated interest from third parties for this asset, management determined that the fair value of the IPR&D asset was deemed di minimis as of December 31, 2023. Accordingly, we recorded a non-cash impairment charge of $12.4 million, which was the carrying value of the IPR&D asset, in the accompanying Consolidated Statements of Operations and Comprehensive Loss for the year ended December 31, 2023 under the caption "Impairment loss on intangible asset". As of December 31, 2023, we had no indefinite-lived intangible assets.

Research and Development

Research and development costs are expensed as incurred. Research and development costs consist of payroll and personnel expense, consulting costs, external contract research and development expenses, which includes fees paid

to other entities that conduct certain research and development activities on our behalf, such as clinical research organizations ("CROs") and contract manufacturing organizations ("CMOs"), raw materials, drug product manufacturing costs, laboratory supplies and allocated overhead, including depreciation and amortization, rent and utilities. Material research and development costs that are paid in advance of performance are capitalized as a prepaid expense and amortized over the service period as the services are provided.

Clinical trial costs are a significant component of research and development expenses, and we outsource a significant portion of these costs to third parties. Third-party clinical trial expenses include investigator fees, site and patient costs, CRO costs, costs for central laboratory testing, data management and CMO costs. The accrual for site and patient costs includes inputs such as estimates of patient enrollment, patient cycles incurred, clinical site activations, and other pass-through costs. These inputs are required to be estimated due to a lag in receiving the actual clinical information from third parties. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected on the Consolidated Balance Sheets as a prepaid asset or accrued expenses. These third-party agreements are generally cancelable, and related costs are recorded as research and development expenses as incurred. Material advance payments for goods or services that will be used or rendered for future research and development activities are recorded as a prepaid asset and recognized as expense as the related goods are delivered or the related services are performed. When evaluating the adequacy of the accrued expenses, we analyze progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period.

Stock-based Compensation

We account for all stock-based compensation granted to employees and non-employees using a fair value method. Compensation expense related to stock-based awards is recognized over the requisite service period of the awards, usually the vesting period, on a straight-line basis, net of estimated forfeitures. The fair value of stock option awards to employees and directors is estimated using the Black Scholes option pricing model, which requires the input of subjective assumptions, including (1) the expected stock price volatility, (2) the expected term of the award, (3) the risk-free interest rate and (4) expected dividends.

We estimate forfeitures at the time of grant and, if necessary, revise the estimate in subsequent periods if actual forfeitures differ from those estimates. Estimates are based on our historical analysis of actual stock option forfeitures. The actual expense recognized over the vesting period is only for those options that vest. For the years ended December 31, 2023 and 2022, forfeiture rates were approximately 11% and 10% respectively.

We calculated the fair value of stock option awards using the Black Scholes option pricing model. The Black Scholes option pricing model requires the input of subjective assumptions, including stock price volatility and the expected life of stock options. The application of this valuation model involves assumptions that are highly subjective, judgmental and sensitive in the determination of compensation cost. Our stock started being publicly traded under ALT beginning in June 2017, and as such we do not have sufficient history to estimate the volatility of our common stock price or the expected life of our options. The expected stock price volatility for stock option awards is based on a weighted-average volatility rate of historical volatility from a representative peer group of comparable companies and our stock price volatility until such time that we have sufficient history to rely on the volatility of our own stock. The average expected life of stock options was determined according to the "simplified method" as described in SAB 107, which is the midpoint between the vesting date and the end of the contractual term. The risk-free interest rate was determined by reference to implied yields available from U.S. Treasury securities with a remaining term equal to the expected life assumed at the date of grant. We have not paid and do not anticipate paying cash dividends. Therefore, the expected dividend rate is assumed to be 0%.

There is a high degree of subjectivity involved when using option pricing models to estimate stock-based compensation. If factors change and we employ different assumptions when valuing our options, the compensation expense that we record in the future may differ significantly from what we have historically reported.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, we are not required to provide the information required by this Item.

Item 8. Financial Statements and Supplementary Data

ALTIMMUNE, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Altimmune, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Altimmune, Inc. (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

Basis for opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accrued and Prepaid Research and Development Expenses

Description of the Matter

As disclosed in Note 6, the Company's total accrued research and development expenses were $5.8 million as of December 31, 2023, which represents the estimated obligation for research and development expenses incurred as of December 31, 2023 but not paid as of that date. In addition, the Company's total prepaid expenses and other current assets were $6.9 million as of December 31, 2023, which included amounts that were paid in advance of services incurred pursuant to research and development activities. As discussed in Note 2 of the consolidated financial statements, material advance payments for goods or services that will be used or rendered for future research and development activities are recorded as a prepaid asset and recognized as expense as the related goods are delivered or the related services are performed. When evaluating the adequacy of the accrued expenses, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs.

How We Addressed the Matter in Our Audit

Auditing the Company's accrued and prepaid research and development expenses was especially challenging due to the application of management judgment about the estimate of services provided. Specifically, the amount of accrued and prepaid research and development expenses recognized is sensitive to the availability of information to make the estimate, including the estimate of the period over which services will be performed, the associated cost of such services, and the level of services performed and progress in the period for which the Company has not yet received an invoice from the supplier. Additionally, due to the duration of clinical trials and the timing of invoicing received from third parties, the actual amounts incurred are not always known by the report date.

To evaluate the Company's estimate of services incurred as of period end pursuant to its research and development activities, our audit procedures included, among others, testing the completeness and accuracy of the underlying data used in the estimates and evaluating the significant assumptions stated above that are used by management to estimate the recorded amounts. To assess the reasonableness of the significant assumptions, we obtained information regarding the nature and extent of progress of clinical trials and other activities from the Company's research and development personnel that oversee the clinical trials. To evaluate the valuation of the accrued research and development expenses, we compared invoices received by the Company subsequent to December 31, 2023 to the amounts recognized by the Company as of that date. To evaluate the valuation of the prepaid research and development expenses, we inspected the Company's contracts with third parties to assess the impact to the amounts recorded.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2017.

Tysons, Virginia
March 27, 2024

ALTIMMUNE, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per-share amounts)

	December 31,	
	2023	2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 135,117	$ 111,097
Restricted cash	41	34
Total cash, cash equivalents and restricted cash	135,158	111,131
Short-term investments	62,698	73,783
Accounts and other receivables	1,111	173
Income tax and R&D incentive receivables	3,742	2,368
Prepaid expenses and other current assets	6,917	5,358
Total current assets	209,626	192,813
Property and equipment, net	651	1,081
Indefinite-lived intangible asset	—	12,419
Other assets	363	615
Total assets	$ 210,640	$ 206,928
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,070	$ 4,804
Accrued expenses and other current liabilities	10,073	12,250
Total current liabilities	12,143	17,054
Noncurrent liabilities	4,398	4,581
Total liabilities	16,541	21,635
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Common stock, $0.0001 par value; 200,000,000 shares authorized; 70,677,400 and 49,199,845 shares issued and outstanding as of December 31, 2023 and 2022, respectively	7	5
Additional paid-in capital	665,427	568,399
Accumulated deficit	(466,331)	(377,884)
Accumulated other comprehensive loss, net	(5,004)	(5,227)
Total stockholders' equity	194,099	185,293
Total liabilities and stockholders' equity	$ 210,640	$ 206,928

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

ALTIMMUNE, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per-share amounts)

	Year Ended December 31,	
	2023	2022
Revenues	$ 426	$ (68)
Operating expenses:		
Research and development	65,799	70,538
General and administrative	18,137	17,134
Impairment loss on intangible asset	12,419	—
Total operating expenses	96,355	87,672
Loss from operations	(95,929)	(87,740)
Other income (expense):		
Interest expense	(35)	(8)
Interest income	7,351	2,870
Other income (expense), net	166	(32)
Total other income (expense), net	7,482	2,830
Net loss before income taxes	(88,447)	(84,910)
Income tax expense (benefit)	—	(197)
Net loss	(88,447)	(84,713)
Other comprehensive income — unrealized gain (loss) on short-term investments	223	(187)
Comprehensive loss	$ (88,224)	$ (84,900)
Net loss per share, basic and diluted	$ (1.66)	$ (1.81)
Weighted-average common shares outstanding, basic and diluted	53,246,937	46,926,349

The accompanying notes are an integral part of the consolidated financial statements

ALTIMMUNE, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(In thousands, except share amounts)

	Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Loss	Equity
Balance at December 31, 2021	40,993,768	$ 4	$ 497,342	$ (293,171)	$ (5,040)	$ 199,135
Stock-based compensation	—	—	8,101	—	—	8,101
Exercise of stock options	358,317	—	950	—	—	950
Vesting of restricted stock awards including withholding, net	8,695	—	(516)	—	—	(516)
Issuance of common stock from Employee Stock Purchase Plan	26,395	—	181	—	—	181
Issuance of common stock in at-the-market offerings, net	5,204,215	1	56,165	—	—	56,166
Issuance of common stock upon cashless exercise of warrants	1,760,854	—	—	—	—	—
Issuance of common stock related to contingent consideration liability	847,444	—	6,176	—	—	6,176
Other increase	157	—	—	—	—	—
Unrealized gain (loss) on short-term investments	—	—	—	—	(187)	(187)
Net loss	—	—	—	(84,713)	—	(84,713)
Balance at December 31, 2022	49,199,845	5	568,399	(377,884)	(5,227)	185,293
Stock-based compensation	—	—	10,640	—	—	10,640
Exercise of stock options	39,303	—	113	—	—	113
Vesting of restricted stock awards including withholding, net	72,646	—	(539)	—	—	(539)
Issuance of common stock from Employee Stock Purchase Plan	41,560	—	215	—	—	215
Issuance of common stock in at-the-market offerings, net	20,454,516	2	86,599	—	—	86,601
Issuance of common stock upon cashless exercise of warrants	869,530	—	—	—	—	—
Unrealized gain (loss) on short-term investments	—	—	—	—	223	223
Net loss	—	—	—	(88,447)	—	(88,447)
Balance at December 31, 2023	70,677,400	$ 7	$ 665,427	$ (466,331)	$ (5,004)	$ 194,099

The accompanying notes are an integral part of the consolidated financial statement

ALTIMMUNE, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (88,447)	$ (84,713)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of contingent consideration liability	—	86
Impairment loss on intangible asset	12,419	—
Stock-based compensation expense	10,640	8,101
Depreciation of property and equipment	477	493
Accretion of discounts on short-term investments	(2,471)	(698)
(Gain) loss on foreign currency exchange	(154)	34
Changes in operating assets and liabilities:		
Accounts receivable	(938)	256
Prepaid expenses and other assets	(1,345)	2,650
Accounts payable	(2,734)	2,770
Accrued expenses and other liabilities	(1,883)	5,393
Income tax and R&D incentive receivables	(1,374)	3,042
Net cash used in operating activities	(75,810)	(62,586)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sales and maturities of short-term investments	102,410	—
Purchases of short-term investments	(88,631)	(73,273)
Purchases of property and equipment, net	(47)	(126)
Net cash provided by (used in) investing activities	13,732	(73,399)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments of deferred offering costs	(195)	—
Proceeds from issuance of common stock in at-the-market offerings, net	86,601	56,166
Proceeds from issuance of common stock from Employee Stock Purchase Plan	215	181
Payment of conditional economic incentive	(90)	—
Proceeds from exercises of stock options	113	950
Payments for tax withholding in share-based compensation	(539)	(516)
Net cash provided by financing activities	86,105	56,781
Net increase (decrease) in cash and cash equivalents and restricted cash	24,027	(79,204)
Cash, cash equivalents and restricted cash at beginning of period	111,131	190,335
Cash, cash equivalents and restricted cash at end of period	$ 135,158	$ 111,131
SUPPLEMENTAL NON-CASH ACTIVITIES:		
Common stock issued related to contingent consideration liability	$ —	$ 6,176

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

ALTIMMUNE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business and Organization

Altimmune, Inc., headquartered in Gaithersburg, Maryland, United States, together with its subsidiaries (collectively, the "Company" or "Altimmune") is a clinical stage biopharmaceutical company incorporated under the laws of the State of Delaware.

The Company is focused on developing treatments for obesity and liver diseases. The Company's pipeline includes next generation peptide therapeutics for obesity and metabolic dysfunction-associated steatohepatitis ("MASH"), previously termed non-alcoholic steatohepatitis ("NASH") (for both, pemvidutide, formerly known as ALT-801), and for chronic hepatitis B ("HepTcell™"). Since its inception, the Company has devoted substantially all of its efforts to business planning, research and development ("R&D"), recruiting management and technical staff and raising capital, and has financed its operations through the issuance of common and preferred stock, long-term debt and proceeds from research grants and government contracts. The Company has not generated any revenues from the sale of any products to date, and there is no assurance of any future revenues from product sales.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements are prepared in conformity with generally accepted accounting principles in the United States ("U.S. GAAP") and in accordance with the rules and regulations of the United States Securities and Exchange Commission ("SEC"). The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Significant estimates and assumptions made in the accompanying consolidated financial statements include, but are not limited to, the valuation of share-based awards, income taxes, and accruals for R&D activities. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable. However, actual results could differ from those estimates.

Segment Information

The Company is managed and operates as a single business focused on the R&D of treatments for various diseases and disorders, and vaccines. The Company is managed by a single management team, and consistent with its organizational structure, the Chief Executive Officer manages and allocates resources at a consolidated level. Accordingly, the Company views its business as one operating segment.

Cash Equivalents

The Company considers all highly liquid investments purchased with remaining maturities of 90 days or less on the purchase date to be cash equivalents, and includes amounts held in money market funds which are actively traded (a Level 1 input).

Restricted Cash

The Company had restricted cash of $41,000 and $34,000 as of December 31, 2023 and 2022, respectively, held in money market savings accounts as collateral. The restricted cash as of December 31, 2023 and 2022 is for the Company's

facility lease obligation. Restricted cash is classified as a component of cash, cash equivalents, and restricted cash in the accompanying Consolidated Balance Sheets and Consolidated Statements of Cash Flows.

Short-term Investments

The Company's short-term investments are comprised of U.S. Treasuries, corporate debt securities and certificates of deposit that have original maturities less than or equal to one year and are classified as available-for-sale ("AFS") securities. Such securities are carried at estimated fair value, net of allowance for credit loss determined based on the Current Expected Credit Loss. Any unrealized holding gains or losses are reported as accumulated other comprehensive income or loss, which is a separate component of stockholders' equity. In the event that the AFS security's fair value is below the amortized cost and (i) the Company intends to sell the AFS security and (ii) the AFS security is required to be sold before recovery of the loss, the AFS security's amortized cost base will be written down to its fair value and the loss will be recognized in the income statement. If the Company intends not to sell the AFS security and the AFS security is not required to be sold before recovery of the loss, the Company evaluates whether a portion of the unrealized loss is a result of credit loss. The portion of unrealized loss related to credit loss will be recorded as allowance for credit loss in the balance sheet with the corresponding credit loss in the income statement and the portion of unrealized loss not related to credit loss will be recognized in other comprehensive income ("OCI"). Dividend and interest income are recognized in other income when earned. The cost of securities sold is calculated using the specific identification method. The Company places all investments with government agencies, or corporate institutions whose debt is rated as investment grade. As of December 31, 2023, none of the unrealized losses on the Company's short-term investments are a result of credit loss, and therefore, any unrealized losses were recognized in OCI.

As of December 31, 2023, the Company had $0.1 million accrued interest on short-term investments included in "Accounts and other receivables" on the accompanying Consolidated Balance Sheets.

Accounts and Other Receivables

Accounts and other receivables include both billed and unbilled amounts, interest and other receivables. The Company makes judgments as to its ability to collect outstanding receivables and provides an allowance for receivables when collection becomes doubtful. Provisions are made based upon a specific review of all significant outstanding invoices and the overall quality and age of those invoices not specifically reviewed. The Company's receivables represent billings for rate adjustment under a government contract that is being closed out, as well as interest and other receivables. The Company believes that the credit risks associated with these receivables are not significant. To date, the Company has not experienced any losses associated with accounts and other receivables and does not maintain an allowance for credit loss.

Fair Value Measurements

The Company records certain financial assets and liabilities at fair value in accordance with the guidance in Financial Accounting Standards Board ("FASB") Accounting Standard Codification Topic 820, *Fair Value Measurements and Disclosures* ("ASC 820"), which defines fair value and establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described below:

Level 1 — Quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company can access at the measurement date.

Level 2 — Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable. If the asset or liability has a specified (contractual) term, a Level 2 input must be observable for substantially the full term.

Level 3 — Unobservable inputs developed using estimates of assumptions developed by the Company, which reflect those that a market participant would use.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment that the Company exercises

in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. There were no transfers into or out of Level 3 of the fair value hierarchy during the years ended December 31, 2023 and 2022.

Financial Instruments

The Company's financial instruments consist of cash, cash equivalents, restricted cash, accounts receivable, short-term investments, accounts payable, accrued expenses, and common stock warrants classified as equity. The carrying amounts of cash, cash equivalents, restricted cash, accounts receivable, accounts payable, and accrued expenses approximate their fair value due to the short-term nature of those financial instruments. Short-term investments are recorded at fair value, with any unrealized holding gains or losses reported as accumulated other comprehensive income or loss.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash, cash equivalents, restricted cash, short-term investments and accounts receivable. Periodically, the Company maintains deposits in financial institutions in excess of government insured limits. Management believes that the Company is not exposed to significant credit risk as the Company's deposits are held at financial institutions that management believes to be of high credit quality. The Company has not experienced any losses in these deposits.

Property and Equipment, Net

The Company records property and equipment at cost less accumulated depreciation and amortization. Expenditures for maintenance and repairs are charged to operations as incurred, whereas major improvements are capitalized as additions to property and equipment. Costs of assets under construction are capitalized but are not depreciated until the construction is substantially complete and the assets being constructed are ready for their intended use.

Depreciation and amortization are recorded using the straight-line method over the estimated useful lives of the assets, as follows:

Asset Category	Estimated Useful Life
Computer and telecommunications	3 – 5 years
Software	3 years
Furniture, fixtures and equipment	5 years
Laboratory equipment	7 years
Leasehold improvements	Lesser of lease term or estimated useful lives

Intangible Assets

The Company records intangible assets acquired in a business combination based on fair value on the date of acquisition. Acquired in-process research and development ("IPR&D") assets that have alternative future use at the time of acquisition are capitalized as an indefinite-lived intangible asset and tested for impairment until the project is completed or abandoned. Upon completion of the project, the indefinite-lived intangible asset will be accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life. If the project is abandoned, the indefinite-lived intangible asset will be charged to expense.

Intangible assets acquired in other transactions are recorded at cost. The Company capitalizes costs incurred in the course of obtaining patents and license issuance fees for the use of proprietary technologies. Costs incurred for obtaining patents are amortized on a straight-line basis over the estimated useful lives of the assets from the time of approval of the patent. Prior to approval, these costs are carried on the balance sheets and not amortized. In the event approval is denied, the cost of the denied application is expensed. License issuance fees are amortized on a straight-line basis over the estimated useful lives of the underlying licensed technology. Amortization costs are classified as R&D expenses.

Impairment or Disposal of Long-lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate the carrying value of such assets may not be recoverable in accordance with the guidance in Financial Accounting Standards Board ("FASB") Accounting Standard Codification Topic 360, Property, Plant and Equipment ("ASC 360"). The Company's long-lived assets include properties and equipment and right of use ("ROU") assets. For long-lived assets, impairment is recognized when the undiscounted cash flows used in the test for recoverability is less than their carrying value. In the event impairment exists, the long-lived asset will be written down to its fair value, and an impairment loss is recorded as the difference between the carrying value and fair value. For the years ended December 31, 2023 and 2022, the Company's qualitative assessment of long-lived assets for impairment testing determined that no impairment indicators were present.

Impairment of Indefinite-lived Intangible Assets

The Company evaluates its indefinite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying value of such assets may not be recoverable in accordance with the guidance in FASB Accounting Standard Codification Topic 350, Intangibles—Goodwill and Other ("ASC 350").

The Company had one IPR&D asset, HepTcell, that it acquired in 2015. This candidate was a viral pathogen immunotherapy product for the treatment of chronic HBV. Since 2020, the Company has been conducting a Phase 2 clinical trial. However, the preliminary data from this trial that management analyzed in December 2023, indicates that the results are not sufficient to warrant moving forward with this product candidate. As a result, the Company expects to stop all further development related to HepTcell and does not anticipate that there would be any third-party interest in the asset. This decision rendered the probability of success, which is one of the key inputs in the fair value measurement of this asset, to be effectively zero or close to zero. With no alternative use nor any anticipated interest from third parties for this asset, management determined that the fair value of the IPR&D asset was deemed di minimis as of December 31, 2023. Accordingly, the Company recorded a non-cash impairment charge of $12.4 million, which was the carrying value of the IPR&D asset, in the accompanying Consolidated Statements of Operations and Comprehensive Loss for the year ended December 31, 2023 under the caption "Impairment loss – intangible asset". As of December 31, 2023, the Company had no indefinite-lived intangible assets.

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are recorded as a current and long-term lease obligation, with a corresponding right of use lease assets.

Lease liabilities represent the Company's obligation to make lease payments arising from leases. ROU assets represent the Company's right to use an underlying asset for the lease term. Lease liabilities and ROU assets are recognized at the lease commencement date based on the present value of lease payments over the lease term. As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise those options. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Short-term leases are leases having a term of twelve months or less. The Company recognizes short-term leases on a straight-line basis and does not record a related lease asset or liability for such leases.

Lease incentives and allowance provided by our landlord for the construction of leasehold improvements are recorded as lease incentive obligations as the related construction costs are incurred, up to the maximum allowance.

Stock-based Compensation

The Company accounts for all stock-based compensation granted to employees and non-employees using a fair value method. The Company estimates the fair value of stock options granted using the Black-Scholes option pricing model on the dates of grant. For restricted stock and restricted stock units granted, fair value is determined based on the grant date closing price of the Company's common stock.

Stock-based compensation awarded to employees is measured at the grant date fair value of stock option grants and is recognized over the requisite service period of the awards, usually the vesting period, on a straight-line basis, net of estimated forfeitures. The Company estimates forfeitures at the time of grant and, if necessary, revises the estimate in subsequent periods if actual forfeitures differ from those estimates. Estimates are based on the Company's historical analysis of actual stock option forfeitures. The actual expense recognized over the vesting period is only for those options that vest.

If awards are modified, the Company compares the fair value of the affected award measured immediately prior to modification to its value after modification. To the extent that the fair value of the modified award exceeds the original award, the incremental fair value of the modified award is recognized as compensation expense on the date of modification for vested awards, and over the remaining vesting period for unvested awards.

R&D Expense

R&D costs are expensed as incurred. R&D costs consist of payroll and personnel expense, consulting costs, external contract R&D expenses, which includes fees paid to other entities that conduct certain R&D activities on the Company's behalf, such as clinical research organizations ("CROs") and contract manufacturing organizations ("CMOs"), raw materials, drug product manufacturing costs, laboratory supplies and allocated overhead, including depreciation and amortization, rent and utilities. Material R&D costs that are paid in advance of performance are capitalized as a prepaid expense and amortized over the service period as the services are provided.

Clinical trial costs are a significant component of R&D expenses, and the Company outsources a significant portion of these costs to third parties. Third party clinical trial expenses include investigator fees, site and patient costs, CRO costs, costs for central laboratory testing, data management and CMO costs. The accrual for site and patient costs includes inputs such as estimates of patient enrollment, patient cycles incurred, clinical site activations and other pass-through costs. These inputs are required to be estimated due to a lag in receiving the actual clinical information from third parties. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected on the Consolidated Balance Sheets as a prepaid asset or accrued expenses. These third-party agreements are generally cancelable, and related costs are recorded as R&D expenses as incurred. Material advance payments for goods or services that will be used or rendered for future R&D activities are recorded as a prepaid asset and recognized as expense as the related goods are delivered or the related services are performed. When evaluating the adequacy of the accrued expenses, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period.

R&D Incentive Credits

The Company is eligible to obtain certain R&D incentive credits, through the participation in the U.K. R&D Small and Medium Enterprise tax relief program ("U.K. R&D credit") and the Australian R&D incentive credit (the "Australia R&D credit") program administered through the Australian Tax Office (the "ATO").

The U.K. R&D credits are calculated as a percentage of qualifying R&D expenses and are payable in cash by the U.K. government to the Company. Qualifying R&D expenses consist of employment costs for research staff, consumables, a proportion of relevant, permitted sub-contract costs and certain internal overhead costs incurred as part of research projects for which the Company does not receive income. The Australia R&D credits provide for a cash refund based on a percentage of certain R&D activities undertaken in Australia by the Company's wholly owned subsidiary, Altimmune AU Pty, Limited. Qualifying R&D expenses must be incurred within the country.

The U.K. and Australian incentive credits are available on the basis of specific criteria with which the Company must comply. The incentive credits are subject to future audits by the government authorities and a statute of limitations. Although the incentive credits may be administered through the local tax authority, the Company has accounted for the incentives outside of the scope of FASB Accounting Standards Codification Topic 740, *Income Taxes* ("ASC 740"), since the incentives are not linked to the Company's taxable income and can be realized regardless of whether the Company has generated taxable income in the respective jurisdictions. The Company accounts for these incentive credits as a government

grant which analogizes with International Accounting Standards 20 ("IAS 20"), *Accounting for Government Grants and Disclosure of Government Assistance*.

The Company records qualifying U.K. R&D expenses as receivable and a corresponding reduction to R&D expense in the Consolidated Statement of Operations and Comprehensive Loss. During the years ended December 31, 2023 and 2022, the Company recognized $1.2 million and $1.8 million, respectively, of R&D credits as a reduction to R&D expense in the Consolidated Statement of Operations and Comprehensive Loss. As of December 31, 2023 and 2022, the Company had $3.0 million and $1.6 million, respectively, of R&D credits included in "Income tax and R&D incentive receivables" on the accompanying Consolidated Balance Sheets.

The Company records qualifying Australian R&D credits as receivable with a full valuation reserve. Cash receipts for Australia R&D credits are recorded as noncurrent liability until it either passes an audit performed by the ATO, or the statute of limitations ends, whichever occurs first. Upon successfully passing an audit or the expiration of the statute of limitations, the Company will clear the liability and a corresponding reduction to R&D expense unless recognition criteria is met in a later year, in which case the R&D credit will be recorded as other income in the Consolidated Statement of Operations and Comprehensive Loss. During the years ended December 31, 2023 and 2022, the Company received $0.4 million and $3.6 million in cash for R&D incentive, respectively. The 2023 incentive credit received is related to R&D costs that the Company incurred during the fiscal year 2022, whereas the 2022 incentive credit received is related to R&D costs that the Company incurred during the fiscal years and 2021 and 2020, both through the participation in the Australian R&D credit program, and is included in "Noncurrent liabilities" on the accompanying Consolidated Balance Sheets.

Income Taxes

The Company accounts for income taxes in accordance with ASC 740. ASC 740 uses the asset and liability approach, which requires the recognition of future tax benefits or liabilities on the temporary differences between the financial reporting and tax bases of our assets and liabilities. Deferred tax assets and liabilities represent future tax consequences of temporary differences between the financial statement carrying amounts and the tax basis of assets and liabilities and for loss carryforwards using enacted tax rates expected to be in effect in the years in which the differences reverse. A valuation allowance is established when necessary to reduce deferred tax assets to the amounts expected to be realized. The Company also recognizes a tax benefit from uncertain tax positions only if it is "more likely than not" that the position is sustainable based on its technical merits. The Company accounts for interest and penalties related to uncertain tax positions as part of its provision for income taxes. To date, the Company has not incurred interest and penalties related to uncertain tax positions. Should such costs be incurred, they would be classified as a component of provision for income taxes.

The Company conducts R&D activities potentially qualified to claim research tax credits for U.S. federal and state purposes under Internal Revenue Code Section 41. The Company has not performed a formal study claiming these credits in the tax returns because the Company does not yet have taxable profits. Once the Company becomes profitable, it will likely have a study prepared, and the amount of R&D tax credits available could generate income tax benefit, subject to an annual Section 383 limitation and valuation allowance for realizability of the deferred tax asset.

Comprehensive Loss

For the years presented, the total comprehensive loss includes net loss and other comprehensive income (loss) which represents unrealized gains or losses on short-term investments.

Net Loss per Share

Basic net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period without consideration for potentially dilutive securities.

The Company computes diluted net loss per common share after giving consideration to all potentially dilutive common equivalents, including all unvested restricted stock, common stock warrants, and common stock options outstanding during the period except where the effect of such non-participating securities would be anti-dilutive.

Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and dilutive common stock equivalents outstanding for the period determined using the treasury-stock and if-converted methods.

Recently issued accounting pronouncements

Recently Adopted:

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU No. 2016-13")*. ASU No. 2016-13 requires financial assets measured at amortized cost to be presented at the net amount expected to be collected and any unrealized loss relating to available-for-sale debt securities to be recorded through an allowance for credit losses. The Company adopted this new accounting standard on January 1, 2023 using a modified retrospective method. The adoption of this update did not have a material impact on the Company's financial statements and related disclosures.

Not Yet Adopted:

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. ASU No. 2023-07 requires public business entities to disclose information about their reportable segments' significant expenses on an interim and annual basis. The amendments in ASU 2023-07 also clarify that entities with a single reportable segment are subject to both new and existing segment reporting requirements under Topic 280. The amendments in ASU 2023-07 are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The amendments in ASU 2023-07 should be applied retrospectively to all prior periods presented in the financial statements. The amendments in this update are effective on the Company's 2024 annual report and quarterly reports beginning on first quarter 2025. The Company is currently evaluating the impact of this amendment on its Consolidated Financial Statements.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. ASU No. 2023-09 requires public business entities on an annual basis to (i) disclose in the rate reconciliation both percentages and amounts for certain categories in a tabular format, with further disaggregation of certain categories when the individual reconciling items meet a quantitative threshold, (ii) disclose income taxes paid, net of refunds received disaggregated by federal, state and foreign, with further disaggregation by individual jurisdictions that meet a qualitative threshold (iii) eliminates the requirement to disclose certain information when it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within 12 months of the reporting date or make a statement that an estimate of the range cannot be made and (iv) eliminates the requirement to disclose cumulative amount of each type of temporary difference in certain circumstances. The amendments in ASU 2023-09 are effective for fiscal years beginning after December 15, 2024, with early adoption permitted for annual financial statements that have not yet been issued. The amendments in ASU 2023-09 should be applied on a prospective basis, although retrospectively application is permitted. The amendments in this update are effective on the Company's 2025 annual report. The Company is currently evaluating the impact of this amendment on its Consolidated Financial Statements.

3. Fair Value Measurement

The Company records cash equivalents and short-term investments at fair value on a recurring basis. Fair value is an exit price, representing the amount that would be received from the sale of an asset or paid to transfer a liability in an orderly transaction between market participants based on assumptions that market participants would use in pricing an asset or liability.

The Company's assets measured at fair value on a recurring basis as of December 31, 2023 consisted of the following (in thousands):

	Fair Value Measurement at December 31, 2023			
	Total	Level 1	Level 2	Level 3
Assets:				
Cash equivalents - money market funds	$ 123,233	$ 123,233	$ —	$ —
Short-term investments	62,698	—	62,698	—
Total	$ 185,931	$ 123,233	$ 62,698	$ —

The Company's assets measured at fair value on a recurring basis as of December 31, 2022 consisted of the following (in thousands):

	Fair Value Measurement at December 31, 2022			
	Total	Level 1	Level 2	Level 3
Assets:				
Cash equivalents - money market funds	$ 105,794	$ 105,794	$ —	$ —
Short-term investments	73,783	—	73,783	—
Total	$ 179,577	$ 105,794	$ 73,783	$ —

Short-term investments have been initially valued at the transaction price and subsequently valued at the end of each reporting period utilizing third party pricing services or other market observable data (Level 2). The pricing services utilize industry standard valuation models, including both income and market-based approaches and observable market inputs to determine value.

Short-term investments with quoted prices as of December 31, 2023 as shown below (in thousands):

	December 31, 2023			
	Amortized Cost	Unrealized (Loss) Gain	Credit loss	Market Value
United States treasury securities	$ 19,472	$ 12	$ —	$ 19,484
Commercial paper and corporate debt securities	31,301	24	—	31,325
Asset backed securities	2,966	(4)	—	2,962
Agency debt securities	8,923	4	—	8,927
Total	$ 62,662	$ 36	$ —	$ 62,698

Short-term investments with quoted prices as of December 31, 2022 as shown below (in thousands):

	December 31, 2022			
	Amortized Cost	Unrealized (Loss) Gain	Credit Loss	Market Value
United States treasury securities	$ 15,868	$ (86)	$ —	$ 15,782
Commercial paper and corporate debt securities	50,747	(71)	—	50,676
Asset backed securities	5,427	(35)	—	5,392
Agency debt securities	1,928	5	—	1,933
Total	$ 73,970	$ (187)	$ —	$ 73,783

Separate disclosure is required for assets and liabilities measured at fair value on a recurring basis from those measured at fair value on a non-recurring basis. Assets recorded at fair value on a non-recurring basis, such as property and equipment and intangible assets are recognized at fair value when they are impaired. During the years ended December 31, 2023 and 2022, the Company had no assets or liabilities that were measured at fair value on a non-recurring basis.

4. Property and Equipment, Net

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

	December 31,	
	2023	2022
Furniture, fixtures and equipment	$ 163	163
Laboratory equipment	342	295
Computers and telecommunications	194	194
Software	178	178
Leasehold improvements	1,749	1,749
Property and equipment, at cost	2,626	2,579
Less: accumulated depreciation and amortization	(1,975)	(1,498)
Property and equipment, net	$ 651	$ 1,081

Depreciation expense related to property and equipment for each of the years ended December 31, 2023 and 2022 was $0.5 million.

5. Leases

The Company's operating leases consist of leases for office and laboratory space in the United States, which expire in April 2025. Rent expense under these leases during each of the years ended December 31, 2023 and 2022 was $0.5 million, which includes short-term leases and variable lease costs that are not included in the lease obligation.

Short-term leases are leases having a term of twelve months or less. The Company recognizes short-term leases on a straight-line basis and does not record a related lease asset or liability for such leases.

The office space lease provides for increases in future minimum annual rental payments as defined in the lease agreements. The office space lease also includes an option to renew the lease as of the end of the term. The Company has determined that the lease renewal option is not reasonably certain of being exercised.

The cash paid for operating lease liabilities for each of the years ended December 31, 2023 and 2022 was $0.5 million.

Supplemental balance sheet information related to the operating leases is as follows (in thousands):

	December 31,	
	2023	2022
Operating lease obligations (see Note 6 and 7)	$ 671	$ 1,124
Operating lease right-of-use assets (included in "Other assets" in Balance Sheet)	$ 363	$ 596
Weighted-average remaining lease term (years)	1.3	2.3
Weighted-average discount rate	7.2 %	7.2 %

Maturities of operating lease liabilities are as follows (in thousands):

Year ending December 31,	
2024	$ 526
2025	176
Total operating lease payments	702
Less: imputed interest	(31)
Total operating lease liabilities (see Note 6 and 7)	$ 671

6. Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2023	2022
Accrued professional services	$ 293	$ 276
Accrued payroll and employee benefits	3,315	2,955
Accrued research and development	5,845	7,295
Lease obligation, current portion (see Note 5)	496	452
Excess tax refund payable	—	1,169
Accrued interest and other	124	103
Total accrued expenses and other current liabilities	$ 10,073	$ 12,250

7. Noncurrent Liabilities

The Company's noncurrent liabilities are summarized as follows (in thousands):

	December 31,	
	2023	2022
Research and development incentive credit	$ 4,023	$ 3,599
Lease obligation, long-term portion (see Note 5)	175	672
Conditional economic incentive grants	160	250
Other	40	60
Total noncurrent liabilities	$ 4,398	$ 4,581

R&D incentive credit Program

During the years ended December 31, 2023 and 2022, the Company received a total of $0.4 million and $3.6 million in cash for R&D incentive credit, respectively. The 2023 incentive credit received is related to R&D costs that the Company incurred during the fiscal year 2022, whereas the 2022 incentive credit received is related to R&D costs that the Company incurred during the fiscal years and 2021 and 2020, both through the participation in the Australian R&D incentive credit program administered through the ATO. The Company recorded the receipt as noncurrent liability until there is reasonable assurance that the Company will comply with the conditions attached to the incentive credit.

Economic Incentive Grants

The Company had two conditional economic incentive grants for a total of $250,000 from Montgomery County, Maryland and the State of Maryland. The Montgomery County grant of $100,000 was received in May 2018, with a term expiring on February 28, 2028. The State of Maryland grant of $150,000 was received in October 2019, with a 10-year term expiring on December 31, 2029. These grants are conditional primarily based on the Company maintaining its current headquarter locations in addition to employing a required number of employees at different reporting dates through the term of the grants. The annual interest rate on both economic incentive grants is 3%.

During the year ended December 31, 2023, the Company repaid approximately $99,000 of the State of Maryland grant, including accrued interest, as the Company didn't meet the required number of employees as of December 31, 2022 as per terms of the grant.

8. Common Stock

The Amended and Restated Certificate of Incorporation, as amended ("Charter"), authorized the Company to issue 200,000,000 shares of common stock, par value $0.0001 per share. As of December 31, 2023, the Company had 70,677,400 shares of common stock issued and outstanding.

The Charter also authorized the Company to issue 1,000,000 shares of preferred stock, par value $0.0001 per share. As of December 31, 2023, the Company had no shares of preferred stock issued and outstanding.

At-the-Market Offerings

On February 28, 2023, the Company entered into an Equity Distribution Agreement (the "2023 Agreement") with Evercore Group L.L.C., JMP Securities LLC and B. Riley Securities, Inc., serving as sales agents (the "Sales Agents"), with respect to an at-the-market offerings program under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock, having an aggregate offering price of up to $150.0 million (the "Shares") through the Sales Agents (the "2023 Offering"). All Shares offered and sold in the 2023 Offering will be issued pursuant to the Company's Registration Statement on Form S-3ASR filed with the SEC on February 28, 2023, which was declared effective immediately, the prospectus supplement relating to the 2023 Offering filed with the SEC on February 28, 2023 and any applicable additional prospectus supplements related to the 2023 Offering that form a part of the Registration Statement. The Company capitalized approximately $0.2 million of other offering costs which will offset the proceeds received from the shares sold under the 2023 Agreement. During the year ended December 31, 2023, the Company sold 20,454,516 shares of common stock under the 2023 Agreement resulting in approximately $86.6 million in proceeds, net of $2.8 million commission and other offering costs, with, $60.6 million remaining available to be sold under the 2023 Agreement. As of December 31, 2023, there was $0.1 million in deferred offering costs included in prepaid expenses and other current assets on the accompanying Consolidated Balance Sheets.

On February 25, 2021, the Company entered into an Equity Distribution Agreement (the "2021 Agreement") with Piper Sandler & Co., Evercore Group L.L.C. and B. Riley Securities, Inc., serving as sales agents (the "2021 Sales Agents"), with respect to an at-the-market offerings program under which the Company offered and sold shares of its common stock, having an aggregate offering price of up to $125.0 million (the "2021 Shares") through the 2021 Sales Agents (the "2021 Offering"). All 2021 Shares offered and sold in the 2021 Offering were issued pursuant to the Company's Registration Statement on Form S-3 filed with the SEC on December 31, 2020, which was declared effective on January 11, 2021, the prospectus supplement relating to the 2021 Offering filed with the SEC on February 25, 2021 and any applicable additional prospectus supplements related to the 2021 Offering that form a part of the Registration Statement. Under the 2021 Agreement, the Company sold 10,004,869 shares of common stock resulting in approximately $121.0 million in proceeds, net of $4.0 million commission and other offering costs. As of December 31, 2023, there were no remaining shares available under the 2021 Agreement.

Public Offering

On July 16, 2020, the Company offered and sold (i) 3,369,564 shares of common stock, at a price to the public of $23.00 per share, and (ii) pre-funded warrants of the Company to purchase 1,630,436 shares of common stock at an exercise price equal to $0.0001 per share (the "Pre-Funded Warrants"), at a price to the public of $22.9999 per share of common stock underlying the Pre-Funded Warrants (equal to the public offering price per share of Common Stock, minus the exercise price of each Pre-Funded Warrant). The Pre-Funded Warrants were classified as equity and were accounted for as a component of additional paid-in capital at the time of issuance. In January 2022, 760,870 of the Pre-Funded Warrants were exercised, resulting in the issuance of 760,870 shares of common stock. Furthermore, on October 18, 2023, warrant holders exercised the remaining 869,566 Pre-Funded Warrants in a net cashless exercise and were issued 869,530 shares of common stock (see Note 9).

9. Warrants

The following common stock warrants were outstanding at December 31, 2023:

	Number of Common Stock Warrants	Per Share Exercise Price	Issuance Date	Expiration Date
Issued with common units in the 2019 Registered Direct Offering	50,000	$ 3.21	March 12, 2019	March 12, 2024
Total	50,000			

The following common stock warrants were outstanding at December 31, 2022:

	Number of Common Stock Warrants	Per Share Exercise Price	Issuance Date	Expiration Date
Issued with common units in the 2018 Unit Offering	3,300	$ 2.7568	October 2, 2018	October 2, 2023
Issued with common units in the 2018 Registered Direct Offering	92,300	$ 5.40	October 10, 2018	October 10, 2023
Issued with common units in the 2019 Registered Direct Offering	50,000	$ 3.21	March 12, 2019	March 12, 2024
Issued with common units in the 2020 Public Offering (see Note 8)	869,566	$ 0.0001	July 16, 2020	—
Total	1,015,166			

On October 18, 2023, warrant holders exercised the remaining 869,566 Pre-Funded Warrants in a net cashless exercise and were issued 869,530 shares of common stock (see Note 8 Common Stock). In addition, in October 2023, 95,600 various other warrants with a weighted-average exercise price of $5.31 expired unexercised. On March 5, 2024, the remaining 50,000 warrants with an exercise price of $3.21 were fully exercised, resulting in the issuance of 50,000 shares of common stock.

A summary of warrant activity is as follows:

	Number of Warrants	Weighted Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)
Warrants outstanding, December 31, 2022	1,015,166		
Exercised (see Note 8)	(869,566)		
Expired	(95,600)		
Warrants outstanding, December 31, 2023	50,000	$ 3.21	0.2

10. Stock-Based Compensation

Stock Options

The Company established the 2001 Employee Stock Option Plan to provide incentive stock options and non-qualified stock options to employees, and the 2001 Non-employee Stock Option Plan to provide non-qualified stock options to the members of the board of directors and advisory board, and non-employees. The 2001 Employee Stock Option Plan and the 2001 Non-employee Stock Option Plan are collectively referred to as the "2001 Plans." In connection with the Company's merger with PharmAthene, Inc. in 2017, the Company issued options from its 2001 Plans to replace options previously granted. The Company de-designated common stock available for issuance under the 2001 Plans. No additional options or restricted stock will be granted under these plans. Options outstanding and unvested restricted stock granted or replaced under these plans will continue to vest over the remaining vesting period through the earlier of exercise, expiration or forfeiture. The replacement options issued after the 2017 mergers will continue to vest over the remaining

vesting period through the earlier of exercise, expiration or forfeiture. Also, in connection with the 2017 mergers, the 2001 Plans were assumed by the Company.

In addition, the Company assumed the PharmAthene, Inc. Amended and Restated 2007 Long-Term Incentive Compensation Plan (the "2007 Plan"). Awards outstanding under the 2007 Plan remained outstanding in accordance with their applicable terms and conditions. No additional awards will be made under the 2007 Plan.

The Company established the 2017 Omnibus Incentive Plan (the "Omnibus Plan") to provide incentive stock options, non-qualified stock options, restricted stock, and other stock-based awards denominated in shares of the Company's common stock, and performance-based cash awards to eligible employees, consultants and directors. In 2018, the Company's shareholders approved an amendment to the Omnibus Plan to increase the number of shares reserved for issuance from 1,500,000 to 5,000,000. The aggregate share reserve will be increased on January 1 of each year commencing in 2019 and ending on and including January 1, 2027 up to an amount equal to the lowest of (i) 4% of the total number of shares of common stock outstanding on a fully diluted basis as of December 31 of the immediately preceding calendar year, and (ii) such number of shares of common stock, if any, determined by the Company's board of directors. Accordingly, on January 1, 2024, the number of shares of Common Stock reserved and available for issuance under the Omnibus Plan increased by 3,055,006. The maximum number of shares of common stock that may be issued under the Omnibus Plan in respect of Incentive Stock Option ("ISO") is 5,000,000 shares. The maximum number of shares of common stock that may be granted to non-employee directors under the Omnibus Plan during any fiscal year is 2,000,000 shares.

On November 29, 2018, the Board approved and adopted the Altimmune Inc. 2018 Inducement Grant Plan (the "Inducement Plan"). The Inducement Plan provides for the grant of equity or equity-based awards in the form of non-qualified stock options, restricted stock awards and other stock-based awards. The Inducement Plan was adopted by the Board without stockholder approval pursuant to Rule 5635(c)(4) of the NASDAQ Listing Rules.

The Board has reserved 2,000,000 shares of the Company's common stock for issuance pursuant to awards granted under the Inducement Plan (subject to customary adjustments in the event of a change in capital structure of the Company), and the Inducement Plan will be administered by the Compensation Committee. In accordance with Rule 5635(c)(4) of the NASDAQ Listing Rules, awards under the Inducement Plan may be only made to an employee who has not previously been an employee or member of the Board or any parent or subsidiary, or following a bona fide period of non-employment by the Company or a parent or subsidiary, if he or she is granted such award in connection with his or her commencement of employment with the Company or a subsidiary and such grant is an inducement material to his or her entering into employment with the Company or such subsidiary.

The 2001 Plans, the 2007 Plan, the Omnibus Plan and the Inducement Plan are collectively referred to as the "Plans." During the year ended December 31, 2023 under the Plans, a total of 1,760,026 options to purchase shares of common stock were granted. As of December 31, 2023, there were 1,605,642 and 1,309,275 shares of common stock available for future grants under the Omnibus Plan and the Inducement Plan, respectively.

The fair value of stock option issued to employees was estimated at the date of grant using Black-Scholes with the following weighted-average assumptions:

	Year Ended December 31,	
	2023	2022
Expected volatility	100.4 %	110.1 %
Expected term (years)	6.0	6.0
Risk-free interest rate	3.8 %	2.4 %
Expected dividend yield	0.0 %	0.0 %

A summary of stock option activity under the Plans is presented below (in thousands, except share and per share data):

	Number of Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (In thousands)
Outstanding, December 31, 2022	3,383,937	$ 9.20	5.9	$ 25,724
Granted	1,760,026	$ 9.71		
Exercised	(24,075)	$ 3.09		
Forfeited or expired	(76,295)	$ 14.20		
Outstanding, December 31, 2023	5,043,593	$ 9.33	5.9	$ 16,919
Exercisable, December 31, 2023	2,441,054	$ 8.75	5.9	$ 10,063
Vested and expected to vest, December 31, 2023	4,757,314	$ 9.30	5.9	$ 16,165

The per share weighted-average grant date fair value of stock options granted during the years ended December 31, 2023 and 2022 were $7.86 and $7.07 per share, respectively. The total intrinsic value of stock options exercised during the years ended December 31, 2023 and 2022 was $0.2 million and $4.4 million, respectively. The total fair value of options vested during the years ended December 31, 2023 and 2022 was $7.0 million and $6.8 million, respectively. As of December 31, 2023, there was $16.0 million of unrecognized compensation cost related to stock options, which is expected to be recognized over a weighted-average period of 2.5 years.

Restricted Stock Units (RSUs)

During the year ended December 2022, the Company granted 319,700 shares of RSUs with a weighted-average grant date fair value of $13.20 per share which vest over four years. During the year ended December 31, 2023, the Company issued 72,646 shares of common stock as a result of the vesting of 115,018 RSUs net of 42,372 shares of common stock withheld to satisfy tax withholding obligations. The fair value of RSUs vested during the years ended December 31, 2023 and 2022 was $1.4 million and $0.6 million, respectively.

A summary of RSUs activities is presented below:

	Shares	Weighted-average Grant Date Fair Value
Unvested, December 31, 2022	414,485	$ 9.81
Granted	319,700	13.20
Vested	(115,018)	10.47
Forfeited or expired	(15,000)	7.05
Unvested, December 31, 2023	604,167	$ 11.55

As of December 31, 2023, total unrecognized compensation expense related to RSUs was $4.6 million, which the Company expects to recognize over a weighted-average period of approximately 2.5 years.

2019 Employee Stock Purchase Plan

On March 29, 2019, the Board adopted the 2019 Employee Stock Purchase Plan (the "2019 ESPP"). A total of 403,500 shares of the Company's common stock have been reserved for issuance under the 2019 ESPP. Subject to any plan limitations, the 2019 ESPP allows eligible employees to contribute through payroll deductions up to 10% of their earnings for the purchase of the Company's common stock at a discounted price per share. The offering periods begin in February and August of each year, with the initial offering period started on August 1, 2019. The common shares issuable under the 2019 ESPP were registered pursuant to a registration statement on Form S-8 on April 4, 2019.

Unless otherwise determined by the administrator, the Company's common stock will be purchased for the accounts of employees participating in the 2019 ESPP at a price per share that is the lesser of 85% of the fair market value of the Company's common stock on the first trading day of the offering period or 85% of the fair market value of the Company's common stock on the last trading day of the offering period. The 2019 ESPP estimated shares to be purchased fair value is included in stock-based compensation expense.

Employees have the ability to purchase shares of the Company's common stock at a price equal to the lower of the first or last trading day of the offering period, which represents an option and, therefore, the 2019 ESPP is a compensatory plan under ASC 718-50, *Employee Stock Purchase Plans*. Accordingly, stock-based compensation expense is determined based on the option's grant-date fair value, employee contributions, and the Company's stock price and is recognized over the requisite service period of the option. The Company used the Black-Scholes valuation model to determine the fair value of ESPP.

During the year ended December 31, 2023, employees purchased 41,560 shares for $0.2 million under the 2019 ESPP. As of December 31, 2023, there were 218,784 shares of common stock available for future issuance under the 2019 ESPP Plan. The Company recognized stock-based compensation expense related to this plan of $0.2 million and $0.3 million for of the years ended December 31, 2023 and 2022, respectively.

Stock-based Compensation Expense

Stock-based compensation expense is classified in the accompanying Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2023 and 2022 as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Research and development	$ 4,758	$ 2,835
General and administrative	5,882	5,266
Total	$ 10,640	$ 8,101

11. Employee Benefit Plans

The Company has a 401(k)-retirement plan in which substantially all of our employees in the United States are eligible to participate in. Eligible employees may elect to contribute up to the maximum limits, as set by the Internal Revenue Service, of their eligible compensation. During the years ended December 31, 2023 and 2022, the Company made discretionary plan contributions of $0.4 million and $0.3 million, respectively.

12. Income Taxes

The components of net loss before income tax benefit are as follows (in thousands):

	Year Ended December 31,	
	2023	2022
U.S. operations	$ (65,697)	$ (72,750)
Non-U.S. operations	(22,750)	(12,160)
Net loss before income tax benefit	$ (88,447)	$ (84,910)

The components of the income tax expense (benefit) are as follows (in thousands):

	Year Ended December 31,	
	2023	2022
U.S. federal		
Current	$ —	$ (144)
U.S. state and local		
Current	—	(53)
Income tax expense (benefit)	$ —	$ (197)

Reconciliation between the effect of applying the federal statutory rate and the effective income tax rate used to calculate the Company's income tax benefit is as follows:

	Year Ended December 31,	
	2023	2022
Federal statutory rate	21.00 %	21.00 %
State income taxes, net of federal benefit	8.74	(0.12)
Research and development tax credit	(3.74)	(2.22)
Acquired in process research and development	—	(0.02)
Rate change	—	1.29
Other	2.90	0.21
Change in valuation allowance	(28.90)	(19.91)
Effective tax rate	— %	0.23 %

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income and for tax carryforwards. Significant components of the Company's deferred tax assets and liabilities are as follows (in thousands):

	December 31,	
	2023	2022
Deferred tax assets:		
Net operating losses	$ 54,109	$ 44,606
Capitalized research and development costs	24,698	11,996
Stock compensation	2,787	2,193
Accrued expenses	757	523
Amortization	357	540
Lease liability	182	309
Depreciation	56	—
Other	110	107
Total deferred tax assets	83,056	60,274
Valuation allowance	(82,958)	(57,245)
Deferred tax assets, net	98	3,029
Deferred tax liabilities:		
IPR&D assets	—	(2,847)
Right of use asset	(98)	(164)
Depreciation	—	(18)
Total deferred tax liabilities	(98)	(3,029)
Total deferred tax assets (liabilities), net	$ —	$ —

The Company assesses the need for a valuation allowance against our deferred tax assets and considers both positive and negative evidence related to the likelihood of realization of the deferred tax assets to determine, based on the weight of available evidence, whether it is more-likely-than-not that some or all of the deferred tax assets will not be realized. This determination requires significant judgment, including assumptions about future taxable income that are based on historical and projected information. The increase in the valuation allowance during the year ended December 31, 2023 primarily relates to increases for current year losses in both the U.S. and foreign locations. The Company has recorded a valuation allowance against its net U.S. and net non-U.S. deferred tax assets which it believes are not more likely than not realizable. Deferred tax liabilities will be applied in the future to offset against net operating losses ("NOLs") that have an indefinite life.

The Company has U.S. federal and state net operating loss carryforwards of approximately $152.7 million and $143.3 million, respectively, as of December 31, 2023, of which a portion of the federal and state amount of $7.1 million and $143.3 million, respectively, has a 20-year carry forward period that will expire at various dates beginning in 2024. Under current law, the remaining federal amount of $145.6 million has an indefinite life and amounts utilized in the future may not exceed 80% of taxable income. The Company also has foreign net operating loss carryforward of approximately $50.9 million which carryforward indefinitely.

Under Section 382 of the Internal Revenue Code of 1986 (“IRC 382”), as amended, substantial changes in the Company’s ownership may limit the amount of NOLs that can be utilized annually in the future to offset its U.S. federal and state taxable income. Specifically, this limitation may arise in the event of a cumulative change in ownership of the Company of more than 50% within any three-year period. The amount of the annual limitation is determined based on the value of the Company immediately before the ownership change. The Company has reduced the NOL and related valuation allowance in historical periods for NOLs that cannot be utilized in the future because of IRC 382.

The Company has reviewed for any ownership changes as defined under IRC Section 382 from January 1, 2021 through November 3, 2023 and determined that the ownership change was less than 50% during that period. The Company’s existing NOLs are subject to limitations arising from previous ownership changes impacting the timing and amount, and the impact of such changes is reflected in the NOL amounts disclosed above. In addition, future changes in the Company’s stock ownership, many of which are outside of the Company’s control, could result in an ownership change.

Beginning January 1, 2022, pursuant to the Tax Cuts and Jobs Act of 2017 ("TCJA"), R&D costs in the current period are required to be capitalized and amortized over five or fifteen years, for domestic and foreign-incurred R&D, respectively.

Significant judgment is required in evaluating tax positions and determining the provision for income taxes. The Company establishes liabilities for tax-related uncertainties based on estimates of whether, and the extent to which, additional taxes may be due. These liabilities are established when the Company believes that its tax return positions are more-likely-than-not to be sustained upon audit by taxing authorities. The Company adjusts these liabilities in light of changing facts and circumstances, such as the outcome of a tax audit. The provision for income taxes includes the impact of changes to these liabilities.

The amount of unrecognized tax benefits was $0.7 million as of both December 31, 2023 and 2022. Any changes in the next twelve months are not anticipated to have a significant impact on the results of operations, financial position or cash flows of the Company. All of the Company’s uncertain tax positions, if recognized, would affect its income tax expense, although the net impact would be zero due to the Company’s valuation allowance position.

The Company has elected an accounting policy to classify interest and penalties related to unrecognized tax benefits as a component of income tax expense. During the year ended December 31, 2022, the company recorded income tax benefit of $0.2 million related to interest received and receivable on income tax refunds. As of December 31, 2023, potential interest and penalties on unrecognized tax benefits were not significant.

The following is a tabular reconciliation of the total amounts of unrecognized tax benefits excluding related interest and penalties (in thousands):

	Year Ended December 31,	
	2023	2022
Beginning balance	$ 711	$ 237
Increases for prior year tax positions	—	474
Ending balance	$ 711	$ 711

The Company files income tax returns in the United States, various U.S. states, U.K. and Australia. The Company is still open to examination by the applicable taxing authorities from 2010 forward, although tax attributes that were generated prior to 2010 may still be adjusted upon examination by federal, state, foreign or local tax authorities if they either have been or will be used in a future period.

13. Net Loss Per Share

Because the Company has reported net loss attributable to common stockholders for the years ended December 31, 2023 and 2022, basic and diluted net loss per share attributable to common stockholders in each year are the same.

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average numbers of shares of common stock outstanding for the period.

Diluted net loss per share is calculated by adjusting weighted-average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period. As such, all unvested restricted stock, RSUs, common stock warrants, and stock options have been excluded from the computation of diluted weighted-average shares outstanding because such securities would have an anti-dilutive impact for all periods presented.

Potential common shares issuable upon conversion, vesting or exercise of unvested restricted stock, common stock warrants, and stock options that are excluded from the computation of diluted weighted-average shares outstanding, as they are anti-dilutive, are as follows:

	Year Ended December 31,	
	2023	2022
Common stock warrants	50,000	145,600
Common stock options	5,105,169	3,397,998
Restricted stock units	604,167	414,485

14. Commitments and Contingencies

Spitfire Acquisition

In July 2019, the Company entered into the Spitfire merger agreement to acquire all of the equity interests of Spitfire Pharma, Inc. ("Spitfire"). Spitfire was a privately held, preclinical pharmaceutical company developing novel peptide products for pharmaceutical indications, including pemvidutide for the treatment of MASH. As part of the agreement, the Company is obligated to make payments of up to $80.0 million upon the achievement of specified worldwide net sales of all products developed using the technology acquired from Spitfire Pharma Inc. (the "Sales Milestone") within ten years following the approval of a new drug application filed with the U.S. Food and Drug Administration (the "FDA").

The contingent payments related to the Sales Milestones are predominately cash-based payments accounted for under FASB Accounting Standards Codification Topic 450, Contingencies. Accordingly, the Company will recognize the Sales Milestones when the contingency is probable and the amount can be reasonably estimated.

Litigation

The Company is not currently subject to any material legal proceedings. The Company is a party in various contracts and subject to disputes, litigation, and potential claims arising in the ordinary course of business none of which are currently reasonably possible or probable of material loss.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 under the Securities Exchange Act of 1934, as of December 31, 2023. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2023, our disclosure controls and procedures were effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

Our management, including our principal executive and principal financial officer, has evaluated any changes in our internal control over financial reporting that occurred during the year ended December 31, 2023, and has concluded that there was no change that occurred during the year ended December 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. Our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management has concluded that our internal control over financial reporting was effective as of December 31, 2023.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating the disclosure controls and procedures, 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. 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 its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

We are a smaller reporting company, and therefore our independent registered public accounting firm has not issued a report on the effectiveness of internal control over financial reporting.

Item 9B. Other Information

Insider Trading Arrangements

On December 19, 2023, Dr. Vipin Garg, our President and Chief Executive Officer entered into a trading plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act. The plan provides for the sale of up to 80,000 shares of our common stock acquired pursuant to vesting of restricted awards granted to Dr. Garg. Dr. Garg's plan will commence on the later of March 19, 2024 or two business days following the filing of our financial results on Form 10-K, and expires on March 19, 2025.

Other than the trading arrangement disclosed above, none of our officers or directors adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement" as defined in Item 408 of Regulation S-K.

We have adopted insider trading policies and procedures governing the purchase, sale, and/or other dispositions of our securities by us, directors, officers and employees.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Directors

Our directors are elected at each annual meeting of stockholders and hold office until the next annual meeting of stockholders and until their successors have been elected and qualified. Our Bylaws provide that the number of Directors constituting the entire Board shall be not less than one nor more than nine as determined by resolution of the Board. Our Board currently has nine Directors, each of whom was elected at the Company's 2023 annual meeting of stockholders.

The names and ages of our directors as of March 27, 2024 are set forth below:

Name	Age	Position
Vipin K. Garg, Ph.D.	66	President, Chief Executive Officer, and Director
Mitchel Sayare, Ph.D.	76	Chairman of the Board
David J. Drutz, M.D.	85	Director
John M. Gill	72	Director
Philip L. Hodges	55	Director
Wayne Pisano	69	Director
Diane Jorkasky, M.D.	72	Director
Klaus O. Schafer, M.D., MPH	74	Director
Catherine Sohn, Pharm D	71	Director

Vipin K. Garg, Ph.D. currently serves as our President and Chief Executive Officer and is a member of the Board of Directors. Dr. Garg joined Altimmune in November 2018 with over three decades of experience in the biotechnology and pharmaceutical industries. He has a proven track record of building and managing both private and publicly traded companies. Before joining Altimmune, from October 2013 to June 2018, he served as President and Chief Executive Officer of Neos Therapeutics, Inc. (since acquired by Aytu BioPharma, Inc. (Nasdaq: AYTU)), where he built a NASDAQ-listed commercial-stage biopharmaceutical company, launching three branded therapeutic products including Adzenys XR-ODT™ and Cotempla XR-ODT™, the first ever XR-ODT medications for the treatment of ADHD. Prior to Neos, he served as president and Chief Executive Officer of Tranzyme Pharma where he progressed a discovery-stage, emerging biotech company to a Nasdaq-listed clinical-stage, drug development company. Prior to joining Tranzyme, Dr. Garg served as Chief Operating Officer of Apex Bioscience, Inc. (acquired by Curacyte AG of Munich, Germany), and held senior management positions at DNX Bio-Therapeutics, Inc. (until its acquisition by Baxter Healthcare Corporation), Sunovion Pharmaceuticals, Inc. (formerly known as Sepracor Inc., now a subsidiary of Sumitomo Dainippon Pharma), and Bio-Response Inc. (acquired by Baxter Healthcare Corporation). Dr. Garg received his Ph.D. in Biochemistry in 1982 from the University of Adelaide, Australia, and his M.S. from IARI Nuclear Research Laboratory, New Delhi, India in 1978. We believe that Dr. Garg's extensive experience in the biotechnology and pharmaceutical industries makes him well qualified to serve as a member of our Board of Directors.

Mitchel Sayare, Ph.D. has been a member of the Board of Directors since April 2010. Dr. Sayare became Chairman of the Board in January 2018 and served as Executive Chairman from June 2018 to November 2018. Until 2010, Dr. Sayare served as the Chairman of the Board of public company ImmunoGen, Inc. (Nasdaq: IMGN) (a position he had held since 1989). In addition, he served as ImmunoGen's Chief Executive Officer from 1986 to December 31, 2009, and as its President from 1986 to 1992, and from 1994 to July 2008. Prior to joining ImmunoGen, he served as Vice President of Development of Xenogen from 1982 to 1985. Prior to that he was Assistant Professor of Biophysics and Biochemistry at the University of Connecticut. Dr. Sayare earned a Ph.D. in biochemistry from Temple University School of Medicine. Dr. Sayare is chairman of the board of AutoIVF, Inc. and of MassPay Holdings, Inc., and is a director of Energesis, Inc. and Advanced Aesthetic Technologies, Inc., all privately-held companies. We believe that Dr. Sayare's substantial experience as a board member and executive officer of biotechnology companies makes him well qualified to serve as a member of our Board of Directors.

David J. Drutz, M.D. has served as a member of our Board of Directors since May 2017, when he was appointed to the Board in connection with the completion of the Merger. Dr. Drutz was first elected to Private Altimmune's Board

of Directors in January 2010 and was elected Board Chairman in October 2011. Dr. Drutz is the President of Pacific Biopharma Associates, LLC, a biopharmaceutical consulting company that he founded in 1999. From 2008 to 2015, he held various positions at DARA BioSciences (Nasdaq: DARA), an oncology supportive care company which was acquired by Midatech Pharma plc, including Director, Chief Executive Officer, Executive Chairman and Chief Medical Officer. He also previously served as Chairman of Tranzyme Pharma (Nasdaq: TZYM) from 2000 to 2010; and Director of MethylGene (TSX: MYG) from 2000 to 2010 and Gentris Corporation from 2007 to 2014. From 1999 to 2008 he was a general partner with Pacific Rim Ventures, a Tokyo-based venture capital firm. Dr. Drutz's management experience includes tenures as VP Biological Sciences and VP Clinical Research at Smith Kline & French Laboratories; VP Clinical Development at Daiichi Pharmaceutical Corporation; and CEO of Inspire Pharmaceuticals (1995 – 1998) and Sennes Drug Innovations (1994 – 1995). Earlier, Dr. Drutz was Professor of Medicine, Chief of the Division of Infectious Diseases, and the founder of the NSF Center for Cell Regulation at the UT Health Science Center, San Antonio. Dr. Drutz received his M.D. from the University of Louisville School of Medicine and postgraduate training in internal medicine and infectious diseases at Vanderbilt University School of Medicine, serving subsequently as a research medical officer in the U.S. Navy (LCDR, USNR). We believe Dr. Drutz's significant experience in biotechnology investment and as a physician make him well qualified to serve as a member of our Board of Directors.

John M. Gill has served as a member of our Board of Directors since August 2004. Mr. Gill served as PharmAthene's President and Chief Executive Officer from March 2015 until the completion of the Merger in May 2017. From 2003 to 2013, Mr. Gill served as the President, Chief Executive Officer, co-founder and a Director of TetraLogic Pharmaceuticals Corporation, a public biopharmaceutical company. Mr. Gill has previously held positions at 3 Dimensional Pharmaceuticals and SmithKline Beecham. After serving in the United States Marine Corps, Mr. Gill earned a B.A. in Accounting and Economics from Rutgers University. We believe Mr. Gill's executive and board experience in the pharmaceutical industry and his substantial financial knowledge and expertise make him well qualified to serve as a member of our Board of Directors.

Philip L. Hodges has served as a member of our Board of Directors since May 2017, when he was appointed to the Board in connection with the completion of the Merger, and was first elected to Private Altimmune's board of directors in September 2003. Mr. Hodges is Managing Partner of Redmont Capital, a private equity firm located in Birmingham, Alabama, which he joined at its inception in 1997. Redmont Capital is a co-founder of Private Altimmune. Mr. Hodges' investment strategy is focused on high-growth small businesses within the health care, life science and technology sectors. He currently serves as a director for several of the firm's portfolio companies. Mr. Hodges holds a Bachelor of Science in Business Administration from the Brock School of Business at Samford University. We believe Mr. Hodges' experience as a life science investor makes him well qualified to serve as a member of our Board of Directors.

Wayne Pisano has served as a member of our Board of Directors since August 2018. Mr. Pisano also has served on the board of directors of Oncolytics Biotech Inc. (Nasdaq: ONCY), a biotechnology company, since May 2013. Mr. Pisano served on the board of directors of Provention Bio, Inc. (Nasdaq: PRVB), a biopharmaceutical company, from April 2018 until April 2023 when it was acquired by Sanofi, and IMV INC. (Nasdaq: IMV) a biopharmaceutical company from October 2011 until March 2021. Mr. Pisano served as president and Chief Executive Officer of VaxInnate Corporation, a biotechnology company, from January 2012 until November 2016. Mr. Pisano joined Sanofi Pasteur in 1997 and was promoted to President and Chief Executive Officer in 2007, the position he successfully held until his retirement in 2011. He has a Bachelor of Science in biology from St. John Fisher College, New York and an MBA from the University of Dayton, Ohio. We believe Mr. Pisano's depth of experience across the spectrum of commercial operations, public immunization policies and pipeline development makes him well qualified to serve as a member of our Board of Directors.

Diane Jorkasky, M.D. has served as a member of our Board of Directors since May 2020. Dr. Jorkasky currently serves as a member of the board of directors of Alzheon, Inc., a private biopharmaceutical company, since 2016. She also served on the board of directors of Q Therapeutics, Inc. from September 2013 until August 2016. From June 2014 to August 2019, she served as Executive Vice President, Chief Medical Officer and Head of Development at Complexa Inc., a clinical stage biopharmaceutical company. Dr. Jorkasky received her M.D. in 1977 from the University of Pennsylvania School of Medicine and is board certified in internal medicine, nephrology and clinical pharmacology. She is a member of the Connecticut Academy of Science and Technology. Dr. Jorkasky is on the faculties of University of California, San Francisco, and Uniformed Service of Health Sciences Medical Schools, with previous faculty appointments at Yale University and the University of Pennsylvania Schools of Medicine. We believe Dr. Jorkasky's executive and board

experience in the pharmaceutical industry and as a physician make her well qualified to serve as a member of our Board of Directors.

Klaus O. Schafer, M.D., MPH has served as a member of our Board of Directors since May 2017, upon completion of the Merger. Dr. Schafer was first elected to Private Altimmune's Board of Directors in 2012. Dr. Schafer has over 35 years of healthcare leadership experience, having held senior positions in government and industry. As former, Acting Deputy Assistant to the Secretary of Defense for chemical and biological defense, he oversaw the Department's $1.0 billion program for vaccine, therapeutics, medical device and sensor development and was instrumental in advancing research into human immune response. As former U.S. Air Force Assistant Surgeon General, he managed all aspects of large integrated health care delivery systems, from clinical care, administration of clinics and hospitals, and oversaw large S&T portfolios, including clinical trials. Former CEO and co-founder of TessArae LLC, a biotech medical sequencing device company. Former Chief Medical Officer and client executive for health at CACI International. He has been an independent consultant since 2002 serving a number of biotech and health-related company advisory boards and Tadpole Ventures, a private venture capital firm. Dr. Schafer earned his M.D. degree at the University of Iowa, medical boards in family practice and aerospace medicine in the Air Force, Master of Public Health at the University of Texas, and a Master of Science at the Dwight D. Eisenhower School of National Security and Resource Strategy. Dr. Schafer is CERT certified in Cybersecurity Oversight from the Carnegie Mellon University Software Engineering Institute. We believe Dr. Schafer's broad experience across multiple aspects of the healthcare, pharmaceutical development industries and government makes him well qualified to serve as a member of our Board of Directors.

Catherine Sohn, Pharm D. has served as a member of our Board of Directors since March 2023. Dr. Sohn also serves on the board of directors of Jazz Pharmaceuticals plc (Nasdaq: JAZZ), a commercial-stage biopharmaceutical company, since July 2012 and Maze Therapeutics, a private clinical-stage biopharmaceutical company, since January 2021. Dr. Sohn was formerly senior vice president of worldwide business development, and a member of the global executive committee at GlaxoSmithKline's Consumer Healthcare division, where she led U.S. and global transactions and prior to that was Vice President of Strategic Product Development at SmithKline Beecham Pharmaceuticals. Since retiring from GlaxoSmithKline, Dr. Sohn has advised CEOs and boards of private life science companies on strategy, strategic product development, partnering, mergers and acquisitions, commercialization of new medicines and vaccines and culture, in her role as President of Sohn Health Strategies. Dr. Sohn received her Doctor of Pharmacy degree from the University of California, San Francisco, a Corporate Directors Certificate from Harvard Business School, a Certificate of Professional Development from Wharton, a Certificate from UC Berkeley Law for environmental, social and corporate governance, has attended Stanford Directors College and is a Certified Licensing Professional Emeritus. Dr. Sohn is also an Adjunct Professor at the University of California, San Francisco. We believe that Dr. Sohn's extensive experience in the biopharmaceutical industry and as a pharmacist make her well qualified to serve as a member of our Board of Directors.

Executive Officers

The names and ages of our executive officers as of March 27, 2024 are set forth below:

Name	Age	Position
Vipin K. Garg, Ph.D.	66	President, Chief Executive Officer, and Director
Richard Eisenstadt, M.B.A.	65	Chief Financial Officer
M. Scot Roberts, Ph.D.	65	Chief Scientific Officer
M. Scott Harris, M.D.	70	Chief Medical Officer
Raymond M. Jordt	51	Chief Business Officer

Vipin K. Garg, Ph.D. is our President, Chief Executive Officer and a Director. See Item 10 - "Directors" for a discussion of Dr. Garg's business experience.

Richard Eisenstadt, M.B.A. currently serves as our Chief Financial Officer. Mr. Eisenstadt has served as Chief Financial Officer of Altimmune since December 2021. He has served in senior financial leadership roles for over twenty-five years. Prior to joining Altimmune, he served as Chief Financial Officer at Aytu BioPharma, Inc. (Nasdaq: AYTU) following its merger with Neos Therapeutics, Inc. (Nasdaq: NEOS) in March 2021. While Chief Financial Officer at Neos, he raised over $340 million in private and public equity and debt financings and supported the transition of the company from clinical stage to commercial operations. Prior to Neos, Mr. Eisenstadt served as Chief Financial Officer at Arborgen,

Inc., a privately-held agriculture biotechnology company, and prior to that, Chief Financial Officer at Tranzyme, Inc. (Nasdaq: TZYM), where he was instrumental in its initial public offering, negotiating several licensing agreements, and financing the company through late-stage clinical development. Mr. Eisenstadt received an M.B.A. from James Madison University and a B.A. in Economics from the University of North Carolina at Chapel Hill.

M. Scot Roberts, Ph.D. currently serves as Chief Scientific Officer of the Company. Dr. Roberts joined Altimmune in December 2012 and has over 20 years of biologics development experience, most recently at ImQuest BioSciences, Inc., where as Chief Scientific Officer from November 2010 until November 2012, he was responsible for managing scientific operations. Dr. Roberts held key positions at Wellstat Biologics Corporation from August 1996 until October 2010, including Director of Research and Development where he was responsible for development of a portfolio of biologic candidates in oncology including a clinical stage oncolytic virus asset. He is an inventor on twelve patent and patent application families, and author of numerous publications in peer-reviewed journals. Dr. Roberts has been an invited speaker at international conferences where he chaired a variety of scientific sessions. Dr. Roberts received an M.S.in Chemistry from Illinois State University and a Ph.D. from the Johns Hopkins School of Medicine, Department of Pharmacology and Molecular Sciences.

M. Scott Harris, M.D. currently serves as Chief Medical Officer of the Company. Dr. Harris joined Altimmune in July 2019, a seasoned medical professional with extensive experience in hepatology and gastroenterology and broad expertise in managing clinical trials from early-stage development through successful Phase 3 trials. He has led multidisciplinary forums on drug development and clinical trial design at national and international scientific meetings, and fostered collaborations between professional medical societies and the FDA. Previously, he was co-founder and chief medical officer of Lyric Pharmaceuticals, helping raise a $21 million Series A round in 2014. He has also served as chief medical officer of Avaxia Biologics, interim chief medical officer of Tranzyme Pharma, and chief medical officer of Ocera Therapeutics. Dr. Harris was also chief medical officer and vice president of Clinical Affairs at Napo Pharmaceuticals where he authored the pivotal clinical study that led to the approval of crofelemer (Mytesi®), the first Phase 2/3 adaptive trial design resulting in a drug approval. Earlier in his career he held senior roles in global clinical development and medical affairs at Otsuka Pharmaceuticals and Abbott. He sits on the faculty of Georgetown University School of Medicine as an Adjunct Professor, where he directs a course on drug development under a grant from the NIH. Dr. Harris has been a consultant on third-world drug development for the Bill and Melinda Gates Foundation and a speaker at national and international forums on drug development. Dr. Harris has an M.D. from Harvard Medical School and an MS in Administrative Medicine and Population Health from the University of Wisconsin Medical School. His post-graduate training includes residencies at John Hopkins Hospital and the University of Pennsylvania, and a Gastroenterology and Hepatology Fellowship at the Yale University School of Medicine.

Raymond M Jordt, M.B.A. currently serves as Chief Business Officer of the Company, which he joined in January 2023. Mr. Jordt is an accomplished executive with over twenty-five years of experience in the pharmaceutical industry. Prior to joining Altimmune, he spent nearly two decades in various corporate and business development roles, including most recently as Head of Transactions at Eli Lilly and Company from August 2020 through December 2022, and prior to that as Senior Director, Corporate and Business Development from 2016 through July 2020. During his tenure at Lilly, he led acquisitions, in/out-licensing, divestitures, collaborations, options and equity investments with biotech and pharmaceutical companies at all stages of development. He has worked across multiple therapeutic areas, including obesity, diabetes, CNS, immunology, dermatology and pain. His efforts led to four approved products and reshaped the portfolios of key business units. Mr. Jordt received an M.B.A. from Indiana University, an M.S. in Biomedical Engineering at the University of Memphis and a B.S. in Biomedical Engineering from Arizona State University.

How nominees to our Board are selected

Candidates for election to our Board of Directors are nominated by our Nominating and Corporate Governance Committee and ratified by our full Board of Directors for nomination to the stockholders. The Nominating and Corporate Governance Committee operates under a charter, which is available on our corporate website at *www.altimmune.com*.

The Nominating and Corporate Governance Committee will give due consideration to candidates recommended by stockholders. Stockholders may recommend candidates for the Nominating and Corporate Governance Committee's consideration by submitting such recommendations directly to the Nominating and Corporate Governance Committee as described below under *Communicating with our Board members*. However, just because a recommended individual meets

the minimum qualification standards does not imply that the Nominating and Corporate Governance Committee will necessarily nominate the person so recommended by a stockholder. The Nominating and Corporate Governance Committee may also engage outside search firms to assist in identifying or evaluating potential nominees.

There are no family relationships among any of our directors and executive officers.

Board leadership structure

Currently, Dr. Sayare serves as the Chairman of the Board and Dr. Garg is the Company's President and Chief Executive Officer. The Board believes that having different individuals serving in the separate roles of Chairman of the Board and Chief Executive Officer is in the best interest of stockholders in the Company's current circumstances because it reflects the Chief Executive Officer's responsibility over management of the Company's operations and the Chairman's oversight of board functions, strategic development and financial stability.

Board committees

The Audit Committee of our Board reviews, acts on and reports to our Board with respect to various auditing and accounting matters, including the recommendation of our independent registered public accounting firm, the scope of the annual audits, the fees to be paid to the independent registered public accounting firm, the performance of the independent registered public accounting firm and our accounting practices. The Audit Committee currently consists of Messrs. Hodges (Chair), Gill and Pisano and Dr. Schafer. The Board has determined that each member of the Audit Committee is an independent director in accordance with Nasdaq listing standards and that each of Messrs. Hodges and Gill is an Audit Committee financial expert, as defined by SEC guidelines and as required by the applicable NASDAQ listing standards.

The Compensation Committee of the Board recommends, reviews and oversees the salaries, benefits and equity incentive plans for our employees, consultants, directors (other than non-employee directors) and other individuals whom we compensate. The Compensation Committee also administers our compensation plans. The Compensation Committee currently consists of Drs. Drutz (Chair), Jorkasky and Schafer and Mr. Hodges. The Board has determined that each member of the Compensation Committee is an "independent director" in accordance with NASDAQ listing standards, a "non-employee director" under the applicable SEC rules and regulations and an "outside director" under the applicable tax rules. The Compensation Committee may form subcommittees and delegate authority to such subcommittees or individuals as it deems appropriate.

The Nominating and Corporate Governance Committee of the Board selects nominees for director positions to be recommended by our Board for election as directors and for any vacancies in such positions, develops and recommends for our Board the Corporate Governance Guidelines of the Company and oversees the annual review of the performance of the Board, each director and each committee. The Nominating and Corporate Governance Committee currently consists of Messrs. Pisano (Chair) and Gill and Drs. Drutz and Sohn. The Board has determined that each member of the Nominating and Corporate Governance Committee is an independent director in accordance with NASDAQ listing standards.

Meetings and attendance

During the fiscal year ended December 31, 2023, the Board held 10 meetings and the Board Committees held a total of 8 meetings. Each director attended 75% or more of the total number of meetings of the Board and the Board Committees of which he or she was a member during the period he or she served as a director in fiscal year 2023. The Company has no specific policy regarding director attendance at our annual meeting of stockholders. Generally, however, a Board meeting is held on the same date as the annual meeting, with directors attending the annual meeting. Our 2023 annual meeting of stockholders was attended by all of the directors recommended for election.

Board involvement in risk oversight

The Company's management is responsible for defining the various risks facing the Company, formulating risk management policies and procedures, and managing the Company's risk exposures on a day-to-day basis. The Board's responsibility is to monitor the Company's risk management processes by informing itself of the Company's material risks

and evaluating whether management has reasonable controls in place to address the material risks. The Board is not responsible, however, for defining or managing the Company's various risks.

The Board of Directors monitors management's responsibility for risk oversight through regular reports from management to the Audit Committee and the full Board. Furthermore, the Audit Committee reports on the matters discussed at the committee level to the full Board. The Audit Committee and the full Board focus on the material risks facing the Company, including strategic, operational (including cybersecurity), legal and regulatory risks, to assess whether management has reasonable controls in place to address these risks. In addition, the Compensation Committee is charged with reviewing and discussing with management whether the Company's compensation arrangements are consistent with effective controls and sound risk management. Finally, risk management is a factor that the Board and the Nominating and Corporate Governance Committee consider when determining who to nominate for election as a director of the Company and which directors serve on the Audit Committee. The Board believes this division of responsibilities provides an effective and efficient approach for addressing risk management.

Code of Business Conduct and Ethics and other governance documents

We have adopted a written Code of Business Conduct and Ethics that applies to our Board of Directors and all of our employees, including our principal executive officer, principal financial officer, principal accounting officer, or persons performing similar functions. A copy of our code of conduct can be found on our website, http://www.altimmune.com. We intend to satisfy the disclosure requirements under Item 5.05 of Form 8-K and under the applicable NASDAQ Global Market rules by posting such information on our website in accordance with such requirements.

You may also obtain a copy of these documents by writing to Altimmune, Inc., 910 Clopper Road, Suite 201S, Gaithersburg, Maryland 20878, Attention: Investor Relations.

Copies of the charters of our Board's Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee, as well as a copy of the Company's Corporate Governance Guidelines, can be accessed in the Investor Relations — Corporate Governance section of our website. The information on, or that can be accessed through our website is not part of this Annual Report and is not incorporated by reference herein.

Communicating with our Board members

Although our Board of Directors has not adopted a formal process for stockholder communications with the Board, we make every effort to ensure that the views of stockholders are heard by the Board or by individual directors, as applicable, and we believe that this has been an effective process to date. Stockholders may communicate with the Board by sending a letter to the Altimmune, Inc. Board of Directors, c/o Corporate Secretary, 901 Clopper Road, Suite 201S, Gaithersburg, Maryland 20878. The Corporate Secretary will receive the correspondence and forward it to the Chairman of the Board, or to any individual director or directors to whom the communication is directed, as appropriate. Notwithstanding the above, the Corporate Secretary has the authority to discard or disregard any communication that is unduly hostile, threatening, illegal or otherwise inappropriate or to take any other appropriate actions with respect to such communications.

In addition, any person, whether or not an employee, who has a concern regarding the conduct of the Company or our employees, including with respect to our accounting, internal accounting controls or auditing issues, may, in a confidential or anonymous manner, communicate that concern in writing by addressing a letter to the Chairman of the Audit Committee, c/o Corporate Secretary, at the address of our corporate headquarters address, which is 910 Clopper Road, Suite 201S, Gaithersburg, Maryland 20878.

Section 16(a) beneficial ownership reporting compliance and Delinquent Section 16(a) Reports

The members of our Board of Directors, our executive officers and persons who hold more than 10% of our outstanding Common Stock are subject to the reporting requirements of Section 16(a) of the Securities Exchange Act of 1934, as amended, which requires them to file reports with respect to their ownership of our Common Stock and their transactions in such Common Stock. Based solely upon a review of the copies of Section 16(a) reports that the Company has received from such persons for transactions in our Common Stock and their Common Stock holdings for the 2023

fiscal year, the Company believes that all reporting requirements under Section 16(a) for such fiscal year were met in a timely manner by its directors, executive officers and beneficial owners of more than 10% of its Common Stock, except that Mr. Gill was not timely in filing one Form 4 during the fiscal year ended December 31, 2023.

Item 11. Executive Compensation

Our named executive officers ("Named Executive Officers") for the year ended December 31, 2023 are:

- Vipin K. Garg, Ph.D., our Chief Executive Officer;
- M. Scott Harris, M.D., our Chief Medical Officer; and
- Raymond M. Jordt, our Chief Business Officer

Elements of Compensation

The compensation arrangement for each Named Executive Officer is intended to encourage performance and to align the Named Executive Officers' interests with those of our stockholders. In setting compensation for our Named Executive Officers, the Compensation Committee and the Board take into account the relative amount of compensation that is delivered on a current and long-term basis and in the form of cash and equity. The combination of performance measures for annual bonuses and the equity compensation programs for executive officers, as well as the multi-year vesting schedules for equity awards encourage employees to maintain both a short-term and a long-term view with respect to Company performance.

The Company's executive compensation program consists of the following elements:

- base salary;
- annual cash bonuses;
- equity awards;
- health and HSA match; and
- 401(k) plan

Base Salary

The Named Executive Officers receive a base salary to compensate them for services rendered to our Company. The base salary payable to each Named Executive Officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, roles and responsibilities.

Annual Performance-Based Bonus

The Named Executive Officers are entitled to receive annual performance-based cash bonuses, the amount of which is based on satisfaction of corporate objectives that are established by the Board of Directors and/or the Compensation Committee. The annual bonuses are intended to encourage the Named Executive Officers to promote the growth of the Company's business.

At the beginning of the year, the Compensation Committee, after reviewing management's self-assessment, evaluates specific achievements and our overall success in the prior year. The Compensation Committee considers our CEO's recommendations, and independently reviews and recommends the total percentage achievement level for each of the executive officers to the Board of Directors for approval.

For the year ended December 31, 2023, upon recommendation of the Compensation Committee, our Board of Directors set broad-based corporate objectives that established the criteria for the funding of our annual bonus plan and focused on the following key objectives:

- Advance candidate pipeline through generation of human clinical data and CMC development (60% weighting);
- Complete strategic assessment of Company assets and define strategic goals (15% weighting);
- Strategic partnerships to maximize program value and further advance pipeline (15% weighting); and
- Manage operations to maximize resources and minimize risk (10% weighting).

For each of these corporate objectives, the Compensation Committee also established criteria for assessing performance in terms of what achievements would be below expectations, meet expectations or exceed expectations, with weighting assigned to each of these objectives as described above. Below expectations achievement of an objective results in payment between 0-80% of the weighting, meets expectations achievement of an objective results in payment between 80-120% of the weighting and exceeds expectations results in payment between 120-150% of the weighting. In January 2024, our Board of Directors, upon the recommendation of the Compensation Committee, completed its assessment of management's achievement of these corporate objectives for 2023, and concluded that these core corporate objectives were achieved by the management team and determined achievement at approximately 100% of the target annual performance-based cash bonuses for our Named Executive Officers. This level was determined based upon, among other things, successful financing of our clinical programs, positive 48-week weight loss data from the obesity trial and initiating a second Phase 2 metabolic development program for metabolic dysfunction-associated steatohepatitis ("MASH").

Equity Awards

The Named Executive Officers are eligible to receive equity awards under the Altimmune, Inc. 2017 Omnibus Incentive Plan (as amended, the "*2017 Plan*"). Awards under the 2017 Plan are intended to align the interests of the Named Executive Officers with those of our stockholders and to create a link between executive pay and the long-term performance of our Common Stock. During the year ended December 31, 2023, we granted our Named Executive Officers stock options and restricted stock units ("RSUs"), as described in more detail in the Outstanding Equity Awards at Fiscal Year-End table below.

Employee Benefits

The Named Executive Officers, like our other employees, participate in health and welfare benefit plans, subject to satisfying eligibility requirements.

401(k) Plan

The Company maintains a tax-qualified retirement plan (the "*401(k) Plan*") that provides eligible employees (including the Named Executive Officers) with an opportunity to save for retirement on a tax-advantaged basis. Eligible employees are able to participate in the 401(k) Plan as of the first day of the month following the date they meet the 401(k) Plan's eligibility requirements, and participants are able to defer up to 100% of their eligible compensation subject to applicable annual limits under the Internal Revenue Code of 1986, as amended (the "Code"). All participants' interests in their deferrals are 100% vested when contributed. The 401(k) Plan permits Altimmune to make matching contributions and profit sharing contributions to eligible participants. Altimmune matches contributions 100% on the first 4% of contributions made by participants.

We believe the benefits described above are necessary and appropriate to provide a competitive compensation package to our Named Executive Officers.

Summary Compensation Table

The following table sets forth the total compensation that was paid to or earned by the Named Executive Officers for the 2023 and 2022 fiscal years.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)(1)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)(2)	Total ($)
Vipin K. Garg, Ph.D.	2023	620,154	—	1,379,448	3,116,499	334,950	31,038	5,482,089
Chief Executive Officer	2022	580,000	—	570,774	1,393,493	319,000	17,157	2,880,424
M. Scott Harris, M.D.	2023	487,569	—	477,848	1,080,331	191,520	2,720	2,239,988
Chief Medical Officer	2022	456,000	—	234,183	572,395	182,400	4,640	1,449,618
Raymond M. Jordt	2023	405,000	—	586,125	1,776,009	162,000	11,850	2,940,984
Chief Business Officer	2022	—	—	—	—	—	—	—

(1) Amounts in this column reflect the aggregate grant date fair value of stock awards and/or stock options granted during the covered year computed in accordance with the provisions of FASB ASC Topic 718. The assumptions used to calculate the amounts for fiscal years 2023 and 2022 are discussed in Item 8, Financial Statements and Supplementary Data.

(2) All other compensation consisted of the following:

Name and Principal Position	Year	401(k) Match ($)	Benefits ($)	HSA Match ($)	Commuting Expense ($)	Total Other Compensation ($)
Vipin K. Garg, Ph.D. Chief Executive Officer	2023	1,934	8,967	2,400	17,737	31,038
M. Scott Harris, M.D. Chief Medical Officer	2023	1,520	—	1,200	—	2,720
Raymond M. Jordt Chief Business Officer	2023	9,450	—	2,400	—	11,850

Narrative to Summary Compensation Table

Agreements with Named Executive Officers

We have entered into employment agreements with each of Dr. Garg, Dr. Harris and Mr. Jordt. The material terms of such agreements are summarized below.

Employment Agreement with Vipin K. Garg, Ph.D.

On November 16, 2018, the Company entered into an employment agreement with Dr. Garg in connection with his employment as the President and Chief Executive Officer of the Company (the "*Employment Agreement*"). Pursuant to the Employment Agreement, Dr. Garg commenced employment with the Company on November 30, 2018.

Under the Employment Agreement, Dr. Garg initially received a base salary of $500,000 and is eligible to receive an annual discretionary incentive bonus of up to 55% of his base salary based on achievement of performance goals established by the Compensation Committee.

Dr. Garg is eligible to participate in the Company's employee benefit plans made available to its similarly situated senior executives. In addition, the Company pays the premium costs for a term life insurance policy for Dr. Garg with a benefit equal to Dr. Garg's base salary and for short- and long-term disability plans that provide for an annual benefit of at least 60% of Dr. Garg's base salary for as long as the disability continues. In addition, during the term of Dr. Garg's employment, so long as Dr. Garg's primary residence is located within 50 miles of his current residence in North Carolina, the Company will reimburse Dr. Garg an amount not to exceed $36,000 during any 12-month period to cover Dr. Garg's commuting expenses, which amount will be grossed up for taxes. During the term of Dr. Garg's employment, and subject to applicable securities laws or listing standards, the Company will use its best efforts to cause Dr. Garg to be nominated

for election as a member of the Company's board of directors at each annual meeting of stockholders at which Dr. Garg is up for election.

In the event of an employment termination, the Company will pay Dr. Garg his earned but unpaid base salary through the date of termination, accrued but unused vacation pay, unreimbursed business expenses and such employee benefits as may be due to Dr. Garg under the terms of the applicable benefit plans (the "*Accrued Benefits*"). In addition, if the Company terminates Dr. Garg's employment for "cause" (as defined below), Dr. Garg will be entitled to payment of any unpaid prior year's annual bonus.

If the Company terminates Dr. Garg's employment without cause or Dr. Garg resigns his employment for "good reason" (as defined below), in addition to the Accrued Benefits, Dr. Garg will be entitled to receive 12 months of base salary continuation payments, 12 months of continued coverage under the health insurance plans in which Dr. Garg participates at the time of the termination and payment of any unpaid prior year's annual bonus. If such employment termination or resignation occurs within one year following a "change in control" (as defined in the Employment Agreement), Dr. Garg is entitled to receive an amount equal to the sum of 18 months of his base salary plus his target annual discretionary incentive bonus for the year of termination, 18 months of continued coverage under the health insurance plans in which Dr. Garg participates at the time of the termination, payment of any unpaid prior year's annual bonus and, if such termination occurs within the one-year period following a change in control, all of Dr. Garg's outstanding unvested equity awards will become vested. If any payments, whether under Dr. Garg's employment agreement or otherwise, would be subject to the golden parachute excise tax under Section 4999 of the Internal Revenue Code (the "*Code*"), such payments will be reduced to the extent necessary to avoid the excise tax if doing so would result in a greater net after tax payment to Dr. Garg. Dr. Garg is required to execute and not revoke a release of claims in order to be eligible to receive severance payments or benefits, other than the Accrued Benefits.

Under the Employment Agreement, "cause" generally means Dr. Garg's (i) material breach of his fiduciary duties, (ii) material breach of his Employment Agreement, (iii) willful failure or refusal to follow written policies, (iv) conviction of, or plea of guilty or nolo contendere to, a felony, or (v) continuing and willful refusal to act as directed by the Board. Under the Employment Agreement, "good reason" generally means (i) a reduction in Dr. Garg's base salary or target annual bonus opportunity, (ii) a material diminution in Dr. Garg's authorities, duties or responsibilities, or (iii) a relocation of Dr. Garg's principal place of employment more than 50 miles from Gaithersburg, Maryland.

Dr. Garg is subject to restrictive covenants during the term of his employment and for a period of one year following the termination of his employment. In particular, Dr. Garg will be prohibited from soliciting the Company's customers, clients and employees and from engaging in sales, marketing or related activities on behalf of himself or another entity that directly competes with the Company and does business in the same geographical areas in which the Company does business.

Employment Agreement with M. Scott Harris, M.D.

On September 9, 2019, the Company entered into an employment agreement with M. Scott Harris, M.D., the Chief Medical Officer. The agreement provided that Dr. Harris would be employed so long as mutually agreeable to Dr. Harris and the Company.

The agreement provided Dr. Harris with an initial base salary of $370,000. In addition, Dr. Harris is eligible to receive an annual discretionary incentive bonus of up to 40% of base salary based as determined by the Compensation Committee. In addition, Dr. Harris would be granted incentive stock options to purchase 107,000 shares of the Company's common stock, and Dr. Harris is eligible to participate in the Company's employee benefit plans made available to its similarly situated senior executives.

If, prior to a "change in control" (as defined in the employment agreement), the Company terminates the employment of Dr. Harris without "cause" or if he resigns for "good reason" (as defined below), in addition to accrued benefits (to which he is entitled on any termination of employment), Dr. Harris will be entitled to receive severance equal to six months of base salary continuation payments, six months of continued coverage under the health insurance plans in which the executive participated at the time of the termination and payment of any unpaid prior year's annual bonus. If such employment termination or resignation occurs within the one-year period following a change in control, he would be

entitled to receive a severance amount equal to the sum of 12 months of his base salary plus his target annual discretionary incentive bonus for the year of termination, six months of continued coverage under the health insurance plans in which he participates at the time of termination, payment of any unpaid prior year's annual bonus and, all of his outstanding unvested equity awards will become vested. The agreement also provides that if any payments, whether under the agreement or otherwise, payable to him would be subject to the golden parachute excise tax under Section 4999 of the Code, such payments will be reduced to the extent necessary to avoid the excise tax if doing so would result in a greater net after tax payment to him. Dr. Harris is required to execute and not revoke a release of claims in Altimmune's favor in order to be eligible to receive the severance payments and benefits.

Under the agreement with Dr. Harris, "cause" generally means his (i) material breach of his fiduciary duties, (ii) material breach of the agreement, (iii) willful failure or refusal to follow Altimmune's written policies, (iv) conviction of, or plea of guilty or nolo contendere to, a felony or (v) continuing and willful failure to act as directed by Altimmune's board of directors or its chief executive officer. Under the agreement, "good reason" generally means (i) a reduction in the Dr. Harris' base salary or target annual bonus opportunity, (ii) a material diminution in authority, duties or responsibilities or (iii) a relocation of his principal place of employment more than 50 miles from Gaithersburg, Maryland.

Under the agreement, Dr. Harris is subject to restrictive covenants during the term of his employment and for a period of six months following termination of employment. In particular, he is prohibited from soliciting the Company's customers, clients and employees and from engaging in sales, marketing or related activities on the executive's behalf or another entity that directly competes with the Company.

Employment Agreement with Raymond M. Jordt

On January 1, 2023, the Company entered into an employment agreement with Raymond M. Jordt, the Chief Business Officer. The agreement provided that Mr. Jordt would be employed so long as mutually agreeable to Mr. Jordt and the Company.

The agreement provided Mr. Jordt with an initial base salary of $405,000. In addition, Mr. Jordt was paid a signing bonus of $85,000, and is eligible to receive an annual discretionary incentive bonus of up to 40% of base salary based as determined by the Compensation Committee. In addition, Mr. Jordt would be granted incentive stock options to purchase 125,000 shares of the Company's common stock and 37,500 RSUs. Mr. Jordt is eligible to participate in the Company's employee benefit plans made available to its similarly situated senior executives.

If, prior to a "change in control" (as defined in the employment agreement), the Company terminates the employment of Mr. Jordt without "cause" or if he resigns for "good reason" (as defined below), in addition to accrued benefits (to which he is entitled on any termination of employment), Mr. Jordt will be entitled to receive severance equal to 12 months of base salary continuation payments, 12 months of continued coverage under the health insurance plans in which the executive participated at the time of the termination and payment of any unpaid prior year's annual bonus. If such employment termination or resignation occurs within the one-year period following a change in control, he would be entitled to receive a severance amount equal to the sum of 12 months of his base salary plus his target annual discretionary incentive bonus for the year of termination, 12 months of continued coverage under the health insurance plans in which he participates at the time of termination, payment of any unpaid prior year's annual bonus and, all of his outstanding unvested equity awards will become vested. The agreement also provides that if any payments, whether under the agreement or otherwise, payable to him would be subject to the golden parachute excise tax under Section 4999 of the Code, such payments will be reduced to the extent necessary to avoid the excise tax if doing so would result in a greater net after tax payment to him. Mr. Jordt is required to execute and not revoke a release of claims in Altimmune's favor in order to be eligible to receive the severance payments and benefits.

Under the agreement with Mr. Jordt, "cause" generally means his (i) material breach of his fiduciary duties, (ii) material breach of the agreement, (iii) willful failure or refusal to follow Altimmune's written policies, (iv) conviction of, or plea of guilty or nolo contendere to, a felony or (v) continuing and willful failure to act as directed by Altimmune's board of directors or its chief executive officer. Under the agreement, "good reason" generally means (i) a reduction in Mr. Jordt's base salary or target annual bonus opportunity, (ii) a material diminution in authority, duties or responsibilities or (iii) a relocation of his principal place of employment more than 50 miles from Fishers, Indiana.

Under the agreement, Mr. Jordt is subject to restrictive covenants during the term of his employment and for a period of six months following termination of employment. In particular, he is prohibited from soliciting the Company's customers, clients and employees and from engaging in sales, marketing or related activities on the executive's behalf or another entity that directly competes with the Company.

Outstanding Equity Awards at 2023 Fiscal Year-End

The following table sets forth certain information with respect to outstanding equity awards of our Named Executive Officers as of December 31, 2023.

		Option Awards					Stock Awards	
Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)(12)
Vipin K. Garg, Ph.D.	11/30/2018	322,907	— (1)	—	3.59	11/30/2028	—	—
	1/2/2020	146,385	3,115 (2)	—	1.92	1/2/2030	—	—
	2/1/2021	171,063	70,437 (3)	—	16.71	2/1/2031	—	—
	2/1/2021	—	—	—	—	—	33,090 (4)	372,263
	2/2/2022	102,209	120,791 (5)	—	7.53	2/2/2032	—	—
	2/2/2022	—	—	—	—	—	56,850 (6)	639,563
	1/30/2023	—	302,900 (7)	—	12.88	1/30/2033	—	—
	1/30/2023	—	—	—	—	—	107,100 (8)	1,204,875
M. Scott Harris, M.D.	9/9/2019	107,000	— (9)	—	2.13	9/9/2029	—	—
	1/2/2020	30,121	1,279 (2)	—	1.92	1/2/2030	—	—
	2/1/2021	63,750	26,250 (3)	—	16.71	2/1/2031	—	—
	2/1/2021	—	—	—	—	—	12,332 (4)	138,735
	2/2/2022	41,984	49,616 (5)	—	7.53	2/2/2032	—	—
	2/2/2022	—	—	—	—	—	23,325 (6)	262,406
	1/30/2023	—	105,000 (7)		12.88	1/30/2033	—	—
	1/30/2023	—	—	—	—	—	37,100 (8)	417,375
Raymond M. Jordt	1/3/2023	—	125,000 (10)	—	15.63	1/3/2033	—	—
	1/3/2023	—	—	—	—	—	37,500 (11)	421,875

(1) This option was granted on November 30, 2018 and 25% became vested and exercisable on the first anniversary of the grant date. The aggregate remaining unvested portion will vest and become exercisable in equal monthly installments over the 36-month period commencing on January 1, 2020.

(2) On January 2, 2020, Dr. Garg and Dr. Harris were granted an option to purchase 149,500 and 61,400, respectively, shares of Common Stock of the Company at an exercise price of $1.92 per share. 25% of the option vests and becomes exercisable on the first anniversary of the grant date and the aggregate remaining unvested portion will vest and become exercisable in equal monthly installments over the 36-month period commencing on February 2, 2021.

(3) On February 1, 2021, Dr. Garg and Dr. Harris were granted an option to purchase 241,500 and 90,000, respectively, shares of Common Stock of the Company at an exercise price of $16.71 per share. 25% of the option vests and becomes exercisable on the first anniversary of the grant date and the aggregate remaining unvested portion will vest and become exercisable in equal monthly installments over the 36-month period commencing on March 1, 2022.

(4) On February 1, 2021, Dr. Garg and Dr. Harris were granted 66,181 and 24,664 RSUs, respectively. The RSUs vest equally over a four-year period commencing on February 1, 2022.

(5) On February 2, 2022, Dr. Garg and Dr. Harris were granted an option to purchase 223,000 and 91,600, respectively, shares of Common Stock of the Company at an exercise price of $7.53 per share. 25% of the option vests and becomes exercisable on the first anniversary of the grant date and the aggregate remaining unvested portion will vest and become exercisable in equal monthly installments over the 36-month period commencing on February 2, 2023.

(6) On February 2, 2022, Dr. Garg and Dr. Harris were granted 75,800 and 31,100 RSUs, respectively. The RSUs vest equally over a four-year period commencing on February 2, 2023.

(7) On January 30, 2023, Dr. Garg and Dr. Harris were granted an option to purchase 302,900 and 105,000, respectively, shares of Common Stock of the Company at an exercise price of $12.88 per share. 25% of the option vests and becomes exercisable on the first anniversary of the grant date and the aggregate remaining unvested portion will vest and become exercisable in equal monthly installments over the 36-month period commencing on January 30, 2024.

(8) On January 30, 2023, Dr. Garg and Dr. Harris were granted 107,100 and 37,100 RSUs, respectively. The RSUs vest equally over a four-year period commencing on January 30, 2024.

(9) This option was granted on September 9, 2019, and 25% became vested and exercisable on the first anniversary of the grant date. The aggregate remaining unvested portion will vest and become exercisable in equal monthly installments over the 36-month period commencing on September 9, 2020.

(10) On January 3, 2023, Mr. Jordt was granted an option to purchase 125,000 shares of Common Stock of the Company at an exercise price of $15.63 per share. 25% of the option vests and becomes exercisable on the first anniversary of the grant date and the aggregate remaining unvested portion will vest and become exercisable in equal monthly installments over the 36-month period commencing on January 1, 2024.

(11) On January 3, 2023, Mr. Jordt was granted 37,500 RSUs. The RSUs vest equally over a four-year period commencing on January 1, 2024.

(12) Represents the fair market value of the shares underlying unvested RSUs as of December 31, 2023, based upon the closing price of our Common Stock on December 29, 2023 (the last trading day of fiscal year 2023) of $11.25.

Director Compensation

In September 2022, the Company's Board approved an update to the then-existing non-employee director compensation policy effective as of January 1, 2023. Accordingly, the Board increased the cash compensation for Audit Committee Members from $7,500 in 2022 to $9,000 in 2023 and for the Compensation Committee Chairperson from $12,000 in 2022 to $15,000 in 2023. Under the program, non-employee directors that qualify under the program receive the cash compensation set forth below, and an additional annual payment of an option to purchase a number of shares of the Company's Common Stock equal to 62 ½ percentile of the Company's peer group based on percentage ownership (the "Annual Director Option Grant Amount"), which will be granted immediately following the date of each annual meeting of stockholders. Any such option will vest in substantially equal monthly installments for 11 months after the date of grant, with the remaining one-twelfth vesting on the earlier of the one-year anniversary of the date of the grant or the date of the next annual meeting of the Company's stockholders. In addition, new non-employee directors that qualify under the program receive an initial award in the form of an option to purchase shares of the Company's Common Stock equal to two times the Annual Director Option Grant Amount upon their election to the board. Any such option shall vest in equal monthly installments during the 36 months following the date upon which the director is first elected to the Board. The vesting of any option grants to our non-employee directors under our non-employee director compensation policy is subject to such non-employee director's continued service as a director and will accelerate in full upon a change in control of our company.

We also have a policy of reimbursing our directors for their reasonable out-of-pocket expenses incurred in attending board of directors and committee meetings.

Under our non-employee director compensation program, each non-employee director that qualifies under the program is eligible to receive compensation for his or her service on our board of directors or committees thereof consisting of annual cash retainers paid quarterly in arrears, as follows:

Position	Retainer
Board Member	$ 40,000
Chairperson of the Board	$ 30,000
Audit Committee Chairperson	$ 20,000
Audit Committee Member	$ 9,000
Compensation Committee Chairperson	$ 15,000
Compensation Committee Member	$ 6,000
Nominating and Corporate Governance Committee Chairperson	$ 10,000
Nominating and Corporate Governance Committee Member	$ 5,000

The table below sets forth the compensation received by each of our non-employee directors for the fiscal year ended December 31, 2023.

Name	Fees earned or paid in cash ($)	Stock Awards ($)	Option Awards ($)[1]	Total ($)
Mitchel Sayare, Ph.D.[2]	70,000	—	49,680	119,680
David J. Drutz, M.D.[3]	60,000	—	49,680	109,680
John M Gill[4]	54,000	—	49,680	103,680
Philip L. Hodges[5]	66,000	—	49,680	115,680
Wayne Pisano[6]	59,000	—	49,680	108,680
Diane K. Jorkasky, M.D.[7]	46,000	—	49,680	95,680
Klaus O. Schafer, M.D., MPH[8]	55,000	—	49,680	104,680
Catherine Sohn, Pharm D[9]	32,250	—	241,215	273,465

(1) Amounts reflect the aggregate grant date fair value of stock options granted during the covered year computed in accordance with the provisions of FASB ASC Topic 718. The assumptions used to calculate the amounts for fiscal years 2022 are discussed in Item 13, Financial Statements and Supplementary Data.

(2) As of December 31, 2023, Dr. Sayare held unexercised options to purchase an aggregate of 131,034 shares of the Common Stock of the Company.

(3) As of December 31, 2023, Dr. Drutz held unexercised options to purchase an aggregate of 119,867 shares of the Common Stock of the Company.

(4) As of December 31, 2023, Mr. Gill held unexercised options to purchase an aggregate of 119,867 shares of the Common Stock of the Company.

(5) As of December 31, 2023, Mr. Hodges held unexercised options to purchase an aggregate of 119,867 shares of the Common Stock of the Company.

(6) As of December 31, 2023, Mr. Pisano held unexercised options to purchase an aggregate of 99,200 shares of the Common Stock of the Company.

(7) As of December 31, 2023, Dr. Jorkasky held unexercised options to purchase an aggregate of 105,590 shares of the Common Stock of the Company.

(8) As of December 31, 2023, Dr. Schafer held unexercised options to purchase an aggregate of 119,867 shares of the Common Stock of the Company.

(9) As of December 31, 2023, Dr. Sohn held unexercised options to purchase an aggregate of 73,100 shares of the Common Stock of the Company.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table sets forth certain information regarding the beneficial ownership of the Company's Common Stock as of March 22, 2024 by (i) each person or group of persons known by us to beneficially own more than five percent of our Common Stock, (ii) each of our named executive officers, (iii) each of our directors and nominees for director and (iv) all of our directors and executive officers as a group.

The following table gives effect to the shares of Common Stock issuable within 60 days of March 22, 2024 upon the exercise of all options and other rights beneficially owned by the indicated stockholders on that date. Beneficial ownership is determined in accordance with Rule 13d-3 promulgated under Section 13 of the Securities Exchange Act of 1934, as amended, and includes voting and investment power with respect to shares. Percentage of beneficial ownership is based on 70,895,286 shares of Common Stock outstanding at the close of business on March 22, 2024. Except as otherwise noted below, each person or entity named in the following table has sole voting and investment power with respect to all shares of our Common Stock that he, she or it beneficially owns.

Unless otherwise indicated, the address of each beneficial owner listed below is c/o Altimmune, Inc., 910 Clopper Road, Suite 201S, Gaithersburg, Maryland 20878.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% or Greater Stockholders:		
Ameriprise Financial, Inc.[(1)]	4,183,682	5.9 %
BlackRock, Inc.[(2)]	4,044,707	5.7
The Vanguard Group[(3)]	3,571,972	5.0
Directors and Named Executive Officers:		
Vipin K. Garg[(4)]	1,180,748	1.6 %
M. Scott Harris[(5)]	349,496	*
Raymond M. Jordt[(6)]	55,409	*
Mitchel Sayare, Ph.D.[(7)]	146,522	*
David J. Drutz, M.D.[(8)]	138,777	*
John M. Gill[(9)]	111,763	*
Philip L. Hodges[(10)]	135,571	*
Klaus O. Schafer, M.D., MPH[(11)]	118,171	*
Wayne Pisano[(12)]	96,823	*
Diane K. Jorkasky, M.D.[(13)]	94,715	*
Catherine Sohn, Pharm D[(14)]	32,197	*
All Executive Officers and Directors as a Group (13 persons)[(15)]	2,888,480	4.0 %

* Represents beneficial ownership of less than one percent of Altimmune's outstanding Common Stock.

(1) This information is based solely on information reported on a Schedule 13G filed with the SEC on February 14, 2024 on behalf of Ameriprise Financial, Inc., TAM UK International Holdings Limited, Threadneedle Holdings Limited, TAM UK Holdings Limited, Threadneedle Asset Management Holdings Limited, TC Financing Ltd, Threadneedle Asset Management Limited and Threadneedle Investment Services Limited, collectively ("Ameriprise Entities"). Ameriprise Financial, Inc., as the parent company of the other Ameriprise Entities, may be deemed to beneficially own the shares reported herein by other Ameriprise Entities. Each of the Ameriprise Entities disclaims beneficial ownership of any shares reported on this Schedule 13G filing. According to the report, Ameriprise Financial, Inc. has shared voting power with respect to 4,183,439 shares of Common Stock of the Company and shared dispositive power with respect to 4,183,682 shares of the Common Stock of the Company. The principal business address of Ameriprise Financial, Inc is 145 Ameriprise Financial Center. Minneapolis, MN 55474.

(2) This information is based solely on information reported on a Schedule 13G filed with the SEC on January 26, 2024 on behalf of BlackRock, Inc. According to the report, BlackRock has sole voting power with respect to 3,976,066 shares of the Common Stock of the Company and sole dispositive power with respect to 4,044,707 shares of the

Common Stock of the Company. The principal business address of BlackRock is 50 Hudson Yards, New York, NY 10001.

(3) This information is based solely on information reported on a Schedule 13G/A filed with the SEC on February 13, 2024 on behalf of The Vanguard Group - 23-1945930. According to the report, The Vanguard Group - 23-1945930 has shared voting power with respect to 24,114 shares of Common Stock of the Company, sole dispositive power with respect to 3,529,736 shares of Common Stock of the Company, and shared dispositive power with respect to 42,236 shares of Common Stock of the Company. The principal business address of The Vanguard Group - 23-1945930 is 100 Vanguard Blvd. Malvern, PA 19355.

(4) Consists of 292,028 shares of Common Stock, and 888,720 shares of Common Stock which can be acquired upon exercise of outstanding options or vesting of restricted stock within 60 days of March 22, 2024.

(5) Consists of 53,633 shares of Common Stock and 295,863 shares of Common Stock which can be acquired upon exercise of outstanding options or vesting of restricted stock within 60 days of March 22, 2024.

(6) Consists of 13,743 shares of Common Stock and 41,666 shares of Common Stock that can be acquired upon the exercise of outstanding options or vesting of restricted stock within 60 days of March 22, 2024.

(7) Consists of 26,363 shares of Common Stock and 120,159 shares of Common Stock that can be acquired upon the exercise of outstanding options within 60 days of March 22, 2024

(8) Consists of 29,785 shares of Common Stock held by Pacific Biopharma Associates, LLC, of which Mr. Drutz is the President and 108,992 shares of Common Stock that can be acquired upon the exercise of outstanding options within 60 days of March 22, 2024.

(9) Consists of 2,771 shares of Common Stock and 108,992 shares of Common Stock that can be acquired upon the exercise of outstanding options within 60 days of March 22, 2024.

(10) Consists of 8,731 shares of Common Stock, 17,848 shares of Common Stock held by Paradigm Venture Partners, L.P., of which Mr. Hodges is deemed to be the beneficial owner of these securities and 108,992 shares of Common Stock that can be acquired upon the exercise of outstanding options within 60 days of March 22, 2024.

(11) Consists of 9,179 shares of Common Stock and 108,992 shares of Common Stock that can be acquired upon the exercise of outstanding options within 60 days of March 22, 2024.

(12) Consists of 8,498 shares of Common Stock and 88,325 shares of Common Stock that can be acquired upon the exercise of outstanding options within 60 days of March 22, 2024.

(13) Consists of 94,715 shares of Common Stock that can be acquired upon the exercise of outstanding options within 60 days of March 22, 2024.

(14) Consists of 32,197 shares of Common Stock that can be acquired upon the exercise of outstanding options within 60 days of March 22, 2024.

(15) Includes 550,266 shares of Common Stock held by the Company’s current directors and executive officers and 2,338,214 shares of Common Stock that can be acquired by the Company’s current directors and executive officers upon the exercise of outstanding options or vesting of restricted stock within 60 days of March 22, 2024.

Equity Compensation Plan Information

The following table provides information regarding the number of securities to be issued under our equity plans, the weighted-average exercise price of options issued under our equity plans and the number of securities remaining available for future issuance under our equity plans, in each case as of December 31, 2023:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights ($)	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders	5,304,942	8.54	1,605,642
Equity compensation plans not approved by security holders	342,818	5.06	1,309,275
Total	5,647,760	8.33	2,914,917

Item 13. Certain Relationships and Related Transactions, and Director Independence

Director independence

The Board of Directors has determined that each of our current directors, other than Dr. Garg, currently meet the independence requirements contained in the NASDAQ listing standards and applicable tax and securities rules and regulations. None of our non-employee directors has or had a relationship with the Company or its subsidiaries that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In compliance with the NASDAQ listing standards, we have a Board of Directors comprised of a majority of independent directors. The NASDAQ listing standards have both objective tests and a subjective test for determining who is an "independent director." The objective tests state, for example, that a director is not considered independent if he is an employee of the Company or is a partner in or controlling stockholder or executive officer of an entity to which the Company made, or from which the Company received, payments in the current or any of the past three fiscal years that exceed 5% of the recipient's consolidated gross revenue for that year. The subjective test states that an independent director must be a person who lacks a relationship that, in the opinion of the Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

None of the non-employee directors were disqualified from "independent" status under the objective tests. In assessing independence under the subjective test, the Board took into account the standards in the objective tests, and reviewed and discussed additional information provided by the directors with regard to each director's business and personal activities as they may relate to Altimmune's management. Based on all of the foregoing, as required by the NASDAQ listing standards, the Board made a substantive determination as to each of the non-employee directors that no relationship exists which, in the opinion of the Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

The Board has not established categorical standards or guidelines to make these subjective determinations, but considers all relevant facts and circumstances.

In addition to Board-level standards for director independence, except as described above under "Item 10 – Board committees," the directors who serve on the Audit Committee and the Compensation Committee each satisfy standards established by the SEC and the NASDAQ listing rules providing that to qualify as "independent" for purposes of membership on the Audit Committee or the Compensation Committee, members of such committees may not accept directly or indirectly any consulting, advisory or other compensatory fee from the Company other than their director compensation. Also, each of the directors who serve on the Compensation Committee has been determined to be a "non-employee director" for purposes of the applicable SEC rules and regulations and an "outside director" for purposes of the applicable tax rules.

In making its independence determinations, the Board considered transactions occurring since the beginning of 2018 between the Company and entities associated with the independent directors or members of their immediate family. In each case, the Board determined that, because of the nature of the director's relationship with the entity and/or the amount involved, the relationship did not impair the director's independence.

The Company does not have a director tenure requirement, as it believes its efforts to regularly refresh the Board with new directors, as well as natural turnover, has achieved the appropriate balance between maintaining longer-term directors with deep institutional knowledge and new directors who bring new perspectives and diversity to the Board. Notwithstanding this belief and the fact that the Company's corporate governance guidelines and NASDAQ Global Market rules do not deem long-tenured directors to be non-independent, the Board reviews director tenure in connection with its director independence determinations.

Review and approval of related party transactions

Our related parties include our directors, executive officers, holders of more than five percent of the outstanding shares of our Common Stock and the foregoing persons' immediate family members. We review relationships and transactions in which the Company and our related parties are participants to determine whether such related persons have a direct or indirect material interest. Our Related Party Transaction Policy requires our Audit Committee to review any related party transactions in which the amount involved will, or may be, expected to exceed $50,000. Additionally, as required under SEC rules, transactions since January 1, 2023 that are determined to be directly or indirectly material to a related party are disclosed below. In addition, the Audit Committee reviews and approves any related party transaction that is required to be disclosed.

Except as described below and other than Board or employment relationships and compensation resulting from those employment relationships, no director, executive officer, holder or more than five percent of the outstanding shares of our Common Stock or immediate family member of any of the foregoing, was a party to any transaction or series of transactions since January 1, 2023, or is to be a party to any currently proposed transaction or series of proposed transactions, in which (i) the Company (including any of its subsidiaries) was, is, or will be a participant, (ii) the amount involved will, or may be, expected to exceed $50,000 for any related party group within the combined periods required to be presented in the financial statements, and (iii) any related party had, has, or will have a direct or indirect interest other than solely as a result of being a director of another entity.

On August 24, 2023, we entered into a Master Services Agreement and on August 28, 2023, a Statement of Work with Inizio Evoke Communications ("Inizio Evoke") (formerly a/k/a Evoke Canale, Inc. ("Evoke")), pursuant to which Inizio Evoke will provide to the Company twelve months of communications planning, which includes strategy planning and account management, media relations and data communications, and social media services. We agreed to pay Inizio Evoke approximately $175,000 per year. Dr. Sohn's daughter, Jennifer Gallo, is an Executive Vice President at Evoke Kyne, a division of Inizio Evoke which may be involved in the services provided. During the year ended December 31, 2023, we paid $55,000 to Inizio Evoke.

Indemnification agreements

We have entered into an indemnification agreement with each of our officers and outside directors. The indemnification agreements and our certificate of incorporation and bylaws require us to indemnify our directors and officers to the fullest extent permitted by Delaware law.

Item 14. Principal Accountant Fees and Services

The following table sets forth the aggregate fees billed to the Company for services during the fiscal years ended December 31, 2023 and 2022 by our independent registered public accounting firm, Ernst & Young LLP ("E&Y"):

Fee Category	2023	2022
Audit Fees (1)	$ 870,936	$ 857,960
Tax Fees (2)	46,278	54,570
Total	$ 917,214	$ 912,530

(1) Audit Fees consist of fees billed for professional services rendered for the audit of the Company's consolidated annual financial statements included in the Company's Annual Report and review of the interim consolidated financial statements included in the Company's Quarterly Reports on Form 10-Q, and services that are normally provided by independent registered public accountants in connection with statutory and regulatory filings or engagements.

(2) Tax Fees were billed for services including assistance with tax compliance and the preparation of tax returns, tax consultation services, assistance in connection with tax audits and tax advice.

Pre-Approval Policies

The Audit Committee, or a designated member thereof, pre-approves all audit, audit-related, tax and other services rendered by the independent registered public accounting firm to the Company or its subsidiaries.

Immediately following the completion of each fiscal year, the Company's independent registered public accounting firm shall submit to the Audit Committee (and the Audit Committee shall request from the independent registered public accounting firm), as soon as possible, a formal written statement describing: (i) the independent registered public accounting firm's internal quality-control procedures; and (ii) all relationships between the independent registered public accounting firm and the Company, including at least the matters set forth in Independence Standards Board Standard No. 1 (Independence Discussion with Audit Committees), in order to assess the independent registered public accounting firm's independence.

Immediately following the completion of each fiscal year, the independent registered public accounting firm also shall submit to the Audit Committee (and the Audit Committee shall request from the independent registered public accounting firm), a formal written statement of the fees billed by the independent registered public accounting firm to the Company in each of the last two fiscal years for each of the following categories of services rendered by the independent registered public accounting firm: (i) the audit of the Company's annual financial statements and the reviews of the financial statements included in the Company's Quarterly Reports on Form 10-Q or services that are normally provided by the independent registered public accounting firm in connection with statutory and regulatory filings or engagements; (ii) assurance and related services not included in clause (i) that are reasonably related to the performance of the audit or review of the Company's financial statements, in the aggregate and by each service; (iii) tax compliance, tax advice and tax planning services, in the aggregate and by each service; and (iv) all other products and services rendered by the independent registered public accounting firm, in the aggregate and by each service.

PART IV

Item 15. Exhibits and Financial Statement Schedules

Financial Statements

Reference is made to the Index to the Consolidated Financial Statements included in Item 8 of this report.

Financial Statement Schedules

Required information is included in the notes to the consolidated financial statements.

Exhibit Index

Exhibit No.	Description
2.1	Agreement and Plan of Merger and Reorganization, dated July 8, 2019, by and among Altimmune, Inc., Springfield Merger Sub, Inc., Springfield Merger Sub, LLC, Spitfire Pharma, Inc. and David Collier, as the Stockholder Representative (incorporated by reference to Exhibit 2.1 to Registrant's Form 8-K filed on July 9, 2019)
3.1	Amended and Restated Certificate of Incorporation, dated October 17, 2017 (incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed on October 18, 2017)
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation regarding a reverse stock split (incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed on September 13, 2018)
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation regarding an increase in authorized shares (incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K filed on September 13, 2018)
3.4	Amended and Restated Bylaws of Altimmune, Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K filed on October 18, 2017)
3.5	Certificate of Designations of the Series B Convertible Preferred Stock, dated August 21, 2017 (incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K filed on August 21, 2017)
4.1	Form of Warrant (incorporated by reference to Exhibit 4.2 to the Registrant's Form 8-K filed on March 11, 2019)
4.2*	Description of Registrant's Securities
10.1†	Altimmune, Inc. 2017 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on May 8, 2017)
10.2†	Amendment No. 1 to the Altimmune, Inc. 2017 Omnibus Incentive Plan (incorporated by reference to Appendix A to the Registrant's definitive proxy statement on Schedule 14A filed on July 26, 2018)
10.3†	Altimmune, Inc. 2001 Employee Stock Option Plan (incorporated by reference to Exhibit 99.1 to the Registrant's Form S-8 filed on May 10, 2017)
10.4†	Altimmune, Inc. 2001 Non-Employee Stock Option Plan (incorporated by reference to Exhibit 99.2 to the Registrant's Form S-8 filed on May 10, 2017)
10.5†	Altimmune, Inc. 2018 Inducement Grant Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Form 8-K filed on December 3, 2018)
10.6†	Altimmune, Inc. 2019 Employee Stock Purchase Plan (incorporated herein by reference to Appendix A to the Registrant's Definitive Proxy Statement, filed on August 22, 2019)

Exhibit No.	Description
10.7†	Altimmune, Inc. Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.7 to the Registrant's Form 10-K filed on February 28, 2023)
10.8§	Amended and Restated License Agreement, dated July 12, 2019, by and between Mederis Diabetes, LLC and Spitfire Pharma, Inc. (incorporated by reference to Exhibit 10.2 to the Registrant's Form 10-Q filed on November 13, 2019)
10.9	Form of Director and Officer Indemnification Agreement (incorporated by reference to Exhibit 10.12 to the Registrant's Form 10-Q filed on August 14, 2017)
10.10†	Employment Agreement, dated November 16, 2018 between Dr. Vipin K. Garg and Altimmune, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on November 27, 2018)
10.11†	Employment Agreement, dated September 9, 2019, by and between Altimmune, Inc. and M. Scott Harris (incorporated by reference to Exhibit 10.4 to the Registrant's Form 10-Q filed on November 13, 2019)
10.12†	Employment Agreement, dated January 1, 2023, by and between Altimmune, Inc. and Raymond M. Jordt (incorporated by reference to Exhibit 10.30 to the Registrant's Form 10-K filed on February 28, 2023)
10.13	Equity Distribution Agreement, dated February 25, 2021, by and among Altimmune, Inc. and Piper Sandler & Co., Evercore Group L.L.C. and B. Riley Securities, Inc. (incorporated by reference to Exhibit 1.1 to the Registrant's Form 8-K filed on February 25, 2021)
10.14	Equity Distribution Agreement, dated February 28, 2023 among the Registrant and Evercore Group L.L.C., JMP Securities LLC and B. Riley Securities, Inc. (incorporated by reference to Exhibit 1.2 to the Registrant's Form S-3ASR filed on February 28, 2023)
21*	Subsidiaries
23.1*	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
24*	Power of Attorney
31.1*	Certification of Principal Executive Officer Pursuant to SEC Rule 13a-14(a)
31.2*	Certification of Principal Financial Officer Pursuant to SEC Rule 13a-14(a)
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350
97*	Policy Relating to Recovery of Erroneously Awarded Compensation
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

† Management contract or compensatory plan or arrangement.

§ Certain portions of this exhibit have been omitted pursuant to a request for confidential treatment.

Financial Statements and Schedules of Subsidiaries and Affiliates

None.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized, in the city of Gaithersburg, State of Maryland, on the 27th day of March 2024.

ALTIMMUNE, INC.

By:/s/ Vipin K. Garg
Vipin K. Garg
Chief Executive Officer

POWER OF ATTORNEY

BY THESE PRESENTS, each person whose signature appears below constitutes and appoints Vipin K. Garg and Richard Eisenstadt his true and lawful attorney-in-fact and agents, with full power of substitution and resubstitution for him and in his name, place and stead, in any and all capacities to sign any and all amendments to this annual report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the U.S. Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact or his substitute, each acting alone, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Vipin K. Garg Vipin K. Garg	President, Chief Executive Officer and Director (Principal Executive Officer)	March 27, 2024
/s/ Richard Eisenstadt Richard Eisenstadt	Chief Financial Officer, (Principal Financial Officer and Principal Accounting Officer)	March 27, 2024
/s/ Mitchel Sayare, Ph.D. Mitchel Sayare, Ph.D.	Chairman of the Board	March 27, 2024
/s/ John Gill John Gill	Director	March 27, 2024
/s/ Philip Hodges Philip Hodges	Director	March 27, 2024
/s/ David Drutz, M.D. David Drutz, M.D.	Director	March 27, 2024
/s/ Klaus O. Schafer, M.D. Klaus O. Schafer, M.D.	Director	March 27, 2024
/s/ Wayne Pisano Wayne Pisano	Director	March 27, 2024
/s/ Diane Jorkasky, M.D. Diane Jorkasky, M.D.	Director	March 27, 2024
/s/ Catherine Sohn, Pharm D. Catherine Sohn, Pharm D.	Director	March 27, 2024

BOARD OF DIRECTORS

Mitchel Sayare, Ph.D.
Director, Chairman of the Board

David J. Drutz, M.D.
President of Pacific Biopharma Associates, LLC

John M. Gill
Director

Philip L. Hodges
Managing Partner of Redmont Capital

Wayne Pisano
Director, Oncolytics Biotech Inc.

Diane K. Jorkasky, M.D.
Director, Alzheon, Inc.

Klaus O. Schafer, M.D., MPH
Director

Catherine Sohn, Pharm D
Director, Maze Therapeutics

EXECUTIVE OFFICERS

Vipin K. Garg, Ph.D.
President, Chief Executive Officer, and Director

Andrew Shutterly, M.S.
Acting Chief Financial Officer

M. Scot Roberts, Ph.D.
Chief Scientific Officer

M. Scott Harris, M.D.
Chief Medical Officer

Raymond M. Jordt, M.B.A.
Chief Business Officer