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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023

OR

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

For the transition period from _____ to _____.

Commission File Number: 001-41696

ACELYRIN, INC.
(Exact name of registrant as specified in its charter)

Delaware
**(State or other jurisdiction of incorporation or
organization)**

85-2406735
(I.R.S. Employer Identification No.)

4149 Liberty Canyon Road
Agoura Hills, California 91301
(Address of principal executive offices)

(805) 730-0360
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock (\$0.00001 par value)	SLRN	Nasdaq Global Select Market

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

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

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

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

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

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

The number of shares of Registrant's common stock issued and outstanding as of November 6, 2023, was 97,339,494.

ACELYRIN, INC.

FORM 10-Q

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials and results thereof, research and development costs, planned regulatory submissions, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “anticipate,” “may,” “will,” “should,” “would,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “believe,” “estimate,” “predict,” “potential,” or “continue” or the negative of these terms or other similar expressions. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- our plans relating to the development of izokibep, lonigutamab, SLRN-517 or any other product candidates we may develop, including additional indications that we may pursue;
 - the characteristics, safety, tolerability and efficacy of izokibep, lonigutamab, SLRN-517 or any other product candidates we may develop;
 - the timing, progress and results of our preclinical and clinical trials, including statements regarding the planned initiation and completion of trials and related preparatory work, and the period during which the results of trials will become available;
 - the timing and costs involved in obtaining and maintaining regulatory approval of izokibep, lonigutamab, SLRN-517 or any other product candidates we may develop, and the timing or likelihood of regulatory filings and approvals, including our expectation to seek special designations for certain of our product candidates for various diseases;
 - our plans relating to commercializing izokibep, lonigutamab, SLRN-517 or any other product candidates we may develop, if approved, including the geographic areas of focus and our ability to grow a sales force;
 - our estimates of the number of patients who suffer from the diseases we target, and the corresponding size of the market opportunities for izokibep, lonigutamab, SLRN-517 or any other product candidates we may develop in each of the diseases we target;
 - our ability to successfully procure the manufacture and supply of izokibep, lonigutamab, SLRN-517 or any other product candidates we may develop for clinical trials and for commercial use, if approved;
 - the rate and degree of market acceptance of izokibep, lonigutamab, SLRN-517 or any other product candidates we may develop, as well as the pricing and reimbursement of izokibep, lonigutamab, SLRN-517 or any other product candidates we may develop, if approved;
 - our continued reliance on third parties to conduct clinical trials of izokibep, lonigutamab, SLRN-517 or any other product candidates we may develop, and for the manufacture and supply of our product candidates;
 - the scope of protection we are able to establish and maintain for intellectual property rights, including izokibep, lonigutamab, SLRN-517 or any other product candidates we may develop;
 - the success of competing therapies that are, or may become, available and other developments relating to our competitors and our industry;
 - existing regulations and regulatory developments in the United States and other jurisdictions;
 - the implementation of our business model and strategic plans for our business and operations;
 - our ability to retain the continued service of our key professionals and to identify, hire, and retain additional qualified professionals;
 - our ability to acquire additional product candidates and advance them into clinical development;
 - our expectations regarding our financial performance, expenses, revenue opportunities, capital requirements and needs for additional financing;
 - our ability to remediate the existing material weaknesses in our internal control over financial reporting;
 - our expectations regarding the impact of the COVID-19 pandemic, geopolitical conflicts and economic uncertainty, including rising interest rates and inflation on our business and operations, including clinical trials, contract manufacturing organizations (“CMOs”), collaborators, contract research organizations (“CROs”) and employees; and
-

- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of risks, uncertainties and assumptions described in the section titled “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in such statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein after we distribute this Quarterly Report on Form 10-Q, whether as a result of any new information, future events or otherwise.

In addition, “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon them.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS (UNAUDITED)

ACELYRIN, INC.

Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)
(unaudited)

	September 30, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	\$ 381,738	\$ 267,110
Short-term marketable securities	406,693	47,510
Prepaid expenses and other current assets	6,207	1,444
Total current assets	794,638	316,064
Prepaid expenses and other assets, non-current	2,482	3,859
Operating lease, right-of-use asset	1,240	-
Property, plant and equipment, net	2,129	-
Total assets	\$ 800,489	\$ 319,923
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities		
Accounts payable	\$ 18,702	\$ 5,947
Accrued research and development expenses	41,295	5,717
Accrued compensation and other current liabilities	5,144	4,237
Severance liability	1,720	-
Total current liabilities	66,861	15,901
Derivative tranche liability	-	10,291
Operating lease liability, non-current	1,252	-
Total liabilities	68,113	26,192
Commitments and contingencies (Note 8)		
Redeemable convertible preferred shares, no par value; no shares authorized, issued and outstanding as of September 30, 2023; 104,461,636 shares authorized as of December 31, 2022; par value of \$0.00001 per share; 40,743,522 shares issued and outstanding as of December 31, 2022; aggregate liquidation preference \$408,000 as of December 31, 2022	-	396,593
Stockholders' equity (deficit)		
Preferred stock, 10,000,000 shares authorized, \$0.00001 par value, no shares issued and outstanding at September 30, 2023; no shares authorized, issued, and outstanding at December 31, 2022	-	-
Common stock, par value of \$0.00001 per share; 790,000,000 and 229,461,636 shares authorized as of September 30, 2023 and December 31, 2022, respectively; 97,240,419 and 2,767,359 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	1	-
Additional paid-in capital	1,125,932	4,302
Accumulated other comprehensive loss	(50)	(86)
Accumulated deficit	(393,507)	(107,078)
Total stockholders' equity (deficit)	732,376	(102,862)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	\$ 800,489	\$ 319,923

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

ACELYRIN, INC.**Condensed Consolidated Statements of Operations and Comprehensive Loss**
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 74,562	\$ 12,509	\$ 272,512	\$ 38,222
General and administrative	19,861	2,887	44,440	8,145
Total operating expenses	94,423	15,396	316,952	46,367
Loss from operations	(94,423)	(15,396)	(316,952)	(46,367)
Change in fair value of derivative tranche liability	—	—	10,291	—
Interest income	10,502	986	20,486	1,399
Other expense, net	(19)	4	(254)	3
Net loss	\$ (83,940)	\$ (14,406)	\$ (286,429)	\$ (44,965)
Other comprehensive gain (loss)				
Unrealized gain (loss) on short-term marketable securities, net	(94)	(62)	36	(200)
Total other comprehensive gain (loss)	\$ (94)	\$ (62)	\$ 36	\$ (200)
Net loss and other comprehensive loss	\$ (84,034)	\$ (14,468)	\$ (286,393)	\$ (45,165)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.87)	\$ (8.17)	\$ (4.68)	\$ (31.66)
Weighted-average common shares outstanding, basic and diluted	96,872,747	1,764,293	61,138,105	1,420,199

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

ACELYRIN, INC.

Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share data)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Gain (Loss)	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance at December 31, 2022	40,743,522	\$ 396,593	2,767,359	\$ —	\$ 4,302	\$ (107,078)	\$ (86)	\$ (102,862)
Issuance of common stock in connection with ValenzaBio acquisition (Note 3)	—	—	18,885,731	—	128,735	—	—	128,735
Stock-based compensation expense	—	—	—	—	7,139	—	—	7,139
Net loss	—	—	—	—	—	(176,450)	—	(176,450)
Unrealized gain on short-term marketable securities, net	—	—	—	—	—	—	86	86
Balance at March 31, 2023	40,743,522	396,593	21,653,090	—	140,176	(283,528)	—	(143,352)
Issuance of common stock upon initial public offering, net of underwriting discounts commissions and issuance costs of \$47,354	—	—	34,500,000	—	573,644	—	—	573,644
Conversion of redeemable convertible preferred stock into common stock in connection with initial public offering	(40,743,522)	(396,593)	40,743,522	1	396,592	—	—	396,593
Issuance of common stock upon settlement of restricted stock units, net of shares withheld for taxes	—	—	303,237	—	(8,325)	—	—	(8,325)
Stock-based compensation expense	—	—	—	—	8,501	—	—	8,501
Net loss	—	—	—	—	—	(26,039)	—	(26,039)
Unrealized gain on short-term marketable securities, net	—	—	—	—	—	—	44	44
Balance at June 30, 2023	—	\$ —	97,199,849	\$ 1	\$ 1,110,588	\$ (309,567)	\$ 44	\$ 801,066
Stock-based compensation expense	—	—	—	—	15,313	—	—	15,313
Issuance of common stock upon exercise of options	—	—	40,570	—	31	—	—	31
Net loss	—	—	—	—	—	(83,940)	—	(83,940)
Unrealized loss on short-term marketable securities, net	—	—	—	—	—	—	(94)	(94)
Balance at September 30, 2023	—	\$ —	97,240,419	\$ 1	\$ 1,125,932	\$ (393,507)	\$ (50)	\$ 732,376
Balance at December 31, 2021	16,285,718	\$ 132,620	2,860,032	\$ —	\$ 250	\$ (42,306)	\$ —	\$ (42,056)
Issuance of Series B redeemable convertible preferred stock, net of issuance costs of \$26	12,228,923	124,974	—	—	—	—	—	—
Issuance of restricted stock awards	—	—	498,940	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	1,610	—	—	1,610
Net loss	—	—	—	—	—	(16,085)	—	(16,085)
Balance at March 31, 2022	28,514,641	257,594	3,358,972	—	1,860	(58,391)	—	(56,531)
Stock-based compensation expense	—	—	—	—	369	—	—	369
Net loss	—	—	—	—	—	(14,474)	—	(14,474)
Unrealized losses on short-term marketable securities	—	—	—	—	—	—	(138)	(138)
Balance at June 30, 2022	28,514,641	\$ 257,594	3,358,972	\$ -	\$ 2,229	\$ (72,865)	\$ (138)	\$ (70,774)
Issuance of Series C redeemable convertible preferred stock, net of derivative liability of \$10,778 and issuance costs of \$223	12,228,881	138,998	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	560	—	—	560
Net loss	—	—	—	—	—	(14,406)	—	(14,406)
Unrealized losses on marketable securities	—	—	—	—	—	—	(62)	(62)
Balance at September 30, 2022	40,743,522	\$ 396,592	3,358,972	—	\$ 2,789	\$ (87,271)	\$ (200)	\$ (84,682)

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

ACELYRIN, INC.

Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (286,429)	\$ (44,965)
Adjustments to reconcile net loss to net cash used in operations:		
Expense related to acquired in-process research and development assets	133,057	-
Stock-based compensation expense	30,953	2,539
Net amortization of premiums and accretion of discounts on marketable securities	(5,564)	78
Change in fair value of derivative tranche liability	(10,291)	-
Depreciation and amortization expense	67	-
Non-cash lease expense	108	-
Changes in assets and liabilities:		
Prepaid expense and other current assets	(3,323)	(2,592)
Prepaid expenses and other assets, non-current	1,724	(1,172)
Accounts payable	11,225	1,167
Accrued research and development expenses	30,773	644
Accrued compensation and other current liabilities	2	873
Operating lease liability	(96)	-
Severance liability	1,720	-
Net cash used in operating activities	(96,074)	(43,428)
Cash flows from investing activities		
ValenzaBio assets acquisition, cash acquired net of acquisition costs	10,007	-
Cash paid to acquire in-process research and development assets	(10,000)	-
Purchase of marketable securities	(537,987)	(262,005)
Proceeds from maturities of short-term marketable securities	128,728	152,518
Sales of marketable securities	56,310	-
Purchase of property, plant and equipment	(2,196)	-
Net cash used in investing activities	(355,138)	(109,487)
Cash flows from financing activities		
Issuance of common stock upon initial public offering, net of commissions and issuance costs	574,134	—
Proceeds from exercise of common stock options	31	-
Proceeds from the issuance of redeemable convertible preferred stock, net of issuance costs	-	263,973
Proceeds allocated to the derivative tranche liability	-	10,778
Payments for deferred offering costs	-	(138)
Taxes paid related to net share settlement of restricted stock units	(8,325)	-
Net cash provided by financing activities	565,840	274,613
Net increase in cash and cash equivalents	114,628	121,698
Cash and cash equivalents at beginning of period	267,110	102,242
Cash and cash equivalent at end of period	\$ 381,738	\$ 223,940
Supplemental disclosure of cash flow information:		
Conversion of 40,743,522 redeemable convertible preferred stock upon the closing of initial public offering	\$ 396,593	\$ —
Common stock issued in connection with ValenzaBio acquisition	\$ 128,735	\$ —
Right-of-use assets obtained in exchange for operating lease liability	\$ 1,348	\$ —

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

ACELYRIN, INC.
Notes to the Condensed Consolidated Financial Statements

1. Description of Business, Organization and Liquidity***Organization and Business***

ACELYRIN, INC. (the “Company”) is a late-stage clinical biopharma company focused on identifying, acquiring, and accelerating the development and commercialization of transformative medicines. The Company was incorporated in the State of Delaware on July 27, 2020. Since its inception, the Company has devoted substantially all of its resources to organizing the Company, hiring personnel, business planning, acquiring and developing its product candidates, performing research and development, enabling manufacturing activities in support of its product development efforts, establishing and protecting its intellectual property portfolio, raising capital, and providing general and administrative support for these activities.

The Company did not have any significant operations from the inception date until August 2021. On August 9, 2021, the Company entered into the License and Collaboration Agreement with Affibody AB, a Swedish company, and licensed worldwide development, manufacturing and commercialization rights to a therapeutic candidate, izokibep, for use in the treatment of inflammatory and autoimmune disorders, excluding rights in certain Asian and Nordic countries. See Note 7 for further details.

On January 4, 2023, the Company closed the acquisition of ValenzaBio, Inc. (“ValenzaBio”) and issued as consideration 18,885,731 shares of its Class A common stock (“Class A Common Stock”). ValenzaBio was a privately held company developing therapies for autoimmune and inflammatory diseases. The ValenzaBio acquisition added additional assets to the Company’s portfolio, including lonigutamab and SLRN-517. See Note 3 for further details.

Reverse Stock Split

In April 2023, the Company effected a reverse split of shares of the Company’s outstanding common stock and redeemable convertible preferred stock at a ratio 1.972-for-1 (the “Reverse Stock Split”). The number of authorized shares and par value per share were not adjusted as a result of the Reverse Stock Split. All references to shares, restricted stock units (“RSUs”) and restricted stock awards (“RSAs”), options to purchase common stock, share data, per share data, and related information contained in the condensed consolidated financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

Initial Public Offering

On May 4, 2023, the Company’s Form S-1 Registration Statement for its initial public offering (the “IPO”) was declared effective, and on May 9, 2023, the Company closed its IPO and issued 34,500,000 shares of common stock at a price to the public of \$18.00 per share, including 4,500,000 shares issued upon the exercise of underwriters’ option to purchase additional shares of common stock. The Company received gross proceeds of \$621.0 million. Net proceeds were approximately \$573.6 million, after deducting underwriting discounts and commissions and offering costs of \$47.4 million. The common stock began trading on the Nasdaq Global Select Market on May 5, 2023, under the symbol “SLRN”.

Immediately prior to the IPO closing, each share of the Company’s redeemable convertible preferred stock then outstanding converted into an equivalent number of shares of Class A Common Stock, and thereafter each share of Class A Common Stock then issued and outstanding was reclassified and became one share of the Company’s common stock.

Liquidity

The Company has incurred significant losses and negative cash flows from operations since its inception. During the nine months ended September 30, 2023 and 2022, the Company incurred net losses of \$286.4 million and \$45.0 million, respectively. The net loss of \$286.4 million in the nine months ended September 30, 2023 includes \$123.1 million of expenses related to acquired in-process research and development assets without alternative future use and \$10.0 million license fee payment to Pierre Fabre incurred in connection with the ValenzaBio acquisition. As of September 30, 2023, the Company had an accumulated deficit of \$393.5 million. Cash used in operating activities was \$96.1 million and \$43.4 million for the nine months ended September 30, 2023 and 2022, respectively.

The Company has historically financed its operations primarily through the sale of shares of its redeemable convertible preferred stock in private placements and the sale of shares of its common stock in its IPO. As of September 30, 2023, the Company had cash and cash equivalents and short-term marketable securities of \$788.4 million. The Company does not have any products approved for sale and has not generated any revenue from product sales to date. The Company expects to continue to incur significant and increasing expenses and substantial losses for the foreseeable future as it continues its development of and seeks regulatory approvals for its product candidates and commercializes any approved products, seeks to expand its product pipeline and invests in its organization. The Company's ability to achieve and sustain profitability will depend on its ability to successfully develop, obtain regulatory approval for and commercialize its product candidates. There can be no assurance that the Company will ever earn revenue or achieve profitability, or if achieved, that the revenue or profitability will be sustained on a continuing basis. Unless and until it does, the Company will need to continue to raise additional capital. Management expects that its cash and cash equivalents and short-term marketable securities will be sufficient to fund its current operating plan and capital expenditure requirements for at least the next 12 months from the date of issuance of these condensed consolidated financial statements.

2. Summary of Significant Accounting Policies

There have been no changes to the significant accounting policies disclosed in Note 2 to the consolidated financial statements for the years ended December 31, 2022 and 2021 included in the Company's final prospectus for the IPO ("Final Prospectus") filed pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (the "Securities Act"), with the U.S. Securities and Exchange Commission (the "SEC") on May 5, 2023, except for performance-based restricted stock unit award.

Basis of Presentation

The condensed consolidated financial statements and accompanying notes are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and applicable rules and regulations of the SEC regarding interim financial reporting.

The accompanying financial statements are consolidated and include the accounts of ACELRYN, INC. and its wholly owned subsidiary, WH2, LLC (the legal successor to ValenzaBio). The subsidiary has not had any operations or any balances from its inception.

Certain information and footnote disclosures normally included in the financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. Accordingly, these condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2022 included in the Final Prospectus filed with the SEC on May 5, 2023. The information as of December 31, 2022, included in the condensed consolidated balance sheets was derived from the Company's audited consolidated financial statements. These unaudited interim condensed consolidated financial statements have been prepared on the same basis as the Company's annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments necessary for a fair statement of the Company's consolidated financial statements. The results of operations for the nine months ended September 30, 2023 are not necessarily indicative of the results that may be expected for the year ending December 31, 2023 or for any other interim period or for any other future year.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting period. On an ongoing basis, the Company evaluates estimates and assumptions, including but not limited to those related to the fair value of its derivative tranche liability, the fair value of its common stock, stock-based compensation expense, accruals for research and development expenses, valuation of deferred tax assets, and uncertain income tax positions. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from those estimates.

Segment Information

The Company has one operating segment. The Company's focus is the research, development and commercialization of product candidates. The Company's chief executive officer ("CEO"), who is the chief operating decision maker, reviews financial information on an aggregate basis for allocating and evaluating financial performance. All long-lived assets are maintained in the United States of America.

Concentration of Credit Risk

Cash and cash equivalents, and short-term marketable securities are financial instruments that potentially subject the Company to concentrations of credit risk. As of September 30, 2023, cash consists of cash deposited with one financial institution, and account balances exceed federally insured limits.

The Company also has investments in money market funds, U.S. Treasury obligations, corporate debt obligations, and federal agency obligations, which can be subject to certain credit risks. The Company mitigates the risks by investing in high-grade financial instruments, limiting its exposure to any one issuer and monitoring the ongoing creditworthiness of the financial institutions and issuers. The Company has not experienced any losses on its financial instruments.

Leases

The Company adopted ASU 2016-02, "Leases (Topic 842)" accounting standard as of January 1, 2022. The contractual arrangements that meet the definition of a lease are classified as operating or finance leases and are recorded on the balance sheets as both a right-of-use asset ("ROU asset") and lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease or the Company's incremental borrowing rate ("IBR"). Lease ROU assets and lease obligations are recognized based on the present value of the future minimum lease payments over the lease term at the lease commencement date. The Company currently does not have any finance leases.

Operating lease ROU assets are adjusted for (i) payments made at or before the commencement date, (ii) initial direct costs incurred, and (iii) tenant incentives under the lease. As the implicit rate for the operating leases are not determinable, the Company determines its IBR based on the information available at the applicable lease commencement date. The IBR is determined by using the rate of interest that the Company would pay to borrow on a collateralized basis an amount equal to the lease payments for a similar term and in a similar economic environment where the asset is located. The Company considers a lease term to be the noncancelable period that it has the right to use the underlying asset, including any periods where it is reasonably certain the Company will exercise any option to extend the contract.

Lease costs for minimum lease payments for operating leases are recognized on a straight-line basis over the lease term. Lease liabilities are increased by interest and reduced by payments each period, and the ROU asset is amortized over the lease term. Variable lease costs are recorded when incurred. In measuring the ROU assets and lease liabilities, the Company has elected to combine lease and non-lease components. The Company excludes short-term leases, if any, having initial terms of 12 months or less at lease commencement as an accounting policy election, and recognizes rent expense on a straight-line basis over the lease term for these types of leases.

The Company did not have any leases as of and prior to January 1, 2023.

Performance-Based Restricted Stock Unit Awards

Performance-based restricted stock units ("PSUs"), awarded to employees vest upon the achievement of certain performance milestones and market conditions (i.e., specified average stock price hurdle) at the end of specified performance periods, subject to continuous service through each respective vest date. The amount of expense recognized is based on the grant date fair value of the PSU tranche corresponding to the performance condition of the tranche which is considered probable. The estimated grant date fair value of the market portion of the PSUs is based on a Monte Carlo simulation under each performance condition outcome. The Monte Carlo valuation model simulates the probabilities of stock price achievement, which requires management to make a number of assumptions including a 20-trading day volume-weighted average stock price, volatility of our peers, and the risk-free interest rate. Compensation expense for each tranche of a PSU award is recognized straight-line over the period commencing on the grant date of the award and ending on the vesting date of the tranche under the PSU award. Cumulative adjustments are recorded at each reporting date to reflect subsequent changes to the estimated outcome of the performance condition until the end of the respective performance period.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (the “FASB”) or other standard setting bodies and adopted by the Company as of the specified effective date. The Company qualifies as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the “JOBS Act”), and has elected not to “opt out” of the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and nonpublic companies, the Company will adopt the new or revised standard at the time nonpublic companies adopt the new or revised standard and will do so until such time that the Company either (i) irrevocably elects to “opt out” of such extended transition period or (ii) no longer qualifies as an emerging growth company. The Company may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for nonpublic companies.

The Company noted no recently issued accounting pronouncements that will impact its condensed consolidated financial statements. No new accounting pronouncements were adopted during the nine months ended September 30, 2023.

3. ValenzaBio Acquisition

On December 20, 2022, the Company entered into the Agreement and the Plan of Merger and Reorganization (the “Merger Agreement”) to acquire ValenzaBio. In connection with the planned ValenzaBio acquisition, the Company formed two wholly owned subsidiaries, WH1, Inc. and WH2 LLC in November 2022. Through the two-step merger and restructuring, WH1 Inc. was merged with and into ValenzaBio with WH1 Inc. ceasing to exist, and ValenzaBio was then merged with and into WH2 LLC, with WH2 LLC continuing as the legal successor to ValenzaBio. (the “Acquisition”). The Acquisition closed on January 4, 2023 (the “Closing Date”), and is anticipated to qualify as a tax-free reorganization for U.S. federal income tax purposes.

The Company concluded that the Acquisition is an asset acquisition as substantially all of the fair value of the gross assets acquired, excluding cash, was concentrated in a single asset, lonigutamab, and the Company did not acquire a workforce or any substantive process capable of significantly contributing to the ability to create outputs.

As consideration, the Company issued 18,885,731 shares of its Class A Common Stock to ValenzaBio stockholders, of which 2,013,673 are being held by Seller LLC for any post-acquisition costs and general indemnities for 12 months from the Closing Date (“Holdback Release Date”), and paid \$7,663 in cash to one non-accredited investor. Additionally, \$0.1 million is payable in cash to Seller LLC to cover Seller LLC’s fees and expenses related to the Acquisition, with any unused amount to be released to ValenzaBio stockholders as soon as practicable following the completion of Seller LLC’s responsibilities. The Company also incurred \$1.2 million of acquisition-related costs that were included in the total consideration and capitalized to assets acquired.

The Company assumed options of certain ValenzaBio option holders who entered into consulting agreements with the Company, which became options for the purchase of an aggregate of 1,249,811 shares of the Company’s Class A Common Stock upon the closing of the Acquisition on January 4, 2023. The assumed options vested in full on March 31, 2023. Each assumed option is exercisable until the earlier of (i) 12 months following the termination of the option holder’s continuous service with the Company, or (ii) the original expiration date of such assumed option.

Outstanding ValenzaBio shares were exchanged into shares of the Company’s Class A Common Stock and the options described above assumed at an exchange ratio of 0.8027010-for-one.

The following table represents the total purchase consideration (in thousands):

Issued Class A Common Stock (1)	\$	128,735
Transaction costs (2)		1,271
Cash (3)		8
Total	\$	<u><u>130,014</u></u>

- (1) Shares were issued for consideration at \$6.86 per share, including 2,013,673 shares that are being held by Seller LLC until the Holdback Release Date. The Company used a third party valuation specialist to assist management in determining the fair value of the shares of Class A Common Stock at the Closing Date.

- (2) Legal and advisory transaction costs of \$1.3 million incurred by the Company in connection with the Acquisition, including \$0.1 million payable in cash to Seller LLC for the expense fund.
- (3) Cash payment of \$7,663 to one non-accredited investor for settlement of vested ValenzaBio options.

The following is the allocation of the purchase consideration to the acquired assets and liabilities (in thousands):

Cash	\$	11,369
Prepaid expenses and other current assets		2,074
In-process research and development assets		123,057
Accounts payable		(1,628)
Accrued research and development expenses		(4,805)
Accrued compensation and other current liabilities		(53)
Total net asset acquired	\$	130,014

In-process research and development (“IPR&D”) assets were related to acquired product candidates: lonigutamab in clinical trials and SLRN-517 in preclinical development. The fair value of in-process research and development assets was based on the present value of future discounted cash flows, which was based on significant estimates. These estimates included the number of potential patients and market prices of future product candidates, costs required to conduct clinical trials, future milestones and royalties payable under acquired license agreements, costs to receive regulatory approval and potentially commercialize product candidates, as well as estimates for probability of success and the discount rate. The estimated fair values of lonigutamab and SLRN-517 assets were \$114.8 million and \$8.2 million, respectively. The Company concluded that acquired assets do not have an alternative future use and recognized the full amount of \$123.1 million as research and development expenses in the condensed consolidated statement of operations and comprehensive loss in January 2023.

There are a number of additional obligations under the Merger Agreement that are separate from the assets and liabilities acquired, including the following:

Assumed options. The assumed options, discussed above, did not have substantive service requirement, and were accounted as a separate transaction from the Acquisition. The fair values of assumed options of \$3.1 million and \$1.8 million was expensed as research and development and general and administrative expenses, respectively, in the condensed consolidated statement of operations and comprehensive loss for the three months ended March 31, 2023.

Settled equity awards. In accordance with the severance obligations of ValenzaBio and per the terms of the Merger Agreement, certain unvested options and restricted stock awards of former ValenzaBio employees, who did not enter into consulting agreements with the Company, were accelerated and net exercised upon the closing of the Acquisition and termination of employment of such ValenzaBio employees. The fair value of unvested equity awards of \$0.9 million was expensed as general and administrative expense in the condensed consolidated statement of operations and comprehensive loss for the three months ended March 31, 2023. Payments in cash to one non-accredited investor for settlement of unvested ValenzaBio options and one former ValenzaBio employee to whom options were promised but not granted at the Closing Date of \$8,387 and \$30,000, respectively, were expensed as general and administrative expenses in the condensed consolidated statement of operations and comprehensive loss for the three months ended March 31, 2023.

Severance payment obligation. In accordance with the severance plan of ValenzaBio, the Company is obligated to make severance payments to certain former ValenzaBio employees of approximately \$5.1 million, including estimated taxes, for a period of three to 18 months from the Closing Date, depending on the position and tenure of such employees with ValenzaBio. The Company recognized the estimated fair value of severance payments obligations of \$2.5 million and \$2.4 million at the Closing Date as research and development and general and administrative expenses, respectively, in the condensed consolidated statement of operations and comprehensive loss for the three months ended March 31, 2023. The fair value of severance payments obligations was estimated based on future expected cash flows discounted to the Closing Date and a discount rate of 8%. The Company will accrete the fair value of severance payments obligations to the amounts payable over the obligation period as either research and development or general and administrative expenses based on the former employees’ functional department.

As of September 30, 2023, severance payments obligations to ValenzaBio employees in the amount of \$1.2 million were included in the condensed consolidated balance sheet. The accretion of severance payments obligations of less than

\$0.1 million and less than \$0.1 million were included in research and development and general and administrative expenses, respectively, in the condensed consolidated statement of operations and comprehensive loss for the nine months ended September 30, 2023. The accretion of severance payments obligations was less than \$0.1 million for the three months ended September 30, 2023.

Amendment to Pierre Fabre Agreement. The Company, ValenzaBio and Pierre Fabre Medicament SAS (“Pierre Fabre”) entered into an amendment to the license and commercialization agreement, which became effective on the Closing Date. The Company paid a \$10.0 million non-refundable license fee to Pierre Fabre. See Note 7 for additional details.

4. Fair Value Measurements

The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

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

Level 2 — Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices 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 assets or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company’s financial instruments measured at fair value on a recurring basis consist of Level 1, Level 2, and Level 3 financial instruments. Usually, marketable securities are considered Level 2 when their fair values are determined using inputs that are observable in the market or can be derived principally from or corroborated by observable market data such as pricing for similar securities, recently executed transactions, cash flow models with yield curves, and benchmark securities. In addition, Level 2 financial instruments are valued using comparisons to like-kind financial instruments and models that use readily observable market data as their basis. Corporate debt obligations, commercial paper, government agency obligations and asset-backed securities are valued primarily using market prices of comparable securities, bid/ask quotes, interest rate yields and prepayment spreads and are included in Level 2.

Financial assets and liabilities are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies, or similar techniques, and at least one significant model assumption or input is unobservable. The Company had no Level 3 financial assets or liabilities as of September 30, 2023. The derivative tranche liability related to the Series C financing second tranche closing (Note 10) was a Level 3 financial liability as of December 31, 2022.

The following table sets forth the Company’s financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

As of September 30, 2023:	Fair Value Measurements as of September 30, 2023			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds (included in cash and cash equivalents)	\$ 84,761	\$ 84,761	\$ -	\$ -
U.S. Treasury obligations (\$223,032 included in cash and cash equivalents)	\$ 514,050	—	514,050	—
Corporate debt obligations (\$46,714 included in cash and cash equivalents)	\$ 140,853	—	140,853	—
Federal agency obligations (\$21,347 included in cash and cash equivalents)	\$ 41,891	—	41,891	—
Total fair value of assets	\$ 781,555	\$ 84,761	\$ 696,794	\$ -

As of December 31, 2022:	Fair Value Measurements as of December 31, 2022			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds (included in cash and cash equivalents)	\$ 238,223	\$ 238,223	\$ -	\$ -
U.S. Government bonds	25,459	-	25,459	-
U.S. Treasury bills	11,404	11,404	-	-
Corporate debt obligations	2,141	-	2,141	-
Federal agency obligations	8,506	-	8,506	-
Total fair value of assets	\$ 285,733	\$ 249,627	\$ 36,106	\$ -
Liabilities:				
Derivative tranche liability	\$ 10,291	\$ -	\$ -	\$ 10,291
Total fair value of liabilities	\$ 10,291	\$ -	\$ -	\$ 10,291

Classified as:	September 30, 2023	December 31, 2022
Cash and cash equivalents	\$ 374,862	\$ 238,223
Short-term marketable securities	406,693	47,510
Total cash equivalents and marketable securities	\$ 781,555	\$ 285,733

The following table sets forth the changes in the fair value of Level 3 liabilities (in thousands):

	Derivative Tranche Liability
Balance as of December 31, 2022	\$ 10,291
Change in fair value	(10,291)
Balance as of September 30, 2023	\$ —

The derivative tranche liability was issued on September 9, 2022 with a fair value of \$10.8 million. The fair value of the derivative tranche liability has been estimated using a probability weighted model. Upon the closing of the IPO, on May 9, 2023, the derivative tranche liability was remeasured at fair value based on its intrinsic value and it was terminated. Intrinsic value was calculated as a difference between the IPO price of \$18.00 per share and \$12.2661, the Series C second tranche closing per share purchase price. The fair value of the derivative tranche liability upon the closing of the IPO was determined to be zero and the Series C Second Tranche Closing was terminated. The following significant assumptions were used to estimate fair value of the derivative tranche liability as of December 31, 2022:

	December 31, 2022
Probability of achieving specified conditions	80 %
Fair value of Series C preferred stock share	\$ 12.2661
Discount rate	25 %

5. Available-For-Sale Marketable Securities

The following tables summarize the estimated fair value of the Company's available-for-sale marketable securities as of September 30, 2023 and December 31, 2022 (in thousands):

As of September 30, 2023:	Total Amortized Cost	Total Unrealized Gains	Total Unrealized Loss	Total Estimated Fair Value
Money market funds (included in cash and cash equivalents)	\$ 84,761	\$ -	\$ -	\$ 84,761
U.S. Treasury obligations (\$223,032 included in cash and cash equivalents)	514,029	51	(30)	514,050
Corporate debt obligations (\$46,714 included in cash and cash equivalents)	140,923	4	(74)	140,853
Federal agency obligations (\$21,347 included in cash and cash equivalents)	41,892	5	(6)	41,891
Total available for sale marketable securities	\$ 781,605	\$ 60	\$ (110)	\$ 781,555

As of December 31, 2022:	Total Amortized Cost	Total Unrealized Loss ⁽¹⁾	Total Estimated Fair Value
Money market funds (included in cash and cash equivalents)	\$ 238,223	\$ -	\$ 238,223
U.S. Government bonds	25,506	(47)	25,459
U.S. Treasury obligations	11,430	(26)	11,404
Corporate debt obligations	2,145	(4)	2,141
Federal agency obligations	8,515	(9)	8,506
Total available for sale marketable securities	\$ 285,819	\$ (86)	\$ 285,733

(1) The Company did not have any gross unrealized gains as of December 31, 2022.

As of September 30, 2023 and December 31, 2022, no significant facts or circumstances were present to indicate a deterioration in the creditworthiness of the issuers of the Company's marketable securities, and the Company has no requirement or intention to sell these securities before maturity or recovery of their amortized cost basis. The Company considered the current and expected future economic and market conditions and determined that its investments were not significantly impacted by such conditions. For all securities with a fair value less than its amortized cost basis, the Company determined the decline in fair value below amortized cost basis to be immaterial and non-credit related, and therefore no allowance for losses has been recorded. During the nine months ended September 30, 2023 and for the year ended December 31, 2022, the Company did not recognize any impairment losses on its investments.

The Company presents accrued interest receivable related to the available-for-sale marketable securities in prepaid expenses and other current assets, separate from short-term investments in the condensed consolidated balance sheet. As of each of September 30, 2023 and December 31, 2022, accrued interest receivable was \$0.7 million and \$0.1 million, respectively. The Company's accounting policy is to not measure an allowance for credit losses for accrued interest receivables and to write-off any uncollectible accrued interest receivable as a reversal of interest income in a timely manner, which it considers to be in the period in which the Company determines the accrued interest will not be collected. The Company has not written off any accrued interest receivables for the three and nine months ended September 30, 2023.

6. Consolidated Balance Sheet Components

Prepaid expenses and other current assets

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

	September 30, 2023	December 31, 2022
Prepaid insurance and other current assets	\$ 1,834	\$ 86
Prepaid research and development expenses	1,645	682
VAT receivable	1,292	—
Prepaid other services	776	288
Interest receivable	660	138
Research and development credit receivable	-	250
Total	\$ 6,207	\$ 1,444

Prepaid expenses and other assets, non-current

Other non-current assets consist of the following (in thousands):

	September 30, 2023	December 31, 2022
Prepaid research and development expenses, non-current	\$ 2,448	\$ 1,964
Security deposits	34	—
Deferred IPO offering costs	—	774
Acquisition transaction costs	-	1,121
Total	\$ 2,482	\$ 3,859

Property, plant and equipment

Property, plant and equipment consisted of the following as of September 30, 2023 (in thousands):

	September 30, 2023
Construction in progress	\$ 1,499
Furniture and fixtures	263
Computer and other equipment	344
Leasehold improvements	90
Total property, plant and equipment, gross	2,196
Less: accumulated depreciation and amortization	(67)
Property, plant and equipment, net	\$ 2,129

There was no property, plant and equipment balance as of December 31, 2022.

Accrued compensation and other current liabilities

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

	September 30, 2023	December 31, 2022
Accrued compensation	\$ 4,016	\$ 3,068
Accrued professional services fees (1)	751	808
Other accrued expenses and current liabilities	377	361
Total	\$ 5,144	\$ 4,237

(1) IPO offering costs included in accrued liabilities were zero and \$0.2 million as of September 30, 2023 and December 31, 2022, respectively.

7. Significant Agreements

Affibody License and Collaboration Agreement

On August 9, 2021, the Company entered into a license agreement with Affibody AB (“Affibody”) (the “Affibody Agreement”) under which Affibody granted the Company exclusive, sublicensable licenses to develop, commercialize and manufacture products containing izokibep for all human therapeutic uses on a worldwide basis, subject to a pre-existing agreement with Inmagene Biopharmaceuticals (“Inmagene”) with respect to certain Asian countries.

The Company chairs a global joint steering committee composed of designees from Affibody, Inmagene and the Company and retains final decision-making authority for izokibep global development. In doing so, the Company is obligated to use commercially reasonable efforts (i) to develop products containing izokibep worldwide, excluding certain defined territories, (ii) for the conduct and finalization of certain ongoing clinical trials, and (iii) to commercialize products containing izokibep for all human therapeutic uses worldwide, excluding certain defined territories, after obtaining the applicable marketing authorization. The Company is responsible for manufacturing both the clinical and commercial supply of licensed product globally.

In connection with the Affibody Agreement, the Company paid a non-refundable upfront license fee in the aggregate amount of \$3.0 million over the course of August 2021 and September 2021, and \$22.0 million in October 2021. The Company is also obligated to pay Affibody (i) an aggregate of up to \$280.0 million, \$30.0 million of which would be due prior to the first approval in the United States, upon the achievement of various development, regulatory and commercialization milestones and (ii) high single-digit to low-teens royalties on net sales of licensed products in the territory where the Company has commercialization rights, subject to certain reductions. Royalties will be due on a licensed product-by-licensed product and country-by-country basis beginning after the first commercial sale of the licensed product, except in Mainland China, Hong Kong, Macau, Taiwan and South Korea, and lasting until the later of (a) the expiration of all valid patent claims or regulatory exclusivity covering the licensed product in that country and (b) ten years after such first commercial sale.

In the event the U.S. Food and Drug Administration (“FDA”) grants the Company (or its affiliates or sublicensees) a priority review voucher for a licensed product, the Company will pay Affibody either: (a) if the Company sells or transfer such priority review voucher to a third-party, approximately one third of the proceeds received from the sale, net of taxes, or (b) if the Company uses the priority review voucher for an indication or product outside the scope of the Affibody Agreement, approximately one third of the fair market value of the priority review voucher as determined in accordance with the Affibody Agreement.

Unless earlier terminated, the Affibody Agreement will continue on a licensed product-by-licensed product basis and country-by-country basis until there are no more royalty payments owed to Affibody on any licensed product thereunder.

The acquisition of the exclusive license was accounted for as an in-process research and development asset acquisition and as the acquired technology did not have an alternative use, the total consideration of \$25.0 million was recorded as research and development expense in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2021. Milestone payments are contingent consideration and are accrued when contingent events occur and achievement of milestones is probable. Royalties will be recognized as cost of sales when products are sold and royalties are payable. No milestone or royalties were probable and estimable as of September 30, 2023 and December 31, 2022.

Pierre Fabre License and Commercialization Agreement

Upon the closing of the Acquisition, the Company became the successor to ValenzaBio’s rights under the March 25, 2021 license and commercialization agreement between ValenzaBio and Pierre Fabre, as amended (the “Pierre Fabre Agreement”). The Company received certain exclusive worldwide licenses, with the right to sublicense, to certain patents, know-how and other intellectual property to develop, manufacture, use and commercialize lonigutamab for non-oncology therapeutic indications. The license from Pierre Fabre extends to any product containing lonigutamab (excluding any fragments or derivatives) as its sole active ingredient (each, a “PF Licensed Product”). The Pierre Fabre Agreement

prohibits the Company from using the licensed intellectual property in any antibody drug conjugate, multi-specific antibodies or any other derivatives of lonigutamab.

In the event the Company decides to sublicense the rights to develop or commercialize a PF Licensed Product in any territory outside of the United States and Canada, Pierre Fabre retains the right of first negotiation to acquire such development and commercialization rights in one or more countries in such territory. Subject to the validation of certain clinical trial criteria by a joint steering committee, Pierre Fabre has the option to reclaim all exclusive rights to develop, commercialize and exploit the PF Licensed Product in such territories and to obtain an exclusive sublicensable license in such territories for any improvements and trademarks to such PF Licensed Product, and to exploit such PF Licensed Product for non-oncology therapeutic indications, subject to certain payment obligations. If Pierre Fabre exercises such option, and intends to sublicense such rights, then the Company has the right of first negotiation to acquire such development and commercialization rights as to that territory, or Pierre Fabre has the right to require the Company to buy out its right to the option for a one-time payment of \$31.0 million or the Company has the right to choose to buy out Pierre Fabre's option by making the one-time payment of \$31.0 million within 30 days from Pierre Fabre's notice of exercise of such option. If Pierre Fabre does not exercise its option within the option period or if the Company buys out Pierre Fabre's right to the option, the option will expire or terminate, respectively. The Company is solely responsible for the development, regulatory approvals and commercialization of each PF Licensed Product except to the extent that Pierre Fabre reclaims rights to a PF Licensed Product in the option territory.

As consideration for the amendment to the Pierre Fabre Agreement, which became effective upon the closing of the Acquisition (see Note 3), the Company paid Pierre Fabre an aggregate license payment of \$10.0 million. The Company is also obligated to (i) make payments of up to \$99.5 million upon the achievement of various development and regulatory milestones, (ii) make milestone payments of up to \$390.0 million upon the achievement of certain commercial milestones, and (iii) pay tiered royalties in the high single-digit to low-teen percentages to Pierre Fabre on worldwide net sales in a given calendar year. Royalties will be payable for each PF Licensed Product in a given country during a period commencing upon the first commercial sale of such PF Licensed Product in such country and continuing until the latest of (a) 10 years after such first commercial sale, (b) expiration of last-to-expire valid claim in a licensed patent in such country and (c) expiration of regulatory exclusivity for such PF Licensed Product in such country. In the event the Company enters into a sublicense with a third party, the Company must also share with Pierre Fabre a percentage of any revenues from option fees, upfront payments, license maintenance fees, milestone payments or the like generated from the sublicense. Such percentage may be between the high single-digits to the low thirties based on which stage of development of a PF Licensed Product the sublicense relates to.

Unless earlier terminated, the Pierre Fabre Agreement will continue on a PF Licensed Product-by-PF Licensed Product and country-by-country basis until there are no more royalty payments owed to Pierre Fabre on any PF Licensed Product thereunder. Either party may terminate the Pierre Fabre Agreement upon an uncured material breach, or upon the bankruptcy or insolvency of the other party. Pierre Fabre may also terminate the agreement if the Company or any of its affiliates institutes a patent challenge against the licensed patents from Pierre Fabre. The Company may also terminate the Pierre Fabre Agreement with or without cause upon nine months' prior written notice, so long as there is no ongoing clinical trial for any PF Licensed Product.

As of September 30, 2023, no milestones were probable and accrued in the condensed consolidated balance sheet. The payment of \$10.0 million for additional license fees was recorded as research and development expenses in the condensed consolidated statement of operations and comprehensive loss for the nine months ended September 30, 2023.

Novelty Nobility License and Commercialization Agreement

Upon the closing of the Acquisition, the Company became the successor to an exclusive license agreement between ValenzaBio and Novelty Nobility (the "Novelty License Agreement") and obtained a worldwide exclusive license for the development and commercialization of SLRN-517, an unmodified IgG1 monoclonal antibody, as a therapeutic treatment.

In connection with the arrangement, the Company is obligated to (i) make development and regulatory milestones of up to \$44.3 million, (ii) make commercial sales milestone payments of up to \$682.0 million and (iii) pay tiered royalties of a low single-digit to high-single-digit percentage on future worldwide net sales.

The Novelty License Agreement is effective on a licensed product-by-licensed product and country-by-country basis until the expiration of the latest to expire royalty term, unless early terminated. The royalty term, with respect to a licensed product and a country is the period commencing on the first commercial sale of such product in such country, and ending

upon the latest to occur of: a) there being no patent right in such country that had at least one valid claim covering the licensed product in whole or in part, or the manufacture or use thereof; b) 10 years from the first commercial sale of such product worldwide; or c) expiration of regulatory exclusivity for such product in such country. The agreement can be early terminated upon (i) a material breach, (ii) abandonment of development by the Company, in which the Company ceases all development activities for the licensed product, (iii) termination by patent challenge, and (iv) insolvency. The Company may terminate the contract at any point, upon 30 days prior written notice to Novelty Nobility, Inc.

As of September 30, 2023, no milestones were probable and accrued in the condensed consolidated balance sheet.

8. Commitments and Contingent Liabilities

License Agreements

The Company is required to pay certain milestones upon the achievement of specific development and regulatory events, upon products' commercialization and products' royalties under its license agreements, including its agreements with Affibody, Pierre Fabre, Novelty Nobility and other non-exclusive license agreements. None of the milestones were achieved or probable, all products were in development, as such, no milestones or royalties were accrued in the condensed consolidated balance sheets as of September 30, 2023 and December 31, 2022.

Research and Development Agreements

The Company enters into various agreements in the ordinary course of business, such as those with suppliers, contract research organizations, contract manufacturing organizations, and clinical trial sites. These contracts generally provide for termination on notice or may have a potential termination fee if a purchase order is canceled within a specified time. As of September 30, 2023, and December 31, 2022, there were no amounts accrued related to termination and cancellation charges in the consolidated balance sheets, as the Company has not determined cancellation to be probable.

Lease

In January 2023, the Company entered into a lease agreement to rent approximately 10,012 square feet of office space in Agoura Hills, California. The term of the lease is 65 months with an option to extend it for an additional three years. Monthly rent payments are approximately \$30,500, subject to an annual 3.0% increase and six months rental abatement during the first year. In addition to the base rent, the Company is obligated to pay variable costs related to its share of operating expenses and taxes. In connection with the lease agreement, the Company made a security deposit of \$34,000, that is included in prepaid expenses and other assets, non-current in the condensed consolidated balance sheet as of September 30, 2023.

As of the lease commencement date the Company recorded \$1.3 million as right-of-use ("ROU") asset and operating lease liability, non-current, in the condensed consolidated balance sheet.

In July 2023, the Company entered into a lease agreement to rent approximately 22,365 square feet of office space in South San Francisco with the commencement date to be determined upon completion of work to be performed by the landlord. The term of the lease is 60 months with an option to extend it for an additional three years at then current market rates. Monthly base rent payments are approximately \$150,000, subject to an annual 3.5% increase and a share of building operating expenses. The lease has not commenced as of September 30, 2023.

Operating lease costs were less than \$0.1 million and \$0.2 million for the three and nine months ended September 30, 2023, respectively, and were recorded in general and administrative expenses and research and development expenses in the condensed consolidated statements of operations and comprehensive loss.

The following table summarizes a maturity analysis of the Company's operating lease liabilities showing the aggregate lease payments as of September 30, 2023 (in thousands):

2023 (remainder of the year)	\$	61
2024		375
2025		386
2026		398
2027		409
Thereafter		280
Total future lease payments		1,909
Less imputed interest		(476)
Total operating lease liability balance		1,433
Less current portion of lease liability (included in Accrued compensation and other current liabilities)		(181)
Operating lease liability, non-current	\$	1,252

The weighted-average remaining lease term was 59 months and the weighted-average discount rate was 12%.

Cash paid for amounts included in the measurement of lease liabilities was less than \$0.1 million.

Legal Contingencies

From time to time, the Company may become involved in legal proceedings arising from the ordinary course of business. The Company records a liability for such matters when it is probable that future losses will be incurred and that such losses can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount. Management is not aware of any legal matters that could have a material adverse effect on the Company's financial position, results of operations or cash flows.

Guarantees and Indemnifications

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. Its exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To the extent permitted under Delaware law, the Company has agreed to indemnify its directors and officers for certain events or occurrences while the director or officer is, or was serving, at a request in such capacity. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of September 30, 2023, the Company did not have any material indemnification claims that were probable or reasonably possible and consequently has not recorded related liabilities.

9. Redeemable Convertible Preferred Stock

In February 2022, the Company closed the Series B Second Tranche financing and issued 12,228,923 shares of Series B redeemable convertible preferred stock (the "Series B Stock") at a price of \$10.2217 per share for gross cash proceeds of \$125.0 million and incurred less than \$0.1 million issuance costs.

In September 2022, the Company entered into a Series C stock purchase agreement and issued 12,228,881 shares of Series C redeemable convertible preferred stock (the "Series C Stock") at a price of \$12.2661 per share for gross cash proceeds of \$150.0 million (the "Series C First Tranche Closing") and incurred issuance costs of \$0.2 million.

Pursuant to the Series C preferred stock purchase agreement, the Company and investors agreed to issue and purchase an additional 12,228,881 shares of Series C Stock at the same purchase price of \$12.2661 per share on June 30, 2023, subject to meeting certain conditions (the "Series C Second Tranche Closing") (see Note 10). If a Series C Stock holder did not purchase the full number of the Series C Second Tranche shares that was required to be purchased by it on the Series C Second Tranche Closing date and this holder became a defaulting purchaser, then each 10 shares of Series C Stock held by such holder would have automatically converted into one share of Class A Common Stock, as adjusted for any stock dividends, splits, recapitalizations and the like in accordance with the Company's then-current certificate of incorporation.

On May 9, 2023, the IPO closing date, each share of the Company's redeemable convertible preferred stock then issued and outstanding automatically converted into one share of the Company's Class A Common Stock, thereafter each share of Class A Common Stock then issued and outstanding was reclassified and became one share of common stock and the Series C Second Tranche Closing was terminated.

The authorized, issued, and outstanding shares of the Company's convertible preferred stock and liquidation preferences as of December 31, 2022 were as follows (in thousands, except for share amounts):

	Shares Authorized	Shares Issued and Outstanding	Aggregate Liquidation Preference	Net Carrying Value
Series A redeemable convertible preferred stock	8,000,000	4,056,795	\$ 8,000	\$ 7,916
Series B redeemable convertible preferred stock	48,230,900	24,457,846	250,000	249,678
Series C redeemable convertible preferred stock	48,230,736	12,228,881	150,000	138,999
Total redeemable convertible preferred stock	104,461,636	40,743,522	\$ 408,000	\$ 396,593

The significant rights, preferences and privileges of the Company's redeemable convertible preferred stock were as follows:

Dividends — The holders of Series A Stock, Series B Stock and Series C Stock were entitled to receive noncumulative dividends at the rate of 8% of the original issue price per share, when, as and if declared by the Board. No dividends were declared and payable for the nine months ended September 30, 2023 and 2022.

Liquidation Rights — In the event of the liquidation, dissolution, or winding up of the Company, or a deemed liquidation event, including a merger or consolidation, or a sale or other disposition of all or substantially all of the Company's assets, the holders of shares of Series C Stock and Series B Stock were entitled to receive, before any payments were made to the holders of Series A Stock or common stock, an amount per share equal to the greater of: (i) Series C Stock and the Series B Stock original issuance price of \$12.2661 and \$10.2217, respectively, plus any dividends declared but unpaid; or (ii) such amount per share as would have been payable had all shares of Series C Stock and Series B Stock been converted into common stock immediately prior to such liquidation, dissolution, winding up or deemed liquidation. Should the Company's legally available assets be insufficient to satisfy the Series C Stock and Series B Stock liquidation preference, the funds were to be distributed with equal priority and pro rata among the holders of the Series C Stock and Series B Stock in proportion to the preferential amount each holder was otherwise entitled to receive.

After full payment to holders of the Series C Stock and Series B Stock, a payment would be made to the holders of Series A Stock, in preference to the holders of the common stock, in an amount per share equal to the greater of: (i) the Series A Stock original issuance price of \$1.9720, plus any dividends declared but unpaid; or (ii) such amount per share as would have been payable had all shares of Series A Stock been converted into common stock immediately prior to such liquidation, dissolution, winding up or deemed liquidation. Should the Company's legally available assets be insufficient to satisfy the Series A Stock liquidation preference, the funds were to be distributed with equal priority and pro rata among the holders of the Series A Stock in proportion to the preferential amount each holder was otherwise entitled to receive.

After the payment to the holders of Series C Stock, Series B Stock and Series A Stock of the full preferential amounts, the entire remaining assets of the Company legally available for distribution were to be distributed with equal priority and pro rata among the holders of common stock in proportion to the number of shares of common stock held by them.

Conversion — Each share of Series A Stock, Series B Stock and Series C Stock was convertible at the option of a holder at any time into a number of shares of the Company's common stock at a conversion rate, which is the Series A Stock, Series B Stock and Series C Stock original issuance price, \$1.9720, \$10.2217 and \$12.2661, respectively, divided by the Series A Stock, Series B Stock and Series C Stock conversion price in effect at the time of conversion. If, after the issuance date of the Series A Stock, Series B Stock and Series C Stock, the Company were to issue or sell, or was deemed to have sold, additional shares of common stock at a price lower than the original issuance price of the Series A Stock or Series B Stock or Series C Stock, except for certain exceptions, the conversion price of the Series A Stock and/or the Series B Stock and Series C Stock would be adjusted. The Series A Stock, Series B Stock and Series C Stock conversion prices were initially equal to the Series A Stock, Series B Stock and Series C Stock original issue prices, and were subject to recapitalization and other adjustments, as provided in the Company's then-current certificate of incorporation. As of December 31, 2022, the conversion rates were one-for-one.

Voting Rights — The holders of redeemable convertible preferred stock and the holders of common stock were to vote together and not as separate classes. Each holder of Series A Stock, Series B Stock and Series C Stock was entitled to the number of votes equal to the number of shares of common stock into which the shares of Series A Stock, Series B Stock and Series C Stock could be converted as of the record date.

For as long shares of redeemable convertible preferred stock remained outstanding, Series A stockholders, Series B stockholders and Series C stockholders, voting as a separate class, were entitled to elect Series A, Series B and Series C members of the Board and had certain protective provisions, as defined in the then-current certificate of incorporation. The holders of redeemable convertible preferred stock and Class A Common Stock, voting together as a single class on an as-converted basis, were entitled to elect three mutual directors.

Redemption — The redeemable convertible preferred stock is recorded in mezzanine equity because while it is not mandatorily redeemable, it will become redeemable at the option of the preferred stockholders upon the occurrence of certain deemed liquidation events that are considered not solely within the Company's control.

10. Derivative Tranche Liability

In connection with the Series C First Tranche Closing, prior to the IPO closing, the Company had an obligation to sell, and investors of the Series C First Tranche Closing had an obligation to purchase, an additional 12,228,881 shares of Series C redeemable convertible preferred stock at \$12.2661 per share on June 30, 2023. The obligation of each investor to purchase shares at the Series C Second Tranche Closing were subject to the fulfillment, on or before such closing, of certain conditions including not closing the Company's first underwritten public offering of its Class A Common Stock under the Securities Act or the closing of a direct listing prior to June 30, 2023. The Series C Second Tranche Closing was terminated at the IPO closing, on May 9, 2023.

Prior to May 9, 2023, the obligation to issue and purchase shares was concluded to be a forward contract derivative liability and was measured at fair value using a probability weighted model at the issuance date. The initial fair value of the forward contract was \$10.8 million and was recorded as a derivative tranche liability. The Company used the following assumptions to estimate the liability as of the issuance date: probability of achieving milestone of 90%; expected term equals the contractual term from September 2022 until June 2023; Series C preferred stock fair value of \$12.2661; and a discount rate of 25%.

Following the termination of the Series C Second Tranche Closing at the closing of the IPO the Company recognized a gain on change in fair value of the derivative tranche liability in the amount of zero and \$10.3 million in the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2023, respectively.

11. Common Stock

On May 9, 2023, immediately prior to the IPO closing, each share of the Company's Class A Common Stock then issued and outstanding was reclassified and became one share of the Company's common stock. As of September 30, 2023 and December 31, 2022, there were no shares of Class B Common Stock outstanding.

As of September 30, 2023 and December 31, 2022, the Company's common stock reserved for future issuance was as follows:

	September 30,	December 31,
	2023	2022
Shares available for future grants under Equity Incentive Plan	4,700,672	1,570,353
Outstanding stock options	8,704,462	5,036,946
Performance-based restricted stock units	2,988,492	-
Outstanding restricted stock units	2,183,413	1,107,213
Options assumed upon ValenzaBio acquisition	1,249,811	—
ESPP Shares available for future grants	900,000	—
Redeemable convertible preferred stock	—	40,743,522
Total shares reserved for future issuance	<u>20,726,850</u>	<u>48,458,034</u>

Founders' Common Stock

On the IPO closing date, according to the terms of the restated certificate of incorporation, each share of the founders' Class A Common Stock issued and outstanding was reclassified and became 1 share of the Company's common stock; no vesting or other terms were modified.

In July 2020, the Company issued 2,839,749 shares of its common stock to founders at a price of \$0.00002 per share. The issuance price was the estimated fair value of the shares as the shares were issued at inception and no intellectual property was contributed by the founders. The founders have voting rights and rights to receive dividends regardless of the vesting of the shares. Issued shares vest monthly over 48 months, as founders continue providing services to the Company. The Company has the right to repurchase unvested shares at the price paid by the founders if services are terminated. Stock-based compensation expense was minimal for these shares. In December 2022, the Company repurchased 591,613 restricted common shares at the original purchase price that were unvested as of the date of repurchase in connection with one founder's resignation. As of September 30, 2023 and December 31, 2022, 295,803 and 562,032 shares were unvested, respectively. During the three and nine months ended September 30, 2023, 88,743 and 266,229 founders' shares vested, respectively.

12. Equity Incentive Plans

In April 2023, the Company's board of directors adopted, and stockholders approved, the 2023 Equity Incentive Plan (the "2023 Plan") that became effective on May 4, 2023. The Company reserved 12,000,000 new shares of common stock for issuance under the 2023 Plan. In addition, 6,920,846 shares issued and outstanding under the Company's 2020 Equity Incentive Plan, as amended (the "2020 Plan"), may be added to the 2023 Plan as such shares become available from time to time if awards terminate, expire, or lapse for any reason without the delivery of shares, or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price. The 2023 Plan also provides that the number of shares initially reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2024 and ending on January 1, 2033, by an amount equal to the lesser of (i) 5% of the shares of common stock outstanding on the last day of the immediately preceding fiscal year, and (ii) such smaller number of shares of stock as determined by the Company's board of directors. No more than 56,762,538 shares of stock may be issued upon the exercise of incentive stock options under the 2023 Plan. The Company may grant incentive stock options, nonstatutory stock options ("NSOs"), restricted stock units ("RSUs"), restricted stock awards ("RSAs"), stock appreciation rights ("SARs"), performance awards and other awards to the Company's officers, employees, directors and consultants. Options under the 2023 Plan may be granted for periods of up to 10 years at exercise prices no less than the fair market value of the common stock on the date of grant and usually vest over four years. The exercise price of an option granted to a 10% stockholder may not be less than 110% of the fair market value of the shares on the date of grant and such option may not be exercisable after the expiration of five years from the date of grant. The grant date fair market value of all awards made under our 2023 Plan and all cash compensation paid by us to any non-employee director for services as a director in any fiscal year may not exceed \$750,000, increased to \$1,000,000 in the fiscal year of their initial service as a non-employee director. The 2023 Plan is the successor to and continuation of the 2020 Plan and no additional awards may be granted under the 2020 Plan. All outstanding awards granted under the 2020 Plan will remain subject to the terms of the 2020 Plan. The 2020 Plan provided for the grant of incentive stock options, nonstatutory stock options, RSUs and RSAs to the Company's officers, employees, directors and consultants. As of September 30, 2023, 4,661,603 shares of the Company's common stock were reserved for issuance under the 2023 Plan.

In April 2023, the Company's board of directors and stockholders adopted the 2023 Employee Stock Purchase Plan (the "ESPP"), which became effective on May 4, 2023. The ESPP authorized issuance of up to 900,000 shares of common stock. The ESPP permits participants to purchase common stock through payroll deductions of up to 15% of their eligible compensation. Employees purchase shares of common stock at a price per share equal to 85% of the lower of the fair market value at the start or end of six-month purchase and offering consecutive periods. The aggregate number of shares reserved for sale under the 2023 ESPP will increase automatically on January 1 for a period of up to 10 calendar years, commencing on January 1, 2024, by the number of shares equal to the lesser of 1% of the Company's total outstanding shares of common stock on the immediately preceding December 31st, and 2,700,000 shares or a lesser number of shares as may be determined by the board of directors.

Stock Options

Stock options issued under the 2020 Plan and 2023 Plan generally vest over a four-year period and expire ten years from the date of grant. Certain options provide for accelerated vesting if there is a change in control, as defined in the individual award agreements and the Company's severance policies.

A summary of option activity under the 2020 Plan and 2023 Plan is as follows:

	Number of Options	Weighted- Average Exercise Price Per Share	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	5,036,946	\$ 4.7872	9.5	\$ 5,488
Options granted	4,771,615	\$ 16.8645		
Options exercised	(40,570)	0.7700		
Options forfeited	(1,063,529)	10.9236		
Outstanding at September 30, 2023	<u>8,704,462</u>	<u>\$ 10.6860</u>	8.9	\$ 26,543
Exercisable at September 30, 2023	<u>1,347,153</u>	<u>\$ 4.3478</u>	6.7	\$ 8,028
Vested and expected to vest at September 30, 2023	<u>8,704,462</u>	<u>\$ 10.6860</u>	8.9	\$ 26,543

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the estimated fair value of the Company's common stock for those stock options that had exercise prices lower than the estimated fair value of the Company's common stock at September 30, 2023 and December 31, 2022. Fair value of shares vested during the three and nine months ended September 30, 2023 was \$6.0 million and \$7.8 million, respectively. The weighted-average grant date fair value of options granted during the three and nine months ended September 30, 2023 was \$16.90 and \$13.69, respectively.

ValenzaBio 2020 Stock Option Plan

On January 4, 2023, in connection with the Acquisition, the Company assumed the ValenzaBio 2020 Stock Option Plan and options to issue 1,249,811 shares of the Company's Class A Common Stock to ValenzaBio option holders, who entered into consulting agreements with the Company. The weighted-average exercise price of assumed options was \$3.6736 per share.

Under the terms of the Merger Agreement, the assumed options vested in full on March 31, 2023. No options were exercised for the three and nine months ended September 30, 2023.

The Company recognized the full amount of stock-based compensation expense of \$4.9 million, including \$3.1 million as research and development expenses and \$1.8 million as general administrative expenses, related to assumed options in the condensed consolidated statement of operations for the nine months ended September 30, 2023.

Restricted Stock Units

In 2022, the Company granted RSU awards for 1,107,213 shares vesting based on satisfaction of certain service and liquidity conditions. On March 23, 2023, the Board approved the acceleration of vesting of 138,401 RSUs. The Company accounted for the changes in vesting terms as a modification and re-measured modified awards at fair value on the modification date.

The estimated fair value of RSUs granted was \$8.0 million after modification.

On May 9, 2023, the IPO closing date, 640,416 RSUs vested and the Company recognized \$5.5 million stock-based compensation expense. The Company issued 303,237 shares and withheld 337,179 shares to satisfy tax withholding obligations of \$8.3 million paid upon the RSU settlement. 466,797 RSUs remained unvested as of September 30, 2023.

On August 16, 2023, the Company granted RSU awards for 1,725,168 shares to certain employees of the Company, which shall vest in four equal installments beginning on May 15, 2024, subject to the employee's continuous service through each applicable vesting date.

Performance-Based Restricted Stock Units

In August 2023, the Company granted PSUs to certain employees and officers of the Company. The PSUs may vest over several years subject to the achievement of (i) certain clinical development milestones over a performance period from the grant date to May 2027 (the “Performance Period”) or (ii) market conditions (i.e., stock price hurdle) based on pre-specified volume-weighted average stock price measurements as of each vesting performance measurement date, and continued employment with the Company through the applicable vesting date(s). The target number of shares under the PSUs is 3,135,104. The ultimate number of PSU shares that may vest, in the aggregate over the Performance Period, could in certain cases be up to 150% of the target number of shares upon the achievement of certain market or performance conditions.

A summary of PSU activity based on the target number of shares is presented in the following table:

	Number of PSUs	Weighted-Average Grant Date Fair Value*
Outstanding at December 31, 2022	—	\$ —
Granted	3,135,104	\$ 27.43
Vested	—	\$ —
Forfeited	(146,612)	\$ 27.43
Outstanding at September 30, 2023	2,988,492	\$ 27.43

*The grant date fair value is based only on the PSUs with market conditions and does not factor in any performance conditions.

As the PSUs granted in 2023 are subject to a market condition, the grant date fair value for such PSUs was based on a Monte Carlo simulation model. The Company estimated the fair value of PSUs based on the grant date price of its common stock of \$26.97 and the following assumptions: expected volatility of 87.71%, risk-free-rate of 4.47%, and zero expected dividend yield. In 2023, the Company granted PSUs to employees with a weighted-average grant date fair value of \$27.43. The unvested awards will expire if it is determined that the vesting conditions have not been met during the applicable three-year performance period.

2023 Employee Stock Purchase Plan

The first purchase period commenced on June 15, 2023 and will end on December 14, 2023. The Company recorded \$0.3 million in accrued liabilities as of September 30, 2023.

Stock-Based Compensation Expense

The Company uses the Black-Scholes valuation model and made the following assumptions to estimate fair value of each option at the grant date for the three and nine months ended September 30, 2023 and 2022:

	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Expected volatility	87.34% - 87.93%	99.91%	75.30% - 92.20%	99.99% - 102.81%
Expected dividend yield	0%	0%	0%	0%
Expected term (in years)	5.95 – 6.04 years	6.08 years	5.77 - 6.08 years	5.90 - 6.08 years
Risk-free interest rate	4.14% - 4.61%	3.05%	3.30% - 4.61%	1.69% - 3.26%

The following table presents the classification of stock-based compensation expense related to awards granted under its equity incentive plans (in thousands):

	Three Months ended September 30,		Nine Months ended September 30,	
	2023	2022	2023	2022
General and administrative expenses	\$ 11,741	\$ 196	\$ 22,292	\$ 1,677
Research and development expenses	3,572	364	8,661	862
Total stock-based compensation expense	\$ 15,313	\$ 560	\$ 30,953	\$ 2,539

The stock-based compensation expense relates to the following equity-based awards:

	Three Months ended September 30,		Nine Months ended September 30,	
	2023	2022	2023	2022
Restricted stock units	\$ 2,345	\$ —	\$ 7,884	\$ —
Performance-based restricted stock units	4,265	—	4,265	—
Stock options	8,577	560	18,661	1,234
ESPP	126	—	143	—
Restricted stock awards	—	—	—	1,305
Total stock-based compensation expense	\$ 15,313	\$ 560	\$ 30,953	\$ 2,539

The Company recognized \$4.9 million stock-based compensation expense related to assumed ValenzaBio options and \$0.9 million related to unvested options and RSAs net-settled at the closing of the Acquisition. As of September 30, 2023, there was \$63.2 million of unrecognized stock-based compensation expense related to granted stock options, which is expected to be recognized over a weighted-average period of 3.4 years. As of September 30, 2023, there was \$46.4 million of unrecognized stock-based compensation expense related to RSUs which will be recognized over the remaining vesting term through May 2027. The Company recognized \$4.3 million in compensation expense during the three and nine months ended September 30, 2023 related to PSUs. This expense is related only to the market conditions. As of September 30, 2023, the Company evaluated the clinical development milestone performance conditions and determined them to be not probable of achievement. As of September 30, 2023, total compensation cost not yet recognized related to unvested PSUs was \$77.7 million, which is expected to be recognized over a weighted-average period of 2.5 years. Total compensation cost not recognized related to unvested PSUs can increase up to \$104.6 million depending on the future achievement of PSUs performance conditions.

13. Related Party Transactions

During the nine months ended September 30, 2022, the Company reimbursed one of its investors \$10,000 for Series B Stock issuance costs.

14. Net Loss Per Share Attributable to Common Stockholders

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Numerator:				
Net loss	\$ (83,940)	\$ (14,406)	\$ (286,429)	\$ (44,965)
Denominator:				
Weighted average common shares outstanding	97,227,070	3,358,972	61,580,296	3,268,666
Less: Weighted-average common shares subject to repurchase	(354,323)	(1,594,679)	(442,191)	(1,848,467)
Weighted-average common shares outstanding, basic and diluted	96,872,747	1,764,293	61,138,105	1,420,199
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.87)	\$ (8.17)	\$ (4.68)	\$ (31.66)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been antidilutive:

	As of September 30,	
	2023	2022
Outstanding options to purchase common stock	8,704,462	2,598,180
Unvested RSUs outstanding	2,183,413	451,247
Outstanding options to purchase common stock assumed upon the ValenzaBio acquisition	1,249,811	0
Common stock subject to repurchase	295,803	1,477,641
Redeemable convertible preferred stock	0	40,743,522
Total	12,433,489	45,270,590

The table above does not include contingently issuable PSUs with performance vesting conditions, which as of September 30, 2023 were not deemed probable to be achieved (see Note 12).

15. Income Taxes

For the three and nine months ended September 30, 2023 and 2022, the Company did not record an income tax provision. The Company continues to maintain a 100% valuation allowance on total deferred tax assets. The Company believes it is more likely than not that the related deferred tax asset will not be realized. As a result, the Company's effective tax rate will remain at 0% because there are no estimated or discrete items that would impact the tax provision.

ITEM 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations and the unaudited interim condensed consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q should be read in conjunction with the financial statements and related notes thereto as of and for the year ended December 31, 2022 and the related Management’s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in the Prospectus dated May 4, 2023 filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the Securities Act), with the Securities and Exchange Commission (“SEC”) on May 5, 2023 (the “Final Prospectus”). This discussion and analysis and other parts of this Quarterly Report on Form 10-Q contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives and expectations for our business. Our actual results and the timing of selected events could differ materially from those described in or implied by these forward-looking statements as a result of several factors, including those set forth under “Risk Factors” in Part II, Item 1A of this Quarterly Report on Form 10-Q. See also the section titled “Special Note Regarding Forward-Looking Statements.”

Overview

ACELYRIN is a late-stage clinical biopharma company focused on identifying, acquiring, and accelerating the development and commercialization of transformative medicines. We are driven by our sense of urgency to bring life-changing therapies to patients globally, a core value that we refer to as “courageous caring.”

Our initial focus is on the treatment of diseases with pathology related to excess activation of the immune system, an area where our management and team bring industry-leading expertise. We acquired our portfolio of product candidates with the intent to develop and commercialize novel therapies that we believe may provide the opportunity to offer clinically meaningful, differentiated benefits for patients by improving upon the efficacy and/or safety of existing therapeutics directed against established targets, such as currently marketed anti-interleukin (IL)-17A agents, or by targeting new modalities. In each case, our strategy is to identify candidates we believe are “diamonds in the rough,” where, based on molecule characteristics, our collective experience and expertise, and the evolving scientific and medical understanding, we can establish a clinical development plan that tests our hypotheses as to what those benefits could mean for patients. Subsequently, we plan to utilize the results from initial clinical trials and the learnings we obtain from emerging biology to potentially expand the application of our candidates to other indications in which there are significant unmet needs.

Our current portfolio consists of multiple clinical stage product candidates being investigated across several indications, representing multi-billion-dollar opportunities in the aggregate.

Our lead product candidate is izokibep, a small protein therapeutic designed to inhibit IL-17A with high potency through tight binding affinity and the potential for robust tissue penetration due to its small molecular size, about one-tenth the size of a monoclonal antibody. Izokibep is being evaluated in multiple late-stage trials in moderate-to-severe hidradenitis suppurativa (HS), psoriatic arthritis (PsA), and uveitis, with plans to initiate an additional Phase 3 program in axial spondyloarthritis (AxSpA). We are also developing lonigutamab, a subcutaneously delivered humanized IgG1 monoclonal antibody against IGF-1R, for the treatment of thyroid eye disease (“TED”), as well as SLRN-517, a monoclonal antibody targeting inhibition of c-KIT, which reduces mast cell proliferation and activity in various allergy and inflammatory diseases such as chronic urticaria.

Specifically, we are currently conducting a:

- Phase 2b/3 trial of izokibep in HS;
- Second Phase 3 trial of izokibep in HS;
- Phase 2b/3 trial of izokibep in PsA;
- Phase 2b/3 trial of izokibep in uveitis;
- Phase 1/2 trial of lonigutamab; and a
- Phase 1/2 trial of SLRN-517.

Since our inception in July 2020, we have devoted substantially all of our resources to organizing our company, hiring personnel, business planning, acquiring and developing our product candidates, performing research and development, conducting clinical trials, enabling manufacturing activities in support of our product development efforts, establishing and protecting our intellectual property portfolio, raising capital, and providing general and administrative support for these activities. We do not have any products approved for sale and have not generated any revenue from product sales. We expect to continue to incur significant and increasing expenses and increasing substantial losses for the foreseeable future as we continue our development of and seek regulatory approvals for our product candidates and commercialize any approved products, seek to expand our product pipeline and invest in our organization. Our ability to achieve and sustain profitability will depend on our ability to successfully develop, obtain regulatory approval for and commercialize our product candidates. There can be no assurance that we will ever earn revenues or achieve profitability, or if achieved, that the revenues or profitability will be sustained on a continuing basis.

We have incurred significant losses and negative cash flows from operations since our inception. Our net loss for the years ended December 31, 2021 and 2022 was \$41.8 million and \$64.8 million, respectively, and \$286.4 million for the nine months ended September 30, 2023. The net loss of \$286.4 million in the nine months ended September 30, 2023 includes \$123.1 million of expenses related to acquired in-process research and development assets without alternative future use and \$10.0 million license fee payment to Pierre Fabre incurred in connection with the ValenzaBio acquisition. As of September 30, 2023, we had an accumulated deficit of 393.5 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and, to a lesser extent, from general and administrative costs associated with our operations. Our net losses and operating losses may fluctuate from quarter to quarter and year to year depending primarily on the timing of acquisition of any new product candidates, the timing of our preclinical studies and clinical trials, our other research and development expenses, and the timing and amount of any milestone or royalty payments due under our existing or future license agreements. We anticipate that our expenses will increase significantly in connection with our ongoing activities. Because of the numerous risks and uncertainties associated with therapeutic product development, we may never achieve or sustain profitability and, unless and until we are able to develop and commercialize our product candidates, we will need to continue to raise additional capital. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through public or private equity or debt financings, or potentially other capital sources, such as collaboration or licensing arrangements with third parties or other strategic transactions. There are no assurances that we will be successful in obtaining an adequate level of financing to support our business plans when needed on acceptable terms, or at all. In addition, we may seek additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration or licensing arrangements with third parties or other strategic transactions, we may have to relinquish rights to our intellectual property, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise capital as and when needed, or on attractive terms, we may have to significantly delay, reduce, or discontinue the development and commercialization of our product candidates or scale back or terminate our pursuit of new in-licenses and acquisitions.

We currently have no sales, marketing or commercialization capabilities. However, we intend to build the necessary sales, marketing and commercialization capabilities and infrastructure over time as our product candidates advance through clinical development. We expect to spend a significant amount in development and marketing costs prior to obtaining regulatory and marketing approval of one or more of our product candidates. We expect that our expenses and capital requirements will increase substantially in the near- to mid-term as we continue our late-stage development efforts for izokibep and to advance lonigutamab and for our preclinical programs; and add clinical, scientific, sales and marketing, operational and financial personnel, including personnel to support our product development and potential future commercialization activity.

As of September 30, 2023, we had \$788.4 million in cash and cash equivalents and short-term marketable securities. On May 9, 2023, we closed our initial public offering (the "IPO") in which we sold an aggregate of 34,500,000 shares of common stock at a price to the public of \$18.00 per share, which included 4,500,000 shares issued upon the full exercise by the underwriters of their option to purchase additional shares of common stock. We received aggregate net proceeds from the IPO of approximately \$573.6 million, after deducting underwriting discounts and commissions and other offering costs. Based on our current operating plan, we estimate that our existing cash and cash equivalents and short-term marketable securities will be sufficient to fund our operating plan and capital expenditure requirements for at least the next 12 months

from the date of this Quarterly Report on Form 10-Q. We have based this estimate on our current assumptions, which may prove to be wrong, and we may exhaust our available capital resources sooner than we expect.

Macroeconomic Trends and the Impact of the COVID-19 Pandemic

We continue to actively monitor the impact of various macroeconomic trends, such as the military conflicts in Ukraine and the Middle East, high rates of inflation, supply chain disruptions and geopolitical instability, and the COVID-19 pandemic on our business. To date, we have not experienced a material financial statement impact or business disruptions, including with our vendors or third parties, as a result of these negative macroeconomic trends or the COVID-19 pandemic. Our business has been, and may continue to be, impacted by the negative macroeconomic trends and the COVID-19 pandemic wherever we have clinical trial sites, contract manufacturing organization facilities or other business operations. For example, the COVID-19 pandemic has caused, and could continue to cause disruption in the operations of CMOs, CROs, and other third parties upon whom we rely.

Economic conditions, such as rising inflation, higher interest rates, changes in regulatory laws and monetary exchange rates, and government fiscal policies, can also have a significant effect on our operations. Moreover, negative macroeconomic conditions could adversely impact our ability to obtain financing in the future on terms acceptable to us, or at all. In addition, the geopolitical instability and related sanctions could continue to have significant ramifications on global financial markets, including volatility in the U.S. and global financial markets.

ValenzaBio Acquisition

On December 20, 2022, we entered into the ValenzaBio Merger Agreement to acquire outstanding equity of ValenzaBio (the “Acquisition”). The Acquisition closed on January 4, 2023. ValenzaBio was a privately held company developing therapies for autoimmune and inflammatory diseases. The acquisition of ValenzaBio added additional assets to our portfolio, including lonigutamab and SLRN-517. We determined that the Acquisition should be accounted for as an asset acquisition after considering whether substantially all of the fair value of the gross assets acquired was concentrated in a single asset or group of assets and whether we acquired a substantive process capable of significantly contributing to our ability to create outputs. As consideration, at the closing, we (i) issued 18,885,731 shares of our common stock to ValenzaBio stockholders and paid \$7,663 in cash to one non-accredited investor, and (ii) assumed options of ValenzaBio optionholders who entered into consulting agreements with us, which became options for the purchase of an aggregate of 1,249,811 shares of our common stock upon the closing of the Acquisition on January 4, 2023. Outstanding shares and options were exchanged at an exchange ratio of 0.8027010-for-one. The assumed options vested on March 31, 2023 and are exercisable until the earlier of (i) 12 months following the termination of the optionholder’s continuous service with us, or (ii) the original expiration date of such assumed option.

License and Collaboration Agreements

Affibody License and Collaboration Agreement

On August 9, 2021, we entered into a license and collaboration agreement with Affibody AB (“Affibody”) (the “Affibody Agreement”) under which Affibody granted us exclusive, sublicensable licenses to develop, commercialize and manufacture products containing izokibep for all human therapeutic uses on a worldwide basis, subject to a pre-existing agreement with Inmagene Biopharmaceuticals (Inmagene) with respect to certain Asian countries.

We chair a global joint steering committee composed of our designees, as well as designees from Affibody and Inmagene. As chair of the global joint steering committee, we retain final decision-making authority for izokibep global development. In doing so, we are obligated to use commercially reasonable efforts (i) to develop products containing izokibep worldwide, excluding certain defined territories, (ii) for the conduct and finalization of certain ongoing clinical trials, and (iii) to commercialize products containing izokibep for all human therapeutic uses worldwide, excluding certain defined territories, after obtaining the applicable marketing authorization. We are responsible for manufacturing both the clinical and commercial supply of licensed product globally.

Pierre Fabre License and Commercialization Agreement

Upon the closing of the Acquisition, we became the successor to ValenzaBio’s rights under the March 25, 2021 license and commercialization agreement between ValenzaBio and Pierre Fabre, as amended (the “Pierre Fabre Agreement”). We received certain exclusive worldwide licenses with the right to sublicense to certain patents, know-how

and other intellectual property to develop, manufacture, use and commercialize lonigutamab for non-oncology therapeutic indications. The license from Pierre Fabre extends to any product containing lonigutamab (excluding any fragments or derivatives) as its sole active ingredient (each, a PF Licensed Product). The Pierre Fabre Agreement prohibits us from using the licensed intellectual property in any antibody drug conjugate, multi-specific antibodies or any other derivatives of lonigutamab.

In the event we decide to sublicense the rights to develop or commercialize a PF Licensed Product in any territory outside of the United States and Canada, Pierre Fabre retains the right of first negotiation to acquire such development and commercialization rights in one or more countries in such territory. Subject to the validation of certain clinical trial criteria by a joint steering committee, Pierre Fabre has the option to reclaim all exclusive rights to develop, commercialize and exploit the PF Licensed Product in such territories and to obtain an exclusive sublicensable license in such territories for any improvements and trademarks to such PF Licensed Product, and to exploit such PF Licensed Product for non-oncology therapeutic indications, subject to certain payment obligations. If Pierre Fabre exercises such option, and intends to sublicense such rights, then we have the right of first negotiation to acquire such development and commercialization rights as to that territory, or Pierre Fabre has the right to require us to buy out its right to the option for a one-time payment of \$31.0 million or we have the right to choose to buy out Pierre Fabre's option by making the one-time payment of \$31.0 million within 30 days from Pierre Fabre's notice of exercise of such option. If Pierre Fabre does not exercise its option within the option period or if we buy out Pierre Fabre's right to the option, the option will expire or terminate, respectively. We are solely responsible for the development, regulatory approvals and commercialization of each PF Licensed Product except to the extent that Pierre Fabre reclaims rights to a PF Licensed Product in the option territory.

Novelty Nobility License and Commercialization Agreement

On January 4, 2023, in connection with the acquisition of ValenzaBio, we became the successor to an exclusive license agreement between ValenzaBio and Novelty Nobility (the "Novelty License Agreement") and obtained a worldwide exclusive license for the development and commercialization of SLRN-517, an unmodified IgG1 monoclonal antibody, as a therapeutic treatment.

For further detail on our license and collaboration Agreements, see Note 7 to our condensed consolidated financial statements entitled "Significant Agreements" in this Quarterly Report on Form 10-Q.

Components of Results of Operations

Operating Expenses

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

Research and Development

Research and development expenses consist of external and internal costs primarily related to acquiring our product candidate pipeline and technologies, and clinical development of our product candidates.

External costs include:

- costs associated with acquiring technology and intellectual property licenses that have no alternative future uses and costs incurred under in-license or assignment agreements, including milestone payments;
- costs incurred in connection with the clinical development of our product candidates, including under agreements with CROs, CMOs and other third parties that conduct clinical trials and manufacture clinical supplies, product candidates, and components on our behalf; and
- costs for third-party professional research and development consulting services.

Internal costs include:

- research and development personnel-related costs, including salaries, benefits, travel and meals expenses and stock-based compensation expense; and
- allocated facilities and other overhead costs, including software, computer supplies and accessories and other miscellaneous expenses.

We expense research and development costs as incurred. Costs of certain activities are recognized based on an evaluation of the progress to completion of specific tasks. However, payments made prior to the receipt of goods or services that will be used or rendered for future research and development activities are deferred and capitalized as prepaid expenses and other current assets on our balance sheets. The capitalized amounts are recognized as expense as the goods are delivered or as related services are performed. Substantially all of our third-party expenses relate to the development of izokibep, lonigutamab, SLRN-517 and other programs. We do not allocate employee costs, laboratory supplies and facilities, including other internal costs, to specific product candidates because these costs are associated with multiple programs and, as such, are not separately classified. We use internal resources primarily for managing our process development, manufacturing, and clinical development activities. We deploy our personnel across all of our research and development activities and, as our employees work across multiple programs, we do not currently track our costs by product candidate indication.

We expect our research and development expenses to increase substantially for the foreseeable future as we advance our product candidates into and through clinical trials, pursue regulatory approval of our product candidates, build our operational and commercial capabilities for supplying and marketing our products, if approved, and expand our pipeline of product candidates. We expect to incur significant manufacturing costs as our CMOs develop scaled commercial manufacturing processes. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our product candidates may be affected by a variety of factors, including the safety and efficacy of our product candidates, clinical data, investment in our clinical programs, competition, manufacturing capability and commercial viability. We may never succeed in achieving regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion of costs of our research and development projects or if, when and to what extent we will generate revenue from the commercialization and sale of our product candidates, if approved by the FDA and other applicable regulatory authorities.

Our future research and development costs may vary significantly based on factors such as:

- the timing and progress of our preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;

- the amount and timing of any milestone payment due under an existing, or any future, license and/or collaboration agreement;
- the number of patients that participate in our clinical trials, and per participant clinical trial costs;
- the number and duration of clinical trials required for approval of our product candidates;
- the number of sites included in our clinical trials, and the locations of those sites;
- delays or difficulties in adding trial sites and enrolling participants in our clinical trials;
- patient drop-out or discontinuation rates;
- potential additional safety monitoring requested by regulatory authorities;
- the phase of development of our product candidates;
- the efficacy and safety profile of our product candidates;
- the timing, receipt, and terms of any approvals from applicable regulatory authorities including the FDA and non-U.S. regulators, including whether we are permitted to accelerate the development of izokibep for moderate-to-severe HS as well as non-infectious uveitis;
- maintaining a continued acceptable safety profile of our product candidates following approval, if any, of our product candidates;
- changes in the competitive outlook;
- the extent to which we establish additional strategic collaborations or other arrangements; and
- the impact of any business interruptions to our operations or to those of the third parties with whom we work.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. For example, in September 2023, we announced that the primary endpoint of HiSCR75 at week 16 did not meet statistical significance in Part B of the Phase 2b/3 trial of izokibep in HS. The factors we believe contributed to the Part B results, including subject discontinuations unrelated to adverse events and a marked increase in placebo response rates during the course of the trial, could negatively impact the results of ongoing and future clinical trials of izokibep, including the ongoing Phase 3 trial of izokibep in HS, our ongoing Phase 2b/3 trial in PsA or trials in other indications. In any event, the negative results in Part B of the Phase 2b/3 trial may significantly extend our development timeline and significantly increase our development costs for HS. In this regard, we had previously planned for the inclusion of the Part B results from our Phase 2b/3 trial of izokibep in HS as part of the planned registrational package for HS. Subject to receiving feedback from the FDA regarding next steps for development of izokibep in HS, we may need to conduct and successfully complete both our ongoing Phase 3 trial in HS, as well as an additional Phase 3 trial in HS.

General and Administrative

Our general and administrative expenses consist primarily of personnel-related costs, legal and external consulting services, including those relating to intellectual property and corporate matters, and allocated overhead, including software, computer supplies and accessories, insurance and other miscellaneous expenses. Personnel-related costs include salaries, annual bonuses, benefits, recruiting fees, travel and meal expenses and stock-based compensation for our general and administrative personnel.

We expect that our general and administrative expenses will increase substantially in the future as a result of expanding our operations, including hiring personnel, preparing for potential commercialization of our product candidates, and facility occupancy costs. We also expect an increase in expenses associated with being a public company, including costs related to accounting, audit, legal, regulatory, and tax-related services associated with maintaining compliance with applicable Nasdaq and SEC requirements; additional director and officer insurance costs; and investor and public relations costs.

Other Income, Net

Other income (expense), net consists primarily of interest income and amortization of premiums and accretion of discounts on short-term marketable securities, net foreign currency transaction loss and gain on remeasurement of derivative tranche liability.

Results of Operations

Comparison of the Three Months Ended September 30, 2023 and 2022

The following table summarizes our results of operations for the three months ended September 30, 2023 and 2022 (dollars in thousands):

	Three Months Ended September 30,		Change	
	2023	2022	\$	%
Operating expenses				
Research and development	\$ 74,562	\$ 12,509	\$ 62,053	496 %
General and administrative	19,861	2,887	16,974	588 %
Total operating expenses	94,423	15,396	79,027	513 %
Loss from operations	(94,423)	(15,396)	(79,027)	513 %
Interest income	10,502	986	9,516	*
Other expense, net	(19)	4	(23)	*
Net loss	\$ (83,940)	\$ (14,406)	\$ (69,534)	483 %

* not meaningful

Research and Development Expenses

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

	Three Months Ended September 30,		Change	
	2023	2022	\$	%
External costs:				
CRO, CMO and Affibody transition services	\$ 62,706	\$ 8,997	\$ 53,709	597 %
Professional consulting services	1,519	468	1,051	225 %
Other research and development costs, including laboratory materials and supplies	23	13	10	77 %
Internal costs:				
Personnel-related costs	9,991	2,990	7,001	234 %
Facilities and overhead costs	323	41	282	*
Total research and development expense	\$ 74,562	\$ 12,509	\$ 62,053	496 %

* not meaningful

Research and development expenses increased by \$62.1 million, from \$12.5 million for the three months ended September 30, 2022, to \$74.6 million for the three months ended September 30, 2023. The increase in research and development expenses was primarily due to costs associated with CMO and CRO expenses, personnel-related costs and professional consulting services.

External CRO, CMO and Affibody transition services expenses increased by \$53.7 million, from \$9.0 million for the three months ended September 30, 2022 to \$62.7 million for the three months ended September 30, 2023. This increase in expenses was primarily as a result of the expansion and advancement of multiple immunology product candidates being investigated in parallel across multiple indications. We incurred development expenses of \$1.9 million under our Affibody transition services agreement for the three months ended September 30, 2022. We did not incur such development expenses during the three months ended September 30, 2023 and do not expect to incur any significant expenses of such nature in future periods, as Affibody transition services were substantially completed during the year ended December 31, 2022. We expect that our CRO and CMO expenses related to our products in development will continue to increase as we progress in the clinical trials of these assets.

Our CRO and CMO expenses by program for the three months ended September 30, 2023 and 2022 were as follows (in thousands):

	Three Months Ended September 30,	
	2023	2022
Izokibep	\$ 55,519	\$ 7,090
Lonigutamab (XLRN-421)	2,724	—
SLRN-517	3,950	—
Other	513	—
Total CRO and CMO expense	\$ 62,706	\$ 7,090

Expenses related to professional consulting services increased by \$1.0 million, from \$0.5 million for the three months ended September 30, 2022 to \$1.5 million for the three months ended September 30, 2023. We recognized less than \$0.1 million consulting services expense during the three months ended September 30, 2023 related to former ValenzaBio research and development employees who entered into consulting agreements with us. Other professional consulting services expenses increased by \$1.0 million, as we engage with other consultants for our research and development activities.

Personnel-related costs increased by \$7.0 million from \$3.0 million for the three months ended September 30, 2022 to \$10.0 million for the three months ended September 30, 2023. Employees' salaries and benefits increased by \$3.8 million for the three months ended September 30, 2023 compared to the three months ended September 30, 2022 related to increased headcount from 27 to 73 employees. Stock-based compensation expense increased by \$3.2 million, from \$0.4 million for the three months ended September 30, 2022 to \$3.6 million for the three months ended September 30, 2023, as a result of additional options granted and an increase in our common stock fair value.

Facilities and allocated overhead costs increased by \$0.3 million from less than \$0.1 million for the three months ended September 30, 2022 to \$0.3 million for the three months ended September 30, 2023, primarily as a result of increased allocated expenses, maintenance agreements expenses, software subscriptions and other IT related expenses.

General and Administrative Expenses

General and administrative expenses increased by \$17.0 million from \$2.9 million for the three months ended September 30, 2022 to \$19.9 million for the three months ended September 30, 2023. These expenses increased primarily as a result of expanding our organizational capability necessary to support the development and commercialization of our broad portfolio of immunology product candidates being investigated in multiple indications.

Employees' salaries and benefits increased by \$2.5 million for the three months ended September 30, 2023 compared to September 30, 2022 as a result of increase in headcount as well as \$0.6 million severance expense related to the departure of the former CFO in August 2023. The stock-based compensation expense increased by \$11.5 million from \$0.2 million for the three months ended September 30, 2022 to \$11.7 million for the three months ended September 30, 2023, due to additional stock options, restricted stock units and performance-based restricted stock units granted as well as due to acceleration of vesting of stock options related to the departure of the former CFO in August 2023. Expenses related to professional consulting services increased by \$2.1 million, from \$0.8 million for the three months ended September 30, 2022 to \$2.9 million for the three months ended September 30, 2023 due to an increase in consulting, legal, recruiting, audit and accounting services to support our Company's growth, business development and other costs of operating as a public company. Facilities and allocated overhead costs increased by \$0.9 million from \$0.1 million for the three months ended September 30, 2022 to \$1.0 million for the three months ended September 30, 2023, primarily as a result of increased allocated expenses, bank fees, rent and insurance expenses, software subscriptions and other IT related expenses.

Total Other Income, Net

Total other income, net increased by \$9.5 million, from \$1.0 million net income for the three months ended September 30, 2022 to \$10.5 million net income for the three months ended September 30, 2023. The increase was primarily related to interest income earned on our available-for-sale marketable securities due to the increase in the balance as the Company completed its IPO in May 2023 and higher interest rates.

We recognized \$10.5 million and \$1.0 million interest income earned on our available-for-sale marketable securities for the three months ended September 30, 2023 and 2022, respectively.

Comparison of the Nine Months Ended September 30, 2023 and 2022

The following table summarizes our results of operations for the nine months ended September 30, 2023 and 2022 (dollars in thousands):

	Nine Months Ended September 30,		Change	
	2023	2022	\$	%
Operating expenses				
Research and development	\$ 272,512	\$ 38,222	\$ 234,290	613 %
General and administrative	44,440	8,145	36,295	446 %
Total operating expenses	316,952	46,367	270,585	584 %
Loss from operations	(316,952)	(46,367)	(270,585)	584 %
Change in fair value of derivative liability	10,291	—	10,291	100 %
Interest income	20,486	1,399	19,087	*
Other expense, net	(254)	3	(257)	*
Net loss	\$ (286,429)	\$ (44,965)	\$ (241,464)	537 %

* not meaningful

Research and Development Expenses

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

	Nine Months Ended September 30,		Change	
	2023	2022	\$	%
External costs:				
License fees and acquired in-process research and development expenses	133,057	—	133,057	100 %
CRO, CMO and Affibody transition services	107,269	30,114	77,155	256 %
Professional consulting services	8,572	1,088	7,484	688 %
Other research and development costs, including laboratory materials and supplies	109	28	81	289 %
Internal costs:				
Personnel-related costs	22,724	6,935	15,789	228 %
Facilities and overhead costs	781	57	724	*
Total research and development expense	\$ 272,512	\$ 38,222	\$ 234,290	613 %

* not meaningful

Research and development expenses increased by \$234.3 million, from \$38.2 million for the nine months ended September 30, 2022, to \$272.5 million for the nine months ended September 30, 2023. The increase was primarily related to License fees and acquired in-process research and development expenses, external CRO, CMO and Affibody transition services expenses and costs related to personnel and professional consulting services.

License fees and acquired in-process research and development expenses include \$123.1 million related to the acquired lonigutamab and SLRN-517 assets, and \$10.0 million related to a non-refundable license fee paid in connection with the amendment of Pierre Fabre Agreement, incurred in connection with the Acquisition. The estimated fair value of lonigutamab asset of \$114.8 million and SLRN-517 asset of \$8.2 million, were expensed as we concluded that these assets were still in clinical and preclinical development and have no alternative future use.

External CRO, CMO and Affibody transition services expenses increased by \$77.2 million, from \$30.1 million for the nine months ended September 30, 2022 to \$107.3 million for the nine months ended September 30, 2023. We incurred development expenses of \$0.2 million and \$15.1 million under our Affibody transition services agreement for the nine months ended September 30, 2023 and 2022, respectively. Affibody transition services were substantially complete during the year ended December 31, 2022, and

we do not expect to incur any such significant expenses in future periods. We expect that our CRO and CMO expenses related to our products in development will continue to increase as we progress in the clinical trials of these assets.

Our CRO and CMO expenses by program for the nine months ended September 30, 2023 and 2022 were as follows (in thousands):

	Nine Months Ended September 30,	
	2023	2022
Izokibep	\$ 90,640	\$ 14,992
Lonigutamab (XLRN-421)	5,779	—
SLRN-517	7,996	—
Other	2,631	—
Total CRO and CMO expense	\$ 107,046	\$ 14,992

Expenses related to professional consulting services increased by \$7.5 million, from \$1.1 million for the nine months ended September 30, 2022 to \$8.6 million for the nine months ended September 30, 2023. We recognized stock-based compensation expense of \$3.1 million and consulting services expense of \$0.7 million for the nine months ended September 30, 2023. These expenses relate to the assumed ValenzaBio options and expenses incurred for former ValenzaBio research and development employees, who entered into consulting agreements with us. Other professional consulting services expenses increased by \$3.7 million, as we engage with other consultants for our research and development activities.

Personnel-related costs increased by \$15.8 million from \$6.9 million for the nine months ended September 30, 2022 to \$22.7 million for the nine months ended September 30, 2023. In January 2023, we recognized \$2.5 million severance obligation expense in connection with the Acquisition. Employees' salaries and benefits increased by \$8.6 million for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 related to increased headcount. Stock-based compensation expense increased by \$4.7 million, from \$0.9 million for the nine months ended September 30, 2022 to \$5.6 million for the nine months ended September 30, 2023, as a result of additional options granted and an increase in our common stock fair value.

Facilities and allocated overhead costs increased by \$0.7 million from \$0.1 million for the nine months ended September 30, 2022 to \$0.8 million for the nine months ended September 30, 2023, primarily as a result of increased allocated expenses, maintenance agreements expenses, software subscriptions and other IT related expenses.

General and Administrative Expenses

General and administrative expenses increased by \$36.3 million from \$8.1 million for the nine months ended September 30, 2022 to \$44.4 million for the nine months ended September 30, 2023.

Employees' salaries and benefits increased by \$5.7 million for the nine months ended September 30, 2023 compared to September 30, 2022 as a result of increase in headcount from 12 to 35 employees as well as \$0.6 million severance expense related to the departure of the former CFO in August 2023. The stock-based compensation expense increased by \$17.9 million from \$1.7 million for the nine months ended September 30, 2022 to \$19.6 million for the nine months ended September 30, 2023. For the nine months ended September 30, 2023, we recognized \$5.5 million related to restricted stock unit awards granted to our chief executive officer that vested upon the IPO closing. For the nine months ended September 30, 2022 we recognized \$1.3 million expense related to vested restricted stock awards granted to our chief executive officer vested in March 2022. In January 2023, in connection with the Acquisition, we recognized \$2.7 million stock-based compensation expenses. The increase in our stock-based compensation expense was due to a result of additional stock options, restricted stock units and performance-based restricted stock units granted and increase in our common stock fair value. In January 2023, in connection with the Acquisition, we also recognized \$2.4 million severance obligation expense. Expenses related to professional consulting services increased by \$7.8 million, from \$1.8 million for the nine months ended September 30, 2022 to \$9.6 million for the nine months ended September 30, 2023 due to an increase in consulting, legal, recruiting, audit and accounting services to support our Company's growth. Facilities and allocated overhead costs increased by \$1.4 million from \$0.3 million for the nine months ended September 30, 2022 to \$1.7 million for the nine months ended September 30, 2023, primarily as a result of increased allocated expenses, bank fees, rent and insurance expenses, software subscriptions and other IT related expenses. Other miscellaneous general and administrative expenses increased by \$1.1 million during the nine months ended September 30, 2023 as compared to the nine months ended September 30, 2022.

Total Other Income, Net

Total other income, net increased by \$29.1 million, from \$1.4 million net income for the nine months ended September 30, 2022 to \$30.5 million net income for the nine months ended September 30, 2023. The increase was primarily related to the change in fair value of the Series C derivative tranche liability and interest income earned on our available-for-sale marketable securities.

We also recognized \$20.5 million and \$1.4 million interest income earned on our available-for-sale marketable securities for the nine months ended September 30, 2023 and 2022, respectively. The increase in the interest income is primarily due to an increase in the balance of cash equivalents and available-for-sale marketable securities as the Company completed its IPO in May 2023 and higher interest rates.

We recognized a gain of \$10.3 million related to the change in fair value of the Series C derivative tranche liability for the nine months ended September 30, 2023. The Series C derivative tranche liability was recognized in September 2022 and represents an obligation to issue Series C redeemable convertible preferred stock shares in the Series C second tranche closing under certain conditions. The Series C derivative tranche liability was recorded at fair value and were remeasured at each reporting period until it was terminated upon the IPO closing in May 2023.

Liquidity, Capital Resources and Capital Requirements

Sources of Liquidity

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from our operations. From inception, we have primarily funded our operations from sales of shares of our redeemable convertible preferred stock in private placements and issuance of our common stock upon the IPO closing in May 2023.

As of September 30, 2023, we had \$788.4 million in cash and cash equivalents and short-term marketable securities. Based on our current operating plan, we estimate that our existing cash and cash equivalents and short-term marketable securities will be sufficient to fund our current operating plan and capital expenditure requirements for at least the next 12 months from the date of this Quarterly Report on Form 10-Q. We have based this estimate on our current assumptions, which may prove to be wrong, and we may exhaust our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with therapeutic product development, we may never achieve or maintain profitability and, unless and until we are able to commercialize our product candidates, if ever, we will continue to be dependent upon equity financing, debt financing, and other forms of capital raises. If we are unable to raise capital as and when needed or on attractive terms, we may have to significantly delay, reduce, or discontinue the development and commercialization of our product candidates or scale back or terminate our pursuit of new in-licenses and acquisitions.

Future Funding Requirements

Our primary uses of cash are to fund our operations, which consist primarily of research and development expenditures related to our programs and, to a lesser extent, general and administrative expenditures. We anticipate that we will continue to incur significant and increasing expenses for the foreseeable future as we continue to advance our product candidates, expand our corporate infrastructure, including the costs associated with being a public company, further our research and development initiatives for our product candidates, and incur costs associated with potential commercialization. We are subject to all of the risks typically related to the development of new drug candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses, and prepaid expenses.

Our future funding requirements will depend on many factors, including the following:

- the timing, scope, progress and results of our preclinical studies and clinical trials for our current and future product candidates;
- the number, scope and duration of clinical trials required for regulatory approval of our current and future product candidates;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities for our product candidates, including any requirement to (and/or as a result of negative or inconclusive clinical trial results for any of our product candidates) conduct more studies or generate additional data beyond that which we currently expect would be required to support a Biologic License Application (BLA);
- the cost of manufacturing clinical and commercial supplies as well as scale up of our current and future product candidates;
- the increase in the number of our employees and expansion of our physical facilities to support growth initiatives;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements, including our license and collaboration agreements with Affibody and Pierre Fabre, and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;

- the cost of filing and prosecuting our patent applications, and maintaining and enforcing our patents and other intellectual property rights;
- the extent to which we acquire or in-license other product candidates and technologies;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against our product candidates;
- the effect of competing technological and market developments;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- our implementation of various computerized informational systems and efforts to enhance operational systems;
- the costs associated with being a public company; and
- the impacts of negative macroeconomic trends, such as high rates of inflation, global supply chain disruptions and geopolitical instability, and the COVID-19 pandemic which may exacerbate the magnitude of the factors discussed above.

Furthermore, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development expenditures.

Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through public or private equity or debt financings, or potentially other capital sources, such as collaboration or licensing arrangements with third parties or other strategic transactions. There are no assurances that we will be successful in obtaining an adequate level of financing to support our business plans when needed on acceptable terms, or at all. In addition, we may seek additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration or licensing arrangements with third parties or other strategic transactions, we may have to relinquish rights to our intellectual property, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise capital as and when needed or on attractive terms, we may have to significantly delay, reduce, or discontinue the development and commercialization of our product candidates or scale back or terminate our pursuit of new in-licenses and acquisitions.

Cash Flows

The following summarizes our cash flows for the periods indicated (in thousands):

	Nine Months Ended September 30,	
	2023	2022
Net cash used in operating activities	\$ (96,074)	\$ (43,428)
Net cash used in investing activities	(355,138)	(109,487)
Net cash provided by financing activities	565,840	274,613
Net increase in cash and cash equivalents	<u>\$ 114,628</u>	<u>\$ 121,698</u>

Operating Activities

Net cash used in operating activities was \$96.1 million and \$43.4 million for the nine months ended September 30, 2023 and 2022, respectively.

Cash used in operating activities in the nine months ended September 30, 2023 was primarily due to our net loss for the period of \$286.4 million, of which \$10.0 million is presented as cash used in investing activities as it related to a license fee payment to Pierre Fabre incurred in connection with the Acquisition. Adjustments to net loss for non-cash items also included \$123.1 million expense related to in-process research and development assets without alternative future use incurred in connection with the Acquisition, \$31.0 million related to stock-based compensation expense, \$10.3 million gain related to the change in fair value of the derivative tranche liability, \$5.6 million gain related to an accretion of discounts on short-term marketable securities, \$0.1 million depreciation and amortization expense and \$0.1 million non-cash lease expense. The changes in operating assets and liabilities of \$42.0 million include an increase of \$30.8 million in accrued research and development expenses, an increase of \$11.2 million in accounts payable, an increase of \$1.7 million in severance liability, and a decrease of \$1.7 million in prepaid expenses and other assets, non-current, partially offset by an increase of \$3.3 million in prepaid expenses and other current assets, and a decrease of less than \$0.1 million in operating lease liability. The increase in accrued research and development expenses and accounts payable were primarily due to costs associated with the development of izokibep, SLRN-517 and lonigutamab. The increase in severance liability related to our obligation to make severance payments to certain former ValenzaBio employees in connection with the Acquisition.

Cash used in operating activities in the nine months ended September 30, 2022 was primarily due to our net loss for the period of \$45.0 million, adjusted by non-cash charge of \$2.5 million related to stock-based compensation expense and \$0.1 million loss related to amortization of premiums and discounts on short-term marketable securities. The changes in operating assets and liabilities of \$1.1 million include an increase of 2.6 million in prepaid expenses and other current assets, and an increase of \$1.2 million in prepaid expenses and other assets, non-current, partially offset by an increase of \$1.2 million in accounts payable, a \$0.9 million increase in accrued compensation and other current liabilities, and an increase of \$0.6 million in accrued research and development expenses .

Investing Activities

Cash used in investing activities for the nine months ended September 30, 2023 of \$355.1 million related to \$538.0 million purchase of marketable securities and accrued interest, \$10.0 million paid to Pierre Fabre for the amended license and commercialization agreement in connection with the Acquisition and \$2.2 million purchases of fixed assets, partially offset by \$128.7 million maturities of short-term marketable securities, \$56.3 million in sales of marketable securities, and \$10.0 million of cash acquired, net of acquisition costs, related to the Acquisition.

Cash used in investing activities for the nine months ended September 30, 2022 of \$109.5 million related to purchase of marketable securities of \$262.0 million, partially offset by proceeds from maturities of short-term marketable securities of \$152.5 million.

Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2023 was \$565.8 million, which consisted of \$574.1 million net proceeds received from issuance of common stock upon the initial public offering, offset by \$8.3 million taxes paid related to net share settlement of restricted stock units and \$0.0 million for payments for deferred offering costs.

Cash provided by financing activities for the nine months ended September 30, 2022 of \$274.6 million related to net proceeds received from the issuance of redeemable convertible preferred stock shares.

Contractual Obligations and Commitments

We enter into contracts in the normal course of business with suppliers, CROs, CMOs, clinical trial sites, and the like. These agreements provide for termination at the request of either party generally with less than one-year notice and, therefore, we believe that our non-cancelable obligations under these agreements are not material. We do not currently expect any of these agreements to be terminated and did not have any non-cancelable obligations under these agreements as of September 30, 2023 and December 31, 2022.

We have milestones, royalties, and/or other payments due to third parties under our existing license and collaboration agreements. See Note 7 to our condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q. We could not estimate when such payments will be due and none of these events were probable to occur as of September 30, 2023 and December 31, 2022.

Leases

In January 2023, we entered into an agreement to lease 10,012 square feet of office space located in Agoura Hills, California. The term of the lease is 65 months with an option to extend the term by an additional three-year period. Monthly rent payments are approximately \$30,500, subject to an annual 3.0% increase and six months rental abatement during the first year. In addition to base rent, we pay our share of operating expenses and taxes.

In July 2023, the Company entered into a lease agreement to rent approximately 22,365 square feet of office space in South San Francisco with the commencement date to be determined upon completion of work to be performed by the landlord. The term of the lease is 60 months with an option to extend it for an additional three years at then current market rates. Monthly base rent payments are approximately \$150,000, subject to an annual 3.5% increase and a share of building operating expenses. The lease has not commenced as of September 30, 2023.

Recently Issued Accounting Pronouncements

See Note 2 to our condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for more information regarding recently issued accounting pronouncements.

Critical Accounting Policies and Significant Judgments and Estimates

A summary of critical accounting policies, significant judgements and estimates are disclosed in Note 2 of the notes to the audited consolidated financial statements for the year ended December 31, 2022 included in the Final Prospectus filed with the SEC on May 5, 2023. There have been no material changes to critical accounting policies and estimates during the nine months ended September 30, 2023.

Off-Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Emerging Growth Company Status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (a) are no longer an emerging growth company or (b) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our condensed consolidated financial statements may not be comparable to those of companies that comply with the new or revised accounting pronouncements as of public company effective dates. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate and Market Risk

The primary objectives of our investment activities are to ensure liquidity and to preserve capital. We are exposed to market risks related to changes in interest rates of our cash equivalents and short-term investments. However, due to the nature of these cash equivalents and investments, we do not believe that a hypothetical 10% increase or decrease in interest rates during any of the periods presented would have had a material effect on our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Foreign Currency Exchange Fluctuations

All of our employees and our operations are currently located in the United States and our expenses are generally denominated in U.S. dollars. However, we do utilize certain research and development services vendors outside of the United States for our manufacturing of drug substances and clinical supplies. As such, our expenses are denominated in both U.S. dollars and foreign currencies. Therefore, our operations are and will continue to be subject to fluctuations in foreign currency exchange rates. To date, foreign currency transaction gains and losses have not been material to our condensed consolidated financial statements, and we have not had a formal hedging program with respect to foreign currency. We do not believe that a hypothetical 10% increase or decrease in exchange rates during any of the periods presented would have had a material effect on our financial statements included elsewhere in Quarterly Report on Form 10-Q.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and research and development costs. We do not believe that inflation had a material effect on our business, results of operations, or financial condition, or on our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2023, the end of the period covered by this Quarterly Report on Form 10-Q. Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”)) are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to a company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Based on their evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were not effective as of September 30, 2023 because of the material weaknesses in our internal control over financial reporting described below.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

We identified material weaknesses in the design and operating effectiveness of our internal control over financial reporting related to the fact that we lacked a sufficient number of professionals to consistently establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives. The lack of sufficient number of professionals further contributed to the following additional material weaknesses. We did not design and maintain an effective risk assessment process at a precise enough level to identify new and evolving risks of material misstatement in the consolidated financial statements. Additionally, we did not design and maintain effective controls over the segregation of duties related to journal entries and account reconciliations. Specifically, certain personnel had the ability to both (i) create and post journal entries within the company’s general ledger system and (ii) prepare and review account reconciliations without a review performed by someone without conflicting duties.

There were no adjustments that resulted from the above material weaknesses. However, these material weaknesses could result in a misstatement of substantially all of our accounts or disclosures that would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected.

Remediation Plans

We have taken and will continue to take certain measures to remediate the material weaknesses described above.

As of September 30, 2023, we have continued with the remediation steps that were initiated in the first quarter of 2023, including, but not limited to, hiring additional accounting personnel to build our finance organization. Specifically, we hired our vice president and controller and a director of technical accounting during the quarter ended March 31, 2023.

We continued to refine the design and testing operating effectiveness of the controls related to the material weaknesses during the quarter ended September 30, 2023. We continue using services of a third-party firm to support management in testing the operating effectiveness of controls. While we believe these measures will remediate the material weaknesses identified and strengthen our internal control over financial reporting, the material weaknesses will not be considered remediated until the controls described above operate for a sufficient period of time and management has concluded, through testing, that these controls are effective.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2023, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

In designing and evaluating the disclosure controls and procedures, management recognizes that because of the inherent limitations in all control systems, any controls and procedures, no matter how well designed and operated, can provide only reasonable not absolute, assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and the benefits of controls and procedures must be considered relative to their costs.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we may become involved in legal proceedings arising from the ordinary course of business. We believe there are currently no pending legal proceedings to which we or our property are subject that could have a material adverse effect on our financial position, results of operations or cash flows.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. Before deciding to invest in shares of our common stock, you should carefully consider the risks described below, together with the other information contained in this Quarterly Report on Form 10-Q, including in the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and in our condensed consolidated financial statements and the related notes included elsewhere in this Quarterly Report on Form 10-Q. We cannot assure you that any of the events discussed below will not occur. These events could adversely impact our business, financial condition, results of operations and prospects. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment.

Risk Factor Summary

Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks that we face, follows this summary. This summary is qualified in its entirety by that more complete discussion of such risks and uncertainties.

- We are a clinical stage biopharma company with a limited operating history, no products approved for commercial sale, have incurred substantial losses since our inception and anticipate incurring substantial and increasing losses for the foreseeable future.
- Preclinical and clinical development involves a lengthy and expensive process, with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates.
- We will require substantial additional financing to achieve our goals and failure to obtain additional capital when needed, or on acceptable terms to us, could cause us to delay, limit, reduce, or terminate our product development or future commercialization efforts.
- Our clinical trials may reveal significant adverse events not seen in our preclinical studies or prior clinical trials and may result in a safety or tolerability profile that could delay or prevent regulatory approval or market acceptance of izokibep, lonigutamab, any of our other product candidates or any future product candidates.
- We face competition from entities that have made substantial investments into the rapid development of novel treatments for immunological indications, including large and specialty pharmaceutical and biotechnology companies, many of which already have approved therapies in our current indications.
- Our business depends entirely on the success of our product candidates and we cannot guarantee that these product candidates will successfully complete development, receive regulatory approval, or be successfully commercialized. If we are unable to develop, receive regulatory approval for, and ultimately successfully commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- Our ongoing and planned Phase 3 clinical trials of izokibep, even if successfully completed, may not be sufficient for approval of izokibep for the applicable indication.
- Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal. We may also be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

- We may have conflicts with our current or future licensors or collaborators that could delay or prevent the development or commercialization of our product candidates.
- We acquired ValenzaBio, and we expect to engage in strategic transactions in the future, which could impact our liquidity, increase our expenses and present significant distractions to our management.
- If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates and any future product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and commercialize our product candidates may be adversely affected.
- We have identified material weaknesses in our internal control over financial reporting. If we fail to remediate these material weaknesses, or if we experience additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

Risks Related to Our Financial Position and Need for Capital

We are a clinical stage biopharma company with a limited operating history, no products approved for commercial sale, have incurred substantial losses since our inception and anticipate incurring substantial and increasing losses for the foreseeable future.

We are a clinical stage biopharma company with a limited operating history. We have no product candidates approved for commercial sale and have not generated any revenue. Biopharmaceutical product development is a highly speculative undertaking. It entails substantial upfront capital expenditures and significant risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval or become commercially viable.

Our lead product candidate is izokibep, an IL-17A inhibitor. In addition, we are advancing lonigutamab, and are also developing SLRN-517, a monoclonal antibody targeting c-KIT. We have and will continue to incur significant development and other expenses related to our clinical development and ongoing operations. Our net loss for the years ended December 31, 2021 and 2022 was \$41.8 million and \$64.8 million, respectively, and \$286.4 million for the nine months ended September 30, 2023. As of September 30, 2023, we had an accumulated deficit of 393.5 million. Substantially all of our losses have resulted from expenses incurred in connection with the acquisition and development of our pipeline and from general and administrative costs associated with our operations. We expect to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our development of our product candidates.

We anticipate that our expenses will increase substantially if, and as, we:

- conduct further clinical trials for izokibep, lonigutamab, SLRN-517 and other programs;
- identify additional product candidates and acquire rights from third parties to those product candidates through licenses or other acquisitions, and conduct development activities, including preclinical studies and clinical trials;
- procure the manufacturing of preclinical, clinical and commercial supply of our current and future product candidates;
- seek regulatory approvals for our product candidates or any future product candidates;
- commercialize our current product candidates or any future product candidates, if approved;
- take steps toward our goal of being an integrated biopharma company capable of supporting commercial activities, including establishing sales, marketing and distribution infrastructure;

- attract, hire and retain qualified clinical, scientific, operations and management personnel;
- add and maintain operational, financial and information management systems;
- protect, maintain, enforce and defend our rights in our intellectual property portfolio;
- defend against third-party interference, infringement and other intellectual property claims, if any;
- address any competing therapies and market developments;
- experience any delays in our preclinical studies or clinical trials and regulatory approval for our product candidates due to the impacts of negative macroeconomic trends, such as high rates of inflation, geopolitical instability and war, and the lingering effects of the COVID-19 pandemic; and
- incur costs associated with operating as a public company.

Even if we succeed in commercializing one or more product candidates, we expect to incur substantial development costs and other expenditures to develop and market additional product candidates. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue or raise additional capital. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and our working capital.

Preclinical and clinical development involves a lengthy and expensive process, with an uncertain outcome, and results of earlier studies and trials may not be predictive of future results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates.

All of our product candidates are either in preclinical or clinical development and their risk of failure is high. It is impossible to predict when or if any of our product candidates will receive regulatory approval. To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through preclinical studies and lengthy, complex and expensive clinical trials that our product candidates are safe and effective in humans. Clinical testing can take many years to complete, and its outcome is inherently uncertain. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. For example, despite encouraging results from the open-label Part A of our Phase 2b/3 trial of izokibep in HS, the primary endpoint of HiSCR75 at week 16 did not meet statistical significance in the Part B portion of such trial. This result significantly harmed our stock price and investor perceptions of the prospects for izokibep in HS, and may significantly extend our development timeline for such indication. The factors we believe contributed to the Part B results were primarily subject discontinuations unrelated to adverse events and a marked increase in placebo response rates during the course of the trial that led to overall placebo response rates that were markedly higher than historical rates in the HS indication. Our clinical trials are subject to significant risk factors that can have a material and negative impact on outcomes, many of which are beyond our control. Such factors include unexpectedly high placebo response rates and patient responder discontinuations unrelated to adverse events, such as we observed in our Phase 2b/3 trial of izokibep in HS. Other factors that can impact our clinical trial results include, without limitation, patient baseline demographics, clinical protocol adherence, physician and patient scored outcome measures, among others. Any such negative impacts could materially and adversely effect our business, development, regulatory approval and commercialization prospects of izokibep, or other product candidates. In addition, differences in trial design make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. A number of companies in the biopharmaceutical industry, including us, have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unfavorable safety profiles, notwithstanding promising results in earlier trials. In addition, results in one indication may not be predictive of results for the same product candidate in another indication. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of such product candidates. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful. Commencing any future clinical trials is subject to finalizing the trial design and submitting an application to the FDA or a similar foreign regulatory authority. Even after we make our submission, the FDA or other regulatory authorities could disagree that we have satisfied their requirements or disagree with our study design, which may require us to complete additional trials, amend our protocols or impose stricter conditions on the commencement of clinical trials. There is typically a high rate of failure of product candidates proceeding through clinical

trials, and failure can occur at any time. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support the approval of our current or any future product candidates.

We expect to continue to rely in part on our collaborators, contract research organizations (“CROs”) and clinical trial sites to ensure the proper and timely conduct of our clinical trials, including the participant enrollment process, and we have limited influence over their performance. We or our collaborators may experience delays in initiating or completing clinical trials due to unforeseen events or otherwise, that could delay or prevent our ability to receive marketing approval or commercialize our current and any future product candidates, including:

- regulators, such as the FDA or comparable foreign regulatory agencies, Institutional Review Boards (“IRBs”), or ethics committees may impose additional requirements before permitting us to initiate a clinical trial, may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site, may not allow us to amend trial protocols, or may require that we modify or amend our clinical trial protocols;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with trial sites and CROs, the terms of which can be subject to extensive negotiation and may vary significantly;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- the number of participants required for clinical trials may be larger, enrollment in clinical trials may be slower, or participants may drop out or fail to return for post-treatment follow-up, in each case at a higher rate than we anticipate (as we experienced with respect to participant discontinuations in the Part B portion of our Phase 2b/3 trial of izokibep in HS);
- the cost of clinical trials may be greater than we anticipate, or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA upon the submission of a Biologic License Application (“BLA”);
- the quality or quantity of data relating to our product candidates or other materials necessary to conduct our clinical trials may be inadequate to initiate or complete a given clinical trial or support marketing approval;
- reports from clinical testing of other therapies may raise safety, tolerability or efficacy concerns about our product candidates; and
- clinical trials of our product candidates may fail to show appropriate safety, tolerability or efficacy, may produce negative or inconclusive results, or may otherwise fail to improve on the existing standard of care, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs.

Participant enrollment, a significant factor in the timing of clinical trials, is affected by many conditions including the size and nature of the patient population, the number and location of clinical sites we enroll, the proximity of participants to clinical sites, the eligibility and exclusion criteria and overall design of the clinical trial, the inability to obtain and maintain participant consents, the ongoing risk that enrolled participants will drop out before completion, competing clinical trials and clinicians’ and patients’ perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies. Risks related to patient enrollment are heightened in longer clinical trials. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same areas as our product candidates, and this competition may reduce the number and types of participants available to us. Participants, including in any control groups, may withdraw from the clinical trial if they are not experiencing improvement in their underlying disease or condition or if they experience other difficulties or issues. Participants may also withdraw from the clinical trial if they experience improvement in their underlying manifestations of disease, and determine that further treatment is not necessary or unduly burdensome relative to their experienced improvement. Additionally, we could encounter delays if treating clinicians encounter unresolved ethical issues associated with enrolling participants in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Even if we are able to enroll a sufficient number of participants in our clinical trials, delays in enrollment or small population size may result in increased costs or may affect the timing or outcome of our clinical trials. We have in the past and may in the future experience participant withdrawals or discontinuations from our trials. Such

withdrawals may compromise the quality of our data or contribute to negative or inconclusive results from trials, as we experienced in the week 16 Part B results of our Phase 2b/3 trial of izokibep in HS. Any of these conditions may negatively impact our ability to successfully complete such trials and/or include results from such trials in regulatory submissions, which could adversely affect our ability to advance the development of our product candidates in a timely and cost-efficient manner, or at all. For example in light of our week 16 Part B results in our Phase 2b/3 trial of izokibep in HS, subject to FDA feedback, the timeline for any potential related BLA submission for such indication may be significantly extended (or ultimately may not occur).

We could also encounter delays if a clinical trial is suspended, put on clinical hold or terminated by us, IRBs, or regulatory authorities, or if a clinical trial is recommended for suspension or termination by its applicable Data Safety Monitoring Board (“DSMB”). A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with applicable regulatory requirements, guidelines or clinical protocols; failure by CROs to perform in accordance with Good Clinical Practice (“GCP”) requirements; inspection of the clinical trial operations or trial site by the FDA, EMA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects; failure to establish or achieve clinically meaningful trial endpoints; changes in governmental regulations or administrative actions; or lack of adequate funding to continue the clinical trial. Clinical trials may also be delayed or terminated as a result of inconclusive or negative interim results. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA, EMA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

We may also, in the future, conduct preclinical and clinical research in collaboration with other academic, pharmaceutical and biotechnology entities. Such collaborations may be subject to additional delays because of the management of the trials, contract negotiations, the need to obtain agreement from multiple parties and may increase our costs and expenses.

Our development costs will increase if we experience delays or other modifications in clinical testing including, but not limited to, required or desired trial population sizes and/or the number of clinical studies required to be conducted to obtain relevant health authority approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could impact our ability to seek regulatory approval, and/or shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates. Any delays in, halts to, or increase in costs in, our clinical development programs may harm our business, financial condition, results of operations and prospects.

We will require substantial additional financing to achieve our goals and failure to obtain additional capital when needed, or on acceptable terms to us, could cause us to delay, limit, reduce, or terminate our product development or commercialization efforts.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Any future debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, selling or licensing our assets, making capital expenditures, declaring dividends or encumbering our assets to secure future indebtedness. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

Future clinical trial outcomes could hinder our ability to raise additional capital when needed, or on terms acceptable to us. For example, the failure to achieve the primary endpoint in the Part B week 16 results of the Phase 2b/3 trial of izokibep in HS materially and negatively impacted our stock price. Delays in financings or limited access to capital may impact the scope, timing and ability to conduct all planned clinical development activities, which could materially and adversely affect our business, operations and financial condition.

If we raise additional funds through future collaborations, licenses and other similar arrangements, we may have to relinquish valuable rights to our future revenue streams or product candidates, or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock. If we are unable to raise additional funds through

equity or debt financings or other arrangements when needed or on terms acceptable to us, we would be required to delay, limit, reduce, or terminate our product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Risks Related to Product Candidate Development and Commercialization

Our clinical trials may reveal significant adverse events not seen in our preclinical studies or prior clinical trials and may result in a safety or tolerability profile that could delay or prevent regulatory approval or market acceptance of izokibep, lonigutamab, any of our other product candidates or any future product candidates.

Undesirable or clinically unmanageable side effects observed in our clinical trials for our product candidates could occur and cause us or regulatory authorities to interrupt, delay or halt our clinical trials and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities. We have observed certain adverse events and serious adverse events (“SAEs”) in our clinical trials of izokibep. Based on the safety profile of the two currently approved anti-IL-17A agents, ixekizumab and secukinumab, certain side effects are expected as part of inhibiting the IL-17A pathway. We have seen, and expect to see, similar results with izokibep, including adverse events and SAEs. These include injection site reactions, infections such as nasopharyngitis, and inflammatory bowel disease. In particular, the potential for new onset or exacerbation of inflammatory bowel disease is a known complication of IL-17 inhibition, is class labelling for all IL-17 inhibitors and therefore an exclusion criteria for our clinical trials of izokibep. In Part A of our Phase 2b/3 trial of izokibep in HS, one participant had new onset Crohn’s disease that was determined by the principal investigator to be possibly drug related. Upon review and following discontinuation of the participant from the trial, we noted such participant had pre-existing gastrointestinal symptoms and should have been excluded from the trial. A second participant with pre-existing diverticulitis had diverticular abscess and sepsis, both determined by the principal investigator to be unrelated to treatment. In the Week 46 data from our Phase 2 trial of izokibep in PsA, eight SAEs were reported, one of which (vulvar cancer) was identified by the principal investigator to be potentially drug-related, and seven of which were deemed not to be drug-related. In addition, candida rates are expected to be observed in 1-3% of trial participants. We expect that additional adverse events and SAEs consistent with known side effects of IL-17A inhibitors may emerge in our ongoing and future clinical trials of izokibep.

If additional adverse events, SAEs or other side effects are observed in any of our clinical trials that are atypical of, or more severe than, the known side effects of the respective class of agents that each of our product candidates are a part of, we may have difficulty recruiting participants to our clinical trials, participants may drop out of our trials, or we may be required to abandon those trials or our development efforts of one or more product candidates altogether. For example, two participants withdrew from our Phase 2 trial of izokibep in PsA due to injection site reactions and erythema and nine participants withdrew from Part A of our Phase 2b/3 trial of izokibep in HS for various reasons including injection site reactions, physical relocation and lost to follow up, and SAEs relating to gastrointestinal symptoms. While we believe that certain side effects could be reversible with sufficient recovery periods, we will need to monitor the severity and duration of side effects in our clinical trials. If such effects are more severe, less reversible than we expect or not reversible at all, we may decide or be required to perform additional studies or to halt or delay further clinical development of any of our product candidates which could result in the delay or denial of regulatory approval by the FDA or other regulatory authorities.

In addition, we believe that one of the benefits of lonigutamab is its potential to improve on the safety and side-effect profile of the sole currently approved therapy in the U.S. for the treatment of TED. If lonigutamab is shown to have similar adverse events, side effects, or other safety or tolerability concerns, such as hearing impairment, then our opportunity to disrupt the current standard of care will be limited. Adverse events and SAEs that emerge during clinical investigation of or treatment with izokibep, lonigutamab, any of our other product candidates or any future product candidates may be deemed to be related to our product candidates. This may require longer and more extensive clinical development, or regulatory authorities may increase the amount of data and information required to approve, market, or maintain izokibep, lonigutamab or any other current or future product candidates and could result in warnings and precautions in our product labeling or a restrictive risk evaluation and mitigation strategy (“REMS”). This may also result in an inability to obtain approval of izokibep, lonigutamab or any other current or future product candidates. We, the FDA, EMA or other applicable regulatory authorities, or an IRB, may suspend clinical trials of a product candidate at any time for various reasons, including a belief that participants in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential product candidates developed in the biotechnology industry that initially showed promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects, like those mentioned above, may inhibit market acceptance of the approved product due to its tolerability versus

other therapies. Any of these developments could materially harm our business, financial condition, results of operations and prospects.

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

From time to time, we publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, which are based on preliminary analyses 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 preclinical study or clinical trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as participants’ enrollment continues and more participants’ data become available or as participants from our clinical trials continue other treatments for their disease. Adverse differences between interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and could adversely affect the success of our business. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects. Further, disclosure of interim, top-line or preliminary data by us or by our competitors could result in volatility in the price of our common stock.

Furthermore, if we fail to replicate the positive results from our preclinical studies or clinical trials in our future clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our current or future product candidates.

We may expend our limited resources to pursue a particular product candidate in specific indications and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus our development efforts on certain selected product candidates in certain selected indications. For example, we are initially focused on our lead product candidates, izokibep for the treatment of HS, PsA, AxSpA and uveitis, and lonigutamab for the treatment of TED. As a result, we may forgo or delay pursuit of opportunities with other product candidates, or other indications for our existing product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs and product candidates for specific indications, including HS, may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

We face competition from entities that have made substantial investments into the rapid development of novel treatments for immunological indications, including large and specialty pharmaceutical and biotechnology companies, many of which already have approved therapies in our current indications.

The development and commercialization of therapies is highly competitive. Our product candidates, if approved, will face significant competition, including from well-established, currently marketed therapies and our failure to demonstrate a meaningful improvement to the existing standard of care may prevent us from achieving significant market penetration. Many of our competitors have significantly greater resources and experience than we do and we may not be able to successfully compete. We face substantial competition from multiple sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions. Our competitors compete with us on the level of the technologies employed, or on the level of development of their products as compared to our product candidates. In addition, many small biotechnology companies have formed collaborations with large, established companies to (i) obtain support for their research, development and commercialization of products or (ii) combine several treatment approaches to develop longer lasting or more efficacious treatments that may potentially directly compete with our current or any future product candidates. We anticipate that we will continue to face increasing competition as new therapies and combinations thereof, and related data emerge.

Our current product candidates, initially under development for treatment of various immunological indications, if approved, would face competition from existing approved immunological treatments, many of which have achieved commercial success. For example, we are currently developing izokibep for the treatment of HS, PsA, AxSpA and uveitis. Many emerging and established life sciences companies have been focused on similar therapeutics. If approved, izokibep would compete with currently approved therapeutics in each such indication as well as other drugs used to treat such patients, such as generic drugs and biosimilars.

We are also developing lonigutamab for the treatment of TED. If approved, lonigutamab would compete with the approved product Tepezza, which has achieved wide-spread use in the treatment of TED. In addition to Tepezza, other therapies, such as corticosteroids, have been used on an off-label basis to alleviate some of the symptoms of TED. In addition, we are developing SLRN-517 for the treatment of chronic urticaria. If approved, SLRN-517 would face competition from both existing marketed therapies as well as other symptomatic treatments such as glucocorticosteroids that have been used to alleviate acute exacerbations of chronic urticaria.

Furthermore, there are a number of product candidates in clinical development by third parties that are intended to treat the indications we are pursuing, some of which are late-stage and may receive approvals in the near term.

To compete successfully, we need to disrupt these currently marketed drugs, meaning that we will have to demonstrate that the relative cost, method of administration, safety, tolerability and efficacy of our product candidates provides a better alternative to existing and new therapies. Our commercial opportunity and likelihood of success will be reduced or eliminated if our product candidates are not ultimately demonstrated to be safer, more effective, more conveniently administered, or less expensive than the current standard of care. Furthermore, even if our product candidates are able to achieve these attributes, acceptance of our products may be inhibited by the reluctance of physicians to switch from existing therapies to our products, or if physicians choose to reserve our products for use in limited circumstances.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we have. If we obtain regulatory approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our current or any future product candidates, the ease with which our current or any future product candidates can be administered and the extent to which participants accept relatively new routes of administration, the timing and scope of regulatory approvals for these product candidates, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our current or any future product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified management and other personnel and establishing clinical trial sites

and participants' registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We are currently conducting, and may in the future conduct, clinical trials for current or future product candidates outside the U.S., and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We are currently conducting clinical trials outside the U.S., including (without limitation) in Europe and Australia, and we expect to continue to conduct trials internationally in the future. The acceptance of data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing 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 and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop being delayed or not receiving approval for commercialization in the applicable jurisdiction.

Even if we receive marketing approval for our current or future product candidates in the U.S., we may never receive regulatory approval to market outside of the U.S.

We plan to seek regulatory approval of our current or future product candidates outside of the U.S. In order to market any product outside of the U.S., however, we must establish and comply with the numerous and varying safety, efficacy and other regulatory requirements of other applicable countries. Approval procedures vary among countries and can involve additional product candidate testing and additional administrative review periods. The time required to obtain approvals in other countries might differ substantially from that required to obtain FDA approval. The marketing approval processes in other countries generally implicate all of the risks detailed above regarding FDA approval in the U.S. as well as other risks. In particular, in many countries outside of the U.S., products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries. Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process in others and would impair our ability to market our current or future product candidates in such foreign markets. Any such impairment would reduce the size of our potential market, which could adversely affect our business, financial condition, results of operations and prospects.

The successful commercialization of our product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors will have an effect on our ability to successfully commercialize those products. Even if 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. We cannot be sure that coverage and reimbursement in the United States, the European Union, Japan or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for biopharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when equivalent generic drugs, biosimilars or less expensive therapies are available. It is possible that a third-party payor may consider our product candidates, if approved, as substitutable and only be willing to cover the cost of the alternative product. Even if we show improved efficacy, safety or improved convenience of administration with izokibep, lonigutamab or any of our product

candidates, if approved, pricing of competitive products may limit the amount we will be able to charge for any of our product candidates, if approved. Third-party payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. In some cases, when new competitor generic and biosimilar products enter the market, there are mandatory price reductions for the innovator compound. In other cases, payors employ “therapeutic category” price referencing and seek to lower the reimbursement levels for all treatments in the respective therapeutic category. Additionally, new competitor brand drugs can trigger therapeutic category reviews in the interest of modifying coverage and/or reimbursement levels. The potential of third-party payors to introduce more challenging price negotiation methodologies could have a negative impact on our ability to successfully commercialize any of our product candidates, if approved.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage for new or innovative devices or therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our products, if approved.

Obtaining and maintaining reimbursement status is time consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, coverage determination is often a time consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of our products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates, if approved. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, 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 newly approved products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

We may not be able to obtain or maintain orphan drug designations for certain of our product candidates, and we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product as an orphan product if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population of greater than 200,000 individuals in the United States, but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the EMA’s Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000

persons in the European Union. There can be no assurance that the FDA or the EMA's Committee for Orphan Medicinal Products will grant orphan drug designation for the indications we are evaluating, including moderate-to-severe HS, non-infectious uveitis and TED, or that we will be able to maintain such designation if granted.

In the United States, orphan designation entitles a party to financial incentives such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers. In addition, if a product candidate that has orphan designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances. The applicable exclusivity period is ten years in Europe, but such exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan designation or if the product is sufficiently profitable so that market exclusivity is no longer justified.

Even if we obtain orphan drug exclusivity for izokibep in moderate-to-severe HS or non-infectious uveitis or lonigutamab in TED, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA or comparable foreign regulatory authority can subsequently approve a later drug for the same condition if such regulatory authority concludes that the later drug is clinically superior, if it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

Risks Related to Our Business and Operations

Our business depends entirely on the success of our product candidates and we cannot guarantee that any or all of our product candidates will successfully complete development, receive regulatory approval, or be successfully commercialized. If we are unable to develop, receive regulatory approval for, and ultimately successfully commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We currently have no products approved for commercial sale or for which regulatory approval to market has been sought. We have invested a significant portion of our efforts and financial resources in the development of our product candidates, each of which is still in clinical development, and expect that we will continue to invest heavily in these product candidates, as well as in any future product candidates we may develop. Our business and our ability to generate revenue, which we do not expect will occur for many years, if ever, are substantially dependent on our ability to develop, obtain regulatory approval for, and then successfully commercialize our product candidates, which may never occur.

Our product candidates will require substantial additional development time, regulatory approval, commercial manufacturing arrangements, establishment of a commercial organization, significant marketing efforts, and further investment before we can generate any revenue from product sales. We currently generate no revenue and we may never be able to develop or commercialize any products. We cannot assure you that we will meet our timelines for our current or future clinical trials, which may be delayed or not completed for a number of reasons, including the negative impacts of geopolitical instability and the COVID-19 or other pandemics or health crises. Our product candidates are susceptible to the risks of failure inherent at any stage of product development, including the appearance of unexpected adverse events or failure to achieve primary endpoints with statistical significance in clinical trials, such as what occurred in the week 16 results of the Part B portion of our Phase 2b/3 trial of izokibep in HS.

Even if our product candidates are successful in clinical trials, we are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive sufficient regulatory approval that will allow us to successfully commercialize any product candidates. If we do not receive FDA or comparable foreign regulatory approval with the necessary conditions to allow commercialization, we will not be able to generate revenue from those product candidates in the United States or elsewhere in the foreseeable future, or at all. Any significant delays in obtaining approval for and commercializing our product candidates could adversely affect our business, financial condition, results of operations and prospects.

We have not previously submitted a BLA for our product candidates or similar marketing application to the FDA or comparable foreign regulatory authorities, for any product candidate, and we cannot be certain that our current or any future product candidates will be successful in clinical trials or receive regulatory approval. The FDA may also consider its approvals of competing products, which may alter the treatment landscape concurrently with their review of our BLA submissions and lead to changes in the FDA's review requirements that have been previously communicated to us and our interpretation thereof. Those could include changes to requirements for clinical data or clinical trial design, and such changes could delay approval or necessitate withdrawal of our BLA submissions.

If approved for marketing by applicable regulatory authorities, our ability to generate revenue from our product candidates will depend on our ability to:

- price our products competitively such that third-party and government reimbursement permits broad product adoption;
- demonstrate the superiority of our products compared to the standard of care, as well as other therapies in development;
- create market demand for our product candidates;
- effectively commercialize any of our products that receive regulatory approval;
- manufacture product in sufficient quantities, and at acceptable quality, timing and cost, to meet commercial demand at launch and thereafter;
- establish and maintain agreements with wholesalers, distributors, pharmacies, and group purchasing organizations on commercially reasonable terms;
- obtain, maintain, protect and enforce patent and other intellectual property rights and regulatory exclusivity for our products;
- maintain compliance with applicable laws, regulations, and guidance specific to commercialization, including interactions with health care professionals, patient advocacy groups, and communication of health care economic information to payors and formularies;
- achieve market acceptance of our products by patients, the medical community, and third-party payors;
- maintain a distribution and logistics network capable of product storage within our specifications and regulatory guidelines, and further capable of timely product delivery to commercial clinical sites; and
- assure that our product will be used as directed and that additional unexpected safety risks will not arise.

Our ongoing and planned clinical trials of izokibep for moderate-to-severe HS as well as non-infectious uveitis, even if successfully completed, may not be sufficient for approval of izokibep for the applicable indication.

We are evaluating izokibep in both moderate-to-severe HS as well as non-infectious uveitis as orphan indications, potentially eligible for orphan drug designation by regulatory authorities. The designation of izokibep as an orphan drug does not guarantee that any regulatory authority will accept fewer trials, accelerate regulatory review of, or ultimately approve izokibep for moderate-to-severe HS or non-infectious uveitis. We intend to continue our clinical development in moderate-to-severe HS and non-infectious uveitis whether or not we receive orphan drug designation. FDA approval of a new biologic or drug generally requires dispositive data from two well-controlled, Phase 3 clinical trials of the relevant biologic or drug in the relevant patient population. Although we have discussed our plans with the FDA, we do not have any formal agreement or guidance from the FDA that our regulatory development plans will be sufficient for submission of a BLA. If the FDA does not agree with our planned strategy, the FDA may ultimately require more Phase 3 clinical trials prior to approval in either indication. In addition, the standard of care may change with the approval of new products in the same indications that we are studying. This may result in the FDA or other regulatory agencies requesting additional trials to show that our product candidate is superior to the new products, such as an additional comparative trial against an approved therapy, which would significantly delay our development timelines and require substantially more resources. In addition, the FDA may only allow us to evaluate a subset of participants that have failed or who are ineligible for approved therapies, which are extremely difficult participants to treat and participants with advanced and aggressive disease, and our product candidates may fail to improve outcomes for such participants. Generally speaking, Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. If we are in the future required to conduct additional Phase 3 clinical trials for each of moderate-to-severe HS as well as non-infectious uveitis, then our development timeline will be significantly extended, and the related expenses will be significantly increased. Additionally, even if such trials are completed, they may not ultimately be sufficient to achieve health authority approval in one or more indications.

In addition, if the FDA grants approval for our product candidates then, as a condition for approval, the FDA may require us to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and izokibep may be subject to withdrawal procedures by the FDA.

Our clinical trial results may also not support approval. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval, including due to the heterogeneity of patient populations, participant discontinuation rates, or apparent improvement in trial participants receiving placebo such as those observed in week 16 results of Part B of the Phase 2b/3 trial of izokibep in HS;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the U.S. or elsewhere;
- the FDA or comparable foreign regulatory authorities will review CMOs' manufacturing process and inspect our CMOs' commercial manufacturing facilities and may not approve our CMOs' manufacturing process or facilities; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

If our product candidates, if approved, do not achieve broad market acceptance, the revenue that we generate from their sales will be limited.

We have never commercialized a product candidate for any indication. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors and others in the medical community. If any product candidate for which we obtain regulatory approval does not gain an adequate level of market acceptance, we may not generate sufficient product revenue or become profitable.

The degree of market acceptance of any of our product candidates will depend on a number of factors, some of which are beyond our control, including:

- the safety, efficacy, tolerability and relative ease of administration of our product candidates, including the potential prevalence and severity of side effects and adverse events, and how such profile compares to those of existing therapies, or those under development;
- the indications for which the products are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the products' FDA-approved labeling, including ones that may be more restrictive than other competitive products;
- distribution and use restrictions imposed by the FDA with respect to such products or to which we agree as part of a mandatory REMS or voluntary risk management plan;
- changes in the standard of care for the targeted indications for such product candidates;
- cost of treatment as compared to the clinical benefit in relation to alternative treatments or therapies;
- the availability of adequate coverage and reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid;
- the extent and strength of our marketing and distribution of such product candidates;

- other potential advantages of, and availability of, alternative treatments already used or that may later be approved for any of our intended indications;
- the timing of market introduction of such product candidates, as well as competitive products;
- the reluctance of physicians to switch their patients' current standard of care;
- our ability to offer such product candidates for sale at competitive prices;
- the extent and strength of our third-party manufacturer and supplier support;
- adverse publicity about our product or favorable publicity about competitive products; and
- potential product liability claims.

Our efforts to educate the medical community and third-party payors as to the benefits of our product candidates may require significant resources and may never be successful. Even if the medical community accepts that our product candidates are safe and effective for their approved indications, physicians and patients may not immediately be receptive and may be slow to adopt them as an accepted treatment of the approved indications. If our current or future product candidates are approved, but do not achieve an adequate level of acceptance among physicians, patients, and third-party payors, we may not generate meaningful revenue from our product candidates and may never become profitable.

We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business.

As of November 6, 2023, we had 117 full-time employees. As our development and commercialization plans and strategies develop, and as we operate as a public company, we expect to expand our employee base for managerial, operational, financial and other resources. In addition, we have limited experience in manufacturing and commercialization. As our product candidates enter and advance through preclinical studies and clinical trials, we will need to expand our development and regulatory capabilities and contract with other organizations to provide manufacturing and other capabilities for us. In the future, we expect to have to manage additional relationships with collaborators or partners, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover additional deficiencies in our existing systems and controls. Our inability to successfully manage our growth and expand our operations could adversely affect our business, financial condition, results of operations and prospects.

We are dependent on the services of our management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our Founder and Chief Executive Officer, Shao-Lee Lin, M.D., Ph.D., and other members of our management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our preclinical studies and clinical trials or the commercialization of our product candidates. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain "key person" life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology and other businesses, particularly in the Los Angeles area and the greater San Francisco Bay Area. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

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

We are exposed to the risk of fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners, CROs, CMOs and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with FDA or other regulations, provide true, complete and accurate information to the FDA, EMA and other similar foreign regulatory bodies, comply with manufacturing standards we may establish, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, and our costs associated with compliance with these laws are likely to increase. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. 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 such 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 material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm.

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 growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets, including in the European Union (“EU”), United Kingdom (“UK”) and Japan, for which we may rely on collaboration with third parties. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market and may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approval in many other 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 product candidates, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval of any of our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business, financial condition, results of operations and prospects could be adversely affected. Moreover, even if we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries.

Our business entails a significant risk of product liability and our ability to obtain sufficient insurance coverage could adversely affect our business, financial condition, results of operations and prospects.

As we conduct clinical trials of our current or future product candidates, we are exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of new treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in FDA, EMA or other investigation of the safety and effectiveness of our future product candidates, our manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our product candidates, termination of clinical trial sites or entire trial programs, withdrawal of clinical trial participants, injury

to our reputation and significant negative media attention, significant costs to defend the related litigation, a diversion of management's time and our resources from our business operations, substantial monetary awards to trial participants or patients, loss of revenue, the inability to commercialize any products that we may develop, and a decline in our stock price. We may need to obtain higher levels of product liability insurance for later stages of clinical development or marketing any of our product candidates. Any insurance we may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could adversely affect our business, financial condition, results of operations and prospects.

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

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

We expect to engage in strategic transactions in the future, which could impact our liquidity, increase our expenses and present significant distractions to our management.

As a core part of our strategy, we intend to enter into strategic transactions, including acquisitions of companies, asset purchases and in-licensing of intellectual property with the potential to acquire and advance new assets or product candidates where we believe we are well qualified to optimize the development of promising therapies. Our ability to realize the anticipated benefits of an acquisition will depend, to a large extent, on our ability to continue the development of assets, technologies and programs we acquire. The expected synergies in development programs, pipelines and other areas of focus may not be realized on a timely basis or at all, and there may be risks associated with the acquisition that we did not previously anticipate. For example, we may learn of unanticipated liabilities that we have assumed in any acquisition.

Additional potential transactions that we may consider in the future include a variety of business arrangements, including strategic partnerships, in-licensing of product candidates, strategic collaborations, joint ventures, restructurings, divestitures, business combinations and investments. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations.

Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the acquisition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could adversely affect our business, financial condition, results of operations and prospects.

Our ability to use our net operating loss ("NOL") carryforwards and certain other tax attributes to offset taxable income or taxes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. As of December 31, 2022, we had federal NOL carryforwards of \$29.0 million and state NOL carryforwards of \$2.9 million. Under the Internal Revenue Code of 1986, as amended (the Code), our U.S. federal net operating losses will not expire and may be carried forward indefinitely but the deductibility of federal net operating losses is limited to no more than 80% of current year taxable income (with certain adjustments). In addition, under Sections 382 and 383 of the Code, if a corporation undergoes 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, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have not completed a Section 382 study to assess whether an ownership change has occurred, including in connection with our IPO, or whether there have been multiple ownership changes since our formation due to the complexity and cost associated with such a study and the fact that there may be additional ownership

changes in the future including as a result of subsequent changes in our stock ownership, some of which may be outside of our control. As a result, if we undergo an ownership change, and our ability to use our pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes is limited, it would harm our future results of operations by effectively increasing our future tax obligations. 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 net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use all or a material portion of our net operating losses and other tax attributes, which could adversely affect our future cash flows.

Recent and future changes to tax laws could materially adversely affect our company.

The tax regimes we are subject to or operate under, including with respect to income and non-income taxes, are unsettled and may be subject to significant change. Changes in tax laws, regulations, or rulings, or changes in interpretations of existing laws and regulations, could materially adversely affect our company. For example, the Tax Cuts and Jobs Act, the Coronavirus Aid, Relief, and Economic Security Act, and the Inflation Reduction Act (the “IRA”) enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects thereof could be repealed or modified in future legislation. For example, the IRA includes provisions that will impact the U.S. federal income taxation of certain corporations, including imposing a 15% minimum tax on the book income of certain large corporations and a 1% excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock. In addition, many countries in Europe, as well as a number of other countries and organizations (including the Organization for Economic Cooperation and Development and the European Commission), have proposed, recommended, or (in the case of countries) enacted or otherwise become subject to changes to existing tax laws or new tax laws that could significantly increase our tax obligations in the countries where we do business or require us to change the manner in which we operate our business.

If our internal information technology systems, or those used by our CROs, CMOs, clinical sites or other contractors or consultants upon which we rely, are or were compromised, become unavailable or suffer security breaches, loss or leakage of data or other disruptions, we could suffer material adverse consequences resulting from such compromise, including but not limited to, operational or service interruption, harm to our reputation, litigation, fines, penalties and liability, compromise of sensitive information related our business, and other adverse consequences.

In the ordinary course of our business, we, and the third parties upon which we rely, process sensitive data and as a result, we and the third parties upon which we rely face a variety of evolving threats which could cause security incidents.

Our internal information technology systems and those of our CROs, CMOs, clinical sites and other contractors and consultants upon which we rely are vulnerable to cyberattacks, computer viruses, bugs, worms, or other malicious codes, malware (including as a result of advanced persistent threat intrusions), and other attacks by computer hackers, cracking, application security attacks, social engineering (including through phishing attacks and impersonation of employees), supply chain attacks and vulnerabilities through our third-party service providers, denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats.

Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer “hackers,” threat actors, “hacktivists,” organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. In particular, ransomware attacks, including those from organized criminal threat actors, nation-states and nation-state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, loss of data (including sensitive customer information), loss of income, significant extra expenses to restore data or systems, reputational loss and the diversion of funds. To alleviate the negative impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments).

Some actors also now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors, for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties upon which we rely, and our customers may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and

operations, supply chain, and ability to produce, sell and distribute our goods and services. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

Additionally, remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

Furthermore, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Additionally, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

While we take steps to detect and remediate vulnerabilities, we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit such vulnerabilities change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, encryption and authentication technology, employee email, and other functions. We also rely on third-party service providers to assist with our clinical trials, provide other products or services, or otherwise to operate our business. 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 our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers 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 award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems (including our services) or the third-party information technology systems that support us and our services.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our services including clinical trials.

The costs related to significant security breaches or disruptions could be material and cause us to incur significant expenses. If the information technology systems of our CROs, CMOs, clinical sites and other contractors and consultants become subject to disruptions or security incidents, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

If any such incidents were to occur and cause interruptions in our operations, it could result in a disruption of our business and development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for a product candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data, or may limit our ability to effectively execute a product recall, if required in the future. To the extent that any disruption or security incident were to result in the loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of any product candidates could be delayed. Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. Any such event could also result in legal claims or proceedings, liability under laws that protect the privacy of personal information and significant regulatory penalties, and damage to our reputation and a loss of confidence in us and our ability to conduct clinical trials, which could delay the clinical development of our product candidates.

Our operations are concentrated in one location, and we or the third parties upon whom we depend may be adversely affected by a wildfire and earthquake or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current operations are predominantly located in California. Any unplanned event, such as flood, wildfire, explosion, earthquake, extreme weather condition, medical epidemic, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Any similar impacts of natural or manmade disasters on our third-party CMOs, CROs or other vendors located globally, could cause delays in our clinical trials and may have a material and adverse effect on our ability to operate our business and have significant negative consequences on our financial and operating conditions. If a natural disaster, power outage or other event occurred that prevented us from using our clinical sites, impacted clinical supply or the conduct of our clinical trials, that damaged critical infrastructure, such as the manufacturing facilities of our third-party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we and our CMOs and CROs or other vendors have in place may prove inadequate in the event of a serious disaster or similar event. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our CMOs, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our development programs may be harmed. Any business interruption could adversely affect our business, financial condition, results of operations and prospects.

Our projections regarding the market opportunities for our product candidates may not be accurate, and the actual market for our products may be smaller than we estimate.

The precise incidence and prevalence for all the conditions we aim to address with our product candidates are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including sales of our competitors, scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect in general, or as to their applicability to our company. Further, new trials may change the estimated incidence or prevalence of these diseases. The total addressable market across all of our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each of our product candidates approved for sale for these indications, the ability of our product candidates to improve on the safety, convenience, cost and efficacy of competing therapies or therapies in development, acceptance by the medical community and patients, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidates or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, financial condition, results of operations and prospects. Further, even if we obtain significant market share for our product candidates, because some of our potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

Our business could be adversely affected by the effects of health pandemics or other health crises, including the ongoing COVID-19 pandemic, which could cause significant disruptions in our operations and those of our CMOs, CROs and other third parties upon whom we rely.

Health pandemics or other health crises, including the ongoing COVID-19 pandemic, have in the past and could again in the future result in quarantines, stay-at-home orders, remote work policies or other similar events that may disrupt businesses, delay our research and development programs and timelines, negatively impact productivity and increase risks associated with cybersecurity, the future magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations. More specifically, these types of events may negatively impact personnel at third-party manufacturing facilities or the availability or cost of materials, which could disrupt our supply chain. Moreover, our trials may be negatively affected. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources. Some patients may not be able or willing to comply with trial protocols if quarantines impede patient movement or interrupt healthcare services. Our ability to recruit and retain patients, principal investigators and site staff (who as healthcare providers may have heightened exposure) may be hindered, which would adversely affect our trial operations. Disruptions or restrictions on our ability to travel to monitor data from our trials, or to conduct trials, or the ability of

patients enrolled in our trials or staff at trial sites to travel, as well as temporary closures of our trial partners and CMOs' facilities, would negatively impact our trial activities. In addition, we rely on independent clinical investigators, CROs and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our preclinical studies and clinical trials, including the collection of data from our trials, and the effects of health pandemics or other health crises, including the COVID-19 pandemic, may affect their ability to devote sufficient time and resources to our programs or to travel to sites to perform work for us. Similarly, our trials could be delayed and/or disrupted. As a result, the expected timeline for data readouts, including incompleteness in data collection and analysis and other related activities, and certain regulatory filings may be negatively impacted, which would adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses and adversely affect our business, financial condition, results of operations and prospects. In addition, impact on the operations of the FDA or other regulatory authorities could negatively affect our planned trials and approval processes. Finally, economic conditions and business activity may be negatively impacted and may not recover as quickly as anticipated. To date, while the COVID-19 pandemic has had a limited impact on our research and development activities related to izokibep, lonigutab and our other product candidates, other than, in certain cases, prices and access to raw materials, the effects of the COVID-19 pandemic continue to evolve and as a result, the ultimate impact of the COVID-19 pandemic (or other health pandemics or health crises) is highly uncertain and subject to change.

Our cash and cash equivalents may be exposed to failure of our banking institutions.

While we seek to minimize our exposure to third-party losses of our cash and cash equivalents, we hold our balances in three financial institutions. Notwithstanding, those institutions are subject to risk of failure. For example, recent events surrounding certain banks, including Silicon Valley Bank ("SVB"), First Republic Bank and Signature Bank, created temporary uncertainty on their customers' cash deposits in excess of Federal Deposit Insurance Corporation limits prior to actions taken by governmental entities. As of September 30, 2023 we have no direct exposure to such banks. While we do not expect further developments with any such banks to have a material impact on our cash and cash equivalents balance, expected results of operations, or financial performance for the foreseeable future, if further failures in financial institutions occur where we hold deposits, we could experience additional risk. Any such loss or limitation on our cash and cash equivalents would adversely affect our business.

Public opinion and scrutiny of immunology treatments may impact public perception of our company and product candidates, or may adversely affect our ability to conduct our business and our business plans.

Public perception may be influenced by claims, such as claims that our product candidates are unsafe, unethical or immoral and, consequently, our approach may not gain the acceptance of the public or the medical community. Negative public reaction to immunology treatments in general could result in greater government regulation and stricter labeling requirements of products to treat immunological diseases, including any of our product candidates, if approved, and could cause a decrease in the demand for any product candidates we may develop. For example, approximately 10% of participants in Phase 2 and Phase 3 trials for teprotumumab reported developing hearing impairment symptoms and a further study conducted by Stanford University in 28 participants receiving teprotumumab suggested that the rate could be over 45%. If the public or medical professionals associate these side effects with all IGF-1R therapies, market acceptance of our product candidates, if approved, may be negatively impacted. Similarly, side effects generally associated with IL-17A inhibitors may negatively impact public perception of us or izokibep. Adverse public attitudes may also adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians specializing in the treatment of those diseases that our product candidates target prescribing, and their patients being willing to receive, treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. Adverse events in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in withdrawal of clinical trial participants, increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates. More restrictive government regulations or negative public opinion could have an adverse effect on our business, financial condition, results of operations and prospects, and may delay or impair the development and, if approved, commercialization of our product candidates or demand for any products we may develop.

We have identified material weaknesses in our internal control over financial reporting. If we fail to remediate these material weaknesses, or if we experience additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting in the future, we may not be able to accurately or timely report our

financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

As of December 31, 2021 and 2022, we had limited accounting personnel and other resources to address our internal control over financial reporting. In connection with the preparation of our financial statements for the years ended December 31, 2021 and 2022, material weaknesses were identified in the design and operating effectiveness of our internal control over financial reporting. These material weaknesses have not been remediated as of September 30, 2023. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

These material weaknesses are related to the fact that we lacked a sufficient number of professionals to consistently establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives. The lack of sufficient number of professionals further contributed to the following additional material weaknesses. We did not design and maintain an effective risk assessment process at a precise enough level to identify new and evolving risks of material misstatement in the financial statements. Additionally, we did not design and maintain effective controls over the segregation of duties related to journal entries and account reconciliations. Specifically, certain personnel had the ability to both (i) create and post journal entries within the company's general ledger system and (ii) prepare and review account reconciliations without a review performed by someone without conflicting duties.

There were no adjustments that resulted from the above material weaknesses. However, these material weaknesses could result in a misstatement of substantially all of our accounts or disclosures that would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected.

We have taken and will continue to take certain measures to remediate the material weaknesses described above.

As of September 30, 2023, we have continued with the remediation steps that were initiated in the first quarter of 2023, including, but not limited to, hiring additional accounting personnel to build our finance organization. Specifically, we hired our vice president and controller and a director of technical accounting during the quarter ended March 31, 2023.

We continued to refine the design and testing operating effectiveness of the controls related to the material weaknesses during the quarter ended September 30, 2023. We continue using services of a third-party firm to support management in testing the operating effectiveness of controls. While we believe these measures will remediate the material weaknesses identified and strengthen our internal control over financial reporting, the material weaknesses will not be considered remediated until the controls described above operate for a sufficient period of time and management has concluded, through testing, that these controls are effective.

The measures we have taken to date, and are continuing to design and implement, may not be sufficient to remediate the material weaknesses we have identified or avoid potential future material weaknesses. If the steps we take do not correct these material weaknesses in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

We acquired ValenzaBio on January 4, 2023. As of December 31, 2022, the management of ValenzaBio identified similar material weaknesses in its internal control over financial reporting as our material weaknesses discussed above, which have not been remediated as of September 30, 2023. Our remediation efforts include steps to address ValenzaBio's material weaknesses.

If we fail to remediate our existing material weaknesses or identify new material weaknesses in our internal control over financial reporting, if we are unable to comply with the disclosure and attestation requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, if we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to conclude that our internal control over financial reporting is effective when we are no longer an emerging growth company, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected. As a result, we could also become subject to investigations by the Nasdaq Global Select Market, the SEC or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and financial condition or divert financial and management resources from our regular business activities.

Risks Related to Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates and any future product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and commercialize our product candidates may be adversely affected.

We rely upon a combination of patents, know-how and confidentiality agreements to protect the intellectual property related to our product candidates and technologies and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries for our product candidates and their uses, as well as our ability to operate without infringing, misappropriating or otherwise violating the proprietary rights of others. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. Although we in-license issued patents, we do not own any issued patents and our pending and future patent applications may not result in patents being issued. We cannot assure you that issued patents will afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products or product candidates.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner, including delays as a result of the COVID-19 pandemic impacting our or our licensors' operations. We may not be able to obtain or maintain patent applications and patents due to the subject matter claimed in such patent applications and patents being in disclosures in the public domain. It is also possible that we will fail to identify patentable aspects of our research and development 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 confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, 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. Consequently, we may not be able to prevent any third parties from using any of our technology that is in the public domain to compete with our technologies or product candidates.

Composition of matter patents for biological and pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. However, we cannot be certain that the claims in our or our collaborators' or licensors' pending patent applications directed to composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office ("USPTO") or by patent offices in foreign countries, or that the claims in any of our or our licensors' issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product candidates for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, clinicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

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 enforce patent rights in the future. As a result, the issuance, scope, validity, enforceability and commercial value of any patent rights are highly uncertain. Our pending and future owned and in-licensed patent applications may not result in patents being issued which protect our technologies or product candidates, effectively prevent others from commercializing our technologies or product candidates or otherwise provide any competitive advantage. In fact, patent applications may not issue as patents at all. The coverage claimed in a patent application can also be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in protecting our product candidates by obtaining and defending patents. For example, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own or our licensors' patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. If a third party can establish that we or our licensors were not the first to make or the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and even if issued, may be challenged and invalidated or rendered unenforceable. As a result, the issuance, inventorship, scope, validity, enforceability and commercial value of our or our licensors' patent rights are highly uncertain.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and our or our licensors' pending patent applications may be challenged in patent offices in the United States and abroad. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. For example, our or our licensors' pending patent applications may be subject to third-party pre-issuance submissions of prior art to the USPTO or our issued patents may be subject to post-grant review ("PGR") proceedings, oppositions, derivations, reexaminations, interferences, inter partes review ("IPR") proceedings or other similar proceedings, in the United States or elsewhere, challenging our or our licensors' patent rights or the patent rights of others. Such submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on one or more of our owned or licensed pending patent applications. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and product candidates, or limit the duration of the patent protection of our technology and product candidates. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

A third party may also claim that our owned or licensed patent rights are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse result in any legal proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly and could allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize our technology, products or product candidates without infringing third-party patent rights.

In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Any failure to obtain or maintain patent protection with respect to our product candidates or their uses could adversely affect our business, financial condition, results of operations and prospects.

We have in-licensed issued patents, but we do not currently own any issued patents relating to our technology, products and product candidates.

Although we exclusively in-license issued patents from Affibody AB ("Affibody") and Pierre Fabre Medicament SAS ("Pierre Fabre") related to izokibep and lonigutamab, respectively, we do not own or license any other issued patents. Additionally, we exclusively in-license one pending non-provisional patent application and two pending Patent Cooperation Treaty ("PCT") applications for SLRN-517, but do not own or exclusively in-license any issued patents relating to such product candidate and there can be no assurance that we will obtain any issued patents directed to SLRN-517. We cannot be certain that the claims in our U.S. pending patent applications, corresponding international patent applications and patent applications in certain foreign jurisdictions, or those of our licensors, will be considered patentable by the USPTO, courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that any issued claims will not be found invalid or unenforceable if challenged. Additionally, our provisional applications may never result in issued patents. Accordingly, there can be no assurance that we or our licensors will obtain any additional issued patents or that any issued patents we or our licensors obtain will provide us with any competitive

advantage. Any failure to obtain adequate patent protection for our product candidates and technology could adversely affect our business, financial condition, results of operations and prospects.

Our rights to develop and commercialize our product candidates are subject, in large part, to the terms and conditions of licenses granted to us by others, such as Affibody and Pierre Fabre. If we fail to comply with our obligations in the agreements under which we in-license or acquire development or commercialization rights to product candidates, or data from third parties, we could lose such rights that are important to our business.

We are heavily reliant upon licenses to certain patent rights and other intellectual property that are important or necessary to the development of izokibep and lonigutamab or our other current or future product candidates. For example, we depend on licenses from Affibody and Pierre Fabre for certain intellectual property relating to the development and commercialization of izokibep and lonigutamab, respectively. However, we have no development, commercialization, and manufacturing rights for izokibep in Mainland China, Hong Kong, Macau, South Korea and Taiwan as well as development rights in certain other Asia-Pacific countries, including, without limitation, Australia, India, New Zealand and Singapore, all of which rights have been granted by Affibody to Inmagene Biopharmaceuticals (“Inmagene”), under a pre-existing license agreement (the “Inmagene Agreement”).

Affibody and Pierre Fabre may have relied upon, and any future licensors may rely upon, third-party companies, consultants or collaborators, or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If our licensors, including Affibody and Pierre Fabre, fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize izokibep, lonigutamab or our other current or future product candidates that are or may be the subject of such licensed rights could be adversely affected. Further development and commercialization of izokibep, lonigutamab, and development of any future product candidates may, require us to enter into additional license or collaboration agreements. For example, our licensors or other third parties may develop intellectual property covering izokibep and lonigutamab which we have not licensed. Our future licenses may not provide us with exclusive rights to use the licensed patent rights and other intellectual property licensed thereunder, or may not provide us with exclusive rights to use such patent rights and intellectual property in all relevant fields of use and in all territories in which we wish to develop or commercialize izokibep, lonigutamab or our other product candidates in the future.

In spite of our efforts, Affibody, Pierre Fabre or any future licensors might conclude that we are in material breach of obligations under our license agreements and may therefore have the right to terminate the license agreements, thereby removing our ability to develop and commercialize product candidates and technology covered by such license agreements. If such in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, our competitors would have the freedom to seek regulatory approval of, and to market, products identical to our product candidates and the licensors to such in-licenses could prevent us from developing or commercializing product candidates that rely upon the patents or other intellectual property rights which were the subject matter of such terminated agreements. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses and compete with our existing product candidates. Any of these events could adversely affect our business, financial condition, results of operations, and prospects.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our financial or other obligations under the license agreement;
- the extent to which our processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those obligations;
- the inventorship or ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, our license agreements are, and future license agreements are likely to be, 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 increase what we believe to be our financial or other obligations under the relevant agreement, either of which could adversely affect 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 current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could adversely affect our business, financial condition, results of operations, and prospects.

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

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates on commercially reasonable terms or at all. Even if we are able to in-license any such necessary intellectual property, it could be on nonexclusive terms, thereby giving our competitors and other third parties access to the same intellectual property licensed to us, and it could require us to make substantial licensing and royalty payments. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have obtained, we may have to abandon development of the relevant program or product candidate, which could adversely affect our business, financial condition, results of operations, and prospects.

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

We may enter into license agreements in the future with others to advance our existing or future research or allow commercialization of our existing or future product candidates. These licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and product candidates in the future. In that event, we may be required to expend significant time and resources to redesign our product candidates, or the methods for manufacturing them, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current manufacturing methods, product candidates, or future methods or product candidates resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

We may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

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

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our future product candidates or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable future product candidates;
- collaborators may own or co-own intellectual property covering our product candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

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

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

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;

- whether the patent applications that we own will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries; and
- whether, if there is a resurgence of COVID-19-related impacts or if other pandemics or health crises arise, we may experience patent office interruption or delays to our ability to timely secure patent coverage to our product candidates.

We cannot be certain that the claims in our or our licensors' pending patent applications directed to our product candidates and/or technologies will be considered patentable by the USPTO or by patent offices in foreign countries. There can be no assurance that any such patent applications will issue as granted patents. One aspect of the determination of patentability of our and our licensors' 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 or our licensors' patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our or our licensors' 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 and our licensors' portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

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

Patents are of national or regional effect. Filing, prosecuting and defending patents on all of our research programs and product candidates in all countries throughout the world would be prohibitively expensive, and our and our licensors' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our or our licensors' inventions in all countries outside the United States, even in jurisdictions where we or our licensors do pursue patent protection, or from selling or importing products made using our or our licensors' inventions in and into the United States or other jurisdictions. Competitors may use our or our licensors' technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection, but enforcement is not as strong as that in the United States. These competitor products may compete with our product candidates, and our and our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Various companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our and our licensors' patents or marketing of competing products in violation of our proprietary rights.

Various countries outside the United States have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. As a result, a patent owner may have limited remedies in certain circumstances, which could materially diminish the value of such patent. If we or our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. 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.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our technologies and product candidates. While we will endeavor to try to protect our technologies and product candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time consuming, expensive and unpredictable.

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

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

- others may be able to make product candidates that are similar to ours but that are not covered by the pending patent applications that we own or the patents or patent applications that we license;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing or otherwise violating our owned or licensed intellectual property rights;
- it is possible that noncompliance with the USPTO and foreign governmental patent agencies requirement for a number of procedural, documentary, fee payment and other provisions during the patent process can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- it is possible that our pending owned or licensed patent applications or those that we may own or license in the future will not lead to issued patents;
- issued patents, if any arise in the future, that we either own or have exclusively licensed may be revoked, modified, or held invalid or unenforceable, as a result of legal challenges by our competitors;
- others may have access to the same intellectual property rights licensed to us in the future on a non-exclusive basis;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our and our licensors' patent applications, including whether the patent applications that we own, presently in-license, or, in the future, in-license will result in issued patents with claims that directed to our product candidates or uses thereof in the United States or in other foreign countries;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents, if they issue in the future, are valid, enforceable and infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patent applications.

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

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

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. There can be no assurance that our operations do not, or will not in the future, infringe, misappropriate or otherwise violate existing or future third-party patents or other intellectual property rights. Identification of third-party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the U.S. can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, product candidates or the use of our product candidates. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents, that may be infringed by the manufacture, use or sale of our technologies or product candidates or will prevent, limit or otherwise interfere with our ability to make, use or sell our technologies and product candidates.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

We cannot provide any assurances that third-party patents and other intellectual property rights do not exist which might be enforced against our current technology, including our research programs, product candidates, their respective methods of use, manufacture and formulations thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

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

Competitors or other third parties may infringe our patents, trademarks or other intellectual property. To counter infringement or unauthorized use, we or one of our licensing partners 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. Our or our licensors' pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. 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 or our licensors' patents are invalid or unenforceable, or both. In patent litigation in

the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, insufficient written description or failure to claim patent-eligible subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours or our licensors 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 or our licensors' patent claims do not cover the invention, or decide that the other party's use of our or our licensors' patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). An adverse outcome in a litigation or proceeding involving our or our licensors' patents could limit our ability to assert our or our licensors' 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 position, and our business, financial condition, results of operations and prospects. 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 whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

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 adversely affect the price of shares of our common stock. Moreover, we cannot assure you that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Intellectual property rights of third parties could adversely affect our ability to commercialize izokibep, lonigutamab, any of our other product candidates or any future product candidates, and we, our licensors or collaborators, or any future strategic partners may become subject to third party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights. We might be required to litigate or obtain licenses from third parties in order to develop or market izokibep, lonigutamab, any of our other product candidates or any future product candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights of third parties. Third parties may allege that we have infringed, misappropriated or otherwise violated their intellectual property. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could adversely affect our ability to compete in the marketplace.

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 product candidates. We cannot be certain that our product candidates will not infringe existing or future patents owned by third parties. Third parties may assert infringement claims against us based on existing or future

intellectual property rights, regardless of their merit. We may decide in the future to seek a license to such third-party patents or other intellectual property rights, but we might not be able to do so on reasonable terms. Proving patent invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. As this burden is a high one, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such United States patent or find that our technologies or product candidates do not infringe any such claims. If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing technology or product candidate. Further, we may be required to redesign the technology or product candidate in a non-infringing manner, which may not be commercially feasible. 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 product candidate. 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, and it could require us to make substantial licensing and royalty payments. 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 technologies or product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may not be aware of patents that have already been issued and that a third party, for example, a competitor in the fields in which we are developing our product candidates, might assert are infringed by our current or future product candidates, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our product candidates. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates, could be found to be infringed by our product candidates. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. The pharmaceutical and biotechnology industries have produced a considerable number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates or methods of use 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 United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents, and there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. 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 adversely affect our business and operations. 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. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

We may choose to challenge the enforceability or validity of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* re-exam, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the European Patent Office ("EPO"), or other foreign patent office. The costs of these opposition proceedings could be substantial and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates.

Our product candidates licensed from various third parties may be subject to retained rights.

Our licensors may retain certain rights under the relevant agreements with us, including the right to use the underlying product candidates for academic and research use, to publish general scientific findings from research related to the product candidates, to make customary scientific and scholarly disclosures of information relating to the product candidates, or to develop or commercialize the licensed product candidates in certain regions. For example, we depend on our license and collaboration agreement with Affibody for the development of izokibep, which grants us an exclusive

license to develop izokibep worldwide, subject to certain rights granted by Affibody to Inmagene under the Inmagene Agreement with respect to the development, commercialization and manufacturing of izokibep in certain Asian countries. Affibody has retained rights under the license and collaboration agreement to the extent necessary to carry out its obligations for manufacturing under the Inmagene Agreement. It is difficult to monitor whether Affibody or Inmagene, or any of our other licensors limit their use of the product candidates to these permitted uses, and we could incur substantial expenses to enforce our rights to our licensed product candidates in the event of misuse.

In addition, the United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act (“Bayh-Dole Act”). The federal government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” for its own benefit. The Bayh-Dole Act also provides federal agencies with “march-in rights.” March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a “nonexclusive, partially exclusive, or exclusive license” to a “responsible applicant or applicants.” If the patent owner refuses to do so, the government may grant the license itself. We may at times choose to collaborate with academic institutions to accelerate our preclinical research or development. While we do not currently engage, and it is our policy to avoid engaging, university partners in projects in which there is a risk that federal funds may be commingled, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. Although none of our licenses to date are subject to march-in rights, if, in the future, we co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining, defending, maintaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, and may diminish our ability to protect our inventions, obtain, maintain, enforce and protect our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our future owned and licensed patents. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (“Leahy-Smith Act”), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings.

Further, because of a lower evidentiary standard in these USPTO post-grant proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our or our licensors’ patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors’ patent applications and the enforcement or defense of our or our licensors’ future issued patents, all of which could adversely affect our business, financial condition, results of operations and prospects.

After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before we file an application covering the same invention, could therefore be awarded a patent covering an invention of ours or our licensors even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to

either (i) file any patent application related to our product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our or our licensors' patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future issued patents, all of which could adversely affect our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. 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 or our licensors' ability to obtain new patents and patents that we or our licensors might obtain in the future. We cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse change in the patent laws of other jurisdictions could also adversely affect our business, financial condition, results of operations and prospects.

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in our or our licensors' 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 product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship 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 adversely affect our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could adversely affect our business, financial condition, results of operations, and prospects.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional or international patent application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our products or product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of products or new product candidates, patents protecting such products or candidates might expire before or shortly after such products or candidates are commercialized. As a result, our owned and licensed patent portfolio

may not provide us with sufficient and continuing rights to exclude others from commercializing products similar or identical to ours.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated as a result of noncompliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and patent applications. We rely on our outside counsel or our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could adversely affect our business, financial condition, results of operations and prospects.

If we do not obtain patent term extension for our product candidate, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any of our product candidates, one or more of our or our licensors' issued U.S. patents or issued U.S. patents that we may own in the future may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 ("Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent extension term ("PTE") of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under Supplemental Protection Certificate ("SPC"). However, we may not be granted any extensions for which we apply because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension, or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

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

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. However, trade secret protection will not protect us from innovations that a competitor develops independently of our proprietary know-how. If a competitor independently develops a technology that we protect as a trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future, may require a license from the competitor to use our own know-how, and if the license is not available on commercially-viable terms, then we may not be able to launch our product candidate. Additionally, trade secrets can be difficult to protect and some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets. If our trade secrets are not adequately protected, our business, financial condition, results of operations and prospects could be adversely affected.

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

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or an equivalent administrative body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, domain name or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Certain of our employees, consultants or advisors have in the past and may in the future be employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. An inability to incorporate such technologies or features would harm our business and may prevent us from successfully commercializing our technologies or product candidates. In addition, we may lose personnel as a result of such claims and any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our technologies, or product candidates, which could adversely affect our business, financial condition, results of operations and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, we or our licensors may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our owned or licensed patents or patent applications. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar technology and therapeutics, without payment to us, or could limit the duration of the patent protection covering our technologies and product candidates. Such challenges may also result in our inability to develop, manufacture or commercialize our technologies and product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our owned or licensed patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future

technologies and product candidates. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

Risks Related to Government Regulation

The regulatory approval process is highly uncertain, and we may be unable to obtain, or may be delayed in obtaining, U.S. or foreign regulatory approval and, as a result, unable to commercialize izokibep, lonigutamab, any of our other product candidates or any future product candidates. Even if we believe our current, or planned clinical trials are successful, regulatory authorities may not agree that they provide adequate data on safety or efficacy.

Izokibep, lonigutamab, any of our other product candidates and any future product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, post-approval monitoring, marketing and distribution of products. Rigorous preclinical studies and clinical trials and an extensive regulatory approval process are required to be completed successfully in the United States and in many foreign jurisdictions before a new product can be marketed. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of our product candidates will obtain the regulatory approvals necessary for us to begin selling them.

Our company has no prior experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when regulating us require judgment and can change, which makes it difficult to predict with certainty their application. Any analysis we perform of data from preclinical studies and clinical trials is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether additional legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or the impact of such changes, if any. Any elongation or de-prioritization of preclinical studies or clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of izokibep, lonigutamab, any of our other product candidates or any future product candidates.

Further, the FDA and its foreign counterparts may respond to any BLA that we may submit by defining requirements that we do not anticipate.

Such responses could delay clinical development of izokibep, lonigutamab, any of our other product candidates or any future product candidates.

Any delay or failure in obtaining required approvals could adversely affect our ability to generate revenue from the particular product candidate for which we are seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which we may market the product or on the labeling or other restrictions.

We are also subject to or may in the future become subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with the FDA approval process described above, as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. FDA approval does not ensure approval by regulatory authorities outside the United States and vice versa. Any delay or failure to obtain U.S. or foreign regulatory approval for a product candidate could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal. We may also

be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we or our existing or future collaborators obtain for our product candidates may also be subject to limitations on the approved indicated uses for which a product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the product candidate.

In addition, if the FDA, EMA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, post-approval monitoring and adverse event reporting, storage, import, export, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. The FDA has significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product from the market. The FDA also has the authority to require a REMS plan after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. The manufacturing facilities we use to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory agencies, including for continued compliance with current Good Manufacturing Practices (“cGMPs”) requirements. The discovery of any new or previously unknown problems with our third-party manufacturers, manufacturing processes or facilities may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. As we expect to rely on third-party manufacturers, we will not have control over compliance with applicable rules and regulations by such manufacturers. Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. The FDA imposes stringent restrictions on manufacturers’ communications regarding use of their products. Although clinicians may prescribe products for off-label uses as the FDA and other regulatory agencies do not regulate a physician’s choice of drug treatment made in the physician’s independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products. In addition, as we do not intend to conduct head-to-head comparative clinical trials for our product candidates, we will be unable to make comparative claims regarding any other products in the promotional materials for our product candidates. If we promote our products, if approved, in a manner inconsistent with FDA-approved labeling or otherwise not in compliance with FDA regulations, we may be subject to enforcement action. If we or our existing or future collaborators, manufacturers or service providers fail to comply with applicable continuing regulatory requirements in the United States or foreign jurisdictions in which we seek to market our product candidates, we or they may be subject to, among other things, fines, warning or untitled letters, holds on clinical trials, delay of approval or refusal by the FDA or similar foreign regulatory bodies to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunction, civil penalties and criminal prosecution.

Subsequent discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning or untitled letters or holds on clinical trials;
- refusal by the Medicines and Healthcare Products Regulatory Agency or the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners;
- suspension or revocation of product license approvals;
- product seizure or detention or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. Changes in FDA staffing could result in delays in the FDA’s responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all.

Recently enacted legislation, future legislation and other healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and may affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the “ACA”) was enacted in the United States, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States and significantly affected the pharmaceutical industry. The ACA, among other things, subjected biologic products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program (“MDRP”) are calculated for drugs and biologics that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the MDRP, extended manufacturer Medicaid rebate obligations to utilization by individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs and biologics, and established a new Medicare Part D coverage gap discount program. Since its enactment, there have been judicial, congressional, and executive branch challenges to the ACA, which have resulted in delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. In addition, there have been a number of health reform initiatives by the Biden administration that have impacted the ACA. For example, on August 16, 2022, President Biden signed the IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or congressional challenges in the future. It is unclear how other such challenges, and the healthcare reform measures of the Biden administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, resulted in reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, in July 2021, the Biden administration released an executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at prescription drugs. In response to Biden’s executive order, on September 9, 2021, the U.S. Department of Health and Human Services (“HHS”) released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although the Medicare drug price negotiation program is currently subject to legal challenges. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report within 90 days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. Moreover, the American Taxpayer Relief Act of 2021, effective January 1, 2024, would eliminate the statutory cap on rebate amounts owed by drug manufacturers under the MDRP, which is currently capped at 100% of the Average Manufacturer Price (“AMP”) for a covered outpatient drug.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions

on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, financial condition, results of operations and prospects.

We expect that the ACA, the IRA, and any other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from 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 product candidates, if approved.

Our current product candidates and any of our future product candidates regulated as biologics in the United States may face competition sooner than anticipated from biosimilars approved through an abbreviated regulatory pathway.

The enactment of the Biologics Price Competition and Innovation Act of 2009 (“BPCIA”) as part of the Patient ACA created an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biological products, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. Certain changes, however, and supplements to an approved BLA, and subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest, or other related entity do not qualify for the 12-year exclusivity period.

Our product candidates are all biological product candidates. We anticipate being awarded market exclusivity for each of our biological product candidates that is subject to its own BLA for 12 years in the United States. However, the term of the patents that cover such product candidates may not extend beyond the applicable market exclusivity awarded by a particular country. For example, in the United States, if all of the patents that cover our particular biological product expire before the 12-year market exclusivity expires, a third party could submit a marketing application for a biosimilar product four years after approval of our biological product, the FDA could immediately review the application and approve the biosimilar product for marketing 12 years after approval of our biological product, and the biosimilar sponsor could then immediately begin marketing. Alternatively, a third party could submit a full BLA for a similar or identical product any time after approval of our biological product, and the FDA could immediately review and approve the similar or identical product for marketing and the third party could begin marketing the similar or identical product upon expiry of all of the patents that cover our particular biological product.

There is also a risk that this exclusivity could be changed in the future. For example, this exclusivity could be shortened due to congressional action or through other actions, including future proposed budgets, international trade agreements and other arrangements or proposals. Additionally, there is a risk that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. The extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. It is also possible that payors will give reimbursement preference to biosimilars over reference biological products, even absent a determination of interchangeability.

Laws and regulations outside the United States differ, including the length and extent of patent and exclusivity protection and pathways for competition to enter the market. For example, in the EU exclusivity is generally 10 years and can be extended to 11 years under certain circumstances. Other countries may have significantly shorter or longer periods of exclusivity. In addition, other countries may have different standards in determining similarity to a reference product. Any market entry of competing products to our product candidates in these other regions could adversely affect our business in those regions.

To the extent that we do not receive any anticipated periods of regulatory exclusivity for our product candidates it could adversely affect our business, financial condition, results of operations and prospects.

Our operations and relationships with healthcare providers, healthcare organizations, customers and third-party payors will be subject to applicable anti-bribery, anti-kickback, fraud and abuse, transparency and other healthcare and privacy laws and regulations, which could expose us to, among other things, enforcement actions, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Our future arrangements with healthcare providers, healthcare organizations, third-party payors and customers will expose us to broadly applicable anti-bribery, fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our products, if approved. In addition, we may be subject to data privacy and security regulation by the U.S. federal government and the states and the foreign governments in which we conduct our business. Restrictions under applicable federal and state anti-bribery and healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal and state healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal criminal and civil false claims laws, including the federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions against individuals or entities, and the Federal Civil Monetary Penalties Laws, which prohibit, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Moreover, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- Health Insurance Portability and Accountability Act (“HIPAA”), which imposes criminal and civil liability, prohibits, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”) and their respective implementing regulations, which impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services involving the storage, use or disclosure of individually identifiable health information for or on behalf of a covered entity and their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;
- the federal legislation commonly referred to as the Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program, with certain exceptions, to report annually to the Centers for Medicare & Medicaid Services (“CMS”) information on certain payments and other transfers of value to clinicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), teaching hospitals, and certain other health care providers (such as physician assistants and nurse practitioners), as well as ownership and investment interests held by the clinicians described above and their immediate family members;
- state privacy laws and regulations that impose restrictive requirements regulating the use and disclosure of personal information, including health information;

- foreign privacy, data protection, and data security laws and regulations, such as the European Union’s General Data Protection Regulation (“EU GDPR”), which imposes comprehensive obligations on covered businesses to, among other things, make contractual privacy, data protection and data security commitments, cooperate with European data protection authorities, implement security measures, give data breach notifications, and keep records of personal information processing activities;
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and
- certain state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to clinicians and other healthcare providers or marketing expenditures and drug pricing information, and state and local laws that require the registration of pharmaceutical sales representatives.

If we or our current or future collaborators, manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could affect our ability to develop, market and sell our product candidates successfully and could harm our reputation and lead to reduced acceptance of our products, if approved by the market.

Efforts to ensure that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any such requirements, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm, any of which could adversely affect our financial results. These risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management’s attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any.

In some countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In addition, many countries outside the U.S. have limited government support programs that provide for reimbursement of drugs such as our product candidates, with an emphasis on private payors for access to commercial products. If reimbursement of our products, if approved is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, and policies related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process or processing) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, employee data, intellectual

property, data we collect about trial participants in connection with clinical trials, and other sensitive third-party data (collectively, sensitive data). Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

Various federal, state, local and foreign legislative and regulatory bodies, or self-regulatory organizations, may expand current laws, rules or regulations, enact new laws, rules or regulations or issue revised rules or guidance regarding data privacy and security. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. Additionally, the California Consumer Privacy Act (“CCPA”) applies to personal information of consumers, business representatives, and employees, and among other things requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights, including the right to opt out of certain disclosures of their information. The CCPA provides for civil penalties of up to \$7,500 per violation as well as a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for certain information collected as part of clinical trials, the CCPA may impact our processing of personal information and increases our compliance costs. Additionally, the California Privacy Rights Act of 2020 (“CPRA”) significantly expands the CCPA, such as granting additional rights to California residents, including the right to correct personal information and additional opt-out rights. The CPRA also establishes a regulatory agency dedicated to enforcing the CCPA and the CPRA. Other states, such as Virginia, Connecticut, Utah and Colorado, have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. While these state privacy laws, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. In addition to government activity, privacy advocacy groups and technology and other industries are considering various new, additional or different self-regulatory standards that may place additional burdens on us.

There are also various laws and regulations in other jurisdictions outside the United States relating to data privacy and security, with which we may need to comply. For example, the EU GDPR and the United Kingdom’s equivalent (“UK GDPR”), collectively, GDPR, impose strict requirements for processing personal data. We also have operations in Asia, and may be subject to new and emerging data privacy regimes such as Japan’s Act on the Protection of Personal Information. Notably, the EU GDPR and UK GDPR impose large penalties for noncompliance, including the potential for fines of up to €20 million under the EU GDPR / £17.5 million under the UK GDPR, or 4% of the annual global revenue of the noncompliant entity, whichever is greater. The EU GDPR and UK GDPR also provide for 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. Additionally, EU member states may introduce further conditions, including limitations, and make their own laws and regulations further limiting the processing of ‘special categories of personal data, including personal data related to health, biometric data used for unique identification purposes and genetic information, which could limit our ability to collect, use and share EU data, and could cause our compliance costs to increase, ultimately adversely affecting our business, financial condition, results of operations and prospects.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. 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 United States and other countries whose privacy laws it 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 United States in compliance with law, such as the EEA and UK’s standard contractual clauses, 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 United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, 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 United States, 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 EU GDPR's cross-border data transfer limitations.

In addition to data privacy and security laws, 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.

Each of these laws, rules, regulations and contractual obligations relating to data privacy and security, and any other such changes or new laws, rules, regulations or contractual obligations could impose significant limitations, require changes to our business, or restrict our collection, use, storage or processing of personal information, which may increase our compliance expenses and make our business more costly or less efficient to conduct. In addition, any such changes could compromise our ability to develop an adequate marketing strategy and pursue our growth strategy effectively or even prevent us from providing certain products in jurisdictions in which we currently operate and in which we may operate in the future or incur potential liability in an effort to comply with such legislation, which, in turn, could adversely affect our business, financial condition, results of operations and prospects. Complying with these numerous, complex and often changing regulations is expensive and difficult, and failure to comply with any data privacy or security laws, whether by us, one of our CROs, CMOs or business associates or another third party, could adversely affect our business, financial condition, results of operations and prospects, including but not limited to: investigation costs; material fines and penalties; compensatory, special, punitive and statutory damages; litigation; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services and/or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; reputational damage; and injunctive relief. The recent implementation of the CCPA, EU GDPR and UK GDPR have increased our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may in the future be required to put in place additional mechanisms to ensure compliance with the CCPA, EU GDPR and UK GDPR and other applicable laws and regulations, which could divert management's attention and increase our cost of doing business. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EEA and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

Any actual or perceived failure by us or our third-party service providers to comply with any federal, state or foreign laws, rules, regulations, industry self-regulatory principles, industry standards or codes of conduct, regulatory guidance, orders to which we may be subject or other legal obligations relating to privacy, data protection, data security or consumer protection could adversely affect our reputation, brand and business. We may also be contractually required to indemnify and hold harmless third parties from the costs or consequences of non-compliance with any laws, rules and regulations or other legal obligations relating to privacy or any inadvertent or unauthorized use or disclosure of data that we store or handle as part of operating our business. Any of these events could adversely affect our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including 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.

We cannot assure you that our CROs, CMOs or other third-party service providers with access to our or our suppliers', manufacturers', trial participants' and employees' sensitive information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security incidents, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, financial condition, results of operations and prospects. We cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing of such information. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

We also publicly post our privacy policies and practices concerning our collection, use, disclosure and other processing of the personal information provided to us by our website visitors and by our customers. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be perceived to have failed to do so. Our publication of our privacy policies and other statements we publish that provide promises and assurances about privacy and security can subject us to potential state and federal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any actual or perceived failure by us to comply with federal, state or foreign

laws, rules or regulations, industry standards, contractual or other legal obligations, or any actual, perceived or suspected cybersecurity incident, whether or not resulting in unauthorized access to, or acquisition, release or transfer of personal information or other data, may result in enforcement actions and prosecutions, private litigation, significant fines, penalties and censure, claims for damages by customers and other affected individuals, regulatory inquiries and investigations or adverse publicity and could cause our customers to lose trust in us, any of which could adversely affect our business, financial condition, results of operations and prospects.

The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

Risks Related to Our Reliance on Third Parties

We may have conflicts with our current or future licensors or collaborators that could delay or prevent the development or commercialization of our product candidates.

We are currently party to license and collaboration agreements with Affibody, Pierre Fabre and Novely Nobility, and we expect to enter into similar strategic transactions in the future. We may have conflicts with our current or future collaborators, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. If any conflicts arise with any of our collaborators, such collaborator may act in a manner that is adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenue: disputes regarding milestone payments or royalties; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations; unwillingness by the collaborator to cooperate in the development or manufacture of a product candidate, including providing us with data or materials; unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement.

We have relied and expect to continue to rely on third parties to conduct our preclinical studies and clinical trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines or terminate the relationship, our development programs could be delayed, more costly or unsuccessful, and we may never be able to seek or obtain regulatory approval for or commercialize our product candidates.

We rely and intend to rely in the future on third-party clinical investigators, CROs, clinical data management organizations to conduct, supervise and monitor preclinical studies and clinical trials of our current or future product candidates. Because we currently rely and intend to continue to rely on these third parties, we will have less control over the timing, quality and other aspects of preclinical studies and clinical trials than we would have had we conducted them independently. These parties are not, and will not be, our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. Additionally, such parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs.

We have no experience as a company in filing and supporting the applications necessary to gain marketing approvals. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each indication to establish the product candidate's safety or efficacy for that indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by, applicable regulatory authorities.

Large-scale clinical trials require significant financial and management resources, and reliance on third-party clinical investigators, CROs, partners or consultants. Relying on third-party clinical investigators or CROs may force us to encounter delays and challenges that are outside of our control. We may not be able to demonstrate sufficient comparability between products manufactured at different facilities to allow for inclusion of the clinical results from participants treated with products from these different facilities, in our product registrations. Further, our third party clinical manufacturers

may not be able to manufacture our product candidates or otherwise fulfill their obligations to us because of interruptions to their business, including the loss of their key staff or interruptions to their raw material supply.

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable trial protocol and legal, regulatory and scientific standards, and our reliance on the CROs, clinical trial sites, and other third parties does not relieve us of these responsibilities. For example, we will remain responsible for ensuring that each of our preclinical studies are conducted in accordance with good laboratory practices (GLPs) and clinical trials are conducted in accordance with GCPs. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with GCP for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections (including pre-approval inspections once a BLA is submitted to the FDA) of trial sponsors, clinical investigators, trial sites and certain third parties including CROs. If we, our CROs, clinical trial sites, or other third parties fail to comply with applicable GCP or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. Moreover, our business may be significantly impacted if our CROs, clinical investigators or other third parties violate federal or state healthcare fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

In the event we need to repeat, extend, delay or terminate our clinical trials because these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, our clinical trials may need to be repeated, extended, delayed or terminated and we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates, and we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be materially and adversely affected.

If any of our relationships with these third parties terminate, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. Switching or adding additional contractors involves additional cost and time and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. In addition, if an agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and/or a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

We rely on third-party manufacturers and suppliers to supply our product candidates. The loss of our third-party manufacturers or suppliers, or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, within acceptable timeframes, or at all, would materially and adversely affect our business.

We do not own or operate facilities for drug manufacturing, storage, distribution or quality testing. We currently rely, and expect to continue to rely, on third-party contract developers and manufacturers, including in Europe and, for lonigutamab, in China, to manufacture bulk drug substances, drug products, raw materials, samples, components, and other materials for our product candidates. Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture product candidates ourselves. There can be no assurance that our preclinical and clinical development

product supplies will not be limited, interrupted, terminated or will be of satisfactory quality or be available at acceptable prices. In addition, any replacement of our manufacturer could require significant effort and time because there may be a limited number of qualified replacements.

The manufacturing process for our product candidates is subject to the FDA, EMA and foreign regulatory authority review. We, and our suppliers and manufacturers, some of which are currently our sole source of supply, must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA, EMA and foreign regulatory authorities. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or comparable foreign regulatory authorities, we may not be able to rely on their facilities for the manufacture of elements of our product candidates. Moreover, we do not conduct the manufacturing process ourselves and are dependent on our CMOs for manufacturing in compliance with current regulatory requirements. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing or otherwise, or if our projected manufacturing capacity or supply of materials becomes limited, interrupted, or more costly than anticipated, we may be forced to enter into an agreement with another third party, which we may not be able to do timely or on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such to another third party.

These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us, or to have another third party, manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with applicable quality standards and regulations and guidelines; and we may be required to repeat some of the development program. The delays and costs associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. Any manufacturing facilities used to produce our product candidates will be subject to periodic review and inspection by the FDA and foreign regulatory authorities, including for continued compliance with cGMP requirements, quality control, quality assurance and corresponding maintenance of records and documents. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party's failure to execute on our manufacturing requirements, comply with cGMPs or maintain a compliance status acceptable to the FDA, EMA or foreign regulatory authorities could adversely affect our business in a number of ways, including:

- an inability to initiate or continue preclinical studies or clinical trials of product candidates;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of existing or future collaborators;
- requirements to cease distribution or to recall batches of our product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

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

We depend on sole source and limited source suppliers for certain drug substances, drug products, raw materials, samples, components, and other materials used in our product candidates. If we are unable to source these supplies on a

timely basis, or establish longer-term contracts with our CMOs, we will not be able to complete our clinical trials on time and the development of our product candidates may be delayed.

We depend on sole source and limited source suppliers for certain drug substances, drug products, raw materials, samples, components, and other materials used in our product candidates. We do not currently have long-term supply contracts with all of our CMOs and they are not obligated to supply drug products to us for any period, in any specified quantity or at any certain price beyond the delivery contemplated by the relevant purchase orders. As a result, our suppliers could stop selling to us at commercially reasonable prices, or at all. While we intend to enter into long-term master supply agreements with certain of our CMOs in the future as we advance our clinical trials or commercialization plans, we may not be successful in negotiating such agreements on favorable terms or at all. If we do enter into such long-term master supply agreements, or enter into such agreements on less favorable terms than we currently have with such manufacturers, we could be subject to binding long-term purchase obligations that may be harmful to our business, including in the event that we do not conduct our trials on planned timelines or utilize the drug products that we are required to purchase. Any change in our relationships with our CMOs or changes to contractual terms of our agreements with them could adversely affect our business, financial condition, results of operations and prospects.

Furthermore, any of the sole source and limited source suppliers upon whom we rely could stop producing our supplies, cease operations or be acquired by, or enter into exclusive arrangements with, our competitors. Additionally, our manufacturing process for izokibep requires special equipment, and identifying additional suppliers able to fabricate such equipment at their facility at acceptable costs may be difficult. Establishing additional or replacement suppliers for these supplies, and obtaining regulatory clearance or approvals that may result from adding or replacing suppliers, could take a substantial amount of time, result in increased costs and impair our ability to produce our products, which would adversely impact our business, financial condition, results of operations and prospects. Any such interruption or delay may force us to seek similar supplies from alternative sources, which may not be available at reasonable prices, or at all. Any interruption in the supply of sole source or limited source components for our product candidates would adversely affect our ability to meet scheduled timelines and budget for the development and commercialization of our product candidates, could result in higher expenses and would harm our business. Although we have not experienced any significant disruption as a result of our reliance on limited or sole source suppliers, we have a limited operating history and cannot assure you that we will not experience disruptions in our supply chain in the future as a result of such reliance or otherwise.

The operations of our suppliers, most of which are located outside of the United States, are subject to additional risks that are beyond our control and that could harm our business, financial condition, results of operations and prospects.

Currently, most of our suppliers are located outside of the United States. As a result of our global suppliers, we are subject to risks associated with doing business abroad, including:

- political unrest, terrorism, labor disputes, and economic instability resulting in the disruption of trade from foreign countries in which our products are manufactured;
- the imposition of new laws and regulations, including those relating to labor conditions, quality, and safety standards, imports, duties, taxes, and other charges on imports, as well as trade restrictions and restrictions on currency exchange or the transfer of funds, particularly new or increased tariffs imposed on imports from countries where our suppliers operate;
- greater challenges and increased costs with enforcing and periodically auditing or reviewing our suppliers' and manufacturers' compliance with cGMPs or status acceptable to the FDA, EMA or foreign regulatory authorities;
- reduced protection for intellectual property rights, including trademark protection, in some countries, particularly China;
- disruptions in operations due to global, regional, or local public health crises or other emergencies or natural disasters, including, for example, potential disruptions due to the ongoing COVID-19 pandemic or other pandemics or health crises;
- disruptions or delays in shipments; and
- changes in local economic conditions in countries where our manufacturers or suppliers are located.

These and other factors beyond our control, particularly in light of the COVID-19 pandemic or any other pandemics or health crises, could interrupt our suppliers' production, influence the ability of our suppliers to export our clinical

supplies cost-effectively or at all, and inhibit our suppliers' ability to procure certain materials, any of which could harm our business, financial condition, results of operations and prospects.

The manufacturing of our product candidates is complex, and our third-party manufacturers may encounter difficulties in production. If our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials, our ability to obtain marketing approval, or provide supply of our products for participants, if approved, could be delayed or halted.

Our product candidates are biopharmaceuticals and the process of manufacturing biopharmaceuticals is complex, time-consuming, highly regulated and subject to multiple risks. Our CMOs must comply with legal requirements, cGMPs and guidelines for the manufacturing of biopharmaceuticals used in clinical trials and, if approved, marketed products. Our CMOs may have limited experience in the manufacturing of cGMP batches of our products.

Manufacturing biopharmaceuticals is highly susceptible to drug product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. If any such drug product loss occurs, the impact to our business could be compounded by the long lead times needed to procure additional drug product due to plant capacity limitations, or other restrictions, at our CMOs. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered at our third-party manufacturers' facilities, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely affect our business. Moreover, if the FDA, EMA or any other regulatory authority determines that our third-party manufacturers' facilities are not in compliance with applicable laws and regulations, including those governing cGMPs, they may deny BLA establishment licensure until the deficiencies are corrected or we replace the manufacturer in our BLA with a manufacturer that is able to ensure safety, purity and potency of the product being manufactured.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with cGMPs, lot consistency and timely availability of raw materials. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA, EMA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and prospects.

Scaling up a biopharmaceutical manufacturing process is a difficult and uncertain task. If our third-party manufacturers are unable, or decide not, to adequately validate or scale-up the manufacturing process at our current manufacturers' facilities, we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be lengthy. If we are able to adequately validate and scale-up the manufacturing process for our product candidates with CMOs, we will in most cases still need to negotiate with such CMOs an agreement for commercial supply and it is not certain we will be able to come to agreement on terms acceptable to us.

We cannot assure you that any stability or other issues relating to the manufacture of any of our current or future product candidates or products will not occur in the future. If our third-party manufacturers were to encounter any of these difficulties, our ability to provide any product candidates to participants in clinical trials and products to participants, once approved, would be jeopardized. Any delay or interruption in clinical trial supplies could delay the completion of planned clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of our product candidates or products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our product candidates or products. We may also have to take inventory write-offs and incur other charges and expenses for product candidates or products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could adversely affect our business and delay or impede the development and commercialization of any of our product candidates or products, if approved, and could have an adverse effect on our business, financial condition, results of operations and prospects.

As part of our process development efforts, we also may make changes to the manufacturing processes at various points during development, for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our current or future product candidates to perform differently and affect the results of our future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform *ex vivo* comparability studies and to collect additional data from participants prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial.

Risks Related to Ownership of Our Common Stock

Our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts or any guidance we may publicly provide, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly and annual fluctuations which may, in turn, cause the price of our common stock to fluctuate substantially. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of izokibep, lonigutamab, and our other product candidates or future development programs;
- results and timing of ongoing and future preclinical studies and clinical trials, or the addition or termination thereof;
- the timing of payments we may make or receive under existing license and collaboration arrangements or the termination or modification thereof;
- our execution of any strategic transactions, including acquisitions, collaborations, licenses or similar arrangements, and the timing and amount of payments we may make or receive in connection with such transactions;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- recruitment and departures of key personnel;
- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such products;
- regulatory developments affecting our product candidates or those of our competitors;
- fluctuations in stock-based compensation expense;
- the continuing impact of negative macroeconomic trends, such as high rates of inflation, supply chain disruptions and geopolitical instability, and the COVID-19 pandemic on our business and operations; and
- changes in general market and economic conditions.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts or any forecasts or guidance we may provide to the market, 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. We believe that quarterly or annual comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Our stock price is likely to continue to be volatile, which could result in substantial losses for investors.

The market price of our common stock is likely to continue to be volatile and could fluctuate widely in response to many factors, including but not limited to:

- volatility and instability in the financial and capital markets;

- announcements relating to our product candidates, including the results of clinical trials by us or our collaborators such as our announcement of week 16 results from the Part B portion of our Phase 2b/3 trial of izokibep in HS, which significantly harmed our stock price;
- announcements by competitors that impact our competitive outlook;
- negative developments with respect to our product candidates, or similar products or product candidates with which we compete;
- developments with respect to patents or intellectual property rights;
- announcements of technological innovations, new product candidates, new products or new contracts by us or our competitors;
- announcements relating to strategic transactions, including acquisitions, collaborations, licenses or similar arrangements;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by equities research analysts and whether our earnings (or losses) meet or exceed such estimates;
- announcement or expectation of financing efforts and receipt, or lack of receipt, of funding in support of conducting our business;
- sales of our common stock by us, our insiders, or other stockholders, or issuances by us of shares of our common stock in connection with strategic transactions, financings or otherwise;
- expiration of market standoff or lock-up agreements, which occurred on October 31, 2023 with respect to lock-up agreements entered into in connection with our IPO;
- conditions and trends in the pharmaceutical, biotechnology and other industries;
- regulatory developments within, and outside of, the United States, including changes in the structure of health care payment systems;
- litigation or arbitration;
- COVID-19 or other pandemics or health crises, natural disasters, or major catastrophic events;
- general economic, political and market conditions and other factors; and
- the occurrence of any of the risks described in this section titled “Risk Factors”.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance.

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

We are an “emerging growth company” as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (iii) exemptions from the requirements of holding

nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not approved previously.

We could be an emerging growth company for up to five years following the completion of our May 2023 initial public offering, although circumstances could cause us to lose that status earlier, including if we are deemed to be a “large accelerated filer,” which occurs when the market value of our shares that is held by non-affiliates equals or exceeds \$700.0 million as of the prior June 30, or if we have total annual gross revenue of \$1.24 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the December 31 of such year, or if we issue more than \$1.0 billion in non-convertible debt during any three-year period before that time, in which case we would no longer be an emerging growth company immediately.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an “emerging growth company” or affirmatively and irrevocably opt out of the exemption provided by Section 7(a)(2)(B) of the Securities Act, upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard.

Anti-takeover provisions in our charter documents and under Delaware law could prevent or delay an acquisition of us that may be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Our restated certificate of incorporation and our restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed “for cause” and only with the approval of two-thirds of our stockholders;
- require super-majority voting to amend some provisions in our restated certificate of incorporation and restated bylaws;
- authorize the issuance of “blank check” preferred stock that our board could use to implement a stockholder rights plan;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting; and
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

In addition, Section 203 of the Delaware General Corporation Law (DGCL) may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.

The exclusive forum provisions in our organizational documents may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or employees, or the underwriters of any offering giving rise to such claim, which may discourage lawsuits with respect to such claims.

Our restated certificate of incorporation, to the fullest extent permitted by law, provides 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 DGCL, our restated certificate of incorporation, or our restated bylaws; or any action asserting a claim that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, or the underwriters of any offering giving rise to such claims, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition, results of operations and prospects.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Our restated bylaws provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the Federal Forum Provision, including for all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any public offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While federal or other state courts may not follow the holding of the Delaware Supreme Court or may determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. In addition, neither the exclusive forum provision nor the Federal Forum Provision applies to suits brought to enforce any duty or liability created by the Exchange Act. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder must be brought in federal court, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions in our restated bylaws, including the Federal Forum Provision. These provisions may limit a stockholders' ability, and/or may result in increased costs for a stockholder, to bring such a claim in a judicial forum of their choosing for disputes with us or our directors, officers, other employees or agents. That may discourage lawsuits against us and our directors, officers, other employees or agents.

Our board of directors are authorized to issue and designate shares of our preferred stock without stockholder approval.

Our amended and restated certificate of incorporation authorizes our board of directors, without the approval of our stockholders, to issue shares of preferred stock, subject to limitations prescribed therein or by applicable law, rules and regulations; to establish the number of shares to be included in each such series of preferred stock; and to fix the designation, powers, preferences and rights of each such series and the qualifications, limitations or restrictions thereof. The powers, preferences and rights of these additional series of convertible preferred stock may be senior to or on parity with our common stock, which may reduce our common stock's value.

Because we do not anticipate paying any dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be our stockholders' sole source of gain.

We have never declared nor paid dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development, operation and expansion of our business and we do not anticipate declaring or paying any dividends in the foreseeable future. As a result, capital appreciation of our common stock, which may never occur, will be our stockholders' sole source of gain on investment for the foreseeable future.

General Risk Factors

Unstable economic and market conditions may have serious adverse consequences on our business, financial condition and stock price.

Global economic and business activities continue to face widespread uncertainties, and global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished

liquidity and credit availability, rising inflation and monetary supply shifts, rising interest rates, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks, and uncertainty about economic and geopolitical stability (for example, related to the ongoing Russia-Ukraine conflict or the recent state of war between Israel and Hamas and the related risk of a larger regional conflict). The extent of the impact of these conditions on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected timeframe, as well as that of third parties upon whom we rely, will depend on future developments which are uncertain and cannot be predicted. There can be no assurance that further deterioration in economic or market conditions will not occur, or how long these challenges will persist. If the current equity and credit markets further deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

If securities or industry analysts do not publish research or reports about our business, or if they publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock is influenced in part by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the industry or securities analysts, or the content and opinions included in their reports and may never obtain research coverage by securities and industry analysts. If analysts cease coverage of us, we could lose visibility in the financial markets, and the trading price for our common stock could be impacted negatively. If any of the analysts who cover us publish inaccurate or unfavorable research or opinions regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline.

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

As a public company we incur significant legal, accounting and other expenses that we did not incur as a private company. The Securities Act, the Exchange Act, Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will continue to need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs over those incurred as a private company and to make some activities more time consuming and costly, particularly after we are no longer an emerging growth company. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements, and these increased costs may require us to reduce costs in other areas of our business. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

Failure to maintain effective internal control over financial reporting could adversely affect our business and if investors lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could be negatively affected.

We are not currently required to comply with the rules of the SEC implementing Section 404 of the Sarbanes-Oxley Act and are therefore not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. However, we are required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which require our management certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of internal control over financial reporting. Our first annual assessment of our internal control over financial reporting will not be required until our second annual report on Form 10-K, though we are required to disclose changes made in our internal control over financial reporting on a quarterly basis. Moreover, as an emerging growth company, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the later of the year following our first annual report required to be filed with the SEC or the date we are no longer an emerging growth company. At such time, our independent registered public accounting firm would need to issue a report that is adverse in the event that there are material weaknesses in our internal control over financial reporting.

To comply with the requirements of being a public company, we have undertaken various actions, and will need to take additional actions, such as implementing numerous internal controls and procedures and hiring additional accounting

or internal audit staff or consultants. Testing and maintaining internal controls can divert our management's attention from other matters that are important to the operation of our business. Additionally, in connection with the preparation of our financial statements for the year ended December 31, 2021 and 2022, material weaknesses were identified in the design and operating effectiveness of our internal control over financial reporting. If we are unable to remediate these material weaknesses, or we identify more material weaknesses that we are not able to timely remediate to meet the applicable compliance deadline for the disclosure and attestation requirements of Section 404 of the Sarbanes-Oxley Act, investors may lose confidence in the accuracy and completeness of our financial reports. As a result, the market price of our common stock could be negatively affected and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC or other regulatory authorities, which could require additional financial and management resources. In addition, if we fail to remedy any material weakness, our financial statements could be inaccurate, and we could face restricted access to capital markets.

Our disclosure controls and procedures may not be effective and may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We are in the process of designing our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Our disclosure controls and procedures may not be effective. Any disclosure controls and procedures, 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 the inherent limitations in all control systems. For example, our principal executive officer and principal financial officer concluded that, as of September 30, 2023, our disclosure controls and procedures were not effective due to material weaknesses in our internal control over financial reporting that have not been remediated as of September 30, 2023.

In any event, these inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. In addition, we do not have a formal risk management program for identifying and addressing risks to our business in other areas.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock is likely to continue to be volatile. The stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. In addition, litigation, including securities class action litigation, has often followed the announcement of adverse clinical or regulatory events such as negative or inconclusive clinical trial results, announcements of significant business transactions, such as the sale or purchase of a company, or announcement of any other strategic transaction. Any of these events may also result in investigations by the SEC or other regulatory authorities. In this regard, given the significant decline in our stock price following our announcement of week 16 results from the Part B portion of our Phase 2b/3 trial of izokibep in HS, it is possible that we could become subject to securities class action litigation. Securities litigation (including the cost to defend against, and any potential adverse outcome resulting from any such proceeding) can be expensive, time-consuming, damage our reputation and divert our management's attention from other business concerns, which could seriously harm our business.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES, USE OF PROCEEDS, AND ISSUER PURCHASES OF EQUITY SECURITIES

Use of Proceeds

The net proceeds from our IPO have been invested according to our approved investment policy in a mix of money market funds and high-quality, fixed income securities. There has been no material change in the planned use of IPO proceeds from that described in the Final Prospectus.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION***Insider Trading Arrangements***

During the three months ended September 30, 2023, the directors and officers (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated the contracts, instructions or written plans for the purchase or sale of the Company's securities set forth in the table below.

Name and Position	Action	Date	Type of Trading Arrangement		Total Shares of Common Stock to be Sold	Expiration Date
			Rule 10b5-1*	Non-rule 10b5-1**		
Shao-Lee Lin, M.D., Ph.D., Founder & Chief Executive Officer	Adoption	August 14, 2023	X		Up to 315,995 ⁽¹⁾	March 1, 2025
Melanie Gloria, Chief Operating Officer	Adoption	August 14, 2023	X		Up to 80,000	November 30, 2024
Mina Kim, Chief Legal and Administrative Officer	Adoption	August 14, 2023	X		Up to 100,000	December 30, 2024
Ron Oyston, Chief People Officer	Adoption	August 14, 2023	X		Up to 15,200	November 1, 2024
Paul M. Peloso, M.D., Chief Medical Officer	Adoption	August 14, 2023	X		Up to 42,202	November 30, 2024

* Contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.

** "Non-Rule 10b5-1 trading arrangement" as defined in Item 408(c) of Regulation S-K under the Exchange Act.

⁽¹⁾Includes: (i) 100,000 shares of common stock; and (ii) up to 215,995 shares of common stock subject to restricted stock unit awards that may vest and be released to Dr. Lin on or prior to March 1, 2025 upon satisfaction of the applicable service conditions. The actual number of shares subject to restricted stock unit awards that will be released to Dr. Lin and sold under the Rule 10b5-1 trading arrangement will be net of the number of shares withheld to satisfy tax withholding obligations arising from the vesting of such awards and is not yet determinable.

ITEM 6. EXHIBITS

Exhibit No.	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
2.1	Agreement and Plan of Merger and Reorganization by and among the Registrant, ValenzaBio, Inc., WH1, INC., WH2, LLC and Seller Representatives LLC dated December 20, 2022.	S-1/A	333-271244	2.1	May 3, 2023
3.1	Amended and Restated Certificate of Incorporation of the Company.	8-K	001-41696	3.1	May 9, 2023
3.2	Amended and Restated Bylaws of the Company.	8-K	001-41696	3.2	May 9, 2023
10.1	Separation Agreement and Release by and between Mardi C. Dier and the Company.	8-K	001-41696	10.1	August 2, 2023
31.1*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1*+	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.ins*	Instance 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.

+ Furnished herewith and not deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

SIGNATURE

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.

November 9, 2023

ACELYRIN, INC.

/s/ Gil M. Labrucherie

Gil M. Labrucherie
Chief Financial Officer

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

I, Shao-Lee Lin, M.D., Ph. D., certify that

1. I have reviewed this Quarterly Report on Form 10-Q of ACELYRIN, INC.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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. 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
 - c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting

November 9, 2023

By: /s/ Shao-Lee Lin
Shao-Lee Lin, M.D., Ph.D.
Chief Executive Officer

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

I, Gil M. Labrucherie, certify that

1. I have reviewed this Quarterly Report on Form 10-Q of ACELYRIN, INC.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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. 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
 - c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting

November 9, 2023

By: /s/ Gil M. Labrucherie
Gil M. Labrucherie
Chief Financial Officer

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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the “Exchange Act”) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Shao-Lee Lin, Chief Executive Officer of ACELYRIN, INC. (the “Company”), and Gil M. Labrucherie, Chief Financial Officer of the Company, each hereby certifies that, to the best of her or his knowledge:

- i. the Quarterly Report on Form 10-Q of the Company for the period ended September 30, 2023, to which this Certification is attached as Exhibit 32.1 (the “Periodic Report”), fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Exchange Act; and
- ii. the information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 9, 2023

/s/ Shao-Lee Lin

Shao-Lee Lin, M.D., Ph.D.

Chief Executive Officer

/s/ Gil M. Labrucherie

Gil M. Labrucherie

Chief Financial Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of ACELYRIN, INC. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.