

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

**FORM 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended September 30, 2025

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: 001-38419

**Arcus Biosciences, Inc.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**47-3898435**

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

**3928 Point Eden Way  
Hayward, California 94545**

(Address of principal executive offices)

**Registrant's telephone number, including area code: (510) 694-6200**

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

Titles of Each Class	Trading Symbol(s)	Name of Each Exchange on which Registered
Common Stock, Par Value \$0.0001 Per Share	RCUS	The New York Stock Exchange

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

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

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

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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

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

As of October 23, 2025, the registrant had 107,973,536 shares of common stock, \$0.0001 par value per share, outstanding.

ARCUS BIOSCIENCES, INC.

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## RISK FACTOR SUMMARY

The following is a summary of the key risks and uncertainties that make an investment in our securities speculative and risky. The below summary does not contain all of the information that may be important to you, and you should read this summary together with the more detailed description of the risks set forth under "Part II. Item 1A. Risk Factors" of the Quarterly Report.

### **Risks Related to our Limited Operating History, Financial Position and Capital Requirements**

- We have a history of operating losses, have never generated any revenue from product sales and anticipate that we will continue to incur significant losses for the foreseeable future.
- We may need to obtain additional funding. If we do not receive or are unable to raise additional capital when needed, we may be forced to restrict our operations or delay, reduce or eliminate our product development programs.

### **Risks Related to the Discovery and Development of our Investigational Products**

- If we are unable to obtain regulatory approval for our investigational products, or experience significant delays in doing so, our business will be materially harmed.
- Preliminary, topline and interim data from our clinical studies that we announce or publish from time to time are subject to audit and verification procedures that could result in material changes in the final data and may change as more patient data become available.
- Enrollment and retention of subjects in clinical trials is expensive and time consuming and can be made more difficult or rendered impossible by competing treatments, clinical trials of competing investigational products, geopolitical instability and public health epidemics, each of which could result in significant delays and additional costs in our product development activities, or in the failure of such activities.
- Serious adverse events, undesirable side effects or other unexpected properties of our investigational products may be identified during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our investigational products or limitations on the use of our investigational products or, if discovered following marketing approval, revocation of marketing authorizations or subsequent limitations on the use of our investigational products.
- A key element of our strategy is the development of intra-portfolio combinations. If we are not successful in discovering, developing and commercializing investigational products that take advantage of different mechanisms of action to achieve superior outcomes relative to the use of single agents or other combination therapies, our ability to achieve our strategic objectives would be impaired.
- Certain of our investigational products may require companion diagnostics in certain indications. Failure to successfully develop, validate and obtain regulatory clearance or approval for such tests could harm our product development strategy or prevent us from realizing the full commercial potential of our investigational products.

### **Risks Related to Reliance on Third Parties, Manufacturing and Commercialization**

- We expect to depend on our collaboration with Gilead Sciences, Inc. ("Gilead") for the research, development, manufacture and commercialization of our investigational products. If this collaboration is not successful, our business could be adversely affected.
- We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.
- Even if we receive marketing approval, we may not be successful in commercializing our investigational products.

- Even if we receive marketing approval for one or more of our investigational products, our commercial success is dependent on obtaining coverage and reimbursement approval for a product from a government or other third-party payor, which coverage may be delayed or may not be sufficient to cover our costs.
- Obtaining and maintaining regulatory approval of investigational products in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. Even if our investigational products are approved by the U.S. Food and Drug Administration ("FDA"), they may never be approved or commercialized outside the United States ("U.S."), which would limit our ability to realize their full market potential.
- Any investigational products for which we intend to seek approval as biologic products may face competition sooner than anticipated.

#### **Risks Related to our In-Licenses and Other Strategic Agreements**

- We are currently party to several in-license agreements under which we acquired rights to use, develop, manufacture and/or commercialize certain of our investigational products. If we breach our obligations under these agreements, we may be required to pay damages, lose our rights to these investigational products or both, which would adversely affect our business and prospects.

#### **Risks Related to Intellectual Property**

- If we are unable to obtain and maintain sufficient intellectual property protection for our investigational products, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.
- We may become involved in lawsuits alleging that we have infringed the intellectual property rights of third parties or to protect or enforce our patents or other intellectual property, which litigation could be expensive, time consuming and adversely affect our ability to develop or commercialize our investigational products.
- Changes in patent law in the U.S. and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our investigational products.
- We may rely on trade secret and proprietary know-how which can be difficult to trace and enforce, and if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

#### **Risks Related to our Business Operations and Industry**

- We expect to expand our business operations, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.
- We face substantial competition, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If their investigational products are shown to be safer or more effective than ours, then our commercial opportunity will be reduced or eliminated.
- Our internal information technology systems, and those of our third-party Contract Research Organizations ("CROs") and other third parties upon which we rely, are subject to failure, security breaches and other disruptions, which could result in a material disruption of our investigational products' development programs, jeopardize sensitive information, prevent us from accessing critical information or result in a loss of our assets, and potentially expose us to notification obligations, loss, liability or reputational damage and otherwise adversely affect our business.
- Failure to comply with privacy and data protection laws, regulations or other obligations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.
- Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and may have a significant adverse effect on our business and results of operations.

## PART I—FINANCIAL INFORMATION

## Item 1. Financial Statements

**ARCUS BIOSCIENCES, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(In millions, except per share amounts)  
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
<b>Revenues:</b>				
License and development services revenue (Includes \$20, \$23, \$192 and \$179 from a related party)	\$ 20	\$ 41	\$ 192	\$ 204
Other collaboration revenue (Includes \$6, \$7, \$22 and \$28 from a related party)	6	7	22	28
Total revenues	26	48	214	232
<b>Operating expenses:</b>				
Research and development (Includes \$13, (\$2), \$19 and (\$32) from a related party)	141	123	402	347
General and administrative (Includes \$3, \$—, \$5, and \$— from a related party)	27	30	84	92
Impairment of long-lived assets (see Note 12, Leases)	—	—	—	20
Total operating expenses	168	153	486	459
Loss from operations	(142)	(105)	(272)	(227)
<b>Non-operating income (expense):</b>				
Interest and other income, net	10	14	31	40
Interest expense	(3)	(1)	(6)	(2)
Total non-operating income, net	7	13	25	38
Loss before income taxes	(135)	(92)	(247)	(189)
Income tax expense	—	—	—	—
Net loss	\$ (135)	\$ (92)	\$ (247)	\$ (189)
<b>Net loss per share:</b>				
Basic and diluted	\$ (1.27)	\$ (1.00)	\$ (2.39)	\$ (2.11)
<b>Shares used to compute net loss per share:</b>				
Basic and diluted	106.5	91.4	103.7	89.6

See accompanying notes.

**ARCUS BIOSCIENCES, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**  
**(In millions)**  
**(unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Net loss	\$ (135)	\$ (92)	\$ (247)	\$ (189)
Other comprehensive income	—	2	—	1
Comprehensive loss	\$ (135)	\$ (90)	\$ (247)	\$ (188)

See accompanying notes.

**ARCUS BIOSCIENCES, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**(In millions, except per share amounts)**  
**(unaudited)**

	September 30, 2025	December 31, 2024
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 238	\$ 150
Marketable securities	593	828
Receivable from collaboration partners (\$— and \$6 from a related party)	11	20
Prepaid expenses and other current assets	15	18
Total current assets	857	1,016
Long-term marketable securities	10	14
Property and equipment, net	42	47
Other noncurrent assets	65	73
Total assets	\$ 974	\$ 1,150
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable (\$29 and \$— to a related party)	\$ 42	\$ 18
Deferred revenue (\$52 and \$85 to a related party)	52	85
Other current liabilities	141	123
Total current liabilities	235	226
Deferred revenue, noncurrent (\$53 and \$234 to a related party)	53	234
Long-term debt	98	48
Other noncurrent liabilities	152	157
Commitments		
Stockholders' equity:		
Common stock and additional paid-in capital: \$0.0001 par value per share; 400.0 shares authorized; 107.1 shares in 2025 and 92.2 shares in 2024 issued and outstanding	1,815	1,617
Accumulated deficit	(1,379)	(1,132)
Total stockholders' equity	436	485
Total liabilities and stockholders' equity	\$ 974	\$ 1,150

See accompanying notes.

**ARCUS BIOSCIENCES, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
(In millions)  
(unaudited)

	Number of shares of common stock	Common stock and additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Total stockholders' equity
Balance at December 31, 2023	75.5	\$ 1,311	\$ (849)	\$ —	\$ 462
Issuance of common stock (see Note 3, Related party - Gilead Sciences, Inc. and Note 13, Stockholders' equity)	15.2	228	—	—	228
Issuance of common stock in connection with our equity award programs	0.2	2	—	—	2
Stock-based compensation	—	20	—	—	20
Other comprehensive loss	—	—	—	(1)	(1)
Net loss	—	—	(4)	—	(4)
Balance at March 31, 2024	90.9	1,561	(853)	(1)	707
Issuance of common stock in connection with our equity award programs	0.4	1	—	—	1
Stock-based compensation	—	20	—	—	20
Net loss	—	—	(93)	—	(93)
Balance at June 30, 2024	91.3	1,582	(946)	(1)	635
Issuance of common stock in connection with our equity award programs	0.2	1	—	—	1
Stock-based compensation	—	19	—	—	19
Other comprehensive income	—	—	—	2	2
Net loss	—	—	(92)	—	(92)
Balance at September 30, 2024	91.5	\$ 1,602	\$ (1,038)	\$ 1	\$ 565
Balance at December 31, 2024	92.2	\$ 1,617	\$ (1,132)	\$ —	\$ 485
Issuance of common stock (see Note 3, Related party - Gilead Sciences, Inc. and Note 13, Stockholders' equity)	13.6	142	—	—	142
Issuance of common stock in connection with our equity award programs	0.1	—	—	—	—
Stock-based compensation	—	16	—	—	16
Net loss	—	—	(112)	—	(112)
Balance at March 31, 2025	105.9	1,775	(1,244)	—	531
Issuance of common stock in connection with our equity award programs	0.5	3	—	—	3
Stock-based compensation	—	15	—	—	15
Net income	—	—	—	—	—
Balance at June 30, 2025	106.4	1,793	(1,244)	—	549
Issuance of common stock (see Note 13, Stockholders' equity)	0.7	8	—	—	8
Stock-based compensation	—	14	—	—	14
Net loss	—	—	(135)	—	(135)
Balance at September 30, 2025	107.1	\$ 1,815	\$ (1,379)	\$ —	\$ 436

See accompanying notes.

**ARCUS BIOSCIENCES, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In millions)  
(unaudited)

	Nine Months Ended September 30,	
	2025	2024
<b>Cash flow from operating activities</b>		
Net loss	\$ (247)	\$ (189)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	45	59
Depreciation and amortization	7	7
Noncash lease expense	5	5
Impairment of long-lived assets	—	20
Amortization of discounts on marketable securities	(10)	(19)
Other items, net	2	2
Changes in operating assets and liabilities:		
Receivable from collaboration partners (\$6 and \$18 from a related party)	9	32
Other assets (\$— and \$6 from a related party)	5	16
Accounts payable (\$29 and \$— to a related party)	24	(2)
Deferred revenue ((\$214) and (\$20) to a related party)	(214)	(14)
Other liabilities	12	13
Net cash used in operating activities	<u>(362)</u>	<u>(70)</u>
<b>Cash flow from investing activities</b>		
Purchases of marketable securities	(679)	(871)
Proceeds from maturities of marketable securities	858	726
Proceeds from sales of marketable securities	70	15
Purchases of property and equipment	(1)	(5)
Net cash provided by (used in) investing activities	<u>248</u>	<u>(135)</u>
<b>Cash flow from financing activities</b>		
Proceeds from issuance of common stock (\$14 and \$228 from a related party)	150	228
Proceeds from debt issuances, net	49	47
Proceeds from issuance of common stock pursuant to equity award plans	3	6
Payments of employee taxes related to net settlement of equity awards	—	(2)
Net cash provided by financing activities	<u>202</u>	<u>279</u>
Net increase in cash, cash equivalents and restricted cash	88	74
Cash, cash equivalents and restricted cash at beginning of period	153	130
Cash, cash equivalents and restricted cash at end of period	<u>\$ 241</u>	<u>\$ 204</u>

See accompanying notes.

**ARCUS BIOSCIENCES, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(unaudited)**

**Note 1. Organization, liquidity and capital resources**

***Organization***

Arcus Biosciences, Inc. (referred to as "Arcus," "we," "our," "us," or the "Company") is a clinical-stage biopharmaceutical company focused on creating best-in-class therapies. Using our robust and highly efficient drug discovery capability, we have created a significant portfolio of investigational products which are in clinical development, with our most advanced molecule, an anti-TIGIT antibody, now in multiple Phase 3 registrational studies targeting lung and gastrointestinal ("GI") cancers. Our deep portfolio of novel small molecules and enabling antibodies allows us to create highly differentiated therapies, which we are developing to treat multiple large indications.

We operate and manage our business as one reportable and operating segment, which is the business of developing and commercializing highly differentiated therapies that have a meaningful impact on patients. See Note 15, Business segment, for more information.

***Liquidity and Capital Resources***

As of September 30, 2025, we had cash, cash equivalents and marketable securities of \$841 million, which we believe will be sufficient to fund our planned operations for a period of at least twelve months following the date of filing of this report.

**Note 2. Summary of significant accounting policies**

***Basis of Presentation***

These interim financial statements should be read in conjunction with the audited Consolidated Financial Statements and the related notes thereto for the year ended December 31, 2024 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on February 25, 2025. There have been no significant changes to our summary of significant accounting policies as disclosed in that filing.

These interim financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") for interim financial information and include all normal and recurring adjustments that management believes are necessary for a fair presentation of the periods presented. The Condensed Consolidated Balance Sheet as of December 31, 2024 has been derived from audited consolidated financial statements at that date but does not include all of the information required by U.S. GAAP for complete financial statements.

Operating results for the three and nine months ended September 30, 2025 are not necessarily indicative of the results that may be expected for the year ending December 31, 2025 or for any future period.

***Use of Estimates***

The preparation of the Condensed Consolidated Financial Statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosures. We base our estimates on historical experience and on various market-specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Estimates are assessed and updated each period to reflect current information. Actual results may differ materially from those estimates.

***Recent Accounting Pronouncements***

In December 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which requires disclosure of disaggregated income taxes paid, prescribes standard categories for the components of the effective tax rate reconciliation, and modifies other income tax-related disclosures. The standard will become effective for the fiscal year ending December 31, 2025, with early adoption permitted. We plan to adopt this guidance beginning with our 2025 Annual Report to be filed in early 2026. We are currently assessing the potential impact of the new standard on our Notes to our Consolidated Financial Statements.

In November 2024, the FASB issued ASU 2024-03 — Income Statement — Reporting Comprehensive Income — Expense Disaggregation Disclosures (Subtopic 220-40) — Disaggregation of Income Statement Expenses. This ASU requires disclosure, in the notes to financial statements, of specified information about certain costs and expenses. We plan to adopt this guidance beginning with our 2027 Annual Report to be filed in early 2028 and all quarterly and Annual Reports thereafter. We expect the adoption of this standard to result in increased disclosures in our Notes to our Consolidated Financial Statements.

In September 2025, the FASB issued ASU 2025-07 — Derivatives and Hedging (Topic 815) and Revenue from Contracts with Customers (Topic 606): Derivatives Scope Refinements and Scope Clarification for Share-Based Noncash Consideration from a Customer in a Revenue Contract. This ASU refines the scope of the guidance on derivatives in Topic 815 and clarifies the guidance on share-based payments from a customer in ASC 606. The standard will become effective for the fiscal year ending December 31, 2027, with early adoption permitted. We are currently assessing the potential impact of this new standard on our Consolidated Financial Statements.

### **Note 3. Related party - Gilead Sciences, Inc.**

In 2020, we and Gilead entered into an Option, License and Collaboration Agreement (the "Gilead Collaboration Agreement"), Common Stock Purchase Agreement (the "Stock Purchase Agreement"), and Investor Rights Agreement (the "Investor Rights Agreement").

The Gilead Collaboration Agreement was amended in 2021 (the "First Gilead Collaboration Agreement Amendment"), in 2023 (the "Second Gilead Collaboration Agreement Amendment"), in the first quarter 2024 (the "Third Gilead Collaboration Agreement Amendment") and in the second quarter 2024 (the "Fourth Gilead Collaboration Agreement Amendment").

The Stock Purchase Agreement was amended in 2021 (the "First Stock Purchase Agreement Amendment"), in 2023 (the "Second Stock Purchase Agreement Amendment"), and was amended and restated in the first quarter 2024 (the "Third Stock Purchase Agreement Amendment"). Gilead's right to purchase shares under the Third Stock Purchase Agreement Amendment expired in July 2025.

The Investor Rights Agreement was amended in 2022 (the "First Investor Rights Agreement Amendment") and was amended and restated in the first quarter 2024 (the "Second Investor Rights Agreement Amendment").

We refer to these agreements collectively as the Gilead Agreements.

#### ***Stock Purchase and Investor Rights Agreements***

In the first quarter 2024, under the Third Stock Purchase Agreement Amendment, Gilead purchased 15.2 million shares of our common stock for total gross proceeds of \$320 million, of which \$87 million was determined to be a premium on the purchase of common stock and allocated to the performance obligations created by the Third Gilead Collaboration Agreement Amendment.

In the first quarter 2025, through our underwritten offering, Gilead purchased 1.4 million shares of our common stock for total gross proceeds of \$15 million.

Gilead had the right under the Stock Purchase Agreement and the related amendments, which expired in July 2025, to purchase up to a maximum of 35% of the Company's then-outstanding voting common stock, at a purchase price equal to the greater of a 20% premium to market (based on a trailing five-day average closing price at option exercise) or the \$33.54 initial purchase price. Based on the value of our common stock at each contract closing, the right to purchase additional shares had no value. Under the Investor Rights Agreement entered into in 2020 and subsequent amendments, Gilead has: the right to designate three members of our board of directors; registration rights for shares that it purchases; and had pro rata participation rights in certain future financings that expired in July 2025. Gilead has exercised its rights to appoint all three board members and we have registered all shares purchased to date.

As of September 30, 2025, Gilead held approximately 29.3% of our outstanding common stock arising from purchases in our public offerings and under the Stock Purchase Agreement and related amendments.

#### ***Collaboration Agreements***

In 2020, we entered into the Gilead Collaboration Agreement, which gave Gilead an exclusive license to develop and commercialize zimberelimab (the anti PD-1 program) in certain markets and time-limited options to acquire exclusive licenses to develop and commercialize any of our then-current and future clinical programs arising during the 10-year collaboration term, contingent upon \$100 million option continuation payments payable on each of the second, fourth, sixth and eighth anniversaries of the agreement. Upon closing of the transaction in 2020, Gilead made an upfront payment of \$175 million.

In 2021, we entered into the First Gilead Collaboration Agreement Amendment pursuant to which Gilead exercised its option to three programs—providing Gilead with exclusive licenses to develop and commercialize domvanalimab and AB308 (collectively, the anti-TIGIT program), etrumadenant (the adenosine receptor antagonist program) and quemliclustat (the CD73 program), in certain markets—for a total payment of \$725 million that was received in 2022. The amendment also (i) provided for a slight reduction in the royalties for these three programs, such that Gilead will pay us tiered royalties as a percentage of revenues ranging from the mid-teens to the low twenties; and (ii) removed the \$100 million option continuation payment that was otherwise due on the second anniversary of the Gilead Collaboration Agreement. With respect to domvanalimab, we are also eligible to receive up to \$500 million in potential U.S. regulatory approval milestones.

Gilead's option to acquire exclusive licenses to develop and commercialize any of our clinical programs arising during the collaboration term, on a program-by-program basis, will expire after a prescribed period following the achievement of a clinical development milestone in such program and our delivery to Gilead of the requisite data package. Gilead may exercise its option to any program at any time prior to expiration of the option and will pay Arcus an option fee of \$150 million per program.

For each program that Gilead opts in to, both companies will co-develop and equally share global development costs, subject to certain opt-out rights that we have, caps on our spending and related subsequent adjustments, and certain other exceptions. For each program, provided we have not exercised our opt-out rights, we have the option to co-promote in the U.S. with equal sharing of related profits and losses. Gilead has the right to exclusively commercialize outside of the U.S., subject to the rights of our existing partners in any territories and will pay us tiered royalties as a percentage of revenues ranging from the high teens to the low twenties.

Under the First Gilead Collaboration Agreement Amendment, Gilead also has option rights to two oncology research programs for which we will lead discovery and early development activities. With respect to these two research programs, Gilead has the right to exercise its option, on a program-by-program basis, either (i) upon our completion of certain investigational new drug ("IND")-enabling activities for an option payment of \$60 million or (ii) following the achievement of a clinical development milestone for an option payment of \$150 million.

In 2023, we entered into the Second Gilead Collaboration Agreement Amendment pursuant to which we expanded our collaboration to provide Gilead with options to license up to four jointly selected research-stage programs that target inflammatory diseases for which we will lead discovery and early development activities. We will receive an upfront payment of \$17.5 million for each initiated program and Gilead will have an option to license each program at two separate, prespecified time points. For the first two research programs, Gilead has the right, on a program-by-program basis, either (i) to exercise its option upon our completion of certain IND-enabling activities for an option payment of \$45 million or (ii) to extend its option and exercise it following the achievement of a clinical development milestone for an option payment of \$150 million. If Gilead exercises its option at the earlier time point for the first two programs, we would be eligible to receive up to \$375 million in regulatory and commercial milestone payments as well as tiered royalties for each optioned program. For any other program option exercise by Gilead, the parties would have rights to co-develop and share global development costs and to co-promote and share profits in the U.S. for that program. We received a total upfront payment of \$35 million for an initial two research programs in 2023. Gilead's options to the other two research programs, as amended under the Fourth Gilead Collaboration Agreement Amendment expired in May 2025.

In the first quarter 2024, we entered into the Third Gilead Collaboration Agreement Amendment. The Third Gilead Collaboration Agreement Amendment, among other things, (i) required Gilead to pay the \$100 million option continuation payment due on the fourth anniversary of the Gilead Collaboration Agreement, which was received in the third quarter 2024 (ii) provides that we will operationalize and fund the Phase 3 PRISM-1 study evaluating quemliclustat in pancreatic cancer subject to Gilead's right to reinstate the study as part of the parties' joint development activities upon regulatory approval, (iii) provides that we will solely fund our share of PACIFIC-8, subject to Gilead's right to reinstate PACIFIC-8 as part of the parties' joint development activities for the TIGIT Program in the first quarter 2026, and (iv) provides that we will fund certain other activities. All other terms of the existing collaboration agreements, remain unchanged.

As of September 30, 2025, Gilead has licenses to domvanalimab, AB308, quemliclustat and zimberelimab. In the second quarter 2025, Gilead returned its license to the adenosine receptor antagonist program, which includes etrumadenant. In the first quarter 2025, Gilead's time-limited exclusive option rights to our HIF-2 $\alpha$  program, which includes casdatifan, expired.

For the three and nine months ended September 30, 2025, under the Gilead Agreements we recognized revenue of \$26 million and \$214 million, respectively, and for the three and nine months ended September 30, 2024, we recognized revenue of \$30 million and \$207 million, respectively. For the three and nine months ended September 30, 2025, we recognized net expense to Gilead of \$16 million and \$24 million, respectively, and for the three and nine months ended September 30, 2024, we recognized net reimbursements from Gilead of \$2 million and \$32 million, respectively, in Operating expense, allocated between R&D and General and Administrative ("G&A") based upon the activity that generated the net expense or reimbursement.

At September 30, 2025, we had a net payable to Gilead of \$29 million, recorded in Accounts payable on our Condensed Consolidated Balance Sheets. At December 31, 2024, we had a net receivable from Gilead of \$6 million, recorded in Receivable from collaboration partners on our Condensed Consolidated Balance Sheets.

For a more detailed discussion on revenues recognized under the Gilead Agreements, see Note 5, Revenues, for more information.

#### **Note 4. License and collaborations**

We enter into licensing agreements, strategic collaborations and other similar arrangements with third parties for the development and commercialization of certain investigational products. These arrangements: may be collaborative and involve two or more parties who are active participants in the operating activities of the collaboration and are exposed to significant risks and rewards depending on the commercial success of the activities; are performed with no guarantee of either technological or commercial success; and are each unique in nature. Such arrangements may include: non-refundable upfront payments; payments for options to acquire certain rights; potential development and regulatory milestone payments and/or sales-based milestone payments; royalty payments; revenue or profit-sharing arrangements; expense reimbursements; and cost-sharing arrangements.

Operating expenses for costs incurred pursuant to these arrangements are reported in their respective expense line items in the Condensed Consolidated Statements of Operations, net of any payments due to or reimbursements due from our collaboration partners, with such reimbursements being recognized at the time the party becomes obligated to pay.

Our significant arrangements are discussed below. For a more detailed discussion on revenues recognized under these arrangements, see Note 5, Revenues.

##### ***Gilead Collaboration***

See Note 3, Related party - Gilead Sciences, Inc., for more information.

##### ***Taiho Collaboration***

In 2017, we entered into an agreement with Taiho Pharmaceutical Co., Ltd ("Taiho") under which we granted them exclusive options to programs arising over a five-year period which ended in September 2022 for an upfront payment of \$35 million. Upon exercising their option to a program, Taiho would obtain exclusive development and commercialization rights to investigational products under the program to Japan and certain other Asian countries (excluding China) (the "Taiho Territory").

For each option to a program that Taiho exercises, except for casdatifan (the HIF-2 $\alpha$  program) see below, they will be obligated to make a payment of \$3 million to \$15 million, depending on the development stage of the optioned program. Upon exercise, Taiho is solely responsible for continued development and commercialization in the Taiho Territory, unless they opt to participate in a global study, in which case they would become obligated to reimburse us for their portion of the global study costs. In addition, for each optioned program we would be eligible to receive clinical and regulatory milestones of up to \$130 million and commercial milestone payments of up to \$145 million with the achievement of certain sales thresholds in the Taiho Territory. We will also receive royalties ranging from high single-digits to mid-teens on net sales of licensed products in the Taiho Territory. Royalties will be payable by product and country commencing on the first commercial sale and ending upon the later of: (a) 10 years; and (b) expiration of the last-to-expire valid claim of our patents covering the manufacture, use or sale.

As of September 30, 2025, Taiho has licenses for the Taiho Territory to (i) etrumadenant (the adenosine receptor antagonist program); (ii) zimberelimab (the anti PD-1 program); (iii) domvanalimab and AB308 (the anti-TIGIT program); and (iv) quemliclustat (the CD73 program), for which Taiho exercised its option and made an option payment of \$15 million in the third quarter 2024.

In October 2025, Taiho exercised its option for casdatifan (the HIF-2 $\alpha$  program) for the Taiho Territory, for an option payment of \$15 million, payable in the fourth quarter 2025. We and Taiho concurrently entered into the Second Amendment where we will lead development for two indications in Japan and we may also be eligible to receive clinical and regulatory milestones of up to \$172 million, commercial milestone payments of up to \$145 million with the achievement of certain sales thresholds in the Taiho Territory and royalties ranging from high single-digits to mid-teens on net sales of the licensed product in the Taiho Territory. We will be responsible for the global study costs.

In 2022, Taiho opted to participate in two global Phase 3 trials of domvanalimab and zimberelimab combinations, STAR-121 and STAR-221, and became obligated to reimburse us for their portion of the global study costs, and to make milestone payments contingent upon successfully satisfying the related clinical milestones. The clinical milestones for domvanalimab and zimberelimab for the STAR-221 study were met in 2023, and Taiho became obligated to pay us \$28 million which has been fully received. The clinical milestones for domvanalimab and zimberelimab for the STAR-121 study were met in the first quarter 2024 and Taiho became obligated to pay us \$26 million, of which \$16 million was received in the first quarter 2024 and the remaining \$10 million was received in the first quarter 2025. In the third quarter 2024, Taiho opted to participate in the global Phase 3 trial of quemliclustat, PRISM-1, and became obligated to reimburse us for their portion of the global study costs and in the first quarter 2025, Taiho dosed their first patient in Japan for PRISM-1, and became obligated to make milestone payments totaling \$19 million of which \$12 million was received in the first quarter 2025 and the remaining \$7 million is due in the first quarter 2026. Due to the nature of this arrangement, these clinical milestones were determined to be advance cost sharing payments for a portion of the related global study Research and Development ("R&D") costs under the collaboration and are deferred and recognized as a reduction in R&D expense as the related global studies are performed, calculated as an estimated percentage of completion based on the estimated total effort for the programs.

We recognized net reimbursements including amortization of advance cost sharing payments from Taiho for the three months ended September 30, 2025 and 2024 of \$7 million and \$3 million, respectively, and for the nine months ended September 30, 2025 and 2024 of \$24 million and \$10 million, respectively, recognized as a reduction in R&D expense. For the three and nine months ended September 30, 2024, we recognized revenue of \$18 million and \$25 million, respectively under this arrangement.

At September 30, 2025 and December 31, 2024, we had \$11 million and \$14 million, respectively, related to these agreements recorded in Receivable from collaboration partners on our Condensed Consolidated Balance Sheets. At September 30, 2025 and December 31, 2024, we had liabilities of \$42 million and \$36 million, respectively related to certain advance cost sharing payments under this arrangement recorded in Other liabilities, allocated between current and noncurrent based on the expected timing of future recognition.

#### ***AstraZeneca Collaboration***

In 2020, we entered into a collaboration with AstraZeneca to evaluate domvanalimab, our investigational anti-TIGIT antibody, in combination with AstraZeneca's durvalumab in a registrational Phase 3 clinical trial in patients with unresectable Stage 3 non-small cell lung cancer ("NSCLC"), known as the PACIFIC-8 trial. The terms of this agreement were amended in the first quarter 2024.

Under the collaboration, as amended, each company will retain existing rights to their respective molecules and any future commercial economics. AstraZeneca will conduct the trial, and each company will supply their respective investigational product to support the trial. We may incur milestones of up to \$24 million upon the achievement of certain clinical trial progress milestones or under certain circumstances if the agreement is terminated early and we will reimburse AstraZeneca annually for a portion of the trial costs. The portion of the costs that we consider to be unavoidable are accrued as incurred and milestones that are deemed probable of occurring are accrued in advance of the achievement of the milestone.

Prior to January 2024, the PACIFIC-8 trial formed part of the Arcus and Gilead joint development program for domvanalimab and our portion of the trial costs were shared with Gilead. At December 31, 2023, we had recognized amounts due from Gilead for these shared costs of \$6 million, recorded in Other noncurrent assets on our Consolidated Balance Sheet. Under the Third Gilead Collaboration Agreement Amendment, we agreed to solely fund our share of PACIFIC-8, subject to Gilead's right to reinstate PACIFIC-8 as part of the parties' joint development activities for the TIGIT Program in the first quarter 2026. For the nine months ended September 30, 2024, we incurred \$6 million under the Third Gilead Collaboration Agreement as R&D expense, reflecting our additional share of costs previously shared with Gilead.

We recognized R&D expense for the three months ended September 30, 2025 and 2024 of \$7 million and \$4 million, respectively, and for the nine months ended September 30, 2025 and 2024 of \$16 million and \$10 million, respectively under this arrangement.

At September 30, 2025 and December 31, 2024, we recognized a total liability of \$28 million and \$26 million, respectively, related to our obligation to AstraZeneca, recorded in Other current liabilities and Other noncurrent liabilities on our Condensed Consolidated Balance Sheets based on the expected timing of payment.

**WuXi Biologics License - anti-PD-1**

In 2017, we entered into an agreement with WuXi Biologics Ireland Limited ("WuXi Biologics") which, as amended, provides us with exclusive rights to (i) develop, use and manufacture products that include an anti-PD-1 antibody, including zimberelimab, worldwide and (ii) commercialize any such products worldwide, except in Greater China. As of September 30, 2025, under this arrangement, we may incur (i) additional regulatory milestone payments of up to \$50 million and commercialization milestone payments of up to \$375 million, (ii) tiered royalties that range from the high single-digits to low teens on net sales of the licensed products and (iii) fees related to any sublicenses.

We did not have any milestones or royalties due under this arrangement for the three and nine months ended September 30, 2025 and 2024.

**WuXi Biologics License - anti-CD39**

In 2020, we entered into an agreement with WuXi Biologics, under which we obtained the exclusive worldwide license to develop and commercialize anti-CD39 antibodies discovered under this arrangement. As of September 30, 2025, we may incur additional clinical and regulatory milestone payments of up to \$14 million and royalty payments in the low single digits on net sales of the licensed products under this agreement.

We did not have any milestones or royalties due under this arrangement for the three and nine months ended September 30, 2025 and 2024.

**Abmuno License**

In 2016, we entered into an agreement (the "Abmuno Agreement") with Abmuno Therapeutics LLC ("Abmuno"), under which we obtained the exclusive worldwide license to develop, use, manufacture, and commercialize products that include an anti-TIGIT antibody, including domvanalimab. As of September 30, 2025, under this arrangement we may incur additional clinical, regulatory and commercialization milestone payments of up to \$88 million.

We did not have any milestones due under this arrangement for the three and nine months ended September 30, 2025 and 2024.

**Note 5. Revenues**

The following table summarizes our revenues by collaboration, category of revenue, and the method of recognition (in millions):

	Over time	Point in time	Three Months Ended September 30,		Nine Months Ended September 30,	
			2025	2024	2025	2024
<b>Gilead collaboration</b>						
License and R&D services	*		\$ 23	\$ 25	\$ 200	\$ 185
Access rights	*		3	5	14	22
<b>Taiho collaboration</b>						
License revenue		*	—	15	—	15
Other	*		—	3	—	10
<b>Total revenues</b>			<b>\$ 26</b>	<b>\$ 48</b>	<b>\$ 214</b>	<b>\$ 232</b>
<b>Total revenues from collaborations</b>			<b>\$ 20</b>	<b>\$ 41</b>	<b>\$ 192</b>	<b>\$ 204</b>
<b>Total revenues from a customer</b>			<b>\$ 6</b>	<b>\$ 7</b>	<b>\$ 22</b>	<b>\$ 28</b>

Revenues from Gilead accounted for 100% and 63% of Total revenues for the three months ended September 30, 2025 and 2024, respectively and 100% and 89% of Total revenues for the nine months ended September 30, 2025 and 2024, respectively.

The following table summarizes the revenue recognized as a result of changes in the deferred revenue balance (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenue recognized from amounts in deferred revenue at the beginning of the period	\$ 26	\$ 33	\$ 214	\$ 212

We had \$105 million and \$319 million of deferred revenue remaining on our Condensed Consolidated Balance Sheets at September 30, 2025 and December 31, 2024, respectively, allocated between current and noncurrent based on the expected timing of future recognition.

#### ***Revenue from the Gilead Collaboration***

In the first quarter 2025, we decided to pause future development of etrumadenant. In June 2025, Gilead terminated its rights to etrumadenant (the adenosine receptor antagonist program). We determined that this was a significant reduction in the scope of the arrangement, which met the accounting definition of a contract modification. As a result, we accounted for this as both a modification of the existing contract and the creation of a new contract. Under the applicable accounting rules for such contract modifications, we did not adjust the accounting for completed performance obligations that were distinct from the modified goods or services. Accordingly, we allocated the updated transaction price of \$256 million, which was comprised of the deferred revenue remaining as of the modification date, to the remaining unsatisfied and partially satisfied performance obligations and updated the measure of progress as of the modification date, which resulted in a cumulative catch-up to revenue of \$143 million. This cumulative catch-up reduced net loss per share, basic and diluted, in the nine months ended September 30, 2025 by \$1.38. See Note 3, Related party - Gilead Sciences, Inc., for more information.

The following table summarizes the allocation of the updated transaction price to the remaining unsatisfied and partially satisfied performance obligations (in millions):

Allocation to performance obligations	Distinct	Combined	Amount
License and R&D services		*	\$ 192
R&D services	*		17
Access rights and option continuation periods	*		30
Rights to certain studies	*		17
Total allocated transaction price			\$ 256

We account for these performance obligations as follows:

#### ***License and R&D Services - Etrumadenant, Quemliclustat and Domvanalimab***

Under the Gilead Collaboration Agreement, Gilead obtained options to the exclusive rights: to our adenosine receptor antagonist program, etrumadenant; to our CD73 program, quemliclustat; and to our anti-TIGIT program, domvanalimab and AB308. Effective December 2021, under the First Gilead Collaboration Agreement Amendment, Gilead exercised these options and obtained exclusive licenses to these programs for a total non-refundable payment totaling \$725 million.

We determined the standalone selling price of each license using a discounted cash flow method and the R&D services for each program, using an expected cost-plus margin approach. For domvanalimab, we determined that the license was distinct based on an evaluation of the delivery of the license, noting that the program was in the later stages of development and the ongoing R&D services do not significantly modify or customize the related intellectual property. For etrumadenant and quemliclustat programs, we determined that the license and R&D services were combined at the inception of the agreement based on an evaluation of the delivery of the license, due to the early stage of the technology and the specialized nature of our know-how. We recognize the amounts allocated to R&D services for domvanalimab and the combined license and R&D for etrumadenant and quemliclustat as each performance obligation is satisfied, calculated as an estimated percentage of completion based on management's estimated total effort for each program.

Effective June 2025, these performance obligations were partially satisfied and we allocated the updated transaction price to these performance obligations based on their standalone selling prices and adjusted revenue based on an updated measure of progress, which resulted in a cumulative catch-up of revenue of \$143 million.

For the three and nine months ended September 30, 2025, we recognized revenue of \$20 million and \$192 million respectively, (including the cumulative catch-up due to Gilead's termination of its rights to etrumadenant). For the three and nine months ended September 30, 2024, we recognized revenue of \$23 million and \$179 million (including the cumulative catch-up due to the Third Gilead Collaboration Agreement Amendment executed in the first quarter 2024), respectively. This was recognized within License and development services revenue in our Condensed Consolidated Statements of Operations.

*Access Rights and Option Continuation Periods*

Under the Gilead Collaboration Agreement entered into in 2020 and related amendments, Gilead has exclusive access to our current programs as well as future programs for a period of ten years, contingent upon option continuation payments totaling \$300 million, consisting of a \$100 million payment on each of the fourth (paid in July 2024), sixth, and eighth anniversaries of the Gilead Collaboration Agreement.

The standalone selling price of the ongoing R&D pipeline access and the option continuation material rights were determined using an expected cost-plus margin approach, with the option continuation material rights probability-adjusted for the likelihood of exercise. We use a time-elapsed input method to measure progress toward satisfying the access rights performance obligation, which is the method we believe most faithfully depicts our performance in transferring the promised services during the time period in which Gilead has access to our R&D pipeline. Accordingly, the revenue allocated to the initial four-year access rights performance obligation was recognized using this input method over the remaining period through July 2024, and for the fourth anniversary access rights continuation, over the two-year period commencing July 2024. For the remaining access rights option continuation periods commencing on the sixth, and eighth anniversaries of the agreement, if Gilead elects to exercise their option, we will recognize the revenue allocated to that option together with the \$100 million continuation payment over the new minimum access period or immediately if the option lapses.

For the three and nine months ended September 30, 2025, we recognized revenue of \$3 million and \$14 million respectively. For the three and nine months ended September 30, 2024, we recognized revenue of \$5 million and \$22 million, respectively. This was recognized within Other collaboration revenue in our Condensed Consolidated Statements of Operations.

*Rights to Certain Studies*

Effective January 2024, under the Third Gilead Collaboration Agreement Amendment, we will solely fund certain studies, but Gilead retains exclusive rights to reinstate into the collaboration each study at specified time-points for a payment.

We have determined that these are material rights and we estimated the standalone selling price of these performance obligations using a discounted cash flow method probability-adjusted for the likelihood of exercise. We will recognize the amount allocated to each right if and when the related study is reinstated into the parties' co-development plans or if the option lapses.

As of September 30, 2025, we have \$17 million of deferred revenue on our Condensed Consolidated Balance Sheet related to these performance obligations.

*R&D Services - Inflammation Programs*

In May 2023, we entered into the Second Gilead Collaboration Agreement Amendment pursuant to which we expanded our collaboration to provide Gilead with options to license up to four jointly selected research-stage programs that target inflammatory diseases for which we will lead discovery and early development activities, see Note 3, Related party - Gilead Sciences, Inc., for more information. In 2023, we received a total upfront payment of \$35 million for an initial two jointly selected research-stage programs. We determined that the Second Gilead Collaboration Agreement Amendment represented a separate contract.

We determined that we have two separate distinct performance obligations to perform R&D services for Gilead related to discovery and early development activities for each research program for which they have made an upfront payment and, at the amendment closing date, we allocated the transaction price of \$35 million equally to the two performance obligations created by this amendment based upon their standalone selling prices. The standalone selling prices of these obligations were determined using an expected cost-plus margin approach. We recognize the amounts allocated to these services as the performance obligation is satisfied, calculated as an estimated percentage of completion based on management's estimated total effort for the program. The options to acquire additional licenses or services did not result in additional performance obligations because they did not provide a material right at contract inception, primarily due to the very early stages of the programs.

For the three and nine months ended September 30, 2025, we recognized revenue of \$3 million and \$8 million respectively. For the three and nine months ended September 30, 2024, we recognized revenue of \$2 million and \$6 million, respectively. This was recognized in Other collaboration revenue in our Condensed Consolidated Statements of Operations.

**Note 6. Income taxes**

The income tax provision or benefit for interim periods is determined using an estimate of our annual effective tax rate, adjusted for discrete items, if any, that are taken into consideration in the relevant period. Each quarter, we update the estimate of the annual effective tax rate, and if the estimated tax rate changes, we record a cumulative adjustment to the provision or benefit.

The One Big Beautiful Bill Act of 2025 ("OBBBA") was enacted on July 4, 2025. The OBBBA contains several changes to corporate taxation, including permanent repeal of the requirement to capitalize domestic research and experimental expenditures for federal income tax purposes for taxable years beginning after December 31, 2024. The OBBBA does not materially impact the Company's effective tax rate or cash flows in the current fiscal year.

We did not record a provision for income taxes for the three and nine months ended September 30, 2025 and 2024 because of forecasted full year net operating losses ("NOLs"), which consider the timing of recognition of deferred revenue for tax purposes and the effects of the option to capitalize and amortize U.S. R&D expenses as allowed by the OBBBA. The effective tax rate differs from the U.S. statutory tax rate primarily due to the valuation allowances on our deferred tax assets and state income taxes.

As of September 30, 2025 and December 31, 2024, we have provided a valuation allowance against U.S. federal and state deferred tax assets. We continue to evaluate the realizability of deferred tax assets and the related valuation allowance. If our assessment of the deferred tax assets or the corresponding valuation allowance were to change, we would record the related adjustment to income during the period in which we make the determination.

We recognize interest and penalties associated with uncertain tax benefits as part of the income tax provision. To date, we have not recognized any interest and penalties, nor have we accrued for or made payments for interest and penalties.

We have not been audited by the Internal Revenue Service, any state, or foreign tax authority. We are subject to taxation in the U.S. and in Australia. Due to NOLs and research credit carryforwards, all of our tax years, from 2015 to 2024, remain open to U.S. federal and California state tax examinations. In addition, our fiscal years from 2020 to 2024 are open to examination in Australia.

**Note 7. Net loss per share**

The following table summarizes potentially dilutive securities excluded from the computation of diluted net loss per share calculations because they would have been antidilutive (in millions):

	September 30, 2025	September 30, 2024
Common stock options issued and outstanding	17.3	15.5
Restricted stock units issued	3.9	3.0
Employee stock purchase plan shares	0.2	0.2
Total potential dilutive securities	21.4	18.7

We have also excluded the effect of Gilead's right to purchase additional shares of our common stock which expired in July 2025, from the calculation as these rights had no intrinsic value at September 30, 2024.

**Note 8. Stock-based compensation**
**Stock-based Compensation Expense**

The following table reflects the components of stock-based compensation expense recognized in our Condensed Consolidated Statements of Operations (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Research and development	\$ 7	\$ 9	\$ 23	\$ 29
General and administrative	7	10	22	30
Total stock-based compensation	\$ 14	\$ 19	\$ 45	\$ 59

**Note 9. Cash, cash equivalents and marketable securities**

The following table summarizes the amortized cost, gross unrealized gains and losses and the fair value of our cash, cash equivalents and marketable securities, all of which are considered available for sale, by type of securities (in millions):

Types of securities as of September 30, 2025	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Money market funds	\$ 171	\$ —	\$ —	\$ 171
U.S. treasury securities	246	—	—	246
Corporate securities and commercial paper	406	—	—	406
Certificate of deposit	18	—	—	18
Total cash, cash equivalents and marketable securities	\$ 841	\$ —	\$ —	\$ 841

Types of securities as of December 31, 2024	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
Money market funds	\$ 120	\$ —	\$ —	\$ 120
U.S. treasury securities	251	—	—	251
Corporate securities and commercial paper	592	—	—	592
U.S. government agency securities	5	—	—	5
Certificate of deposit	24	—	—	24
Total cash, cash equivalents and marketable securities	\$ 992	\$ —	\$ —	\$ 992

The following table summarizes the fair values of our cash, cash equivalents and marketable securities by location in the Condensed Consolidated Balance Sheets and contractual maturity (in millions):

Location in Condensed Consolidated Balance Sheets	Contractual Maturity	September 30, 2025	December 31, 2024
Cash and cash equivalents	—	\$ 238	\$ 150
Marketable securities	Within one year	593	828
Long-term marketable securities	Between one and three years	10	14
Total cash, cash equivalents and marketable securities		\$ 841	\$ 992

Realized gains or losses recognized on the sale of available-for-sale marketable securities were not material for the three and nine months ended September 30, 2025 and 2024 and are included in Interest and other income, net, in the Condensed Consolidated Statements of Operations. The cost of a security sold is determined using the specific-identification method.

We limit the credit risk associated with our investments by placing them with banks and institutions we believe are highly credit worthy and investing in highly rated investments. We held a total of 21 and 54 positions in securities which were in unrealized loss positions as of September 30, 2025 and December 31, 2024, respectively, which were immaterial individually and in aggregate. We do not intend to sell our securities with unrealized loss positions and have concluded we will not be required to sell the securities before recovery of the amortized cost for the investment at maturity. No credit related losses have been recognized for any of the periods presented.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash within the Condensed Consolidated Balance Sheets to the total shown in the Condensed Consolidated Statements of Cash Flows (in millions):

	As of September 30,	
	2025	2024
Cash and cash equivalents	\$ 238	\$ 201
Restricted cash (included in Other noncurrent assets)	3	3
<b>Total cash, cash equivalents and restricted cash</b>	<b>\$ 241</b>	<b>\$ 204</b>

Restricted cash at September 30, 2025 and 2024 represents cash balances held as security in connection with our facility lease agreements.

#### Note 10. Condensed consolidated balance sheet components

##### *Prepaid Expenses and Other Current Assets*

Prepaid expenses and other current assets consisted of the following (in millions):

	September 30, 2025	December 31, 2024
Prepaid expenses and other assets	\$ 12	\$ 13
Accrued interest receivable	3	5
<b>Total prepaid expenses and other current assets</b>	<b>\$ 15</b>	<b>\$ 18</b>

##### *Other Current Liabilities*

Other current liabilities consisted of the following (in millions):

	September 30, 2025	December 31, 2024
Accrued research and development	\$ 84	\$ 65
Accrued personnel expenses	28	31
Current portion of lease liabilities	13	12
Other	16	15
<b>Total other current liabilities</b>	<b>\$ 141</b>	<b>\$ 123</b>

#### Note 11. Long-term debt

The following table summarizes our borrowings (in millions):

	September 30, 2025	December 31, 2024
Long-term debt, non-current (Contractual maturity 2029)	\$ 100	\$ 50
Unamortized discounts, issuance costs and payment-in-kind interest, net	(2)	(2)
<b>Total long-term debt</b>	<b>\$ 98</b>	<b>\$ 48</b>

On August 27, 2024, we and Hercules Capital, Inc. ("Hercules") entered into a loan and security agreement (the "Hercules Agreement"), under which Hercules agreed to lend us up to \$250 million in term loans in various tranches subject to minimum draw requirements for each tranche. Under the terms of this agreement, \$50 million was drawn at closing and \$50 million was drawn in the second quarter 2025, with an additional \$50 million committed and fully available at our sole option in minimum increments of \$25 million. A second tranche of \$100 million will be available subject to future approval by Hercules.

The term loans have an interest only period for the first 48 months from the agreement date and bear cash interest at a rate equal to the greater of (i) 10.45% or (ii) the prime rate plus 1.95%. The agreement allows us to defer up to 2.0% of the cash interest as payment-in-kind interest which is added to the principal at a 1.10 multiple and effective July 1, 2025, we have elected the maximum payment-in-kind deferral.

The aggregate future minimum payments due under the Hercules Agreement, including principal payments, payment-in-kind interest incurred to date, and the end of term charge, are as follows (in millions):

<b>Maturity Date</b>	<b>Amount</b>	
2028	\$	30
2029		78
Total payments	\$	108

During the three and nine months ended September 30, 2025, we recognized \$4 million and \$7 million of interest expense, respectively. During the three and nine months ended September 30, 2024, we recognized \$1 million of interest expense. The effective interest rate of the debt, including payment-in-kind interest, amortization of the debt discount, and issuance costs, was 13.08% commencing with the quarter ended September 30, 2025 compared to 13.39% for the quarters ended March 31, 2025 and prior.

## **Note 12. Leases**

The following table summarizes our cash and non-cash information related to our operating leases (in millions):

	<b>Nine Months Ended September 30,</b>	
	<b>2025</b>	<b>2024</b>
Cash paid for amounts included in measurement of lease liabilities	\$ 13	\$ 12

In the first quarter 2024, we evaluated our plans for a portion of our office space that we expected to sublease, and identified indicators of impairment to certain right-of-use assets associated with the leased space where the asset value was determined to be non-recoverable based upon a discounted cash flow analysis, resulting in an impairment charge of \$20 million for the three months ended March 31, 2024 and the nine months ended September 30, 2024.

As of September 30, 2025 and December 31, 2024, we have provided deposits for letters of credit totaling \$3 million to secure our obligations under our leases, which are included in Other noncurrent assets on the Condensed Consolidated Balance Sheets.

## **Note 13. Stockholders' equity**

### **Common Stock**

#### *Gilead Stock Purchase Agreement*

In the first quarter 2024, under the Third Stock Purchase Agreement Amendment, Gilead purchased 15.2 million shares of our common stock at a price of \$21.00 per share for total gross proceeds of \$320 million. Of the \$320 million equity investment, \$87 million was determined to be a premium on the purchase of common stock and allocated to the performance obligations created by the Third Gilead Collaboration Agreement Amendment, see Note 5, Revenues, for more information. Net proceeds from Gilead's equity investment were \$228 million after allocating the premium and deducting direct offering expenses of \$5 million.

#### *Underwritten Offering*

In the first quarter 2025, we sold through an underwritten offering, 13.6 million shares of our common stock at a price per share of \$11.00, for total gross proceeds of approximately \$150 million, before deducting underwriting discounts, commissions and offering expenses. As part of this underwritten offering, Gilead purchased 1.4 million shares of our common stock for total gross proceeds of \$15 million.

#### *At-the-Market Facility*

In the third quarter 2025, we issued and sold under our equity distribution agreement 0.6 million shares of our common stock for total gross and net proceeds of \$8 million.

**Note 14. Fair value measurements**

We determine the fair value of financial and non-financial assets and liabilities using the fair value hierarchy, which establishes three levels of inputs that may be used to measure fair value, as follows:

- Level 1 inputs include unadjusted quoted prices in active markets for identical assets or liabilities;
- Level 2 inputs include observable inputs other than Level 1 inputs, such as quoted prices for similar assets or liabilities; quoted prices for identical or similar assets or liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability; and
- Level 3 inputs include unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the underlying asset or liability. Our Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies or similar valuation techniques and significant management judgment or estimation.

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

The following tables summarize the types of assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy (in millions):

Fair value measurement as of September 30, 2025	Level 1	Level 2	Level 3	Total
<b>Assets</b>				
Money market funds	\$ 171	\$ —	\$ —	\$ 171
U.S. treasury securities	—	246	—	246
Corporate securities and commercial paper	—	406	—	406
Certificate of deposit	—	18	—	18
Total assets measured at fair value	\$ 171	\$ 670	\$ —	\$ 841
<b>Fair value measurement as of December 31, 2024</b>				
Fair value measurement as of December 31, 2024	Level 1	Level 2	Level 3	Total
<b>Assets</b>				
Money market funds	\$ 120	\$ —	\$ —	\$ 120
U.S. treasury securities	—	251	—	251
Corporate securities and commercial paper	—	592	—	592
U.S. government agency obligations	—	5	—	5
Certificate of deposit	—	24	—	24
Total assets measured at fair value	\$ 120	\$ 872	\$ —	\$ 992
<b>Liabilities</b>				
Liability for sale of future royalties	\$ —	\$ —	\$ 21	\$ 21
Total liabilities measured at fair value	\$ —	\$ —	\$ 21	\$ 21

**Liability for sale of future royalties**

In 2021, we entered into an agreement with BVF Partners L.P. ("BVF"), under which BVF funded the discovery and development of compounds for the treatment of inflammatory diseases (the "BVF Program") for \$15 million in non-refundable payments. In return, we were obligated to: perform R&D activities in the BVF Program; make contingent payments upon the achievement of certain clinical and regulatory milestones; and pay mid- to high-single digit royalties on any net product sales generated by this program. We account for the BVF agreement as a liability primarily because at the time the agreement was entered into we had significant continuing involvement in generating the cash flows due to BVF.

During the first quarter 2025, new preclinical information led to the decision to discontinue the BVF Program which decreased the likelihood of achieving regulatory and commercial success. These changes in assumptions are accounted for prospectively, resulting in the amortization of the net carrying amount of the liability to the initial carrying amount of \$15 million using an imputed effective interest rate of negative 6.1%, on the unamortized portion of the liability, which will be applied until there is a change in future cash flow expectations or the debt is legally extinguished. The imputed effective interest for periods shown prior to first quarter 2025 was 10.1%. Changes in this liability related to interest accretion are recognized in Non-operating income (expense) in the Condensed Consolidated Statements of Operations. The liability for sale of future royalties is reflected at the unamortized carrying amount and thus is no longer considered to be at fair value commencing the first quarter 2025, with the estimated fair value being immaterial.

The liability is reported in Other noncurrent liabilities in the Condensed Consolidated Balance Sheets and changes were as follows (in millions):

	Nine Months Ended September 30,	
	2025	2024
Beginning balance	\$ 21	\$ 19
Interest accretion	—	2
Ending balance	<u>\$ 21</u>	<u>\$ 21</u>

### Long-term debt

As of September 30, 2025, the estimated fair value of our long-term debt approximated the carrying amount. The fair value of the long-term debt was estimated for disclosure purposes only and was determined based on other inputs that are observable, and thus categorized as Level 2 in the fair value hierarchy.

### Note 15. Business segment

We operate and manage our business as one reportable and operating segment, which is the business of developing and commercializing highly differentiated therapies that have a meaningful impact on patients. Our chief operating decision maker ("CODM") is the Chief Executive Officer, who decides how to allocate resources and assesses segment performance based on the net loss reported in the Condensed Consolidated Statements of Operations.

The table below is a summary of the segment net loss, including significant segment expenses (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Total revenues	26	48	214	232
Less:				
Late-stage development programs <sup>(1)</sup>	78	69	207	196
Early-stage development and preclinical programs <sup>(2)</sup>	33	34	113	92
Compensation and personnel costs	59	62	187	190
Depreciation and amortization	2	2	7	7
Impairment of long-lived assets	—	—	—	20
Interest income, net	(7)	(13)	(25)	(38)
Income tax expense	—	—	—	—
Other segment items <sup>(3)</sup>	24	23	71	68
Partnership reimbursements	(28)	(37)	(99)	(114)
Segment and Consolidated net loss	<u>\$ (135)</u>	<u>\$ (92)</u>	<u>\$ (247)</u>	<u>\$ (189)</u>

(1) R&D expenses incurred related to a Phase 3 clinical program intended to result in registration of a new product. This includes all unallocated program-level expense not directly attributable to a specific clinical trial once a molecule enters into one or more Phase 3 clinical trials.

(2) R&D expenses incurred for activities ranging from early-stage development and preclinical to Phase 2 clinical trials. This includes all unallocated program-level expense not directly attributable to a specific clinical trial unless the related program has entered into one or more Phase 3 clinical trials.

(3) Other segment items includes non-allocated program costs and other G&A costs.

Total segment assets at September 30, 2025 and 2024 were \$1.0 billion and \$1.3 billion, respectively.

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

*You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited Condensed Consolidated Financial Statements and related notes in Part I, Item 1 of this Quarterly Report on Form 10-Q and with our audited Consolidated Financial Statements and related notes thereto for the year ended December 31, 2024, included in our Annual Report on Form 10-K filed with the SEC on February 25, 2025.*

### **Forward Looking Statements and Website Information**

The discussion contained herein and other parts of this report contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations, and intentions. The words "believe," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect," "could," "plan," "potential," "predict," "seek," "should," "would", "advance", "future", "prepare" or the negative version of these words and similar expressions are intended to identify forward-looking statements. Such statements reflect our beliefs and opinions on the relevant subject based upon information available to us as of the date of this Quarterly Report on Form 10-Q. While we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. Our actual results could differ materially from those discussed in these forward-looking and other statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this report titled "Risk Factors."

We intend to use our website [www.arcusbio.com](http://www.arcusbio.com) as a means of disclosing material non-public information and for complying with our disclosure obligations under the Regulation FD. Such disclosures will be included on the company's website under the heading "Investors & Media." Accordingly, investors should monitor such portions of the company's website, in addition to following the company's press releases, SEC filings and public conference calls and webcasts (if any). The information contained on, or that may be accessed through our website is not part of, and is not incorporated into, this Quarterly Report on Form 10-Q.

### **Overview**

We are a clinical-stage biopharmaceutical company focused on creating best-in-class therapies. Using our robust and highly efficient drug discovery capability, we have created a significant portfolio of investigational products which are in clinical development, with our most advanced molecule, an anti-TIGIT antibody, now in multiple Phase 3 registrational studies targeting lung and GI cancers. Our deep portfolio of novel small molecules and enabling antibodies allows us to create highly differentiated therapies, which we are developing to treat multiple large indications. We expect our clinical-stage portfolio to continue to expand and to include molecules targeting immuno-oncology ("IO"), cancer cell-intrinsic and immunological pathways. Our vision is to create, develop and commercialize highly differentiated therapies that have a meaningful impact on patients.

### **Our Clinical Product Portfolio**

We currently have seven clinical programs focused on unique targets including HIF-2 $\alpha$ , TIGIT, PD-1, adenosine A2a and A2b receptors, CD73, CD39, and AXL. In 2020, we entered into the Gilead Collaboration Agreement with Gilead to strategically advance our portfolio through a collaborative relationship. The Gilead Collaboration Agreement and subsequent amendments provide Gilead with exclusive licenses to our anti-PD-1 program (including zimberelimab), anti-TIGIT program (including domvanalimab) and CD73 program (including quemliclustat). They also have time-limited exclusive option rights to our clinical programs. In the second quarter 2025, Gilead returned its license to the adenosine receptor antagonist program (including etrumadenant). Our HIF-2 $\alpha$  program (including casdatifan) is no longer subject to Gilead's option under the Gilead Collaboration Agreement and Gilead has no further rights to the program.

The following chart summarizes our current clinical pipeline:

Molecule	Indication	Study	Line & Regimen	Phase 1	Phase 1b	Phase 2	Phase 3
<b>CASDATIFAN (CAS)</b> <small>HIF-2<math>\alpha</math> INHIBITOR</small>	KIDNEY CANCER	<b>PEAK-1</b>	Post-IO cas + cabo vs. cabo	[Progress bar: Phase 1, Phase 1b, Phase 2]			
	KIDNEY CANCER	<b>eVOLVE</b>	1L PIb: cas + volru P3: cas + volru vs volru vs nivo + ipi	[Progress bar: Phase 1]			
	KIDNEY CANCER	<b>ARC-20</b>	1L, 2L+ cas, cas + cabo, cas + zim	[Progress bar: Phase 1]			
<b>DOMVANALIMAB (DOM)*</b> <small>PD-1 SILENT ANTI-TIGIT ANTIBODY</small>	GASTROINTESTINAL CANCER	<b>STAR-221</b>	1L dom + zim + chemo vs. nivo + chemo	[Progress bar: Phase 1, Phase 1b, Phase 2]			
	GASTROINTESTINAL CANCER	<b>EDGE-Gastric</b>	1L dom $\pm$ zim $\pm$ FOLFOX	[Progress bar: Phase 1, Phase 1b]			
	LUNG CANCER	<b>STAR-121</b>	1L dom + zim + chemo vs. pembro + chemo	[Progress bar: Phase 1, Phase 1b, Phase 2]			
	LUNG CANCER	<b>PACIFIC-8</b>	Stage III, unresectable, PD-L1 $\geq$ 1% dom + durvalumab vs. durvalumab	[Progress bar: Phase 1, Phase 1b, Phase 2]			
	LUNG CANCER	<b>EDGE-Lung</b>	1L dom + zim $\pm$ quemli $\pm$ chemo	[Progress bar: Phase 1, Phase 1b]			
	LUNG CANCER	<b>VELOCITY-Lung</b>	1L, 2L dom $\pm$ zim $\pm$ sacituzumab govitecan	[Progress bar: Phase 1, Phase 1b]			
<b>QUEMLICLUSTAT (QUEMLI)*</b> <small>CD73 INHIBITOR SMALL MOLECULE</small>	PANCREATIC CANCER	<b>PRISM-1</b>	1L quemli + gem/nab-pac vs. gem/nab-pac	[Progress bar: Phase 1, Phase 1b, Phase 2]			
	LUNG CANCER	<b>EDGE-Lung</b>	1L dom + zim $\pm$ quemli $\pm$ chemo	[Progress bar: Phase 1, Phase 1b]			
<b>AB598</b> <small>ANTI-CD39</small>	GASTROINTESTINAL CANCER	<b>ARC-25</b>	1L AB598 + zim + chemo	[Progress bar: Phase 1, Phase 1b]			
<b>AB801</b> <small>AXL INHIBITOR</small>	LUNG CANCER	<b>ARC-27</b>	2L+ AB801 + chemo	[Progress bar: Phase 1, Phase 1b]			

cabo: cabozantinib; cas: casdatifan; chemo: chemotherapy; dom: domvanalimab; gem/nab-pac: gemcitabine/nab-paclitaxel; IO: immuno-oncology; ipi: ipilimumab; nivo: nivolumab; pembro: pembrolizumab; quemli: quemliclustat; rego: regorafenib; volru: volrustomig; zanza: zanzalintinib; zim: zimberelimab.

\* Gilead and Arcus co-develop globally and share co-commercialization rights in the U.S. for domvanalimab, zimberelimab and quemliclustat. Gilead holds commercialization rights outside of the U.S. subject to any third-party rights.

\*\*+/- biologic, e.g. bevacizumab or biosimilar, will be included for all patients in whom it is not contraindicated.

## Significant Developments

The following is a summary of the recent significant developments affecting our business:

### *Corporate Developments*

- In October 2025, Taiho exercised its option for an exclusive license to casdatifan, an investigational small molecule HIF-2 $\alpha$  inhibitor, in Japan and certain other territories in Asia (excluding mainland China). In exchange, Taiho will make an option exercise payment to us along with milestone payments upon the achievement of clinical, regulatory and commercialization milestones, and, additionally pay royalties on net sales.

### *HIF-2 $\alpha$ Program (casdatifan)*

- In October 2025, we presented new data for our HIF-2 $\alpha$  inhibitor, casdatifan, across all four monotherapy cohorts (n=121) of the Phase 1/1b ARC-20 study in late-line metastatic kidney cancer, most of whom had progressed on at least two prior lines of therapy, including both an anti-PD-1 and a VEGFR tyrosine kinase inhibitor ("TKI"). At the time of data cut-off (August 15, 2025):
  - For the pooled analysis of all four monotherapy cohorts, with 15.2 months of median follow-up: median progression-free survival ("mPFS") was 12.2 months, the 18-month landmark PFS was 43%, the 12-month landmark PFS was 50% and the confirmed overall response rate ("cORR") was 31%.
  - For the 100mg QD cohort (the Phase 3 PEAK-1 dose and formulation), with 12.4 months of median follow-up: mPFS was not reached, the 18-month landmark PFS was not reached; the 12-month landmark PFS was 60% and the cORR was 35%.
  - No unexpected safety signals were observed at the time of DCO, and casdatifan had an acceptable and manageable safety profile across all doses. Across all four cohorts, one patient discontinued treatment due to anemia, and four patients (3%) discontinued due to hypoxia.
- In October 2025, we announced eVOLVE-RCC02, a Phase 1b/3 study sponsored and operationalized by AstraZeneca, evaluating casdatifan plus volrustomig, AstraZeneca's investigational anti-PD-1/CTLA-4 bispecific antibody, in first-line, metastatic clear cell renal cell carcinoma ("ccRCC"), has paused recruitment.
  - The Phase 1b portion of the study has recruited rapidly and in the context of this rapid enrollment, following observations of potentially immune-mediated adverse events ("AEs"), none of which exceeded Grade 3, a decision was made to temporarily pause recruitment, while continuing to treat participants already enrolled into the study. No grade 4 or 5 events were observed and the majority of AEs were grade 1 or 2.
  - We and AstraZeneca will continue to monitor these participants to further characterize the safety profile of the combination with longer follow-up. These data, along with any discussions with health authorities, will inform next steps for the study.

### *TIGIT Program (domvanalimab)*

- In October 2025, we presented the first overall survival results from Arm A1 of the Phase 2 EDGE-Gastric study in patients with locally advanced unresectable or metastatic gastric, gastroesophageal junction or esophageal adenocarcinoma. At data cutoff (March 3, 2025), safety and efficacy were evaluated in all patients enrolled and treated (n=41) and median study follow-up was 26.4 months.
  - Median overall survival ("mOS") was 26.7 months in the overall patient population, 26.7 months in patients with PD-L1 expression  $\geq 1\%$  as measured by TAP scoring (SP263 assay) and not reached in patients with PD-L1 expression  $\geq 5\%$ .
  - No unexpected safety signals were observed at the time of data cut off. The safety profile of domvanalimab plus zimberelimab and chemotherapy was generally well tolerated and is consistent with that of anti-PD-1 plus chemotherapy.
- Concurrent with our first presentation of this data at European Society for Medical Oncology ("ESMO") congress in October 2025, these data were published in Nature Medicine.

### *Adenosine-Pathway Program (quemliclustat)*

- In October 2025, we announced that we completed enrollment of PRISM-1, a Phase 3 trial of quemliclustat combined with gemcitabine/nab-paclitaxel versus gemcitabine/nab-paclitaxel in first-line metastatic pancreatic ductal adenocarcinoma, within 12 months of study initiation.

## Components of Operating Results

### Revenues

We have not generated any revenue from product sales and do not expect to generate any revenue from product sales for the foreseeable future. All revenue recognized to date has been through research, collaboration and license arrangements with strategic partners.

#### *License and Development Services Revenue*

Our license and development services revenue consists of amounts recognized from the portions of the nonrefundable upfront payments received from Gilead and Taiho and allocated to performance obligations for licenses or R&D activities performed by us as we develop our investigational products under the terms of our collaboration agreements. License and development services revenues are recognized based upon the timing of the delivery of a license or service if delivery is complete, or based on estimates of each performance obligation's percentage of completion at the period end if it is still in process. We calculate percentage of completion as a ratio of effort incurred to date on each performance obligation to the total estimated effort to be incurred to satisfy that performance obligation.

#### *Other Collaboration Revenue*

Other collaboration revenue consists primarily of amounts recognized from the portions of the nonrefundable upfront payments received from Gilead and Taiho and allocated to performance obligations relating to their access to our investigational pipeline or our obligation to perform certain discovery and early development activities. Revenue related to access rights is recognized over the period of access, and revenue related to discovery and early development activities is recognized as the performance obligation is satisfied.

### Operating Expenses

#### *Research and Development Expenses*

Our R&D expenses consist of costs incurred in connection with the R&D of our pipeline programs. These expenses include preclinical and clinical expenses, payroll and personnel expenses, including stock-based compensation for our employees in R&D, laboratory supplies, product licenses, consulting costs, contract research, and depreciation. Shared facility expenses are allocated to functional groups proportionally based on usage. Under certain collaboration agreements we agree to share R&D expenses with our partners. Such cost sharing arrangements may result in receiving reimbursement from our partners or require that we reimburse our partners for qualified expenses. We expense both internal and external R&D costs as they are incurred. We record advance payments for services that will be used or rendered for future R&D activities as prepaid expenses and recognize them as an expense as the related services are performed. We recognize reimbursement for shared costs incurred by us and reimbursed by our partners as a reduction in R&D expense as the underlying costs are incurred.

We do not allocate all our costs by investigational product, as a significant amount of R&D expenses include internal costs, such as payroll and other personnel expenses, and certain external costs that are not recorded at the investigational product level. In particular, with respect to internal costs, several of our departments support multiple R&D programs, and we do not allocate those costs by investigational product.

The level of our future R&D investment will depend on a number of factors and uncertainties, including the breadth of the joint development program agreed to with Gilead for the optioned programs, the outcome of our efforts, and the amount of cost reimbursements or milestone payments we receive from our collaborators. We expect our R&D expenses to peak in 2025 and then decline meaningfully during the next few years as we advance our programs towards regulatory approval. We also expect to advance new programs into the clinic. All of this will require significant growth in our development capabilities and infrastructure. In addition, our joint development programs with Gilead for the optioned molecules are anticipated to include a significant number of later-stage clinical trials, which typically include a larger number of subjects, are of a longer duration and include more geographic regions. As we advance our clinical-stage programs and prepare to seek regulatory approval, we will also need to increase our late-stage manufacturing activities. As a result, we expect our preclinical, clinical, and contract manufacturing expenses to increase significantly relative to what we have incurred to date.

In addition, under our arrangements with WuXi Biologics, Abmuno and AstraZeneca, we may incur additional clinical and regulatory milestone payments based on the development progress of our investigational products. We may also be required to pay royalties in the event of a successful product launch and our receipt of commercial revenues. Therefore, we are unable to predict the timing or the final cost to complete our clinical programs or validation of our manufacturing and supply processes and delays may occur due to numerous factors. Factors that could cause or contribute to delays or additional costs include, but are not limited to, those discussed in "Item 1A. Risk Factors" of the Quarterly Report.

#### *General and Administrative Expenses*

G&A expenses consist principally of personnel-related costs including payroll and stock-based compensation for personnel in executive, finance, human resources, information technology, business and corporate development, and other administrative functions. Shared facility expenses are allocated to functional groups proportionally based on usage. Our G&A expenses also include professional fees for legal, consulting, and accounting services, rent and other facilities costs, fixed asset depreciation, and other general operating expenses not otherwise classified as R&D expenses. We do not receive significant reimbursements of these costs through our collaboration with Gilead. We anticipate that our G&A expenses will be stable for the remainder of this year.

#### *Impairment of Long-Lived Assets*

Impairment charges consist of impairment of right-of-use assets resulting from updated plans in the first quarter 2024 for a portion of our office space.

#### *Non-Operating Income, net*

Non-operating income, net consists primarily of interest earned on our investments in fixed-income marketable securities, interest expense on our loan financing with Hercules and non-cash interest income/expense incurred under the effective interest method on our liability for sale of future royalties to BVF.

### Results of Operations

The following table summarizes our results of operations (in millions):

	Three Months Ended September 30,		Change	Nine Months Ended September 30,		Change
	2025	2024		2025	2024	
<b>Revenues:</b>						
License and development services revenue	\$ 20	\$ 41	(51%)	\$ 192	\$ 204	(6) %
Other collaboration revenue	6	7	(14%)	22	28	(21) %
Total revenues	26	48	(46%)	214	232	(8) %
<b>Operating expenses:</b>						
Research and development	141	123	15%	402	347	16%
General and administrative	27	30	(10%)	84	92	(9%)
Impairment of long-lived assets	—	—	—%	—	20	(100%)
Total operating expenses	168	153	10%	486	459	6%
Loss from operations	(142)	(105)	35%	(272)	(227)	20%
Non-operating income, net	7	13	(46%)	25	38	(34%)
Loss before income taxes	(135)	(92)	47%	(247)	(189)	31%
Income tax expense	—	—	*	—	—	*
Net loss	\$ (135)	\$ (92)	47%	\$ (247)	\$ (189)	31%

\* Not meaningful

#### *Total Revenues*

The decrease in Total revenues for the three months ended September 30, 2025 was primarily driven by the prior year license revenue of \$15 million as a result of Taiho's exercise of its option for quemlielustat in the third quarter 2024 and lower development service revenues from the Gilead Collaboration.

The decrease in Total revenues for the nine months ended September 30, 2025 was primarily driven by lower development services revenue from the Gilead Collaboration and the prior year \$15 million license revenue as a result of Taiho's exercise of its option for quemliclustat in the third quarter 2024. The overall decrease was partially offset by the cumulative catch-up of \$143 million in the second quarter 2025 relating to pausing future development of etrumadenant and Gilead's related return of its license to the program, compared to the prior year cumulative catch-up of \$107 million as a result of the Third Gilead Collaboration Agreement Amendment in the first quarter 2024.

See Note 5, Revenues, to our Condensed Consolidated Financial Statements in Part I, Item 1 of this report for further discussion of the amount and timing of revenues recognized from our license and collaboration agreements.

*Research and Development Expenses*

We group all of our R&D activities and the related expenditures into categories as described below:

Category	Description	Program Level Expenses	Key Clinical Trials
Late-stage development programs	R&D expenses incurred related to a Phase 3 clinical program intended to result in registration of a new product. This includes all unallocated program-level expense not directly attributable to a specific clinical trial once a molecule enters into one or more Phase 3 clinical trials.	domvanalimab zimberelimab quemliclustat** casdatifan**	ARC-10* STAR-121 STAR-221 PACIFIC-8 PEAK-1 PRISM-1
Early-stage development and preclinical programs	R&D expenses incurred for activities ranging from early-stage development and preclinical to Phase 2 clinical trials. This includes all unallocated program-level expense not directly attributable to a specific clinical trial unless the related program has entered into one or more Phase 3 clinical trials.	quemliclustat** casdatifan** etrumadenant AB598 AB801	ARC-7 ARC-8 ARC-9 ARC-20 ARC-25 ARC-26* ARC-27 EDGE-Lung EDGE-Gastric eVOLVE STELLAR-009* VELOCITY-Lung VELOCITY-HNSCC***
Compensation and personnel costs	Internal costs, such as salaries, non-cash stock-based compensation, and other personnel expenses for our R&D employees that are not allocated to specific programs or trials.	—	—
Other costs	Facilities, depreciation, and other external costs that are not recorded at the investigational product level.	—	—
Partnership reimbursements	Reimbursements from our collaboration partners for shared costs incurred by us and recognized as a reduction in R&D expense.	—	—

\* Study discontinued or completed

\*\* Quemliclustat moved from early-stage development and preclinical program to a late-stage development program in the third quarter 2024. Casdatifan moved from early stage development and preclinical to a late-stage development program in the third quarter 2025.

\*\*\* Head and Neck Squamous Cell Carcinoma ("HNSCC")

The following table summarizes our R&D expenses by category (in millions):

Category	Three Months Ended September 30,		Change	Nine Months Ended September 30,		Change
	2025	2024		2025	2024	
Late-stage development programs	\$ 78	\$ 69	13 %	\$ 207	\$ 196	6 %
Early-stage R&D and preclinical programs	33	34	(3)%	113	92	23 %
Compensation and personnel costs	44	44	— %	138	134	3 %
Other costs	14	13	8 %	43	39	10 %
Partnership reimbursements	(28)	(37)	(24)%	(99)	(114)	(13)%
Total research and development	\$ 141	\$ 123	15 %	\$ 402	\$ 347	16 %

The increase in R&D expenses for the three months ended September 30, 2025 was primarily due to costs incurred for our late-stage programs, resulting from increased enrollment and start-up activities for PRISM-1 and PEAK-1 and partially offset by lower costs from STAR-221. Increases in compensation and personnel costs were partially offset by a \$2 million decrease in non-cash stock-based compensation.

The increase in R&D expenses for the nine months ended September 30, 2025 was primarily driven by higher costs in our early-stage development activities, driven by Phase 2 activities for casdatifan, and clinical and manufacturing costs incurred for our late-stage programs, resulting from increased enrollment and start-up activities for PRISM-1 and PEAK-1 and partially offset by lower costs for STAR-221. Increases in compensation and personnel costs were partially offset by a \$6 million decrease in non-cash stock-based compensation.

R&D expense by quarter may fluctuate due to the timing of clinical manufacturing and standard-of-care therapeutic purchases with a corresponding impact on reimbursements. We expect R&D expenses to decline commencing in the fourth quarter 2025 as costs related to the domvanalimab Phase 3 development program decrease significantly.

#### *General and Administrative Expenses*

The decrease in G&A expenses for the three months ended September 30, 2025 was primarily driven by a decrease in compensation and personnel costs driven by a \$3 million decrease in non-cash stock-based compensation, partially offset by an increase in expenses shared under the Gilead Collaboration.

The decrease in G&A expenses for the nine months ended September 30, 2025 was primarily driven by a decrease in compensation and personnel costs driven by a \$8 million decrease in non-cash stock-based compensation, partially offset by an increase in expenses shared under the Gilead Collaboration.

#### *Impairment of Long-Lived Assets*

The impairment expense for the nine months ended September 30, 2024 was due to our 2024 evaluation and sublease of a portion of our office space, resulting in an impairment charge of \$20 million.

#### *Non-Operating Income, net*

The decrease in Non-operating income, net for the three months ended September 30, 2025 as compared to the three months ended September 30, 2024, was primarily due to lower investment yields due to a smaller portfolio of investments and interest expense on our long-term debt agreement which we entered into in the third quarter 2024, with an additional draw in June 2025.

The decrease in Non-operating income, net for the nine months ended September 30, 2025 as compared to the nine months ended September 30, 2024, was primarily due to lower yields due to a smaller portfolio of investments and the interest expense on our long-term debt agreement which we entered into in the third quarter 2024, with an additional draw in June 2025.

#### *Income Tax Expense*

There was no Income tax expense for the three and nine months ended September 30, 2025 or 2024 due to forecasted full year net operating losses.

### **Liquidity and Capital Resources**

Our cash and investments are held in a variety of interest-bearing instruments, including money market funds, U.S. government treasury and agency obligations, investments in corporate securities and certificates of deposit. Based on our existing business plan, we believe that our cash, cash equivalents, marketable securities and existing facilities as of

September 30, 2025 will be sufficient to fund our planned level of operations for a period of at least twelve months following the date of filing of this report and provide funding through our initial pivotal read-outs for domvanalimab, quemliclustat and casdatifan, which include PEAK-1.

### **Sources of Liquidity**

To date, we have financed our operations primarily from the sale of our equity securities, upfront or milestone payments from our research, collaboration and license agreements with our strategic partners including Gilead and debt financing. We will need additional funding to support our continuing operations and pursue our long-term development strategy. Until such time that we can generate significant revenue from sales of our investigational products, if ever, we may finance our operations through the sale of equity, debt financings or other capital sources, including existing or potential collaborations with other companies or other strategic transactions. See "Item 1A. Risk Factors" for a discussion of the factors that could impact our liquidity.

In 2023, we entered into an equity distribution agreement pursuant to which we may, from time to time, sell shares of our common stock having an aggregate offering price of up to \$200 million. See Note 13, Stockholders' equity, in Part I, Item 1, to our Condensed Consolidated Financial Statements for further discussion.

In the first quarter 2024, we amended and restated the Stock Purchase Agreement and sold 15.2 million shares of our common stock to Gilead at a purchase price of \$21.00 per share for total gross proceeds of \$320 million. Of the \$320 million equity investment, \$87 million was determined to be a premium on the purchase of common stock and allocated to the performance obligations created by the Third Gilead Collaboration Agreement Amendment. Gilead acquired an additional 1.4 million shares of our common stock in the February 2025 underwritten offering and subsequently held approximately 29.3% of our outstanding common stock as of September 30, 2025.

In the third quarter 2024, we obtained a \$250 million term loan facility from Hercules. Under the terms of the term loan facility, \$50 million was drawn at closing, \$50 million was drawn in the second quarter 2025 and an additional \$50 million is committed and fully available at our sole option in minimum increments of \$25 million. A second tranche of \$100 million will be available to support strategic initiatives, subject to future approval by Hercules. See Note 11, Long-term debt, in Part I, Item 1, to our Condensed Consolidated Financial Statements for further discussion.

In February 2025, we issued through an underwritten offering, 13.6 million shares of our common stock at a price of \$11.00 per share, for total gross proceeds of approximately \$150 million, before deducting underwriting discounts, commissions and offering expense.

### **Cash Flows**

The following table summarizes our cash flow activities for each of the periods presented below (in millions):

Net cash provided by (used in):	Nine Months Ended September 30,	
	2025	2024
Operating activities	\$ (362)	\$ (70)
Investing activities	\$ 248	\$ (135)
Financing activities	\$ 202	\$ 279

#### *Operating Activities*

Net cash used in operating activities was \$362 million for the nine months ended September 30, 2025 compared to \$70 million for the same period in the prior year. The change in operating cash flows is primarily due to the prior year receipt of the \$87 million allocated to the performance obligations created by the Third Gilead Collaboration Agreement Amendment and the timing of receipts from Taiho for development milestones for STAR-121, STAR-221, and PRISM-1.

#### *Investing Activities*

Cash provided by investing activities for the nine months ended September 30, 2025 was primarily due to net proceeds from marketable securities of \$249 million.

Cash used in investing activities for the nine months ended September 30, 2024 was primarily due to net purchases of marketable securities of \$130 million.

#### *Financing Activities*

Cash provided by financing activities for the nine months ended September 30, 2025 was due to net proceeds of \$150 million from issuance of our common stock, primarily due to the February 2025 underwritten offering, and \$49

million from our borrowings under the Hercules Agreement and proceeds of \$3 million for stock issued under our equity award plans.

Cash provided by financing activities for the nine months ended September 30, 2024 was due to net proceeds of \$228 million from issuance of our common stock to Gilead under the Third Stock Purchase Agreement Amendment, \$47 million from our borrowings under the Hercules Agreement, and proceeds of \$6 million for stock issued under our equity award plans.

### **Contractual Obligations and Commitments**

There have been no material changes to our contractual obligations outside the ordinary course of business during the three months ended September 30, 2025, as compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2024, other than the following:

We are obligated to make principal loan payments and an end of term charge under the loan and security agreement with Hercules that we entered into on August 27, 2024 and under which we drew an additional \$50 million in June 2025. See Note 11 to our Condensed Consolidated Financial Statements in Part I, Item 1 for further discussion.

### **Critical Accounting Judgments and Estimates**

Our Condensed Consolidated Financial Statements have been prepared in accordance with U.S. GAAP. The preparation of these Condensed Consolidated Financial Statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the Condensed Consolidated Financial Statements, as well as the reported revenue and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in the notes to our Condensed Consolidated Financial Statements and our Annual Report on Form 10-K filed with the SEC on February 25, 2025, we believe that the accounting policy discussed below is critical to understanding our historical and future performance, as this policy relates to the more significant areas involving management's significant judgments and estimates.

#### ***Revenue Recognition***

##### *Standalone selling price*

As part of the accounting for contracts with customers, we develop assumptions that require judgment to determine the standalone selling price of each performance obligation identified in the contract.

In the first quarter 2025, we decided to pause future development of etrumadenant. In June 2025, Gilead terminated its rights to etrumadenant (the adenosine receptor antagonist program). We determined that this was a significant reduction in the scope of the arrangement, which met the definition of a contract modification. We accounted for this contract modification as both a modification of the existing contract and the creation of a new contract. (See Note 5, Revenues, in Part I, Item 1 for further discussion). We determined the standalone selling price of certain performance obligations and allocated the total transaction price to each performance obligation on a relative standalone selling price basis. The estimation of the standalone selling price included estimates for forecasted costs, development timelines, discount rates, and probabilities of technical and regulatory success.

Under the applicable accounting rules for such contract modifications, we did not adjust the accounting for completed performance obligations that were distinct from the modified goods or services. However, we were required to adjust revenue previously recognized to reflect the effect of the contract modification due to the updated transaction price allocated to the partially satisfied performance obligations and the updated measure of progress as of the modification date. Accordingly, we recognized a cumulative catch-up to revenue of \$143 million based on the updated transaction price and measure of progress for the partially satisfied performance obligations.

A hypothetical 10% change in the updated standalone selling prices or the updated measure of progress as of the modification date related to Third Gilead Collaboration Agreement Amendment would have changed the cumulative catch-up to revenue recognized during the current quarter and year to date period by as much as \$3 million.

##### *Changes in total estimated effort*

Revenue related to certain performance obligations that are satisfied over time could be materially impacted as a result of changes in the total estimated effort required to satisfy those obligations.

For example, if we are unable to advance an investigational product to regulatory approval or if we and Gilead agree to terminate joint development of an investigational product, this could result in a decrease in the estimated effort and cost of satisfying the related performance obligation as well as an increase in the estimated percentage of completion and a corresponding cumulative catch-up adjustment to revenue. In contrast, development delays or increases in the total effort required to advance an investigation product could result in a decrease in the estimated percentage of completion and a corresponding reversal of revenue. At September 30, 2025, we had \$105 million in deferred revenue related to upfront cash payments for certain performance obligations related to R&D programs that are satisfied over time, of which a substantial amount would be recognized if we were unable to advance the underlying investigational product to regulatory approval or if we and Gilead were to agree to terminate development of the underlying investigational product.

A hypothetical 10% change in the total estimated effort required to satisfy, R&D activities or combined license and R&D activities, performance obligations under our agreements would have changed the related revenue recognized by as much as \$58 million, for both the current quarter and year to date.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from changes in interest rates and foreign currency exchange rates. Our market risks have not changed materially from those discussed in our Annual Report on Form 10-K filed with the SEC on February 25, 2025.

**Item 4. Controls and Procedures.**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Securities Exchange Act of 1934, as amended ("Exchange Act") reports is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met.

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15. Based upon, and as of the date of this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II—OTHER INFORMATION

### Item 1. Legal Proceedings.

We are not currently a party to any material legal proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

### Item 1A. Risk Factors.

*You should consider carefully the following risk factors, together with all the other information in this report, including our Condensed Consolidated Financial Statements and notes thereto, and in our other public filings with the SEC. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described when evaluating our business.*

#### **Risks Related to our Limited Operating History, Financial Position and Capital Requirements**

*We have a history of operating losses, have never generated any revenue from product sales and anticipate that we will continue to incur significant losses for the foreseeable future.*

We are a clinical-stage biopharmaceutical company with a limited operating history that may make it difficult to evaluate the success of our business to date and to assess our future viability. All of our investigational products are in development, and none have been approved for commercial sale, nor have we ever generated any revenue from product sales. Our revenues to date have been primarily from upfront and milestone payments, R&D support and clinical materials reimbursement from our strategic partners. For the nine months ended September 30, 2025 and year ended December 31, 2024, we had net loss of \$247 million and net loss of \$283 million, respectively. As of September 30, 2025, we had an accumulated deficit of \$1.4 billion. While we may receive income from year to year under the Gilead Agreement and the Taiho Agreement, we generally expect to incur substantial and increasing levels of operating losses over the next several years and for the foreseeable future as we advance our investigational products. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

To become and remain profitable on a sustained basis, we must develop and eventually commercialize a product with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our investigational products, obtaining marketing approval for these investigational products, manufacturing, marketing and selling those products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in these activities, and even if we succeed in commercializing one or more of our investigational products, we may never generate revenues that are significant or large enough to achieve sustained profitability. In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. If we do achieve profitability from product sales, we may not be able to sustain or increase profitability on a quarterly or annual basis, and we will continue to incur substantial R&D and other expenditures to develop and market additional investigational products. Our failure to become and remain profitable on a sustained basis would decrease the value of the company and could impair our ability to raise capital, maintain our R&D efforts, expand our business or continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

*We may need to obtain additional funding. If we do not receive or are unable to raise additional capital when needed, we may be forced to restrict our operations or delay, reduce or eliminate our product development programs.*

The development of biopharmaceutical investigational products is capital intensive. Since our inception, we have used substantial amounts of cash to fund our operations and expect our expenses to increase substantially during the next few years as our investigational products advance through large late-stage or registrational clinical trials. If we obtain marketing approval for any of our investigational products, we expect to incur significant commercialization expenses related to marketing, sales, manufacturing and distribution.

As of September 30, 2025, we had \$841 million of cash, cash equivalents and marketable securities, which, together with our available facilities, we believe will be sufficient to provide funding through our initial pivotal read-outs for domvanalimab, quemliclustat and casdatifan, which include PEAK-1. This is based on disciplined prioritization of our resources to these programs. For example, we have paused further development for etrumadenant in third-line metastatic colorectal cancer to focus our resources on our late stage clinical portfolio and research programs. However, we cannot

guarantee that we will not need additional capital and if so, that we will be able to obtain additional capital in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate some or all of our R&D programs or future commercialization efforts. In addition, if we need and are able to raise additional capital, raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our intellectual property or investigational products. Our future capital requirements will depend on many factors related to the cost and timing of developing our investigational products, including:

- the number, scope, rate of progress and costs of clinical programs and investigational products, as well as drug discovery, preclinical development activities, and laboratory testing;
- the scope of any cost sharing arrangements with our strategic partners;
- the timing and amount of milestone payments and option fees we receive under the Gilead Collaboration Agreement and the Taiho Agreement;
- the cost, timing and outcome of regulatory review of our investigational products; and
- the cost associated with commercializing our investigational products, if they receive marketing approval.

### **Risks Related to the Discovery and Development of our Investigational Products**

*If we are unable to obtain regulatory approval for our investigational products, or experience significant delays in doing so, our business will be materially harmed.*

We have no products approved for sale and our investigational products must be approved by the FDA in the U.S. and similar regulatory authorities outside the U.S., such as the European Medicines Agency ("EMA"), prior to commercialization. The process of obtaining marketing approvals, both in the U.S. and abroad, is expensive and takes many years, if approval is obtained at all, and can vary substantially based upon a variety of factors. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the investigational product's safety and efficacy, or with respect to biological investigational products, safety, purity and potency. Securing marketing approval also requires, among other things, the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities, among other requirements. Our investigational products may not be effective, may be only moderately effective, may not have an acceptable durability of response, may not have an acceptable risk-benefit profile or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining marketing approval or limit their commercial use. Our investigational products may not be approved even if they achieve their primary endpoints in any Phase 3 clinical trials or other registrational trials we or our collaborators conduct.

The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining when or whether marketing approval will be obtained for any of our investigational products. Regulatory authorities 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 an investigational product. 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 also cause delays in or prevent the approval of an application. For example, since a key element of our strategy is the development of intra-portfolio combinations, regulatory authorities may disagree that we have sufficiently demonstrated the contribution of each investigational product or other agent in our combination trials to any observed therapeutic effects and require further studies to further characterize the activity of each component within the combination.

The FDA or comparable regulatory authorities can delay, limit or deny approval of an investigational product for many reasons, including:

- such authorities may disagree with the design or execution of our clinical trials;
- negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance or persuasiveness required by the FDA or comparable foreign regulatory authorities for approval;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our investigational products;

- the population studied in our clinical trials may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- such authorities may not accept clinical data from trials that are conducted at clinical facilities or in countries where the standard of care is potentially different from that of their own country;
- we may be unable to demonstrate that an investigational product's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities may not agree that the data collected from clinical trials of our investigational products are acceptable or sufficient to support the submission of a BLA, new drug application ("NDA") or other submission or to obtain regulatory approval in the U.S. or elsewhere;
- such authorities may disagree with us regarding the formulation, labeling and/or the product specifications of our investigational products;
- such authorities may find deficiencies in the manufacturing processes or facilities of the third-party manufacturers with which we contract for clinical and commercial supplies; or
- such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission.

We may be unable to establish any long-term supply agreements with third-party manufacturers or to do so on acceptable terms, which increases the risk of failing to timely obtain sufficient quantities of our investigational products or such quantities at an acceptable cost.

Even if we are able to obtain marketing approvals for any of our investigational products, those approvals may be for indications that are not as broad as desired or may contain other limitations that would adversely affect our ability to generate revenue from sales of those products. Moreover, if we are not able to differentiate our product against other approved products within the same class of drugs our business would be materially harmed and our ability to generate revenue from that class of drugs would be severely impaired. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that investigational product and would materially adversely impact our business and prospects.

If we experience delays in obtaining approval or if we fail to obtain approval of our investigational products, the commercial prospects for our investigational products may be harmed and our ability to generate revenues will be materially impaired.

***Clinical drug development is a lengthy, expensive and uncertain process. If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our investigational products, if approved, may be delayed and the credibility of our management team may be adversely affected and, as a result, our stock price may decline.***

The R&D of drugs and biological products is an extremely risky industry. Only a small percentage of investigational products that enter the development process ever receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any investigational product, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety, purity, potency and/or efficacy of our investigational products in humans. Clinical testing is expensive, can take many years to complete and its outcome is uncertain.

Further, from time to time, we may provide guidance regarding the expected timing or costs of various scientific, clinical, regulatory and other product development goals; including goals regarding the commencement or completion of, or the availability of data from, scientific studies and clinical trials and the submission of regulatory filings. Any such guidance will be based on a variety of assumptions, such as the rate of events in a trial. The actual timing or cost of these goals can vary dramatically compared to our guidance, in some cases for reasons beyond our control. If we do not meet such guidance the commercialization of our products may be delayed and the credibility of our management team may be adversely affected and, as a result, our stock price may decline.

***The results of preclinical studies and early clinical trials are not always predictive of future results.***

The results of preclinical and early clinical trials of our investigational products and other products with the same mechanism of action may not be predictive of the results of later-stage clinical trials. For example, we have presented data from multiple Phase 2 studies (such as ARC-8 and EDGE-Gastric) that are evaluating the same or similar regimen in the same setting as one of our current or potentially future Phase 3 studies. Data from these Phase 2 studies may not be

predictive of the results of any of our Phase 3 studies even if evaluating the same regimen and setting. Clinical trial failure may result from a multitude of factors including flaws in study design, dose selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing. A number of companies in the biopharmaceutical industry have suffered setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from clinical trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may further delay, limit or prevent marketing approval. In particular, results from uncontrolled trials, meaning trials in which there is no control group such as a placebo group, are inherently difficult to interpret. This difficulty is compounded in clinical trials such as ours, in which two or more investigational products that have not yet been approved are being evaluated. Accordingly, the data generated during preclinical or early clinical trials evaluating our investigational products may not be predictive of future clinical trial results for these or other investigational products when studied in a randomized environment or larger patient populations or with different study designs.

***Any difficulties or delays in the commencement or completion, or the termination or suspension, of our current or planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue or adversely affect our commercial prospects.***

Before obtaining approval from regulatory authorities for the commercialization of any of our investigational products, we must conduct extensive clinical trials to demonstrate the safety, purity, potency, or efficacy of the investigational candidate in humans. Before we can initiate clinical trials for any investigational products in the U.S. or in other jurisdictions, we must submit the results of preclinical studies to the FDA or comparable regulatory authorities along with other information, including information about the investigational product's chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory submission. The FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies for any investigational product before it allows us to initiate clinical trials under any IND or similar regulatory submission, which may lead to delays and increase the costs of our preclinical development programs. Moreover, even if we commence clinical trials, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Any such delays in the commencement or completion of our ongoing and planned clinical trials for our investigational products could significantly affect our product development timelines and product development costs and harm our financial position.

We do not know whether our planned clinical trials will begin on time or be completed on schedule, if at all. The timing for commencement, data readouts and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- obtaining allowance or approval from regulatory authorities to commence a trial or reaching a consensus with regulatory authorities on trial design;
- the FDA or comparable foreign regulatory authorities disagreeing as to the implementation of our clinical trials;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- obtaining approval from one or more institutional review boards, or ethics committees at clinical trial sites;
- Institutional Review Board ("IRB") refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes or amendments to the clinical trial protocol;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- failure by our CROs to perform in accordance with good clinical practice ("GCP") requirements or applicable regulatory rules and guidelines in other countries;

- manufacturing sufficient quantities of our investigational products, or obtaining sufficient quantities of combination therapies for use in clinical trials;
- subjects failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow-up, including subjects failing to remain in our trials;
- patients choosing an alternative product for the indications for which we are developing our investigational products or participating in competing clinical trials;
- lack of adequate funding to continue a clinical trial or costs being greater than we anticipate;
- subjects experiencing severe or serious unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies that could be considered similar to our investigational products;
- selection of clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;
- or failure of our Contract Manufacturing Organization ("CMO") to produce clinical trial materials in sufficient quantities in accordance with current Good Manufacturing Practice ("cGMP"), regulations or other applicable requirements; and
- third parties being unwilling or unable to satisfy their contractual obligations to us in a timely manner.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or applicable clinical trial protocols, adverse findings from inspections of clinical trial sites by the FDA or comparable foreign regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using an investigational product, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to regulators or to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we continue to do for our investigational products, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled subjects in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, and political and economic risks, including war, relevant to such foreign countries. In addition, many of the factors that cause, or lead to, the termination suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of an investigational product. Any resulting delays to our clinical trials could shorten any period during which we may have the exclusive right to commercialize our investigational products. In such cases, our competitors may be able to bring products to market before we do, and the commercial viability of our investigational products could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects.

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

From time to time, we publish preliminary, topline or interim data from our clinical studies. Such publications are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. For example, topline and preliminary data remain subject to audit confirmation and verification procedures that may result in the final data being materially different from the topline or preliminary data we previously published. Interim data are also subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. As a result, interim, topline and preliminary results that we report may differ from future results of the same studies and should be viewed with caution until the final data are available. As such material changes between previously reported topline, preliminary and interim results and final data could significantly harm our business prospects and our stock price may decline.

***Most of our clinical trials are open-label studies and may be susceptible to bias.***

Most of our clinical trials, including some of our Phase 3 trials, are open-label studies in which both the patient and investigator know whether the patient is receiving the investigational products or either an existing approved drug or placebo. Open-label clinical trials are susceptible to bias that may exaggerate any therapeutic effect or overestimate the risk associated with the investigational product. Patients may perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Investigators may interpret the information of the treated group more favorably given their awareness of the treatment regimen or may attribute safety risks to the investigational product. If regulatory agencies feel that we have not implemented sufficient controls to prevent such biases or that the controls we have implemented were ineffective, we may experience delays or negative outcomes in our applications for drug approval. In addition, the FDA and other regulatory authorities may disfavor the use of open-studies, or otherwise not agree that the results from open-label studies, regardless of outcome, will support submission of an application for marketing approval in the indications we are targeting, and we may be required to conduct randomized trials evaluating our investigational products before we are able to obtain marketing approval of our investigational products, if ever.

***Enrollment and retention of subjects in clinical trials is expensive and time consuming and can be made more difficult or rendered impossible by competing treatments, clinical trials of competing investigational products, geopolitical instability and public health epidemics, each of which could result in significant delays and additional costs in our product development activities, or in the failure of such activities.***

We may encounter delays in enrolling, or be unable to enroll and maintain, a sufficient number of subjects to complete any of our clinical trials. Patient enrollment and retention in clinical trials is a significant factor in the timing and cost of clinical trials and depends on many factors, including among other things, the size of the patient population required for analysis of the trial's primary endpoints, the nature of the trial protocol, our ability to recruit clinical trial investigators with the appropriate competencies and experience, the existing body of safety and efficacy data with respect to the investigational product (including data that we report in our other clinical trials using the same investigational products) or with respect to other investigational products with the same mechanism of action as our investigational products, the number and nature of competing products or investigational products and ongoing clinical trials of competing investigational products for the same indication, the proximity of subjects to clinical trial sites, the eligibility criteria for the clinical trial and our ability to obtain and maintain subject consents.

Geopolitical instability and public health outbreaks may also have an adverse impact on our clinical trial operations. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our investigational products. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will have limited influence over their actual performance. Failures in planned subject enrollment or retention may result in increased costs or program delays and could render further development impossible.

***Serious adverse events, undesirable side effects or other unexpected properties of our investigational products may be identified during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our investigational products or limitations on the use of our investigational products or, if discovered following marketing approval, revocation of marketing authorizations or subsequent limitations on the use of our investigational products.***

As we continue to develop our investigational products and initiate clinical trials of additional investigational products, serious adverse events, undesirable side effects or unexpected characteristics may emerge causing us to abandon these investigational products or limit their development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Even if our investigational products initially show promise in early clinical trials, the side effects of drugs are frequently only detectable after they are tested in larger, Phase 3 clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. Sometimes, it can be difficult to determine if the serious adverse or unexpected side effects were caused by the investigational product or another factor, especially in oncology subjects who may suffer from other medical conditions and be taking other medications.

Additionally, adverse developments in clinical trials of investigational products conducted by others or adverse events associated with commercial products offered by others may cause the FDA or other regulatory oversight bodies to suspend or terminate our clinical trials or change the requirements for approval of any of our investigational products, or otherwise adversely affect the clinical and commercial development of our investigational products.

Additionally, if any of our investigational products receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a risk evaluation and mitigation strategy ("REMS") to ensure that the benefits of treatment with such investigational product outweigh the risks, which REMS may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. We may also be required to engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product that we develop.

Other potentially significant negative consequences associated with adverse events include:

- institutional review boards, ethics committees, or safety monitoring committees may recommend that enrollment or dosing be placed on hold or that additional safety measures be implemented for ongoing clinical trials;
- we may be required to suspend marketing of a product, or we may decide to remove such product from the marketplace;
- regulatory authorities may withdraw or change their approvals of a product;
- regulatory authorities may require additional warnings or contraindications on the label or limit access of a product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to create a medication guide outlining the risks of a product for patients, or to conduct post-marketing studies;
- we may be required to change the way a product is dosed, distributed, or administered, or conduct additional clinical trials;
- we may be subject to limitations on how we may promote the product;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients; and
- a product may become less competitive, and our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our investigational products and prevent us from achieving or maintaining market acceptance of our investigational products, if approved by the FDA or other regulatory authorities.

***Adverse findings from clinical trials conducted by third parties investigating the same investigational products as us in different territories or different investigational products directed to the same target as one of our programs could adversely affect our development program.***

Lack of efficacy, adverse events, undesirable side effects, or other adverse findings may emerge in clinical trials conducted by third parties investigating the same investigational products as us in different territories or different investigational products directed to the same target as one of our programs. For example, we and Gloria Biosciences each licensed our rights to the same anti-PD-1 antibody (which we refer to as zimberelimab) from WuXi Biologics. Gloria Biosciences refers to this antibody as GLS-010 and is conducting clinical trials with GLS-010 in China. We have no control over their clinical trials or development program, and adverse findings from the results or their conduct of clinical trials could adversely affect our development of zimberelimab or even the viability of zimberelimab as an investigational product. We may be required to report Gloria Biosciences' adverse events or unexpected side effects to the FDA or comparable foreign regulatory authorities, which could, among other things, order us to cease further development of zimberelimab. We may face similar risks from any independent development conducted with our investigational products by Gilead and Taiho, following any exercise of their respective options to our programs.

Further, we have no control over the clinical trials or development programs of third parties developing investigational products directed to the same target as one of our programs. Adverse findings or clinical trial results from such trials could adversely affect the commercial prospects of our investigational products and cause our stock price to fluctuate or decline.

***A key element of our strategy is the development of intra-portfolio combinations. If we are not successful in discovering, developing and commercializing investigational products that take advantage of different mechanisms of action to***

***achieve superior outcomes relative to the use of single agents or other combination therapies, our ability to achieve our strategic objectives would be impaired.***

A key element of our strategy is to build a broad portfolio of investigational products that will allow for the development of intra-portfolio combinations. We believe that by developing or licensing these investigational products, we can control the combinations we pursue and, if and when approved, maximize the commercial potential of these combinations. However, these combinations have not been tested before and may fail to demonstrate synergistic activity against immunological targets, may fail to achieve superior outcomes relative to the use of single agents or other combination therapies, may exacerbate adverse events associated with one of the investigational products when used as monotherapy, or may fail to demonstrate sufficient safety or efficacy traits in clinical trials to enable us to complete those clinical trials or obtain marketing approval for the combination therapy. Any of these events could delay our programs. In addition, our early clinical trials may test more than one investigational product in uncontrolled studies, and it may be difficult to interpret the results of those uncontrolled trials or evaluate the contribution of each investigational agent in such combination.

Even if we are successful in developing combination therapies, competition from other investigational products in the same class which are either already approved or further along in development than ours may prevent us from realizing the commercial potential of our combination therapies and prevent us from achieving our strategic objectives.

***Development of combination therapies may present more or different challenges than development of single agent therapies.***

Many of our investigational products are being pursued in combination with one or more additional products or investigational products. The development of combination therapies may be more complex than the development of single agent therapies and generally requires that sponsors demonstrate the contribution of each investigational product to the claimed effect and the safety and efficacy of the combination as a whole. This requirement may make the design and conduct of clinical trials more complex, requiring more clinical trial subjects. We also may not be able to meet the FDA's current or future approval standards required for combination therapies or combination products, if we decided to administer or package a combination therapy as a single drug product. For example, under the "combination rule", the FDA may not file or approve a fixed-dose combination product unless each component of a proposed drug product is shown to make a contribution to the claimed effects and the dosage of each component (amount, frequency, duration) is safe and effective for the intended population. To satisfy these requirements, the FDA may recommend we conduct a clinical factorial study, designed to assess the effects attributable to each drug in the combination product. Moreover, the applicable requirements for approval of a combination therapy may differ from country to country.

In the event that one of our investigational products were to fail to demonstrate sufficient safety and efficacy or establish its contribution to the claimed effects of a combination therapies, we would need to identify alternatives. For example, we expect that our anti-PD-1 antibody, zimberelimab, will form the backbone of many of the investigational combination therapies we are pursuing. If we are unable to demonstrate the contribution of zimberelimab to the claimed effects of an investigational combination therapy, we would need to identify an anti-PD-1 antibody for use in such combination therapy. In the event we are unable to do so or are unable to do so on commercially reasonable terms, our business and prospects would be materially harmed.

***Certain of our investigational products may require companion diagnostics in certain indications. Failure to successfully develop, validate and obtain regulatory clearance or approval for such tests could harm our product development strategy or prevent us from realizing the full commercial potential of our investigational products.***

Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as a medical device and may require separate regulatory authorization prior to commercialization of either the companion diagnostic or the relevant investigational product. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. Depending on the data from our clinical trials, we may utilize diagnostic tests, during our clinical trial enrollment process to help identify patients with characteristics that we believe will be most likely to respond to our investigational products. For example, certain clinical trials that we are conducting, such as our STAR-221 trial, use a diagnostic test to measure PD-L1 levels in tumor samples provided by enrolled patients. Our future trials may also use a diagnostic test to help identify eligible patients. In addition, we have significant efforts directed to identifying changes in various cells and proteins to understand their relationship, if any, to the clinical activity observed in our clinical trials and to assess if such cells and/or proteins could be used as predictive biomarkers to select for patients more likely to respond to our investigational products. However, we cannot be certain that we will be able to identify any such biomarkers, that such biomarkers will result in us identifying the appropriate patients for our investigational products or that we or any third-party collaborators will be able to validate any diagnostic tests incorporating any predictive biomarkers we may identify.

We currently do not have any plans to develop diagnostic tests internally. We are therefore dependent on the sustained cooperation and effort of third-party collaborators in developing and, if our investigational products are approved for use only with an approved companion diagnostic test, obtaining approval and commercializing these tests. If these parties are unable to successfully develop and obtain marketing authorization for companion diagnostics for use with any of our investigational products, or experience delays in doing so, the development of our investigational products may be adversely affected and we may not be able to obtain marketing authorization for these investigational products. Furthermore, our ability to market and sell, as well as the commercial success, of any of our investigational products that require a companion diagnostic will be tied to, and dependent upon, the receipt of required regulatory authorization and the continued ability of such third parties to make the companion diagnostic commercially available on reasonable terms in the relevant geographies. Any failure to develop, validate, obtain and maintain marketing authorization and supply for a companion diagnostic we need will harm our business prospects.

***The design or our execution of our ongoing and future clinical trials may not support marketing approval.***

The design or execution of a clinical trial can determine whether its results will support marketing approval, and flaws in the design or execution of a clinical trial may not become apparent until the clinical trial is well advanced. In some instances, there can be significant variability in safety or efficacy results between different trials with the same investigational product due to numerous factors, including differences in trial protocols, size and type of the patient populations, variable adherence to the dosing regimen or other protocol requirements and the rate of dropout among clinical trial participants. The FDA or comparable foreign regulatory authorities may disagree with our trial designs and our interpretation of data from preclinical studies or clinical trials. Even if we adhere to guidance or advice given by the FDA or comparable foreign regulatory authorities, such adherence does not guarantee that the FDA will agree with our trial designs or data interpretations or prevent the FDA from changing the requirements for the approval of any investigational product.

***We have conducted, and continue to conduct, portions of our clinical trials outside the U.S., and the FDA may not accept data from trials conducted in foreign locations.***

We have conducted, and we expect to continue to conduct, portions of our clinical trials outside the U.S. Although the FDA may accept data from clinical trials conducted outside the U.S., acceptance of these data is subject to certain conditions imposed by the FDA. For example, in cases where data from foreign clinical trials are intended to serve as the sole basis for regulatory approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, if the study was not otherwise subject to an IND, the FDA will not accept the data as support for an application for regulatory approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an

onsite inspection if deemed necessary. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. We cannot assure you that the FDA will accept data from trials conducted outside the U.S. If the FDA does not accept the data from such clinical trials, we would likely need to conduct additional trials, which would be costly and time-consuming and delay or permanently halt our development of our investigational products.

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

The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies, may also slow the time necessary for new drugs, and biologics or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. Separately, in the first half of 2025, it was announced federal agencies such as the FDA and Department of Health and Human Services began laying off a large number of employees. If recent or future decreases in headcount at the FDA, or other geopolitical or global health concerns, hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

#### **Risks Related to Reliance on Third Parties, Manufacturing and Commercialization**

***We expect to depend on our collaboration with Gilead for the research, development, manufacture and commercialization of our investigational products. If this collaboration is not successful, our business could be adversely affected.***

Our strategy for fully developing and commercializing our investigational products is dependent upon maintaining our current arrangements with Gilead and our other strategic partners. Our ability to leverage these arrangements to produce commercial success will depend, among other things, on our collaborators' cooperation and ability to successfully meet their responsibilities with regards to a clinical program. We cannot predict the success of any collaboration that we enter into. Our partnership with Gilead poses a number of risks that could materially impact our operations and financial condition including, but not limited to, the following:

- conflicts may arise between us and Gilead, such as conflicts regarding the combinations or indications to pursue or concerning the interpretation of clinical data, the commercial potential of any optioned investigational products, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration;
- if our joint development program does not result in the successful development and commercialization of products or if Gilead terminates the collaboration agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration;
- we will be heavily dependent on Gilead for its further development and commercialization of the investigational products from the programs that it opts in to;
- we may not be successful in this collaboration due to various other factors, including our ability to demonstrate proof of concept in one or more clinical studies so that Gilead will exercise its option to these programs;
- we have appointed three individuals that were designated by Gilead to our board of directors pursuant to the terms of the Investor Rights Agreement and Gilead owns approximately 29.3% of our outstanding common stock as of September 30, 2025. As a result, they may be able to exert significant influence over our company;

- Gilead could independently develop, or develop with third parties, products that compete directly or indirectly with our investigational products if Gilead believes that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; and
- it will be difficult for us to enter into new collaborations for any programs to which Gilead has option rights.

Given the breadth of the collaboration with Gilead, our ability to form new collaborations in the future will be limited. If Gilead declines to exercise its option to a program, we may need to enter into new collaborations for such programs with companies that have more resources and experience than us. We may not be successful in these efforts because third parties may not view our investigational products as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third-party for development and commercialization of an investigational product, we can expect to relinquish some or all of the control over the future success of that investigational product to the third-party. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

***We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.***

We are and expect to remain dependent on third parties, such as CROs, clinical investigators and consultants, to conduct our ongoing clinical trials and any future clinical trials of our investigational products. The timing of the initiation and completion of these trials will therefore be partially controlled by such third parties and may result in delays to our development programs.

There is no guarantee that any CROs, investigators or other third parties that help conduct or participate in our clinical trials will devote adequate time and resources to such trials or perform as contractually required. While we have and will have agreements governing the activities of our CROs, investigators and other consultants, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards and requirements, and our reliance on our CROs and other third parties does not relieve us of our regulatory responsibilities.

If any of these third parties fails to meet expected deadlines, fails to adhere to our clinical protocols, fails to meet regulatory requirements or guidelines (including any GCPs or comparable requirements enforced by the FDA or comparable foreign regulatory authorities), or otherwise performs in a substandard manner, our ability to use data generated from our clinical trials may be jeopardized the timelines for our clinical trials may be extended or delayed, or our development activities may be suspended or terminated. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in our ongoing clinical trials unless we are able to transfer those subjects to another qualified clinical trial site. In addition, our CROs have the right to terminate their agreements with us in the event of an uncured material breach and under other specified circumstances, and if so terminated, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms or at all. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires our management's time and focus.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the utility of certain data from the clinical trial may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any NDA or BLA we submit to the FDA, or equivalent marketing application to other regulatory authorities outside the U.S. Any such delay or rejection could prevent us from commercializing our investigational products, which would have material adverse impact on our business, financial condition and prospects.

***Supply by third parties of the investigational products, standard-of-care drugs or comparator agents used in our clinical trials may become limited or interrupted, or more costly, which could delay, prevent or impair our development efforts.***

Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies to handle living cells. We rely, and expect to continue to rely, on third-parties for the manufacture and supply of our investigational products for preclinical and clinical testing, as well as for commercial manufacture if any of our investigational products are approved. If any of these third-parties fail to perform these activities for us, nonclinical or

clinical development of our investigational products could be delayed, which could have an adverse effect on our business, financial condition, results of operations, and/or growth prospects. Further, we currently have limited manufacturing arrangements for our investigational products and expect that each of our investigational products will only be covered by single source suppliers for the foreseeable future. Our reliance on limited manufacturing arrangements increases the risk that we will not have and may not be able to obtain sufficient quantities of our investigational products for use in our clinical trials and, if approved, commercial activities. For example, WuXi Biologics, located in China, is currently our sole manufacturer of zimberelimab and domvanalimab. We regularly assess our supply needs against our manufactured quantities, however, if WuXi Biologics, or any other manufacturer that we rely on, is unable or unwilling to provide the quantity of material we require, there is no guarantee that any reserves we have of our investigational products will be sufficient for our future clinical development plans. If any reserves we have are depleted and we are unable to establish a reliable source of supply, our development efforts, and if approved, commercial activities, could be delayed or impaired.

Any supply chain challenges may affect our ability to supply clinical sites with our investigational products and any standard-of-care drugs and comparator agents that we use in our clinical trials. These supply chain challenges can include longer lead times for the manufacturers of our investigational products to obtain raw materials, longer timeframes to procure or lack of supply for standard-of-care drugs or comparator agents used in our clinical trials, and transit delays at each point in the manufacturing, supply or distribution chain. For example, we use various standard-of-care chemotherapies, including 5-fluorouracil and oxaliplatin in our STAR-221 clinical trial, and carboplatin in certain of our clinical trials. However, certain of the countries where we conduct these clinical trials are experiencing a shortage in the supply of these chemotherapies. These supply chain challenges may prevent us from enrolling subjects into our clinical trials, may result in increased costs for our clinical trials, and may otherwise delay, prevent or impair our development efforts. See the risk factor titled "Unfavorable global economic, political and trade conditions could adversely affect our business, financial condition or results of operations and may exacerbate the effects of the risks described herein."

***Our manufacturing partners are subject to extensive regulation. In the event any of our manufacturers fail to comply with such regulations or perform its obligations, our business may be adversely affected and we may need to delay or halt the development of our investigational products.***

We do not control the manufacturing process of our contract manufacturing partners and are completely dependent on them for compliance with cGMP requirements for manufacture of our investigational products, including assuring that their processes have adequate quality control, quality assurance and qualified personnel. In the event that any of our manufacturers fail to comply with regulatory requirements, such as the requirement to implement and operate quality systems to control and assure the quality of investigational products and products approved for sale and other requirements imposed by cGMP regulations, or if any of our manufacturers fail to perform its obligations to us in relation to quality, timing or otherwise, we may be forced to suspend or terminate our development activities.

In particular, we currently do not have the capabilities or resources to manufacture our investigational products ourselves and any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture our investigational products may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third-party and a feasible alternative may not exist. If we are required to change manufacturers for any reason, including as a result of geopolitical tensions, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines, and we may be required to conduct additional clinical trials or perform additional development activities to demonstrate comparability of lots of our investigational products to those produced by prior manufacturers.

Our or a third-party's failure to execute on our manufacturing requirements on commercially reasonable terms and in compliance with cGMP or other regulatory requirements could adversely affect our business in a number of ways, including:

- an inability to initiate or complete clinical trials of our investigational products in a timely manner;
- delays in submitting regulatory applications, or receiving regulatory approvals, for our investigational products;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of our investigational products; and
- in the event of approval to market and commercialize an investigational products, an inability to meet commercial demands.

***Our employees, clinical trial investigators, CROs, consultants, vendors, collaboration partners and any potential commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.***

We are exposed to the risk of fraud or other misconduct by our employees, clinical trial investigators, CROs, consultants, vendors, collaboration partners and any potential commercial partners. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA laws and regulations or those of comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information, (ii) manufacturing standards, (iii) federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the U.S. and abroad, or (iv) laws that require the true, complete and accurate reporting of financial information or data. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, as well as a disclosure program and other applicable policies and procedures, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

***Even if we receive regulatory approval for any investigational product, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense.***

Following potential approval of any our investigational products, the FDA may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly and time-consuming post-approval studies, post-market surveillance or clinical trials to monitor the safety and efficacy of the product. The FDA may also require a REMS as a condition of approval of our investigational products, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our investigational products, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our products 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 cGMPs and GCP requirements for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our products, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our investigational products and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

In addition, if any of our investigational products are approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about drug and biological products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for an investigational product, physicians may nevertheless, in their independent medical judgment, prescribe it to their patients in a manner that is inconsistent with the approved label. The FDA does not regulate the behavior of physicians in their choice of treatments but the FDA does restrict manufacturer's communications on the subject of off-label use of their products. If

we are found to have promoted such off-label uses, we may become subject to liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our investigational products. In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our investigational products. We also cannot predict the likelihood, nature or extent of government. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

***Even if we receive marketing approval, we may not be successful in commercializing our investigational products.***

We have no sales, marketing or distribution capabilities or experience. If any of our investigational products ultimately obtains regulatory approval, we, whether alone or in collaboration with Gilead for programs that we commercialize together, may not be able to effectively or successfully market the product due to a number of factors, including:

- the imposition by regulatory authorities of significant restrictions on a product's indicated uses, marketing or distribution;
- the imposition by regulatory authorities of costly and time-consuming post-approval studies, post-market surveillance or additional clinical trials;
- our failure to establish sales and marketing capabilities;
- the failure of our products to achieve the degree of market acceptance by physicians, patients, hospitals, cancer treatment centers, healthcare payors and others in the medical community necessary for commercial success;
- unfavorable pricing regulations or third-party coverage and reimbursement policies; and
- inaccuracies in our estimates of the addressable patient population resulting in a smaller market opportunity than we believed.

***Even if we receive marketing approval for one or more of our investigational products, our commercial success is dependent on obtaining coverage and reimbursement for a product from a government or other third-party payor, which coverage may be delayed or may not be sufficient to cover our costs.***

Our commercial success is dependent on obtaining coverage and reimbursement for any product for which we receive approval from private or government third-party payors, which is a time-consuming and costly process that could require us and any collaborators to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. There may be significant delays in obtaining such coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded therapeutics and therapeutics administered under the supervision of a physician. Additionally, our collaborators will be required to obtain coverage and reimbursement for any related companion diagnostics tests they develop separate and apart from the coverage and reimbursement we seek for our investigational products, once approved.

Reimbursement may also impact the demand for, and the price of, any product for which we obtain marketing approval. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with those medications. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance and we expect to experience pricing pressures in connection with the sale of any of our investigational products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes.

Increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for recently approved products and, as a result, they may not cover or provide adequate payment. Even if we show improved efficacy or improved convenience of administration, third-party payors may deny or revoke the reimbursement status of our product candidates, if approved, or establish prices for our product candidates at levels that are too low to enable us to realize an appropriate return on our investment. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, and may not be able to obtain a satisfactory financial return.

No uniform policy for coverage and reimbursement for products exist among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that may require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance or that step edits or other conditions on reimbursement will not be imposed. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

Our ability to obtain coverage and reimbursement approval for any of our investigational products, if approved, could have a material adverse effect on the demand for that investigational product, and on our business and our overall financial condition.

***Obtaining and maintaining regulatory approval of investigational products in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. Even if our investigational products are approved by the FDA, they may never be approved or commercialized outside the U.S., which would limit our ability to realize their full market potential.***

In order to market any products within a country, we or our collaborators must establish and comply with numerous and varying regulatory requirements of such country regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us or our collaborators and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. However, obtaining and maintaining regulatory approval of investigational products in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, the approval of zimberelimab for the treatment of recurrent or refractory classical Hodgkin's Lymphoma in China by Gloria Biosciences does not improve the chances of FDA approval for any BLA that we may submit for zimberelimab in the U.S. in any indication. In addition, our or our collaborators' failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any investigational products approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we or our collaborators fail to comply with regulatory requirements in international markets or fail to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed.

***Any investigational products for which we intend to seek approval as biologic products may face competition sooner than anticipated.***

The Biologics Price Competition and Innovation Act ("BPCIA") created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until twelve years from the date on which the reference product was first licensed. During this twelve-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The law is complex and is still being interpreted and implemented by the FDA. As a result, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

Zimberelimab and domvanalimab are biological products and we may develop additional biological products in the future. We believe that any of our current and future investigational products approved as a biological product under a

BLA should qualify for the twelve-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our investigational products to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors.

#### **Risks Related to our In-Licenses and Other Strategic Agreements**

***We are currently party to several in-license agreements under which we acquired rights to use, develop, manufacture and/or commercialize certain of our investigational products. If we breach our obligations under these agreements, we may be required to pay damages, lose our rights to these investigational products or both, which would adversely affect our business and prospects.***

We rely, in part, on license and other strategic agreements, which subject us to various obligations, including diligence obligations with respect to development and commercialization activities, reporting and notification obligations, payment obligations for achievement of certain milestones and royalties on product sales, negative covenants and other material obligations. We may need to devote substantial time and attention to ensuring that we are compliant with our obligations under these agreements. If we fail to comply with the obligations under our license agreements or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and our licensors may have the right to terminate the license. If our license agreements are terminated, we may not be able to develop, manufacture, market or sell the products covered by our agreements and those being tested or approved in combination with such products. Such an occurrence could materially adversely affect the value of the investigational product being developed under any such agreement and any other investigational products being developed or tested in combination. Domvanalimab, which we in-licensed from Abmuno, and zimberelimab, which we in-licensed from WuXi Biologics, are being evaluated in combination in our two most advanced Phase 3 studies, STAR-121 and STAR-221. In the event we breach any of our license agreements with Abmuno and/or WuXi Biologics, and our license agreements are terminated, we would have to cease these development activities, or we would have to negotiate a new or reinstated agreement, which may not be available to us on equally favorable terms, or at all.

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

***We may not realize the benefits of any acquisitions, in-license or other collaborations or strategic alliances that we enter into.***

We have entered into in-license agreements with multiple licensors and option agreements to enable the development and commercialization of our investigational products worldwide. In the future, we may seek to enter into acquisitions or additional licensing arrangements with third parties to expand our pipeline or that we believe will complement or augment our development and commercialization efforts with respect to our investigational products and any future investigational products that we may develop. These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, investigational products or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. As a result, if we enter into in-license, acquisition or collaboration agreements, or strategic partnerships, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business.

## Risks Related to Intellectual Property

***If we are unable to obtain and maintain sufficient intellectual property protection for our investigational products, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.***

Our success depends in large part on our ability to obtain and maintain patent protection in the U.S. and other countries with respect to our investigational products and research programs. We seek to protect our proprietary position by filing patent applications in the U.S. and abroad related to our novel discoveries and technologies that are important to our business, however, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will protect our investigational products and their intended uses or prevent others from commercializing competitive technologies or products;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; and/or
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose.

Obtaining and enforcing patents is expensive and time-consuming and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Even if we successfully file and prosecute a patent application, we may not be able to maintain and/or enforce the issued patent. We may determine that filing or maintaining such a patent or any action to enforce a patent may be too high or not in the best interest of our company or our stockholders. It is also possible that we will fail to identify patentable aspects of our R&D results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our R&D output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

We also cannot be certain that the claims in our pending patent applications directed to our investigational products and/or technologies will be considered patentable by the U.S. Patent and Trademark Office ("USPTO") or by patent offices in foreign countries. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our investigational products is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our investigational products. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the U.S. or foreign countries.

***We may become involved in lawsuits alleging that we have infringed the intellectual property rights of third parties or to protect or enforce our patents or other intellectual property, which litigation could be expensive, time consuming and adversely affect our ability to develop or commercialize our investigational products.***

The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our products candidates. Third parties may assert infringement claims against us based on existing or future intellectual property rights. If we were sued for patent infringement, we would need to demonstrate that our investigational products, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are

invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult. For example, in the U.S., proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. If we are found to infringe a third-party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing investigational product or product. Alternatively, we may be required to obtain a license from such third-party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing investigational product. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our investigational products or force us to cease some of our business operations, which could materially harm our business.

In addition, we may find that competitors are infringing our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against which we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy.

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 litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, we cannot assure you that we will have sufficient financial or other resources to defend or pursue such litigation, which typically last for years before they are concluded. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

***We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.***

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may become subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor.

While we may litigate to defend ourselves against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our investigational products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

***We may not be able to protect our intellectual property rights outside of the U.S.***

Patents are of national or regional effect, and filing, prosecuting and defending patents on all of our investigational products throughout the world would be prohibitively expensive. As such, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals or biologics, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. In addition, certain developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. Further, we file patent applications in Russia and the Eurasian patent office, which is headquartered in Moscow. Sanctions against Russia may make it difficult to file and maintain patents in these countries, and Russia has taken actions against "unfriendly" countries, including the U.S., which may adversely affect the scope of and/or our ability to enforce our intellectual property rights. In any of these countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third-party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

***Changes in patent law in the U.S. and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our investigational products.***

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. However, the patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to obtain and enforce patent rights in the future. Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries could increase the uncertainties and costs. For example, in September 2011 the Leahy-Smith America Invents Act (the "America Invents Act") was signed into law and included a number of significant changes to U.S. patent law as then existed. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. After March 2013, under the America Invents Act, the U.S. transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

In addition, in 2012, the European Patent Package, or EU Patent Package, regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court, or UPC, for litigation involving European patents. Implementation of the EU Patent Package occurred on June 1, 2023. Under the UPC, all European patents, including those issued prior to ratification of the European Patent Package, will by default automatically fall under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan-European injunctions. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. Under the EU Patent Package as currently proposed, we will have the right to opt our patents out of the UPC over the first seven years of the court's existence, but doing so may preclude us from realizing the benefits of the new unified court. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC.

***We may rely on trade secret and proprietary know-how which can be difficult to trace and enforce and, if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to seeking patents for some of our technology and investigational products, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Elements of our investigational product, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees, third parties with which we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Trade secrets and know-how can be difficult to protect. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. We and any third parties with which we share facilities enter into written agreements that include confidentiality and intellectual property obligations to protect each party's property, potential trade secrets, proprietary know-how, and information. We further seek to protect our potential trade secrets, proprietary know-how, and information in part, by entering into non-disclosure and confidentiality agreements with parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U.S. are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third-party, our competitive position would be harmed.

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

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

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

Patent rights are of limited duration. Given the amount of time required for the development, testing and regulatory review of new investigational products, patents protecting such candidates might expire before or shortly after such investigational products are commercialized. Even if patents covering our investigational products are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. A patent term extension based on regulatory delay may be available in the U.S. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain patent term extension or restoration, or the term of any such extension is

less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

### **Risks Related to our Business Operations and Industry**

*We expect to expand our business operations, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.*

We expect to grow our business operations, including adding employees in sales and marketing, if any of our investigational products receives marketing approval. To manage our anticipated future growth, we must:

- identify, recruit, integrate, maintain and motivate additional qualified personnel;
- manage our development efforts effectively, including the initiation and conduct of clinical trials for our investigational products; and
- improve our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to develop, manufacture and commercialize our investigational products will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, as well as a disproportionate amount of its attention, away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our investigational products and, accordingly, may not achieve our research, development and commercialization goals.

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

Our ability to compete in the highly competitive biopharmaceuticals industry depends upon our ability to attract, retain and motivate highly skilled and experienced personnel with scientific, medical, regulatory, manufacturing and management skills and experience. We conduct our operations in the San Francisco Bay Area, a region that is home to many other biopharmaceutical companies as well as many academic and research institutions, resulting in fierce competition for qualified personnel and rapidly increasing wages. Our industry also has experienced a high rate of turnover in recent years. While we have expanded a number of our in-office roles to permit remote work arrangements, allowing us to seek talent from outside the San Francisco Bay Area, we still may not be able to attract or retain qualified personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical companies. Many of the other biopharmaceutical companies we compete with have greater financial and other resources, different risk profiles and a longer history in the industry than we do. Our competitors may provide higher compensation, more diverse opportunities and/or better opportunities for career advancement. Any or all of these competing factors may limit our ability to continue to attract and retain high quality personnel, which could negatively affect our ability to successfully develop and commercialize our investigational products and to grow our business and operations as currently contemplated.

*We are highly dependent on the services of our founders, Terry Rosen, Ph.D., who serves as our Chief Executive Officer, and Juan Jaen, Ph.D., who serves as our President.*

We are highly dependent on the services of our founders, Terry Rosen, Ph.D., who serves as our Chief Executive Officer, and Juan Jaen, Ph.D., who serves as our President. Although we have entered into employment agreements with them, they are not for a specific term, and each of them may terminate their employment with us at any time, though we are not aware of any present intention of either of these individuals to leave us.

Drs. Rosen and Jaen have significant experience identifying and developing biopharmaceuticals. We believe that their drug discovery and development experience, and overall biopharmaceutical company management experience, would be difficult to replace. However, the historical results, past performance and/or acquisitions of companies with which they were affiliated do not necessarily predict or guarantee similar results for our company. Further, Drs. Rosen and Jaen have certain other business and personal commitments outside of serving as the Chief Executive Officer and President of Arcus, including serving on the boards of other companies and foundations, which may result in diversion of their focus and attention on our company.

***We face substantial competition, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If their investigational products are shown to be safer or more effective than ours, then our commercial opportunity will be reduced or eliminated.***

We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immunotherapies for the treatment of cancer, which is highly competitive with rapidly changing standards of care. As such, our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop or that would render any products that we may develop obsolete or non-competitive. Our competitors also may obtain marketing approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

We are aware of several pharmaceutical companies developing products in the same class as our investigational products, some of which are further along in development than our corresponding assets.

As more investigational products within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. Consequently, the results of our clinical trials for investigational products in that class will likely need to show a risk benefit profile that is competitive with or more favorable than those products and investigational products in order to obtain marketing approval or, if approved, a product label that is favorable for commercialization. If the risk benefit profile is not competitive with those products or investigational products, or if the approval of other agents for an indication or patient population significantly alters the standard of care with which we tested our investigational products, we may have developed a product that is not commercially viable, that we are not able to sell profitably or that is unable to achieve favorable pricing or reimbursement. In such circumstances, our future product revenue and financial condition would be materially and adversely affected.

***Our internal information technology systems, and those of our third-party CROs and other third parties upon which we rely, are subject to failure, security breaches and other disruptions, which could result in a material disruption of our investigational products' development programs, jeopardize sensitive information, prevent us from accessing critical information or result in a loss of our assets, and potentially expose us to notification obligations, loss, liability or reputational damage and otherwise adversely affect our business.***

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information, including but not limited to intellectual property, proprietary business information and personal information (collectively, "Sensitive Information").

We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party contractors and other parties who have access to our sensitive information. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties we rely on experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if these third parties fail to satisfy their privacy- or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such an award. In addition, supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

Despite the implementation of security measures, given the size and complexity and the increasing amounts of sensitive information that they maintain, our internal information technology systems and those of our third-party CROs and other third parties upon which we rely are vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyberattacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information and other assets), which may compromise our system infrastructure, lead to data leakage, impair key business processes or other critical business operations, delay our development programs, or result in the loss of assets or other liability. Our reliance on internet technology and the number of our employees who are working remotely has increased the opportunities for cybercriminals to exploit vulnerabilities. There can be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and information. Further, we cannot assure you that our data protection efforts and our investment in information technology will prevent

breakdowns, data leakages, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition.

Furthermore, as the cyber threat landscape evolves, these attacks are growing in frequency, sophistication and intensity, and becoming increasingly difficult to detect. There can be no assurance that we and our third-party CROs and other third parties upon which we rely will be successful in detecting, preventing or fully recovering systems or data from all breakdowns, service interruptions, attacks or breaches of systems that could adversely affect our business and operations and/or result in the loss or disclosure of critical or sensitive data or other assets, which could result in financial, legal, business or reputational harm to us. Ransomware attacks have risen dramatically and we may be forced to pay to unlock our data and information, re-access our systems and resume our ability to conduct business operations. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. The loss of clinical trial data for our investigational products could significantly increase our costs to recover or reproduce the data and result in delays in our development programs, impair our ability to obtain marketing approval and reduce the commercial opportunity for our investigational products.

We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of any third parties we rely), but we may not be able to detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Moreover, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, Sensitive Information, which could result in financial, legal, business, and reputational harm to us. In particular, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

Although we maintain insurance coverage to insure against losses suffered as a result of malicious intrusions and cyberattacks, such coverage may be insufficient to fully compensate us for the loss or there may be disputes with our insurers about the availability of insurance coverage for our claims. Cyber insurance may become increasingly difficult to maintain and we may not be able to maintain coverage at a reasonable cost or in an amount adequate to compensate for any loss or satisfy any liability that may arise. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations.

Our sensitive information could be leaked, disclosed, or revealed as a result of or in connection with the use of generative artificial intelligence ("AI") technologies by our employees, personnel, or the third parties upon whom we rely. Any sensitive information (including confidential, competitive, proprietary, or personal data) that is inputted into a third-party generative AI platform could be leaked or disclosed to others, including if sensitive information is used to train the third parties' AI model.

***Unfavorable global economic, political and trade conditions could adversely affect our business, financial condition or results of operations and may exacerbate the effects of the risks described herein.***

Current global economic conditions are highly volatile due to a number of reasons, including geopolitical instability, such as trade war, the military conflicts between Russia and Ukraine, the conflicts between Israel and Hamas, recent inflation that increased our operating expenses and disruptions in the capital and credit markets that may reduce our ability to raise additional capital when needed on acceptable terms, if at all.

Emerging international trade relations, new legislation and tariffs may also adversely impact our operations and/or financial condition by limiting or preventing the activities of third parties that we engage, increasing import costs or increasing the cost of our operations. New or increased tariffs, export controls or other trade barriers could result in higher prices for the materials we use and, if any of our investigational products are approved, could materially impact our supply chain and manufacturing costs for such products. Recent congressional legislative actions, proposed executive orders, sanctions, tariffs and other measures discourage contracting with Chinese companies on the development or manufacturing of pharmaceutical products and may restrict trade with China. WuXi Biologics, located in China, is currently our sole manufacturer of zimmerelimab and domvanalimab. If WuXi Biologics becomes subject to trade restrictions, sanctions,

increased tariffs or other regulatory requirements by the U.S. government, or if the U.S. or Chinese government take retaliatory actions due to recent or increased tensions between the U.S. and mainland China, it could materially impact our ability to obtain additional supply of zimberelimab and domvanalimab or significantly increase our manufacturing costs. Finding a replacement manufacturer could require significant effort and/or be prohibitively expensive, and we may not be able to do so in a timely manner which could have an adverse impact on our operations, operating results and financial condition.

Furthermore, the recent inflationary environment related to increased aggregate demand and supply chain constraints has increased our operating expenses and may continue to affect our operating expenses. Economic conditions may also strain our suppliers, possibly resulting in supply disruptions that impact our ongoing clinical trials and other operations. A significant worsening of global economic conditions could materially increase these risks we face.

Any new or prolonged downturn of global economic conditions could harm our business operations, and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

***Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.***

Our future profitability may depend, in part, on our ability to commercialize our investigational products in foreign markets for which we may rely on collaboration with third parties. We are not permitted to market or promote any of our investigational products before we receive marketing approval from the applicable regulatory authority in that foreign market, and we may never receive such marketing approval for any of our investigational products. To obtain marketing approval in many foreign countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our investigational products, and we cannot predict success in these jurisdictions. If we obtain approval of our investigational products and ultimately commercialize our investigational products in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for our investigational products in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third-party intellectual property rights;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our investigational products could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

***We or the third parties upon which we depend may be adversely affected by earthquakes, fires or other natural disasters.***

Our headquarters and main research facility are located in the San Francisco Bay Area, which in the past has experienced severe earthquakes and fires. In addition, fires and other natural disasters may increase in frequency and severity over time due to climate change. If these earthquakes, fires, other natural disasters, terrorism and similar unforeseen events beyond our control were to prevent us from using all or a significant portion of our headquarters or research facility, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We do not have a disaster recovery or business continuity plan in place and may incur substantial expenses as a result of the absence or limited nature of our internal or third-party service provider disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material

adverse effect on our business. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical trials, our development plans and business.

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

We have incurred substantial losses during our history and our ability to generate profits in the future is uncertain. Unused NOL carryforwards the tax year ended December 31, 2017 and prior tax years will carry forward to offset future taxable income, if any, until such unused NOLs expire. Unused NOLs generated after December 31, 2017, under current tax law, will not expire. Our NOLs may be carried forward indefinitely. In addition, the future deductibility of such NOLs will be limited to 80% of current year taxable income in any given year.

Both our current and our future unused losses (and tax credit carryforwards) may be subject to further limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "IRC"), if we undergo an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period. We performed an analysis under IRC Section 382 and 383 through October 31, 2020 with respect to our NOL and credit carryforwards. We concluded that an ownership change, as defined under IRC Section 382, occurred in previous years, but that such ownership change did not result in the expiration of our NOL or credit carryforwards prior to utilization. We may incur additional ownership changes in the future in connection with any equity issuance. If we experience any such ownership change, we may be limited in our ability to use our NOL and credit carryforwards and be required to make material cash tax payments.

Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited. For example, California recently enacted a franchise tax law limiting the usability of California state NOLs to offset taxable income for tax years beginning on or after January 1, 2024 and January 1, 2027. Similar laws in the future could accelerate or permanently increase state taxes owed. Therefore, even if we attain sustained profitability, we may be unable to use all or a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows.

***Changes in tax laws and regulations or exposure to additional tax liabilities could adversely affect our financial results.***

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. We actively monitor legislative and regulatory developments that may affect our tax liability in order to identify and evaluate if such proposals would have a material impact, whether detrimental or beneficial, on our financial results. 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. For example, the provisions of the Tax Cuts and Jobs Act of 2017, as amended by the statute commonly referred to as the "One Big Beautiful Bill Act of 2025", eliminate the option to currently deduct non-U.S. R&D expenditures and require taxpayers to capitalize and amortize non-U.S. R&D expenditures over fifteen years. We cannot predict whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law.

**Risks Related to Our Industry**

***Product liability lawsuits against us could cause us to incur substantial liabilities and could limit our commercialization of any investigational products that we may develop.***

We face an inherent risk of product liability exposure related to the testing of our investigational products in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our investigational products or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- delay or termination of clinical trials;
- decreased demand for any investigational products or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial subjects;

- initiation of investigations by regulators;
- significant costs to defend the related litigation and diversion of management's time and our resources;
- substantial monetary awards to study subjects or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as our investigational products advance through clinical trials and if we successfully commercialize any products. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

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

We and third parties upon whom we rely may be subject to federal, state, and foreign data protection, privacy, and information security laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations. In the U.S., numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission ("FTC") Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under Health Insurance Portability and Accountability Act ("HIPAA"). While we do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly regulated under HIPAA, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

The legislative and regulatory landscape for privacy and data security continues to evolve, and we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data security in the U.S., the European Union (the "EU"), the United Kingdom (the "UK") and other jurisdictions. This increased focus on privacy and data security issues may negatively affect our operating results and our business. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (collectively, "CCPA") applies to personal information of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future.

Foreign data protection laws also apply to health-related and other personal data obtained outside the U.S. The EU General Data Protection Regulation (the "EU GDPR"), the UK General Data Protection Regulation (the "UK GDPR" and, together with the EU GDPR, the "GDPR") and Canada's Personal Information Protection and Electronic Documents Act ("PIPEDA"), or the applicable provincial alternatives, impose strict requirements, including the obligation to appoint data protection officers in certain circumstances, rights for individuals to be "forgotten" and to data portability, and the obligation to make public notification of significant data breaches. Under the GDPR, data protection authorities can impose temporary or definitive bans on data processing and other corrective actions or fines of up to 4% of our total worldwide turnover or up to €20 million under the EU GDPR/£17.5 million pounds sterling under the UK GDPR (in either case, whichever is higher), or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. In Canada, PIPEDA and various related provincial laws, as well as Canada's Anti-Spam Legislation ("CASL"), may apply to our operations. We also target customers in Asia and may be subject to new and emerging data privacy regimes, including China's Personal Information Protection Law ("PIPL").

We may also be subject to new laws governing the privacy of consumer health data. For example, Washington's My Health My Data Act ("MHMD") broadly defines consumer health data, places restrictions on processing such data

(including imposing stringent requirements for consent), provides consumers certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law. Other states are considering and may adopt similar laws.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the U.S. or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area ("EEA") and the UK have significantly restricted the transfer of personal data to the U.S. and other to countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the U.S. in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant organizations based in the U.S. who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the U.S. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the U.S., or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the U.S., are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. We publish privacy policies, notices and other statements regarding data privacy and security. If these policies, notices or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

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

Our failure (or that of the third parties upon whom we rely) to comply with U.S. and foreign data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Claims that we or the third parties upon whom we rely have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis; if viable, these claims carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

***Our business operations expose us to broadly applicable fraud and abuse, transparency, government price reporting, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.***

Our operations are subject to various U.S. federal and state health care laws, including fraud and abuse, transparency and other healthcare laws and regulations, and similar laws in other jurisdictions in which we conduct our

business. These laws may impact, among other things, our research and proposed sales, marketing and education programs and constrain the business of financial arrangements and relationships with healthcare providers, physicians and other parties through which we market, sell and distribute our products for which we obtain marketing approval. The laws that may affect our ability to operate include, but are not limited to the federal Anti-Kickback Statute; federal civil and criminal false claims laws, such as the False Claims Act; HIPAA; federal and state consumer protection and unfair competition laws; the federal transparency requirements under the federal Physician Payments Sunshine Act (the "Sunshine Act"); state and foreign law equivalents of each of these federal laws; and state and foreign laws that require pharmaceutical companies to implement compliance programs. Many of these laws are discussed in detail under "Item 1. Business—Government Regulation—Other U.S. Healthcare Laws and Compliance Requirements" in our Annual Report on Form 10-K filed with the SEC on February 25, 2025.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have continued their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. We have entered into consulting and advisory board arrangements with physicians and other healthcare providers, including some who could influence the use of our investigational products, if approved. Because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant civil, criminal and administrative penalties such as fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, 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, and the curtailment or restructuring of our operations, any of which could substantially disrupt our operations. If any of the physicians or other healthcare providers or entities with which we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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

In the U.S. and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of investigational products, restrict or regulate post-approval activities, and affect the ability to profitably sell investigational products for which marketing approval is obtained. Among policy makers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. Current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any product candidates approved for sale. New and changing laws and regulations may also create uncertainty about how such laws and regulations will be interpreted and applied. If we are found to have violated laws and regulations, it could materially adversely affect our business.

Various initiatives are discussed in detail under "Item 1. Business—Government Regulation—Healthcare Reform" in our Annual Report on Form 10-K filed with the SEC on February 25, 2025. More recently, the One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of any product candidate that we commercialize.

The Trump administration has issued executive orders that address the pricing of pharmaceuticals in the U.S. and propose a so-called most favored nation pricing policy, which would tie the price of drugs in the U.S. to the lowest price in a group of other countries. While it is unclear whether and how the Trump proposals will be implemented, the Trump policies are likely to have a negative impact on the pharmaceutical industry. Even proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business.

Moreover, the federal government and the individual states in the United States have become increasingly active in developing proposals, passing legislation and implementing regulations designed to control drug pricing, including price or patient reimbursement constraints, discounts, formulary flexibility, marketing cost disclosure, drug price increase

reporting, and other transparency measures. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states, while some states are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Some measures are designed to encourage importation from other countries. These types of initiatives may result in additional reductions in Medicare, Medicaid, and other healthcare funding, and may otherwise affect the prices we may obtain for our product candidates that receive approval.

These and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage and payment criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs. Additional state and federal healthcare reform measures may be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. We cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business.

***We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.***

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

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

We, and the third parties with which we share our facilities, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Each of our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Each of our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. We could be held liable for any resulting damages in the event of contamination or injury resulting from the use of hazardous materials by us or the third parties with which we share our facilities, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our R&D. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

## Risks Related to Owning our Common Stock

### *The stock price of our common stock has been and may continue to be volatile or may decline regardless of our operating performance.*

The market price of our common stock has fluctuated and may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- overall performance of the equity markets;
- our operating performance and the performance of other similar companies;
- results from our ongoing clinical trials and future clinical trials with our current and future investigational products or of our competitors;
- changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock;
- regulatory, trade or legal developments in the U.S. and other countries, including changes in tariffs or other trade restrictions and the changes in the structure of healthcare payment systems;
- the level of expenses related to future investigational products or clinical development programs;
- our failure to achieve product development goals in the timeframe we announce;
- announcements of acquisitions, strategic alliances or significant agreements by us or by our competitors;
- recruitment or departure of key personnel;
- the economy as a whole and market conditions in our industry;
- trading activity by a limited number of stockholders who together beneficially own a majority of our outstanding common stock;
- the size of our market float; and
- any other factors discussed in this report.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many immuno-oncology companies. Stock prices of many immuno-oncology companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and adversely affect our business.

### *The amount of our future losses is uncertain and our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.*

Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and success or failure of clinical trials for our investigational products or competing investigational products, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- our progress towards the achievement of any product development goals or milestones we announce, including any delays or failures which lead to the suspension or termination of any clinical trial or development program;
- the timing and cost of, and level of investment in, R&D activities relating to our investigational products, which may change from time to time;
- option fees received by us in connection with option exercises by Gilead and/or Taiho pursuant to their respective option agreements and/or payments received by us from Gilead or Taiho in connection with the achievement of certain development and/or regulatory milestones;
- amounts payable by us in connection with the achievement of development, regulatory and commercial milestones under our in-license and other strategic agreements;

- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional investigational products;
- our ability to obtain marketing approval for our investigational products, and the timing and scope of any such approvals we may receive;
- the changing and volatile U.S. and global economic environments, including the impact of tariffs, inflation and rising interest rates, and domestic or international political instability; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

***The concentration of our stock ownership will likely limit our stockholders' ability to influence corporate matters, including the ability to influence the outcome of director elections and other matters requiring stockholder approval.***

Based upon shares outstanding as of September 30, 2025, our executive officers, directors and the holders of more than 5% of our outstanding common stock, in the aggregate, beneficially owned approximately 55.0% of our common stock. In particular, as of September 30, 2025, Gilead owns approximately 29.3% of our outstanding common stock and we have appointed its three designees to our board of directors pursuant to the terms of the Investor Rights Agreement. As a result, these stockholders, acting together, have significant influence over all matters that require approval by our stockholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other stockholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a change of control of our company that other stockholders may view as beneficial.

***Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.***

Our status as a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may make the acquisition of our company more difficult, including the following:

- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by a majority vote of our entire board of directors, the chairman of our board of directors or our chief executive officer, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the requirement for the affirmative vote of holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of the voting stock, voting together as a single class, to amend the provisions of our amended and restated certificate of incorporation relating to the management of our business or our

amended and restated bylaws, which may inhibit the ability of an acquirer to effect such amendments to facilitate an unsolicited takeover attempt; and

- advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for our stockholders to realize value in a corporate transaction.

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

Our amended and restated certificate of incorporation and our bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws or any action asserting a claim against us that is governed by the internal affairs doctrine. In addition, to prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our bylaws provide that the federal district courts of the U.S. will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees and may discourage these types of lawsuits. While the Delaware courts have determined that these types of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of these provisions, which may require significant additional costs associated with resolving such action in other jurisdictions, and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

## **General Risk Factors**

***Sales of substantial amounts of our shares may cause the price of our common stock to decline.***

The price of our common stock could decline if there are substantial sales of our common stock, including any sales by us, our directors, executive officers, significant stockholders or the sales agents under the equity distribution agreement, or if there is a large number of shares of our common stock available for sale and the market perceives that sales will occur. We have also registered shares of common stock that we have issued and may issue under our employee equity incentive plans. These shares can be sold freely in the public market upon issuance, subject to vesting conditions and, in the case of our affiliates, volume limitations under Rule 144 under the Securities Act.

***If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could result in sanctions or other penalties that would harm our business.***

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the New York Stock Exchange. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting.

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. GAAP. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance

that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. Accordingly, we cannot assure you that we will not in the future identify one or more material weaknesses in our internal control over financial reporting, which may have a negative impact on our ability to timely and accurately produce financial statements, may result in a material misstatement of our Consolidated Financial Statements or may negatively impact the confidence level of our stockholders and other market participants with respect to our reported financial information.

Ensuring that we have adequate internal controls over financial reporting is a costly and time-consuming effort that needs to be re-evaluated frequently. Further, remote work arrangements have led to changes in work patterns that can make it more difficult to properly perform our controls and may create risks that result in deficiencies in the design of our controls. To the extent necessary, implementing any changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business.

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

None.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

None.

**Item 5. Other Information.**

***Rule 10b5-1 Trading Arrangements***

The adoption, modification or termination of contracts, instructions or written plans for the purchase or sale of our securities by our Section 16 officers and directors for the three months ended September 30, 2025, which are intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act, were as follows:

Name and Title	Action	Date	Total Shares to be Sold	Expiration Date
Robert C. Goeltz II Chief Financial Officer	Adoption	September 10, 2025	50,138	January 29, 2027
Juan Jaen President	Adoption	August 8, 2025	265,993	November 13, 2026

**Item 6. Exhibits.**

The documents listed below are incorporated by reference or are filed with this Quarterly Report on Form 10-Q, in each case as indicated therein (numbered in accordance with Item 601 of Regulation S-K).

Exhibit Number	Exhibit Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	<a href="#">Amended and Restated Certificate of Incorporation</a>	10-Q	001-38419	3.1	May 9, 2018
3.2	<a href="#">Amended and Restated Bylaws</a>	8-K	001-38419	3.1	May 26, 2020
31.1*	<a href="#">Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>				
31.2*	<a href="#">Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>				
32.1†	<a href="#">Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>				
32.2†	<a href="#">Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>				
101.INS	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.

† This certification is deemed furnished but not filed for purposes of section 18 of the Exchange Act, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

**SIGNATURES**

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

**ARCUS BIOSCIENCES, INC.**

Date: October 28, 2025

By: \_\_\_\_\_  
**Terry Rosen, Ph.D.**  
**Chief Executive Officer**  
***(Principal Executive Officer)***

Date: October 28, 2025

By: \_\_\_\_\_  
**Alexander Azoy**  
**Chief Accounting Officer**  
***(Principal Accounting Officer)***

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

I, Terry Rosen, certify that:

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

Date: October 28, 2025

By:

/s/ Terry Rosen

**Terry Rosen, Ph.D.**  
**Chief Executive Officer**  
**(Principal Executive Officer)**



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

In connection with the Quarterly Report of Arcus Biosciences, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

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

Date: October 28, 2025

By:

/s/ Terry Rosen

**Terry Rosen, Ph.D.**  
**Chief Executive Officer**  
**(Principal Executive Officer)**

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

In connection with the Quarterly Report of Arcus Biosciences, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

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

Date: October 28, 2025

By:

/s/ Robert C. Goeltz II

**Robert C. Goeltz II**  
**Chief Financial Officer**  
**(Principal Financial Officer)**