Filed Pursuant to Rule 424(b)(3)
Registration No. 333-267283

Prospectus Supplement No. 1
(To Prospectus dated September 15, 2022)

Comera Life Sciences Holdings, Inc.
5,000,000 Shares of Common Stock

This prospectus supplement no. 1 (this "Prospectus Supplement") updates, amends and supplements the prospectus dated September 15, 2022 (as amended or supplemented from time to time, the "Prospectus") which forms a part of the Registration Statement on Form S-1 (Registration Statement No. 333-267283) filed by Comera Life Sciences Holdings, Inc. ("Holdco"). Capitalized terms used in this Prospectus Supplement and not otherwise defined herein have the meanings specified in the Prospectus.

This Prospectus Supplement is being filed to update, amend and supplement the information included or incorporated by reference in the Prospectus with the information contained in our Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission (the "SEC") on November 14, 2022 (the "Quarterly Report"). Accordingly, we have attached the Quarterly Report to this Prospectus Supplement.

This Prospectus Supplement is not complete without, and may not be delivered or utilized except in combination with, the Prospectus, including any amendments or supplements thereto. This Prospectus Supplement should be read in conjunction with the Prospectus and any amendments or supplements thereto. If there is any inconsistency between the information in the Prospectus and this Prospectus Supplement, you should rely on the information in this Prospectus Supplement.

The Holdco Common Stock is listed on The Nasdaq Capital Market ("Nasdaq") under the symbol "CMRA" and the Holdco Warrants are listed on Nasdaq under the symbol "CMRAW". On November 11, 2022, the closing sale price of the Holdco Common Stock as reported on Nasdaq was $1.49 per share, and the closing sale price of the Holdco Warrants as reported on Nasdaq was $0.05 per warrant.

Investing in our securities involves a high degree of risk. Before buying any securities, you should carefully read the discussion of the risks of investing in our securities in "Risk Factors" beginning on page 10 of the Prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of the securities to be issued under the Prospectus or passed upon the accuracy or adequacy of the Prospectus. Any representation to the contrary is a criminal offense.

The date of this Prospectus Supplement is November 14, 2022.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2022

OR

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

For the transition period from _____ to _____

Commission File Number: 1-41403

Comera Life Sciences Holdings, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**87-4706968**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
12 Gill Street Suite 4650 Woburn, Massachusetts	**01801**
(Address of principal executive offices)	**(Zip Code)**

(617) 871-2101
(Registrant's telephone number, including area code)
Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

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	**CMRA**	**The Nasdaq Stock Market LLC**
Warrants	**CMRAW**	**The Nasdaq Stock Market LLC**

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

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

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

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

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

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

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes ☒ No ☐

As of November 11, 2022, the registrant had 19,849,116 shares of common stock, $0.0001 par value per share, outstanding.

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Item 1. Condensed Consolidated Financial Statements.

COMERA LIFE SCIENCES HOLDINGS, INC.
BALANCE SHEETS
(unaudited)

		September 30, 2022	December 31, 2021
Assets			
Current assets:			
Cash and cash equivalents		$ 2,669,354	$ 6,510,140
Accounts receivable		293,821	—
Due from related parties		—	286
Prepaid expenses and other current assets		1,325,753	270,648
Total current assets		4,288,928	6,781,074
Restricted cash		50,000	50,000
Property and equipment, net		192,590	234,167
Right of use asset		362,401	320,373
Security deposit		43,200	32,200
Total assets		$ 4,937,119	$ 7,417,814
Liabilities, Convertible Preferred Stock and Stockholders' Deficit			
Current liabilities:			
Accounts payable		$ 1,436,692	$ 416,941
Accrued expenses and other current liabilities		887,012	506,611
Insurance premium financing		911,124	—
Lease liability - current		195,253	121,552
Total current liabilities		3,430,081	1,045,104
Derivative warrant liabilities		331,612	—
Lease liability - noncurrent		171,596	201,504
Total liabilities		3,933,289	1,246,608
Commitments and contingencies (Note 17)			
Series A convertible preferred stock		4,431,838	—
Convertible preferred stock		—	20,857,453
Stockholders' equity (deficit):			
Common stock, $0.0001 par value; 150,000,000 shares authorized; 16,653,466 and issued and outstanding at September 30, 2022 and December 31, 2021, respectively	308,443 shares	1,665	31
Additional paid-in capital		28,511,656	2,213,547
Accumulated deficit		(31,941,329)	(16,899,825)
Total stockholders' deficit		(3,428,008)	(14,686,247)
Total liabilities, convertible preferred stock and stockholders' deficit		$ 4,937,119	$ 7,417,814

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

COMERA LIFE SCIENCES HOLDINGS, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue	$ 234,922	$ 87,767	$ 476,982	$ 246,498
Cost of revenue	60,963	48,364	160,030	122,073
Operating expenses:				
Research and development	394,800	263,620	1,250,570	1,262,329
General and administrative	2,314,554	689,483	8,027,316	2,373,621
Total operating expenses	2,709,354	953,103	9,277,886	3,635,950
Loss from operations	(2,535,395)	(913,700)	(8,960,934)	(3,511,525)
Other income (expense), net:				
Change in fair value of derivative warrant liabilities	500,327	—	1,954,767	—
Reverse recapitalization issuance costs in excess of gross proceeds	—	—	(6,566,821)	—
Common stock purchase agreement issuance costs	(1,029,077)	—	(1,029,077)	—
Gain on debt extinguishment	—	—	—	160,588
Change in fair value of convertible notes	—	—	—	(76,738)
Interest expense	(12,696)	—	(12,773)	—
Other expense, net	—	—	(426,666)	—
Total other (expense) income, net	(541,446)	—	(6,080,570)	83,850
Net loss and comprehensive loss	(3,076,841)	(913,700)	(15,041,504)	(3,427,675)
Less: accretion of convertible preferred stock to redemption value	(86,816)	—	(287,984)	—
Net loss attributable to common stockholders or unit holders	$ (3,163,657)	$ (913,700)	$ (15,329,488)	$ (3,427,675)
Net loss per share or unit attributable to common stockholders or unit holders—basic and diluted	$ (0.20)	$ (6.34)	$ (1.85)	$ (0.87)
Weighted-average number of common shares or units used in computing net loss per share or unit attributable to common stockholders or unit holders—basic and diluted	16,024,011	144,163	8,294,938	3,955,649

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

COMERA LIFE SCIENCES HOLDINGS, INC.
STATEMENTS OF CONVERTIBLE PREFERRED STOCK, STOCKHOLDERS' DEFICIT AND MEMBERS' CAPITAL
(unaudited)

	Series A Convertible Preferred Stock		Convertible Preferred Stock		Common Stock		Capital Units		Incentive Units		Additional Paid-in	Accumulated	Total Stockholders' Deficit and Members' Capital
	Shares	Amount	Shares	Amount	Shares	Amount	Units	Amount	Units	Amount	Capital	Deficit	
Balance as of December 31, 2021, as originally stated	—	$ —	13,802,758	$ 20,857,453	400,000	$ 400	—	$ —	—	$ —	$ 2,213,178	$ (16,899,825)	$ (14,686,247)
Retroactive application of reverse recapitalization	—	—	—	—	(91,557)	(369)	—	—	—	—	369	—	—
Balance as of December 31, 2021, as adjusted	—	—	13,802,758	20,857,453	308,443	31	—	—	—	—	2,213,547	(16,899,825)	(14,686,247)
Issuance of common stock upon exercise of stock options	—	—	—	—	735,859	74	—	—	—	—	429,356	—	429,430
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	42,556	—	42,556
Net loss	—	—	—	—	—	—	—	—	—	—	—	(2,879,395)	(2,879,395)
Balance as of March 31, 2022	—	—	13,802,758	20,857,453	1,044,302	105	—	—	—	—	2,685,459	(19,779,220)	(17,093,656)
Issuance of common stock upon exercise of stock options, net of shares withheld to settle tax withholding requirements	—	—	—	—	679,265	68	—	—	—	—	230,003	—	230,071
Conversion of convertible preferred stock	—	—	(13,802,758)	(20,857,453)	10,643,403	1,064	—	—	—	—	20,856,389	—	20,857,453
Issuance of common stock in connection with the Transaction and Maxim Private Placement, net of redemptions, net tangible assets, and issuance costs of $7.5 million	—	—	—	—	3,570,215	357	—	—	—	—	3,443,393	—	3,443,750
Issuance of convertible preferred stock, net of issuance costs of $161,535	4,305	4,143,854	—	—	—	—	—	—	—	—	—	—	—
Accretion of convertible preferred stock to redemption value	—	201,168	—	—	—	—	—	—	—	—	(201,168)	—	(201,168)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	56,739	—	56,739
Net loss	—	—	—	—	—	—	—	—	—	—	—	(9,085,268)	(9,085,268)
Balance as of June 30, 2022	4,305	4,345,022	—	—	15,937,185	1,594	—	—	—	—	27,070,815	(28,864,488)	(1,792,079)
Issuance of common stock upon exercise of Public Warrants	—	—	—	—	100	—	—	—	—	—	1,150		1,150
Issuance of common stock in connection with common stock purchase agreement	—	—	—	—	420,000	42	—	—	—	—	748,846	—	748,888
Issuance of Commitment Shares	—	—	—	—	296,181	29	—	—	—	—	649,971	—	650,000
Accretion of convertible preferred stock to redemption value	—	86,816	—	—	—	—	—	—	—	—	(86,816)	—	(86,816)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	127,690	—	127,690
Net loss	—	—	—	—	—	—	—	—	—	—	—	(3,076,841)	(3,076,841)
Balance as of September 30, 2022	4,305	$ 4,431,838	—	$ —	16,653,466	$ 1,665	—	$ —	—	$ —	$ 28,511,656	$ (31,941,329)	$ (3,428,008)

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

COMERA LIFE SCIENCES HOLDINGS, INC.
STATEMENTS OF CONVERTIBLE PREFERRED STOCK, STOCKHOLDERS' DEFICIT AND MEMBERS' CAPITAL (Continued)
(unaudited)

	Series A Convertible Preferred Stock		Convertible Preferred Stock		Common Stock		Capital Units		Incentive Units		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit and Members' Capital
	Shares	Amount	Shares	Amount	Shares	Amount	Units	Amount	Units	Amount			
Balance as of December 31, 2020	—	$ —	—	$ —	—	$ —	9,429,006	$ 10,681,040	1,987,474	$ —	$ 918,922	$ (11,448,047)	$ 151,915
Vesting of incentive units	—	—	—	—	—	—	—	—	25,416	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	13,878	—	13,878
Net loss	—	—	—	—	—	—	—	—	—	—	—	(533,405)	(533,405)
Balance as of March 31, 2021	—	—	—	—	—	—	9,429,006	10,681,040	2,012,890	—	932,800	(11,981,452)	(367,612)
Vesting of incentive units	—	—	—	—	—	—	—	—	7,523	—	—	—	—
Conversion of capital units into convertible preferred stock	—	—	9,429,006	10,681,040	—	—	(9,429,006)	(10,681,040)	—	—	—	—	(10,681,040)
Cancellation of incentive units upon corporate reorganization	—	—	—	—	—	—	—	—	(2,020,413)	—	—	—	—
Issuance of convertible preferred stock, net of issuance costs of $60,327	—	—	3,487,676	8,066,740	—	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	1,024,444	—	1,024,444
Net loss	—	—	—	—	—	—	—	—	—	—	—	(1,980,570)	(1,980,570)
Balance as of June 30, 2021	—	—	12,916,682	18,747,780	—	—	—	—	—	—	1,957,244	(13,962,022)	(12,004,778)
Issuance of convertible preferred stock, net of issuance costs of $60,327	—	—	886,076	2,109,673	—	—	—	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	—	—	308,443	31	—	—	—	—	179,969	—	180,000
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	34,288	—	34,288
Net loss	—	—	—	—	—	—	—	—	—	—	—	(913,700)	(913,700)
Balance as of September 30, 2021	—	$ —	13,802,758	$ 20,857,453	308,443	$ 31	—	$ —	—	$ —	$ 2,171,501	$ (14,875,722)	$ (13,660,316)

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

COMERA LIFE SCIENCES HOLDINGS, INC.
STATEMENTS OF CASH FLOWS
(unaudited)

	Nine Months Ended September 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (15,041,504)	$ (3,427,675)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	226,985	1,072,610
Depreciation expense	70,184	61,928
Noncash lease expense	1,765	2,951
Gain on debt extinguishment	—	(160,588)
Change in fair value of convertible notes	—	76,738
Reverse recapitalization issuance costs in excess of gross proceeds	6,566,821	—
Noncash common stock purchase agreement issuance costs	650,000	—
Change in fair value of derivative warrant liabilities	(1,954,767)	—
Changes in operating assets and liabilities:		
Accounts receivable	(293,821)	109,868
Prepaid expenses and other current assets	460,895	(16,069)
Due from related parties	286	1,810
Accounts payable	1,019,751	130,063
Accrued expenses and other current liabilities	380,401	22,905
Security deposits	(11,000)	—
Deferred revenue	—	(28,949)
Net cash used in operating activities	(7,924,004)	(2,154,408)
Cash flows from investing activities:		
Purchases of property and equipment	(28,607)	(11,464)
Net cash flows used in investing activities	(28,607)	(11,464)
Cash flows from financing activities:		
Proceeds from issuance of preferred stock, net of offering costs	—	9,349,675
Net proceeds from Transaction and Maxim Private Placement	3,307,162	—
Repayment of insurance premium financing	(604,876)	—
Proceeds from issuance of convertible notes	—	750,000
Proceeds from common stock purchase agreement	748,888	—
Proceeds from exercise of public warrants	1,150	—
Proceeds from exercise of stock options	659,501	180,000
Net cash provided by financing activities	4,111,825	10,279,675
Net (decrease) increase in cash, cash equivalents and restricted cash	(3,840,786)	8,113,803
Cash, cash equivalents and restricted cash at beginning of period	6,560,140	180,427
Cash, cash equivalents, and restricted cash at end of period	$ 2,719,354	$ 8,294,230
Supplemental information:		
Cash and cash equivalents	$ 2,669,354	8,269,230
Restricted cash	50,000	25,000
Total cash, cash equivalents, and restricted cash shown in statements of cash flows	$ 2,719,354	$ 8,294,230
Supplemental disclosure of noncash investing and financing activities:		
Acquisition of right-of-use asset	$ 162,634	$ 404,625
Financing of insurance premiums	$ 1,516,000	$ —
Conversion of capital units into convertible preferred stock	$ —	$ 10,681,040
Conversion of convertible preferred stock into common stock	$ 20,857,453	$ —
Settlement of convertible notes for convertible preferred stock	$ —	$ 826,738
Issuance of common stock to settle stock issuance costs	$ 3,443,750	$ —
Issuance of Series A preferred stock to settle stock issuance costs	$ 910,000	$ —
Accretion on convertible preferred stock	$ 287,984	$ —
Issuance of Series A preferred stock to settle underwriting fees payable assumed in Transaction	$ 3,395,389	$ —
Derivative warrant liabilities assumed in Transaction	$ 2,286,379	$ —

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

1. Organization

Formation and Organization

Comera Life Sciences Holdings, Inc. ("CLS Holdings", "Comera" or the "Company") was incorporated in Delaware on January 25, 2022 as a wholly-owned subsidiary of Comera Life Sciences, Inc. ("Legacy Comera") for the purpose of effecting the Transaction (as defined below).

Legacy Comera was formed in the state of Delaware on January 2, 2014 as ReForm Biologics, LLC. On April 30, 2021, Legacy Comera completed a corporate reorganization (the "Reorganization") and changed its name to ReForm Biologics, Inc. As part of the Reorganization, each issued and outstanding capital unit of Legacy Comera as of the date of the Reorganization was exchanged for shares of convertible preferred stock of Legacy Comera and previously outstanding incentive units of Legacy Comera were cancelled. On January 7, 2022, Legacy Comera changed its name to Comera Life Sciences, Inc. to emphasize Comera's vision of a compassionate new era in medicine. On May 19, 2022, in connection with the closing of the Transaction, Legacy Comera became a wholly-owned subsidiary of CLS Holdings.

Comera is a biotechnology company dedicated to promoting a compassionate new era in medicine. The Company applies a deep knowledge of formulation science and technology to transform essential biologic medicines from intravenous ("IV") to subcutaneous ("SQ") forms. This revolutionary technology provides patients and families with the freedom of self-injectable care, allowing them to realize the potential of these life changing therapies, and to unlock the vast potential of their own lives. To accomplish this, Comera is developing an internal portfolio of proprietary therapeutics that incorporate Comera's innovative proprietary formulation platform, SQore™. Comera also collaborates with pharmaceutical and biotechnology companies, applying the SQore™ platform to Comera's partners' biologic medicines to deliver enhanced formulations that facilitate self-injectable care.

Transaction

On May 19, 2022 (the "Closing Date"), the Company consummated the acquisition of all of the issued and outstanding shares of OTR Acquisition Corp. ("OTR") and Legacy Comera (the "Transaction"), in accordance with the Business Combination Agreement dated January 31, 2022 (as amended on May 19, 2022, the "Business Combination Agreement") by and among the Company, Legacy Comera, OTR, CLS Sub Merger 1 Corp., a Delaware corporation, ("Comera Merger Sub"), and CLS Sub Merger 2 Corp., a Delaware corporation ("OTR Merger Sub"). Pursuant to the terms of the Business Combination Agreement, a transaction between OTR and Legacy Comera was effected through the merger of Comera Merger Sub with and into Legacy Comera, with Legacy Comera surviving the merger as a wholly-owned subsidiary of CLS Holdings, and through a merger of OTR Merger Sub with and into OTR, with OTR surviving the merger as a wholly-owned subsidiary of CLS Holdings. OTR was formed in the state of Delaware for the purpose of effecting a merger, share exchange, asset acquisition, stock purchase, recapitalization, reorganization or other similar business combination with one or more businesses or entities.

As further described in Note 3, the Transaction was accounted for as a reverse recapitalization because Legacy Comera has been determined to be the accounting acquirer. Under the reverse recapitalization model, the Transaction treated for as Legacy Comera issuing equity for the net assets of OTR, with no goodwill or intangible assets recorded.

Unless the context otherwise requires, "Comera," "Company," "we," "us," and "our" refer to Comera Life Sciences Holdings, Inc., and its subsidiaries at and after the Closing (as defined below) and give effect to the Closing. "CLS Holdings", "Legacy Comera" and "OTR" refer to Comera Life Sciences Holdings, Inc., Comera Life Sciences, Inc. and OTR Acquisition Corp., respectively, prior to the Closing.

2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") and in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

The condensed consolidated financial statements do not include all the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with Legacy Comera's financial statements and related notes for the years ended December 31, 2021 and 2020 included in the Current Report on Form 8-K filed with the SEC on September 6, 2022.

The financial information as of September 30, 2022 and 2021, and the three and nine months ended September 30, 2022 and 2021, is unaudited. In the opinion of management, all adjustments, consisting only of normal recurring adjustments considered necessary for the fair presentation of financial position, results of operations, and cash flows at the dates and for the periods presented, have been included. The balance sheet data as of December 31, 2021 was derived from Legacy Comera's audited financial statements. The results of the Company's operations for any interim periods are not necessarily indicative of the results that may be expected for any other interim period or for a full fiscal year.

Emerging Growth Company and Smaller Reporting Company Status

The Company is an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933 (the "Securities Act"), as modified by the Jumpstart Our Business Startups Act of 2012, (the "JOBS Act"), and it may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Securities Exchange Act of 1934) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that an emerging growth company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. The Company has elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, the Company, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of the Company's consolidated financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

The Company is also a "smaller reporting company" as defined in the Securities Exchange Act of 1934 (the "Exchange Act"). The Company may continue to be a smaller reporting company even after the Company is no longer an emerging growth company. The Company may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as the market value of the Company's voting and non-voting Common Stock held by non-affiliates is less than $250.0 million measured on the last business day of the Company's second fiscal quarter, or the Company's annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of the Company's voting and non-voting Common Stock held by non-affiliates is less than $700.0 million measured on the last business day of the Company's second fiscal quarter.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including but not limited to, risks associated with completing preclinical studies and clinical trials, receiving regulatory approvals for product candidates, development by competitors of new biopharmaceutical products, dependence on key personnel, protection of proprietary technology, compliance with government regulations, entering into collaborations with partners for the Company's SQore™ platform and the ability to secure additional capital to fund operations. Significant discovery, research and development efforts, including clinical testing and regulatory approval, are required prior to commercialization of any potential product candidates. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from product sales.

Through September 30, 2022, the Company has funded its operations primarily with proceeds from the issuance of equity instruments, convertible notes, and preferred stock. The Company has incurred recurring losses since its inception, including a net loss of $15.0 million for the nine months ended September 30, 2022. In addition, as of September 30, 2022, the Company had an accumulated deficit of $31.9 million. The Company expects to continue to generate operating losses for the near future. The future viability of the Company is dependent on its ability to raise additional capital to finance its operations. The Company's inability to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies. There can be no assurance that the current operating plan will be achieved or that additional funding will be available on terms acceptable to the Company, or at all.

The Company does not believe the cash and cash equivalents on hand as of September 30, 2022 of $2.7 million will be sufficient to fund its operations and capital expenditure requirements for the next twelve months from the date the condensed

consolidated financial statements are issued. The Company will be required to raise additional capital to continue to fund operations and capital expenditures. Such funding may not be available on acceptable terms, or at all. If the Company is unable to access additional funds when needed, it may not be able to continue operations or the Company may be required to delay, scale back or eliminate some or all of its ongoing research and development efforts and other operations. The Company's ability to access capital when needed is not assured and, if not achieved on a timely basis, will materially harm its business, financial condition and results of operations. These uncertainties create substantial doubt about the Company's ability to continue as a going concern. The accompanying condensed consolidated financial statements have been prepared on a basis which assumes that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business.

COVID-19

In March 2020, COVID-19 was declared a global pandemic by the World Health Organization and continues to present a substantial public health and economic challenge around the world. The length of time and full extent to which the COVID-19 pandemic may directly or indirectly impact the Company's business, results of operations and financial condition will depend on future developments that are highly uncertain, subject to change and difficult to predict.

The Company plans to continue to closely monitor the ongoing impact of the COVID-19 pandemic on the Company's employees and other business operations. In an effort to provide a safe work environment for the Company's employees, the Company has, among other things, limited employees in the Company's office and lab facilities to those where on-site presence is needed for their job activities, implemented various social distancing measures in the Company's offices and labs and are providing personal protective equipment for the Company's employees present in the Company's office and lab facilities, as needed. The Company is continuing to monitor the impact and effects of the COVID-19 pandemic and the Company's response to it, and the Company expects to continue to take actions as may be required or recommended by government authorities or that are determined to be in the best interests of the Company's employees and other business partners in light of the pandemic.

Use of Estimates

The preparation of condensed consolidated financial statements in accordance with GAAP requires management to make estimates and assumptions, based on judgments considered reasonable, which affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of expenses during the reporting periods. The Company bases its estimates and assumptions on historical experience, known trends and events and various other factors that management believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, the valuation of the derivative warrant liabilities, Legacy Comera's common stock, and stock-based compensation. Changes in estimates are recorded in the period in which they become known. Due to the risks and uncertainties involved in the Company's business and evolving market conditions and, given the subjective element of the estimates and assumptions made, actual results may differ from estimated results.

Summary of Significant Accounting Policies

The significant accounting policies of the Company are set forth in Note 2 to the consolidated financial statements included in the Current Report on Form 8-K filed with the SEC on September 6, 2022, and the accounting policies followed by the Company for interim financial reporting are consistent with the accounting policies therein and as supplemented below.

Reverse Recapitalization

The Transaction was accounted for as a reverse recapitalization, with OTR being treated as the "acquired" company and Legacy Comera being treated as the "acquirer" for accounting purposes based upon the pre-merger shareholders of Legacy Comera holding the majority of the voting interests of CLS Holdings, Legacy Comera's existing management team serving as the initial management team of CLS Holdings, Legacy Comera's appointment of the majority of the initial board of directors of CLS Holdings, and Legacy Comera's operations comprising the ongoing operations of the Company. The Transaction was accounted for as the equivalent of Legacy Comera issuing stock for the net assets of OTR, accompanied by a reverse recapitalization. Accordingly, all historical financial information presented in these condensed consolidated financial statements represents the accounts of CLS Holdings and Legacy Comera "as if" CLS Holdings and Legacy Comera, both entities under common control, are the predecessor. The net loss per share or unit, prior to the Transaction, has been adjusted to share amounts reflecting the exchange ratio (the "Exchange Ratio") established in the Transaction.

Convertible Preferred Stock

The Company accounts for convertible preferred stock subject to possible redemption in accordance with the guidance in ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480"). The Series A Preferred Stock is redeemable at the option of the holder upon the occurrence of a qualified financing. As the Series A Preferred Stock is considered to be contingently redeemable, it has been classified outside of permanent equity. The Series A Preferred Stock has been accreted to its redemption value since the contingent event is considered probable of occurring.

Derivative Warrant Liabilities

The Company classifies as equity any warrants that (i) require physical settlement or net-share settlement or (ii) provide the Company with a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). The Company classifies as assets or liabilities any warrants that (i) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside the company's control), (ii) gives the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement) or (iii) that contain reset provisions that do not qualify for the scope exception. The Company assesses classification of its common stock warrants and other freestanding warrant instrument at each reporting date to determine whether a change in classification between assets and liabilities is required.

The Company's freestanding warrant instruments consist of private placement warrants to purchase shares of common stock ("Private Placement Warrants") and public warrants to purchase shares of common stock ("Public Warrants") that were converted in connection with the Transaction. Following the Transaction, the Public Warrants are considered equity classified instruments since the shares underlying the Public Warrants are not redeemable and the Company has one single class of voting common stock, which does not preclude them from being considered indexed to the Company's equity and allows the Public Warrants to meet the criteria for equity classification per ASC 815, *Derivatives and Hedging* ("ASC 815"). Warrants that are determined to require equity classification are measured at fair value upon issuance and are not subsequently remeasured unless they are required to be reclassified.

The Private Placement Warrants are considered liability classified instruments because their settlement amount differs depending on the identity of the holder which precludes them from being considered indexed to the Company's equity. Accordingly, the Company recognizes the Private Placement Warrants as liabilities at fair value and adjusts the instruments to fair value using quoted prices of instruments with similar terms. The liabilities are subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized in the Company's consolidated statements of operations and comprehensive loss.

Reclassification of Prior Year Presentation

Certain prior year amounts within prepaid expenses and other current assets (Note 5) have been reclassified for consistency with current period presentation. These reclassifications had no effect on the reported results of operations or financial position.

Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but before the condensed consolidated financial statements are issued to provide evidence relative to certain estimates or to identify matters that require additional disclosure. The Company evaluated all events and transactions through the date these condensed consolidated financial statements were filed with the SEC.

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by us as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on the Company's consolidated financial statements and disclosures.

3. Transaction and Reverse Recapitalization

On May 19, 2022, the Company consummated the acquisition of all of the issued and outstanding shares of OTR Acquisition Corp. and Comera Life Sciences, Inc., in accordance with the Business Combination Agreement.

Upon closing (i) Comera Merger Sub merged with and into Legacy Comera, with Legacy Comera surviving such merger as a direct wholly-owned subsidiary of CLS Holdings (the "Comera Merger") and (ii) OTR Merger Sub merged with and into OTR, with OTR surviving such merger as a direct wholly-owned subsidiary of CLS Holdings (the "OTR Merger"). At the closing of the Transaction (the "Closing"), by virtue of the Comera Merger, all shares of Legacy Comera common stock, par value $0.001 per share ("Legacy Comera Common Stock"), issued and outstanding immediately prior to the Closing (including shares of Legacy Comera Common Stock issued upon conversion of Legacy Comera preferred stock immediately prior to the Closing) were canceled and converted into the right to receive shares of CLS Holdings common stock, par value $0.0001 per share ("CLS Holdings Common

Stock") and all outstanding Legacy Comera unvested stock options and Legacy Comera vested incentive stock options were converted into options to purchase shares of CLS Holdings Common Stock, all Legacy Comera vested in-the-money non-qualified stock options outstanding were net exercised for shares of Legacy Comera Common Stock and, upon the Closing as described above, those shares of Legacy Comera Common Stock were converted into the right to receive shares of CLS Holdings Common Stock.

In addition, at the Closing, CLS Holdings placed 3,150,000 shares of CLS Holdings Common Stock (the "Earn-Out Shares") into escrow. If, at any time during the period beginning on the Closing Date and expiring at the close of business on the second anniversary of the Closing Date (the "Earn-Out Period"), the volume-weighted average price of CLS Holdings Common Stock is equal to or greater than $12.50 for any 20 trading days within a period of 30 consecutive trading days (the "Earn-Out Trigger"), then within 10 business days following the achievement of the Earn-Out Trigger, the Earn-Out Shares will be released to the former holders of Legacy Comera Common Stock on a pro rata basis. If a change of control occurs during the Earn-Out Period that results in the holders of shares of CLS Holdings Common Stock receiving consideration equal to or in excess of $12.50 per share, then the Earn-Out Trigger shall be deemed to be satisfied if (i) the aggregate proceeds paid to, or in the event of an asset sale, available for distribution to, stockholders of CLS Holdings in such change of control transaction divided by (ii) (a) the number of outstanding shares of CLS Holdings Common Stock immediately prior to the consummation of such change of control transaction plus (b) Earn-Out Shares, is equal to or exceeds $12.50.

Upon the Closing, by virtue of the OTR Merger, all shares of common stock of OTR issued and outstanding immediately prior to the Closing were converted on a one-to-one basis into the right to receive shares of CLS Holdings Common Stock and all warrants of OTR outstanding were converted into warrants to purchase shares of CLS Holdings Common Stock. Holders of OTR Common Stock included in the units sold in the initial public offering of OTR were entitled to exercise redemption rights in connection with the Transaction. Holders of 9,769,363 shares of OTR Common Stock exercised their right to have their shares redeemed which resulted in the issuance of 3,472,654 shares of CLS Holdings Common Stock in the Transaction to the former stockholders of OTR.

In connection with the Transaction, CLS Holdings, Legacy Comera, OTR and Maxim Group LLC ("Maxim") entered into a Settlement and Release Agreement ("Settlement Agreement") pursuant to which CLS Holdings, Comera, OTR and Maxim agreed, among other things that (1) all deferred underwriting fees owed to Maxim pursuant to the underwriting agreement between OTR and Maxim dated November 17, 2020 (the "Underwriting Agreement") would be satisfied by the issuance by CLS Holdings to Maxim of 3,395 shares of CLS Holdings Series A Convertible Perpetual Preferred Stock, par value $0.0001 per share ("Series A Preferred Stock") equal in value to $3.4 million; (2) Maxim would waive its right of first refusal contained in the Underwriting Agreement to act for OTR, or any successor, in future public and private offerings; (3) certain fees owed to Maxim under the advisory agreement between Legacy Comera and Maxim, dated October 13, 2020, as amended on August 16, 2021 and January 25, 2022 (the "Comera Advisory Agreement") would be satisfied by the issuance by CLS Holdings to Maxim of 910 shares of Series A Preferred Stock equal in value to $910 thousand; (4) Maxim would invest $1.0 million in a private placement of CLS Holdings Common Stock (the "Maxim Private Placement") at a value of $10.25 per share for 97,561 shares, which shares would receive certain registration rights under a separate registration rights agreement (the "Maxim Registration Rights Agreement"), (5) the shares of CLS Holdings Common Stock issued to Maxim as a success fee for the Transaction under the Comera Advisory Agreement which were previously registered, would be unrestricted and freely tradable; and (6) certain of Maxim's rights to fees for transactions and financings consummated after the Transaction would be limited to transactions and financings with four specified counterparties previously introduced by Maxim.

The following summarizes the shares of CLS Holdings Common Stock issued and outstanding immediately following the Transaction as of May 19, 2022:

	Shares	%
Legacy Comera Stockholders	12,022,595	76%
OTR Public Stockholders	677,987	4%
OTR Founders	2,611,838	16%
Maxim (1)	624,765	4%
Total (2)	15,937,185	100%

(1) Represents (i) 97,561 shares of the CLS Holdings Common Stock purchased by Maxim in a private placement, (ii) 344,375 shares of the CLS Holdings Common Stock issued to Maxim by the Legacy Comera shareholders to settle Maxim's success fee, and (iii) 182,829 shares of the CLS Holdings Common Stock issued to Maxim in exchange for a like number of shares of OTR common stock received in connection with OTR's initial public offering.

(2) Excludes 3,150,000 Earn-Out Shares.

The following table presents the net tangible assets acquired from OTR and reconciles the elements of the Transaction to the consolidated statements of cash flows:

	Transaction
Cash	$ 5,643,508
Deferred underwriting fee payable	(3,395,389)
Derivative warrant liabilities	(2,286,379)
Net tangible assets acquired from OTR	(38,260)
Cash proceeds received from Maxim Private Placement	1,000,000
Gross proceeds from Transaction and Maxim Private Placement	961,740
Less: total issuance costs	(7,528,561)
Reverse recapitalization issuance costs in excess of gross proceeds	(6,566,821)
Add: derivative warrant liabilities assumed	2,286,379
Add: issuance of common stock to settle success fee	3,443,750
Add: issuance of Series A preferred stock to settle stock issuance costs and underwriting fees payable	4,305,389
Less: Series A preferred stock issuance costs	(161,535)
Net cash proceeds from Transaction and Maxim Private Placement	$ 3,307,162

The following table presents the net cash proceeds from the Transaction and Maxim Private Placement and reconciles the elements of the Transaction to the consolidated statements convertible preferred stock, stockholders' deficit and members' capital:

	Transaction
Net cash proceeds from Transaction and Maxim Private Placement	$ 3,307,162
Add: Series A preferred stock issuance costs	161,535
Add: reverse recapitalization issuance costs in excess of gross proceeds	6,566,821
Less: derivative warrant liabilities assumed	(2,286,379)
Less: issuance of Series A preferred stock to settle stock issuance costs and underwriting fees payable	(4,305,389)
Issuance of common stock in connection with the Transaction and Maxim Private Placement, net of redemptions, net tangible assets, and issuance costs	$ 3,443,750

The Transaction was accounted for as a reverse recapitalization because Legacy Comera was determined to be the accounting acquirer. Under the reverse recapitalization model, the Transaction was treated as Legacy Comera issuing equity for the net assets of OTR, with no goodwill or intangible assets recorded. All outstanding common stock instruments, prior to the Transaction, have been retroactively adjusted to share amounts reflecting the Company's current capital structure, including adjustments based on the Exchange Ratio. Accordingly, certain amounts have been reclassified and retroactively adjusted to reflect the reverse recapitalization pursuant to the Transaction for all periods presented within the consolidated balance sheets and statements of convertible preferred stock, stockholders' deficit and members' capital.

Earn-Out Shares

The estimated fair value of the Earn-Out Shares at the Closing Date was approximately $8.63 per share, or $27.2 million in the aggregate. If the Earn-Out Trigger is not achieved for the two-year period following the Closing Date, the Earn-Out Shares will be cancelled and returned to treasury. The contingent obligation to issue Earn-Out Shares to Legacy Comera stockholders is considered indexed to the Company's own stock and meets the equity classification under ASC 815.

While the Earn-Out Shares are legally issued and placed into escrow, they are not considered outstanding for accounting purposes until resolution of the earn-out contingency.

The estimated acquisition-date fair value of the Earn-Out Shares was determined using a Monte Carlo simulation valuation model using a distribution of potential outcomes on a weekly basis over the Earn-Out Period using the most reliable information available. Assumptions used in the valuation at the Closing Date were as follows:

	Assumptions
Fair value of common stock	$ 9.91
Selected volatility	90.00%
Risk-free interest rate	2.60%
Contractual term (years)	2.0

Transaction Costs

In connection with the Transaction, the Company incurred direct and incremental costs of approximately $7.5 million related to the equity issuance, including $4.4 million of noncash expenses related to common stock and Series A Preferred Stock issued to Maxim, consisting primarily of investment banking and other professional fees. The costs related to the equity issuance were recorded to additional paid-in capital as a reduction of gross proceeds from the Transaction and Maxim Private Placement. The costs related to the equity issuance which exceeded gross proceeds received from the Transaction and Maxim Private Placement were recognized as a loss within other expense, net.

The Company incurred approximately $1.5 million of expenses primarily related to advisory, legal, and accounting fees in conjunction with the Transaction, which were recorded in general and administrative expenses in the consolidated statements of operations and comprehensive loss.

4. Fair Value of Financial Assets and Liabilities

The following table presents the Company's fair value hierarchy for its liabilities, which are measured at fair value on a recurring basis as of September 30, 2022:

	Fair Value Measurements at September 30, 2022 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Private Placement Warrants	$ —	$ 331,612	$ —	$ 331,612

There were no assets for which fair value was required to be disclosed as of September 30, 2022. There were no assets or liabilities for which fair value was required to be disclosed as of December 31, 2021. During the nine months ended September 30, 2022, there were no transfers between Level 1, Level 2 and Level 3.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	September 30, 2022	December 31, 2021
Prepaid insurance	$ 1,274,263	$ —
Contract assets	—	85,018
Insurance recovery receivable	—	136,250
Other	51,490	49,380
Prepaid expenses and other current assets	$ 1,325,753	$ 270,648

6. Property and Equipment, Net

Property and equipment, net consisted of the following:

	September 30, 2022	December 31, 2021
Lab equipment	$ 587,650	$ 587,650
Leasehold improvements	36,149	17,973
Computer equipment	32,178	21,747
Other equipment	9,411	9,411
	665,388	636,781
Less accumulated depreciation	(472,798)	(402,614)
Property and equipment, net	$ 192,590	$ 234,167

Depreciation expense for the nine months ended September 30, 2022 and 2021 was $70 thousand and $62 thousand, respectively.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	September 30, 2022	December 31, 2021
Accrued bonus	$ 447,488	$ 349,000
Professional fees	255,822	123,756
Accrued vacation	27,851	25,945
Other	155,851	7,910
Accrued expenses and other current liabilities	$ 887,012	$ 506,611

8. Insurance Premium Financing

In May 2022, the Company entered into a finance agreement with First Insurance Funding in order to fund a portion of its insurance policies. The amount financed is $1.5 million and incurs interest at a rate of 4.00%. The Company is required to make monthly payments of $154 thousand through March 2023. The outstanding balance as of September 30, 2022 was $0.9 million.

9. Legacy Comera Convertible Preferred Stock

Prior to the Transaction, the authorized capital stock of Legacy Comera included 14,051,702 shares of $0.001 par value preferred stock, of which 9,429,006 shares were designated as Series A Convertible Preferred Stock ("Legacy Comera Series A Preferred Stock") and 4,622,696 shares were designated as Series B Convertible Preferred Stock ("Legacy Comera Series B Preferred Stock").

In April 2021, Legacy Comera issued 6,000,000, 1,266,667, 527,752, 1,016,669, 514,932, and 102,986 shares of Series A-1, A-2, A-3, A-4, A-5, and A-6 Preferred Stock, respectively. The Legacy Comera Series A Preferred Stock was issued in settlement of previously outstanding capital units of ReForm Biologics, LLC as part of the Reorganization.

Immediately prior to the Transaction, all issued and outstanding shares of Legacy Comera Series A and B Preferred Stock were converted into Legacy Comera Common Stock.

10. Convertible Preferred Stock

As of September 30, 2022, the Company's amended and restated certificate of incorporation (the "Articles") provides for a class of authorized stock known as preferred stock, consisting of 1,000,000 shares, $0.0001 par value per share, issuable from time to time in one or more series. In connection with the Transaction, a certificate of designation was filed to designate and authorize the issuance of up to 4,305 shares of Series A Preferred Stock.

Convertible preferred stock consisted of the following as of September 30, 2022:

	Par Value	Shares Authorized	Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A Preferred Stock	$ 0.0001	4,305	4,305	$ 4,431,838	$ 4,431,838	342,754

In May 2022, the Company issued 4,305 shares of Series A Preferred Stock. The Series A Preferred Stock was issued in connection with the Transaction and the Settlement Agreement (Note 3) in settlement of $4.3 million of advisory fees owed to Maxim with an original purchase price of $1,000 per share (the "Series A Original Purchase Price"). The Company incurred $162 thousand of issuance costs in connection with the Series A Preferred Stock.

As of September 30, 2022, the holders of the Series A Preferred Stock have the following rights and preferences:

Voting Rights—

The holders of the Series A Preferred Stock are entitled to vote, together with the holders of common stock, on all matters submitted to the stockholders for a vote and are entitled to the number of votes equal to the number of whole shares of common stock into which such holders of preferred stock could convert on the record date for determination of stockholders entitled to vote. Except for the actions requiring the approval or consent of the holders of preferred stock, the holders of preferred stock shall vote together with the holders of common stock and vote as a single class.

Dividends—

The holders of Series A Preferred Stock shall be entitled to receive, prior and in preference to the declaration or payment of any dividend on any other currently-outstanding capital stock, dividends when, as and if declared by the Board of Directors, payable quarterly on January 1, April 1, July 1 and October 1 of each calendar year (each date a "Series A Quarterly Dividend Payment Date"), commencing on and including July 1, 2022, which dividends shall be paid in cash at a rate of 8.0% per annum on the Series A Original Purchase Price for the first six Series A Quarterly Dividend Payment Dates, which shall increase by 2% per annum from and after each successive Series A Quarterly Dividend Payment Date, up to a maximum of 18%. Such dividends shall cumulate quarterly at the Series A Dividend Rate if not declared and paid on a Series A Quarterly Dividend Payment Date. As of September 30, 2022, no cash dividends have been declared or paid and the Company has $288 thousand of cumulative dividends in arrears.

Liquidation Rights—

In the event of any voluntary or involuntary liquidation event, dissolution, winding up of the Company or upon the occurrence of certain events considered to be deemed liquidation events, each holder of the then outstanding Series A Preferred Stock will be entitled to receive a preferential payment equal to the Series A Original Purchase Price plus the aggregate amount of dividends then accrued, prior and in preference to any distributions to the holders of the common stock. After payments have been made in full to the holders of the Series A Preferred Stock, then, to the extent available, the remaining amounts will be distributed among the holders of the common stock, pro rata based on the number of shares of common stock held by each holder.

Conversion—

Each share of preferred stock is convertible into common stock, at any time, at the option of the holder, and without the payment of additional consideration, determined by dividing the Series A Original Issuance Price by $12.56 (as may be adjusted for stock splits, dilutive issuances and the like, the "Series A Conversion Price"); provided, however, in no event shall outstanding shares of Series A Preferred Stock be converted into more than 19.99% of the outstanding shares of common stock. The Company shall at all times reserve and keep available out of its authorized but unissued shares of common stock to effect the conversion of three hundred percent (300%) of all shares of Series A Preferred Stock then outstanding.

The Company evaluated its preferred stock and determined that its Series A Preferred Stock is considered an equity host. In making this determination, the Company's analysis followed the whole instrument approach which compares an individual feature against the entire preferred stock instrument which includes that feature. The Company's analysis was based on a consideration of the economic characteristics and risks of the preferred stock. More specifically, the Company evaluated all of the stated and implied substantive terms and features, including: (1) whether the preferred stock included redemption features, (2) how and when any redemption features could be exercised, (3) whether the holders of preferred stock were entitled to dividends, (4) the voting rights of the preferred stock and (5) the existence and nature of any conversion rights. As a result of the Company's conclusion that the preferred stock represents an equity host, the conversion feature for the Series A Preferred Stock is considered to be clearly and closely related to the preferred stock host instrument. Accordingly, the conversion feature for Series A Preferred Stock is not considered an embedded derivative that requires bifurcation.

Redemption—

The preferred stock is redeemable upon the occurrence of certain deemed liquidation events, as discussed above. In addition, the Company, may at any time, redeem the whole or any part of the outstanding Series A Preferred Stock at a redemption price of $1,000 per share, subject to adjustment, plus all accumulated and unpaid dividends (the "Series A Redemption Price"). Further, if the Company closes on the issuance or sale of common stock or equivalents, including, without limitation, pursuant to an equity line of credit facility, a registered offering, a private investment in public equity or otherwise, resulting in net proceeds to the Company of at

least $5,000,000, each holder of Series A Preferred Stock shall have the right to cause the Company to apply up to 30% of the aggregate proceeds from such issuance or sale in excess of $5,000,000, to the redemption of any or all of such holder's Series A Preferred Stock at the Series A Redemption Price.

As the preferred stock is considered to be contingently redeemable, the preferred stock has been classified outside of permanent equity. Since the contingent redemption is considered probable, the Series A Preferred Stock will be accreted to its redemption value at each reporting date. The Company recorded accretion of $87 and $288 thousand during the three and nine months ended September 30, 2022, respectively, which is considered a deemed dividend.

11. Common Stock

As of September 30, 2022, the authorized capital stock of the Company included 150,000,000 shares of common stock, $0.0001 par value. The voting, dividend and liquidation rights of the holders of the Company's common stock are subject to and qualified by the rights, powers and preferences of the holders of the Series A Preferred Stock set forth above.

In connection with the Settlement Agreement, the Company sold 97,561 shares of common stock to Maxim for aggregate proceeds of $1.0 million in a private placement.

Each share of common stock entitles the holder to one vote, together with the holders of the preferred stock on an as converted to common stock basis, on all matters submitted to the stockholders for a vote. Common stockholders are entitled to receive dividends, as may be declared by the Board, if any, subject to the preferential dividend rights of the preferred stock. Through September 30, 2022, no cash dividends have been declared or paid.

As of September 30, 2022, the Company has reserved the following shares of common stock for future issuance:

Exercise of outstanding stock options	1,982,641
Available for issuance under equity compensation plans	77,197
Exercise of outstanding common stock warrants	11,041,332
Conversion of Series A Preferred Stock	1,028,262
Reserved for issuance pursuant to the Purchase Agreement	4,283,819
Total shares of authorized common stock reserved for future issuance	18,413,251

Common Stock Purchase Agreement

On August 31, 2022, the Company entered into a purchase agreement (the "Purchase Agreement") with Arena Business Solutions Global SPC II, Ltd. ("Arena"), pursuant to which Arena has committed to purchase up to $15.0 million (the "Commitment Amount") of the Company's common stock, subject to an increase, at the Company's option, to $30.0 million of the Company's common stock (the "Additional Commitment Amount"). Under the terms and subject to the conditions of the Purchase Agreement, the Company has the right, but not the obligation, to sell to Arena, and Arena is obligated to purchase up to $15.0 million of the Company's common stock, subject to increase at the Company's option by the Additional Commitment Amount. Such sales of common stock by the Company will be subject to certain limitations, and may occur from time to time, at the Company's sole discretion, over the approximately 36-month period commencing on the date of the Purchase Agreement, provided that the registration statement (the "Registration Statement") covering the resale by Arena of the shares of the Company's common stock purchased under the Purchase Agreement remains effective, and the other conditions set forth in the Purchase Agreement are satisfied. The purchase price of the shares of the Company's common stock will be equal to 96% of the simple average of the daily VWAP of the Company's common stock immediately preceding the time of sale as computed under the Purchase Agreement.

The Company determined that its right to sell shares of the Company's common stock to Arena represents a freestanding put option under ASC 815, but has a fair value of zero, and therefore no additional accounting was required. The Company issued 296,181 shares of common stock (the "Commitment Shares") to Arena as a commitment fee in connection with entering into the Purchase Agreement. The $650 thousand fair value of the Commitment Shares along with $376 thousand of other issuance costs related to the Purchase Agreement were recognized as a loss within other expense, net.

As of September 30, 2022, the Company had sold 420,000 shares of common stock under the Purchase Agreement at a weighted-average price of $1.78 per share, resulting in net proceeds of $0.7 million for the nine months ended September 30, 2022.

12. Stock-Based Compensation

2014 Restricted Unit Plan

On March 4, 2014, Legacy Comera established the 2014 Restricted Unit Plan (the "2014 Plan"). A total of 2,500,000 incentive units were authorized as part of the 2014 Plan, under which participants would receive membership interests in Legacy Comera. The 2014 Plan was extinguished on April 30, 2021 as a result of the Reorganization.

2021 Stock Option and Grant Plan

On April 30, 2021, Legacy Comera established the 2021 Stock Option and Grant Plan (the "2021 Plan"), which provided for the grant of incentive stock options, non-statutory stock options, restricted stock awards, unrestricted stock awards and restricted stock units. In connection with the closing of the Transaction, option awards outstanding under the 2021 Plan were exchanged for options to purchase shares of CLS Holdings Common Stock (the "Exchanged Options"), with proportional adjustments to the number of shares underlying the options and the exercise price of the options approved by the compensation committee and board of directors of Legacy Comera. Other than with respect to the exercise price and the number of shares of CLS Holdings Common Stock underlying the Exchanged Options, the Exchanged Options remain subject to the terms and conditions of the Legacy Comera option awards issued pursuant to the 2021 Plan. The Exchanged Options are outstanding under and count against the number of shares reserved for issuance pursuant to the 2022 Equity and Incentive Plan (the "2022 Plan"). Following the closing of the Transaction, no additional awards may be granted under the 2021 Plan.

As of September 30, 2022, there are 1,168,441 Exchanged Options outstanding which are potentially exercisable for 1,168,441 shares of CLS Holdings Common Stock at a weighted-average exercise price of $0.59 per share.

2022 Equity and Incentive Plan

On May 10, 2022, the Company established the 2022 Plan, which provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, unrestricted stock awards, restricted stock units, stock appreciation rights, cash awards and dividend equivalent rights. Incentive stock options may be granted only to the Company's employees, including officers. Non-statutory options, restricted stock awards, unrestricted stock awards, restricted stock units, stock appreciation rights, cash awards and dividend equivalent rights may be granted to employees, directors, consultants and key persons of the Company.

The total number of common shares authorized to be issued under the 2022 Plan was 2,059,838. The share pool will automatically increase on January 1 of each year by four percent of the number of shares of Stock outstanding on the immediately preceding December 31, or such lesser number of shares as approved by the board of directors. As of September 30, 2022, there were 1,982,641 options outstanding with a weighted-average exercise price of $1.70 and 77,197 shares available for future grants under the 2022 Plan.

Shares underlying awards that are forfeited, cancelled, reacquired by the Company prior to vesting, satisfied without the issuance of common stock, or are otherwise terminated under the 2022 Plan without having been fully exercised (including the Exchanged Options) will be available for future awards.

Stock Option Valuation

The assumptions that the Company used to determine the grant-date fair value of stock options granted were as follows, presented on a weighted-average basis:

	Nine Months Ended September 30, 2022
Expected option life (years)	6.1
Risk-free interest rate	3.18%
Expected volatility	62.65%
Expected dividend yield	—%

Stock Option Activity

The following table summarizes the Company's stock option activity for the nine months ended September 30, 2022:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2021	2,689,935	$ 0.59		$ 767
Granted	814,200	3.30		
Exercised	(1,385,310)	0.59		
Cancelled or forfeited	(136,184)	0.59		
Outstanding as of September 30, 2022	1,982,641	$ 1.70	9.1	$ 1,192
Exercisable as of September 30, 2022	406,894	$ 0.59	8.8	$ 415

The aggregate intrinsic value of stock options 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 as of September 30, 2022.

The weighted-average grant date fair value of options granted during the nine months ended September 30, 2022 and 2021 was $1.97 and $0.41, respectively.

As of September 30, 2022, total unrecognized compensation cost related to the unvested stock options was $1.9 million, which is expected to be recognized over a weighted-average period of 3.5 years.

Stock-Based Compensation

Stock-based compensation expense was allocated as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Cost of revenue	$ 484	$ 448	$ 1,409	$ 19,530
Research and development	2,670	2,829	7,681	410,644
General and administrative	124,536	31,011	217,895	642,436
Total stock-based compensation	$ 127,690	$ 34,288	$ 226,985	$ 1,072,610

13. Common Stock Warrants

During the nine months ended September 30, 2022, there were 100 warrants exercised. There were no warrants issued or expired during the same period.

The warrants were assumed as part of the Transaction and the following represents a summary of the warrants outstanding and exercisable at September 30, 2022:

					Number of Shares Underlying Warrants	
Description	Issue Date	Classification	Exercise Price	Expiration Date	Outstanding Shares	Exercisable Shares
Private Placement Warrants	Nov 17, 2020	Liability	$ 11.50	May 19, 2027	5,817,757	5,817,757
Public Warrants	Nov 17, 2020	Equity	$ 11.50	May 19, 2027	5,223,575	5,223,575
					11,041,332	11,041,332

Public Warrants

Public Warrants may only be exercised for a whole number of shares. No fractional shares will be issued upon exercise of the Public Warrants. The Public Warrants were assumed in connection with the Transaction and became exercisable on June 19, 2022.

The Public Warrants are redeemable at the option of the Company, in whole and not in part, at a price of $0.01 per underlying share, provided that the last reported sales price of the Company's common stock has been at least $18.00 per share (subject to adjustment), on each of twenty (20) trading days within the thirty (30) trading-day period ending on the third trading day prior to the date on which notice of the redemption is given.

Private Placement Warrants

The Private Placement Warrants are identical to the Public Warrants, except that (i) the Private Placement Warrants will be exercisable on a cashless basis and be non-redeemable so long as they are held by the initial purchasers or their permitted transferees and (ii) the Private Placement Warrants and the common stock issuable upon exercise of the Private Placement Warrants will be entitled to registration rights. If the Private Placement Warrants are held by someone other than the initial purchasers or their permitted transferees, the Private Placement Warrants will be redeemable by the Company on the same basis as the Public Warrants.

14. Concentrations of Risk

The Company has certain customers whose revenue individually represented 10% or more of the Company’s total revenue or whose accounts receivable balances individually represented 10% or more of the Company’s total accounts receivable.

For the nine months ended September 30, 2022 and 2021, two customers accounted for 97% and 100% of revenue recognized, respectively.

As of September 30, 2022, two customers accounted for 100% of accounts receivable.

15. Income Taxes

The Company had no income tax expense due to operating losses incurred for the three and nine months ended September 30, 2022 and 2021.

Management of the Company evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets and determined that it is more likely than not that the Company will not recognize the benefits of the deferred tax assets. As a result, a full valuation allowance was recorded as of September 30, 2022.

The Company applies ASC 740, *Income Taxes*, for the financial statement recognition, measurement, presentation, and disclosure of uncertain tax positions taken or expected to be taken in income tax returns. Unrecognized tax benefits represent tax positions for which reserves have been established. A full valuation allowance has been provided against the Company’s deferred tax assets, so that the effect of the unrecognized tax benefits is to reduce the gross amount of the deferred tax asset and the corresponding valuation allowance. The Company has no material uncertain tax positions as of September 30, 2022. The Company has never been examined by the Internal Revenue Service, or any other jurisdiction, for any tax years and, as such, all years within the applicable statutes of limitations are potentially subject to audit.

16. Net Loss per Share or Unit – Basic and Diluted

For the three and nine months ended September 30, 2022 and 2021, basic net loss per share or unit was computed by dividing the net loss attributable to common stockholders or unit holders by the weighted average number of common shares or units outstanding. Prior to April 30, 2021, undistributed losses were allocated equally to each class of member units, including vested incentive units, since they shared equally in the residual net assets of Legacy Comera upon liquidation, subject to their different distribution participation rights. Subsequent to April 30, 2021, undistributed losses were allocated entirely to common stockholders since neither the convertible preferred stock nor the contingently returnable Earn-Out Shares are required to share in the losses of the Company.

As the Transaction has been accounted for as a reverse recapitalization, the shares or units and net loss per share or unit, prior to the Transaction, have been retroactively adjusted to amounts reflecting the Exchange Ratio established in the Transaction.

For the three and nine months ended September 30, 2022 and 2021, diluted net loss per share or unit is the same as basic net loss per

share or unit since the effect of considering unvested incentive units, options to purchase common stock, warrants to purchase common stock, Earn-Out Shares, and convertible preferred stock in the calculation would be anti-dilutive.

The following potentially dilutive common stock or member unit equivalents, presented based on amounts outstanding at each period end, were excluded from the computation of diluted net loss per share or unit because including them would have had an anti-dilutive effect:

	Nine Months Ended September 30,	
	2022	2021
Options to purchase common stock	1,982,641	2,674,384
Earn-Out Shares	3,150,000	—
Convertible preferred stock (as converted to common stock)	342,754	10,643,403
Warrants to purchase common stock	11,041,332	—

The following table sets forth the calculation of basic and diluted net loss per share or unit:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net loss available to common stockholders or unit holders— basic and diluted	$ (3,163,657)	$ (913,700)	$ (15,329,488)	$ (3,427,675)
Weighted-average number of common shares or units used in computing net loss per share or unit attributable to common stockholders or unit holders—basic and diluted	16,024,011	144,163	8,294,938	3,955,649
Net loss per share or unit attributable to common stockholders or unit holders—basic and diluted	$ (0.20)	$ (6.34)	$ (1.85)	$ (0.87)

17. Commitments and Contingencies

Leases

On March 8, 2018, the Company entered into a noncancelable operating lease agreement for office and laboratory space in Woburn, Massachusetts (the "Woburn Lease"). On March 10, 2021, the Company extended the Woburn Lease through June 30, 2024 with a monthly lease payment of $12 thousand. On March 4, 2022, the Company executed the first amendment to the Woburn Lease (the "Amendment") which increased the size of the leased office and laboratory space with an aggregate monthly lease payment to $18 thousand, subject to annual increases beginning in November 2022 based on the consumer price index, in addition to payment of a proportional share of operating costs.

The maturities and balance sheet presentation under all non-cancelable operating leases as of September 30, 2022, are as follows:

	Operating Leases
Maturity of lease liabilities	
2022 (remaining 3 months)	$ 54,386
2023	217,545
2024	123,077
Total lease liabilities	395,008
Less imputed interest	(28,159)
Present value of operating lease liability as of September 30, 2022	$ 366,849
Reported as of September 30, 2022	
Lease liabilities — current	$ 195,253
Lease liabilities — noncurrent	171,596
	$ 366,849

As the Company's leases do not provide an implicit rate, the Company estimated its incremental borrowing rate based on the information available at each lease commencement date in determining the present value of the lease payments. The weighted-average discount rate used for leases as of September 30, 2022 is 8.0%. The weighted-average lease term as of September 30, 2022 is 1.8 years. During the nine months ended September 30, 2022 and 2021 operating cash flows used for operating leases was $142 thousand

and $100 thousand, respectively. During the nine months ended September 30, 2022 and 2021, lease cost was $145 thousand and $103 thousand, respectively.

Amounts included in restricted cash as of September 30, 2022 and December 31, 2021 consist of cash held to collateralize a letter of credit issued as a security deposit in connection with the Company's lease of its corporate facility and for certain credit cards.

Legal Proceedings

The Company, from time to time, may be party to litigation arising in the ordinary course of business. The Company was not subject to any material legal proceedings as of September 30, 2022, and, to the best of the Company's knowledge, no material legal proceedings are currently pending or threatened.

Indemnification Agreements

The Company enters into standard indemnification agreements in the ordinary course of business. Pursuant to the agreements, the Company agrees to indemnify, hold harmless, and to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally the Company's business partners, in connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third-party with respect to the Company's products. The term of these indemnification agreements is generally perpetual any time after execution of the agreement. In addition, the Company has entered into indemnification agreements with members of its board of directors and its executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. In addition, the Company maintains officers and directors insurance coverage. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. Through September 30, 2022, the Company had not experienced any losses related to these indemnification agreements and no material claims were outstanding.

Other Matters

In February 2022, the Company determined it was affected by a business email compromise fraud which resulted in a diversion of the Company's capital to unknown parties. This incident led to a loss of $136 thousand of cash for the year ended December 31, 2021, and an additional $590 thousand in the nine months ended September 30, 2022 which was recorded as other expense, net in the Company's statements of operations and comprehensive loss. The Company has insurance related to this event which fully offset the loss recorded during the year ended December 31, 2021, and partially offset the loss recorded during the nine months ended September 30, 2022, resulting in a net loss of $426 thousand. The Company implemented a variety of measures to further enhance its cybersecurity protections and minimize the impact of any future cyber incidents.

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

Unless the context otherwise requires, all references in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" section to "Comera," "Company," "we," "us," and "our" refer to Comera Life Sciences Holdings, Inc., and its subsidiaries at and after consummation of the Transaction. All references to "CLS Holdings", "Legacy Comera" and "OTR" refer to Comera Life Sciences Holdings, Inc., Comera Life Sciences, Inc. and OTR Acquisition Corp., respectively, prior to the Closing. You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q as well as the consolidated financial statements and the related notes included in the Current Report on Form 8-K filed with the SEC on September 6, 2022. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks, uncertainties and assumptions. You should read the "Forward-Looking Statements" and "Risk Factors" sections of this Quarterly Report on Form 10-Q for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Forward Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements. All statements other than statements of historical fact contained herein, including statements regarding our business plans or strategies, projected or anticipated benefits or other consequences of our plans or strategies, projected or anticipated benefits from acquisitions to be made by us, or projections involving anticipated revenues, earnings, or other aspects of our operating results, are forward-looking statements. Words such as "anticipates," "assumes," "believes," "can," "could," "estimates," "expects," "forecasts," "guides," "intends," "is confident that," "may," "plans," "seeks," "projects," "targets," and "would," and their opposites and similar expressions, as well as statements in future tense, are intended to identify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and may not be accurate indications of when such performance or results will actually be achieved. Forward-looking statements are based on information we have when those statements are made or our management's good faith belief as of that time with respect to future events and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

- our ability to maintain the listing of our securities on the Nasdaq;
- the effect of the COVID-19 pandemic on our business;
- the price of our securities may be volatile due to a variety of factors, including volatility in the capital markets generally, changes in the competitive and highly regulated industries in which we plan to operate, variations in performance across related parts competitors, changes in laws and regulations affecting our business and changes in the capital structure;
- the ability to implement business plans, forecasts, and identify and realize additional opportunities;
- the risk of downturns and the possibility of rapid change in the highly competitive industry in which we operate;
- the risk that we and our current and future collaborators are unable to successfully develop and commercialize our products or services, or experience significant delays in doing so;
- the risk that we may never achieve or sustain profitability;
- the risk that we will need to raise additional capital to execute our business plan, which may not be available on acceptable terms or at all;
- the risk that we experience difficulties in managing our growth and expanding operations;
- the risk that third-party suppliers and manufacturers are not able to fully and timely meet their obligations;
- the risk that we are unable to secure or protect our intellectual property;
- general economic conditions; and
- other risks and uncertainties described in this Quarterly Report on Form 10-Q, including those under the section entitled "Risk Factors".

Should one or more of these risks or uncertainties materialize or should any of the assumptions made by the management of the Company prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements.

Except to the extent required by applicable law or regulation, the Company undertakes no obligation to update these forward-looking statements to reflect events or circumstances after the date of this Quarterly Report on Form 10-Q or to reflect the occurrence of unanticipated events.

Overview

Comera is a pre-clinical biotechnology company dedicated to promoting a compassionate new era in medicine by applying a deep knowledge of formulation science and technology to transform essential biologic medicines from intravenous to subcutaneous forms. Although Comera's product candidates are at the pre-clinical stage and none have been approved for commercial sale, Comera's internal portfolio of proprietary techniques known as the SQore™ platform, is designed to potentially transform essential biologic medicines from intravenous ("IV") to subcutaneous ("SQ") forms, optimize current versions of subcutaneous biologics, and produce biosimilar versions of existing subcutaneous products. If successful, this transformation in administration could provide patients using biological products through intravenous infusion, and their families, the freedom of self-injectable care which, Comera believes, would allow them to enjoy both the potential benefits of biologic treatments and the potential of their own lives while simultaneously lowering healthcare costs. To accomplish this, Comera is developing an internal portfolio of proprietary therapeutic product candidates using its innovative proprietary formulation platform, SQore™. Comera also collaborates with pharmaceutical and biotechnology companies, applying the SQore™ platform to our partners' biologic medicines to deliver enhanced SQ formulations.

Business

Comera is a preclinical stage life sciences company dedicated to promoting a compassionate new era in medicine. We apply a deep knowledge of formulation science and proprietary technology to optimize biologic medicines. Our internal portfolio of proprietary techniques known as our SQore™ platform, is designed to potentially:

- transform essential biologic medicines from IV to SQ forms;
- optimize current versions of subcutaneous biologics; and
- produce biosimilar versions of existing subcutaneous products.

We aim to develop these potentialities in order to transform administration from IV to SQ and thereby provide patients using biological products through intravenous infusion, and their families, with the freedom of self-injectable care which, we believe, would allow them to enjoy both the potential benefits of biologic treatments and the potential of their own lives while simultaneously lowering healthcare costs and increasing patient compliance.

The SQore™ platform, which is the foundation of our work, is supported by an extensive patent portfolio and encompasses years of knowledge and development from our team of scientists, including industry-leading experts in polymer engineering and interfacial dynamics (the way that different molecules interact) who are inventors on dozens of patents and have published widely-cited research in their fields. We believe that our combined polymer and small molecule capability will allow us to leverage a mechanistic understanding of protein-protein and protein-solvent interactions to identify suitable excipients for specific formulations, that allows the active, therapeutic ingredient to enter the body and arrive with sufficient potency.

We aim to achieve our mission by developing our own portfolio of therapeutic product candidates and by collaborating with pharmaceutical and biotechnology companies to transform their biologic medicines into enhanced SQ formulations.

Since our founding in 2014, we primarily engaged in early-stage, preclinical studies, commissioned on a fee-for-service basis by larger pharmaceutical companies and have not yet developed any products approved for marketing. Our studies for larger companies were generally early-stage investigations, often amounting to proof-of-concept work, aimed at moving existing formulations from IV infusion to SQ delivery via injection.

In 2021, we brought on a new leadership team and carried out a transition of our business model. We shifted away from simple "fee for services" formulation work and focused our efforts on engaging with higher-value-add partners in integrated, collaborative projects to develop formulations for their key products. We are currently working with multiple companies under research and development service agreements. These agreements typically have a term of less than 12 months and provide for an initial payment by the company of a fee to Comera for the evaluation by Comera of its proprietary technology for viscosity reduction with the other company's proprietary biotherapeutic agent. The agreements set forth the detailed research plans and the related timeline for completion of the research. The agreements provide that each party retains ownership of its technology throughout the process. Upon completion of the project, the parties may negotiate in good faith the terms of a license agreement. If the parties do not successfully negotiate a license, each party retains ownership of its technology and neither party may use the joint invention. Because these

research and development service agreements may result in the future negotiation and execution of licensing agreements, we believe these projects provide far greater opportunities for generating revenue. When we meet our partners' defined project criteria for the formulations, we will seek a license agreement to receive license fees, milestone payments, and longer-term and more stable royalty revenue on commercial assets that are vital to our partners.

On January 7, 2022, we changed our name to Comera Life Sciences, Inc. from ReForm Biologics, Inc. to emphasize our vision of a compassionate new era in medicine.

On May 19, 2022, we consummated the acquisition of all of the issued and outstanding shares of OTR Acquisition Corp. and Comera Life Sciences, Inc. The transaction was accounted for as a reverse recapitalization.

SQore™ Platform

Comera's SQore™ platform, supported by an extensive patent portfolio and encompassing years of development and experience, is designed to enable the conversion of IV biologics to SQ versions. We believe that our team of experienced scientists includes industry-leading experts in polymer engineering and interfacial dynamics who are inventors on dozens of patents and have published widely-cited research in their fields. This expertise complements our solid grounding in traditional protein chemistry. Our combined polymer and small molecule capability allows us to leverage a mechanistic understanding of protein-protein and protein-solvent interactions to tailor excipient selection for specific formulation needs. This scientific foundation supports the SQore™ platform for our formulation work. Based on this platform, our technology has the potential to lower healthcare costs, increase patient compliance and enhance patient lives – all major factors which we believe will help set Comera apart from its peers in the years ahead.

The Transaction

On May 19, 2022 (the "Closing Date"), the Company consummated the acquisition of all of the issued and outstanding shares of OTR Acquisition Corp. ("OTR") and Legacy Comera (the "Transaction"), in accordance with the Business Combination Agreement dated January 31, 2022 (as amended on May 19, 2022, the "Business Combination Agreement") by and among the Company, Legacy Comera, OTR, CLS Sub Merger 1 Corp., a Delaware corporation, ("Comera Merger Sub"), and CLS Sub Merger 2 Corp., a Delaware corporation ("OTR Merger Sub"). Pursuant to the terms of the Business Combination Agreement, a transaction between OTR and Legacy Comera was effected through the merger of Comera Merger Sub with and into Legacy Comera, with Legacy Comera surviving the merger as a wholly-owned subsidiary of CLS Holdings, and through the merger of OTR Merger Sub with and into OTR, with OTR surviving the merger as a wholly-owned subsidiary of CLS Holdings.

The Transaction was accounted for as a reverse recapitalization because Legacy Comera was determined to be the accounting acquirer. Under the reverse recapitalization model, the Transaction was treated as Legacy Comera issuing equity for the net assets of OTR, with no goodwill or intangible assets recorded. All outstanding common stock instruments, prior to the Transaction, have been retroactively adjusted to share amounts reflecting the Company's current capital structure, including adjustments based on the Exchange Ratio. Accordingly, certain amounts have been reclassified and retroactively adjusted to reflect the reverse recapitalization pursuant to the Transaction for all periods presented within the consolidated balance sheets and statements of convertible preferred stock, stockholders' deficit and members' capital. See Notes 1, 2 and 3 to our condensed consolidated financial statements for additional information.

Financial Overview

Revenue

Through September 30, 2022, we have generated revenue from research agreements with various partners. These arrangements generally represent formulation development collaborations with rights to negotiate product-specific licenses for a broad spectrum of protein-based therapeutics. Initially, arrangements have provided compensation for research efforts. The arrangements also provide that if the research efforts are successful, additional development and commercialization arrangements may be separately negotiated and executed, which may include upfront payments, milestones, and royalties on commercial sales. We generally expect revenue to increase as we execute additional research agreements and as planned development and collaboration arrangements are executed.

We have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the near future. If development efforts for our pipeline programs are successful and result in regulatory approval, we may generate product revenue in the future.

Cost of Revenue

Cost of revenue generally consists of personnel expenses (comprised of salaries, bonuses, employee benefits and stock-based compensation expenses), and direct materials costs, third-party laboratory costs, and other costs necessary to complete the research arrangements. In addition, costs include allocated depreciation of laboratory equipment and amortization of leasehold improvements, and certain overhead expenses including facilities costs. Costs associated with revenue are recorded as the research is performed. We generally expect cost of revenue to increase as revenue increases, however margins on our customer contracts may vary widely.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the enhancement of our product platform and with the discovery and development of our pipeline programs. We expense research and development costs as incurred. These expenses include:

- expenses incurred under agreements with contract research organizations, and contract manufacturing organizations, as well as consultants that conduct research and development activities on our behalf;
- employee-related expenses, including salaries, related benefits, travel and stock-based compensation expense for employees engaged in research and development functions;
- costs related to compliance with regulatory requirements; and
- allocated facilities costs, depreciation and other expenses, which include rent and utilities.

We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers.

Research and development activities are central to our business model. Current activities primarily relate to the enhancement of our SQore™ technology platform and other research activities, as well as initiation of formulation development work and manufacturing activities for our pipeline programs. We expect that our research and development expenses will increase substantially over the next several years including increased costs related to the development of pipeline programs, particularly as we increase personnel costs, including stock-based compensation, contractor costs and facilities costs and direct costs paid to contract research, development, and manufacturing organizations to conduct pipeline research and development activities on our behalf. In addition, if we elect to in-license or otherwise acquire additional pipeline products or additional intellectual property, we will also incur additional expenses which may include upfront, milestone and royalty payments payable to third parties.

The successful discovery, development and commercialization of our pipeline programs is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the discovery or development of any of our potential pipeline programs or when, if ever, material net cash inflows may commence from any of our pipeline programs.

Our research and development expenses are not currently tracked on a program-by-program basis. Our research and development expenses consist primarily of external costs, such as fees paid to outside consultants, contract research organizations, contract manufacturing organizations, and central laboratories, and internal costs such as employee costs and facility expenses, including depreciation or other indirect costs.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, related benefits, travel and stock-based compensation expense for personnel in executive, finance and administrative functions. General and administrative expenses also include professional fees for legal, consulting, accounting and audit services. In addition, general and administrative expenses also include costs incurred in connection with the Transaction, expenses primarily related to advisory, legal, and accounting fees.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities, and as a result of operating as a public company, including compliance with federal securities laws, legal, audit, additional insurance expenses, investor relations activities, and other administrative and professional services. We anticipate the additional costs for these services will substantially increase our general and administrative expenses. Additionally, if and when we believe a regulatory approval of a pipeline programs appears likely, we anticipate an increase in payroll and expense as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our pipeline programs.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are 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. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 of the consolidated financial statements included in the Current Report on Form 8-K filed with the SEC on September 6, 2022 and supplemented in Note 2 of our Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report on Form 10-Q, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Stock-Based Compensation

We account for stock-based compensation in accordance with FASB ASC Topic 718, *Compensation – Stock Compensation*. We measure stock options and other equity-based awards granted based on the fair value on the date of the grant and recognize the corresponding compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. We have only issued equity-based awards with service-based vesting conditions and record the expense for these awards using the straight-line method.

We estimate the fair value of each stock option grant using the Black-Scholes option-pricing model, which uses as inputs the estimated fair value the underlying equity and assumptions we make for the volatility of our equity, the expected term of our equity awards, the risk-free interest rate for a period that approximates the expected term of our equity awards and our expected dividend yield.

If any of the assumptions used in the Black-Scholes model change significantly, stock-based compensation for future awards may differ materially compared with the awards granted previously.

Determination of the Fair Value of Common Stock

As prior to consummation of the Transaction there was no public market for our equity, the estimated fair value of our equity was determined by our board of directors as of the date of each option grant, with input from management, considering third-party valuations as well as our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent third-party valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation.

For financial reporting purposes, we performed valuations, with the assistance of a third-party specialist, at various dates. In conducting the valuations, our board of directors, with input from management, considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, including:

- the prices at which we sold preferred stock and the superior rights and preferences of the capital units or preferred stock relative to our incentive units or Legacy Comera Common Stock at the time of each grant;
- the progress of our research and development programs, including the status of preclinical studies and planned clinical trials for our pipeline programs;
- our stage of development and commercialization and our business strategy;
- external market conditions affecting the biotechnology industry, and trends within the biotechnology industry;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our equity;
- the likelihood of achieving a liquidity event or a sale of our company in light of prevailing market conditions; and
- the analysis the market performance of similar companies in the biopharmaceutical industry.

The assumptions underlying these valuations represent management's best estimates, which involve inherent uncertainties and the application of management judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different.

The dates of our valuations have not always coincided with the dates of our stock option grants. In determining the fair value of the shares underlying options, we considered, among other things, the most recent contemporaneous valuations of our ordinary shares and our assessment of additional objective and subjective factors we believed were relevant as of the grant date. The additional factors considered when determining any changes in fair value between the most recent contemporaneous valuation and the grant dates included our stage of development and commercialization and our business strategy, our operating and financial performance and current business conditions.

Our valuations were prepared using the option-pricing method, or OPM, which treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceeded the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. The future value of the common stock is discounted back to the valuation date at an appropriate risk- adjusted discount rate and probability weighted to arrive at an indication of value for the common stock.

Results of Operations

Nine Months Ended September 30, 2022 Compared with Nine Months Ended September 30, 2021

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

	Nine Months Ended September 30,		Change	
	2022	2021	Dollar	Percentage
Revenue	$ 476,982	$ 246,498	$ 230,484	94 %
Cost of revenue	160,030	122,073	37,957	31 %
Operating expenses:				
Research and development	1,250,570	1,262,329	(11,759)	(1)%
General and administrative	8,027,316	2,373,621	5,653,695	238 %
Total operating expenses	9,277,886	3,635,950	5,641,936	155 %
Loss from operations	(8,960,934)	(3,511,525)	(5,449,409)	155 %
Other (expense) income, net	(6,080,570)	83,850	(6,164,420)	(7,352)%
Net loss and comprehensive loss	$ (15,041,504)	$ (3,427,675)	$ (11,613,829)	339 %

Revenue

Revenue was $477 thousand for the nine months ended September 30, 2022, compared to $246 thousand for the nine months ended September 30, 2021. The increase of $230 thousand is primarily related to research activities performed under customer contracts during the nine months ended September 30, 2022.

Cost of Revenue

Cost of revenue was $160 thousand for the nine months ended September 30, 2022, compared to $122 thousand for the nine months ended September 30, 2021. The increase of $38 thousand is primarily related to higher direct labor costs incurred during the nine months ended September 30, 2022, due to an increase in research activities performed under customer contracts which had more favorable margins compared with the prior period.

Research and Development Expenses

The following table sets forth our research and development expenses for the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,		Change	
	2022	2021	Dollar	Percentage
Employee related	$ 687,464	$ 934,711	$ (247,247)	(26)%
Lab supplies and materials	322,251	143,011	179,240	125%
Occupancy and facility related	121,220	119,479	1,741	1%
Other	119,635	65,128	54,507	84%
Total research and development expense	$ 1,250,570	$ 1,262,329	$ (11,759)	(1)%

Research and development expenses were $1.3 million for the nine months ended September 30, 2022, compared to $1.3 million for the nine months ended September 30, 2021. The overall decrease of $12 thousand and the decrease in employee related expenses of $247 thousand is primarily related to a stock compensation expense charge of $383 thousand recorded in the prior period related to the vested awards issued in connection with the Reorganization. The overall decrease is partially offset by an increase in lab supplies and materials of $179 thousand and the employee related decrease is partially offset by an increase in salaries and related benefits of $148 thousand. The increase in lab supplies and materials is primarily associated with an increase in research activities in the nine months ended September 30, 2022 as compared to the nine months ended September 30, 2021 as the Company continues to develop its platform.

General and Administrative Expenses

General and administrative expenses were $8.0 million for the nine months ended September 30, 2022, compared to $2.4 million for the nine months ended September 30, 2021. The increase of $5.7 million is primarily related to $1.5 million of transaction related expenses, along with increases in expenses in connection with the Company's growth and costs associated with transitioning to a public company. These increases include $797 thousand of consulting fees, $616 thousand of legal fees, $559 thousand of accounting fees, $488 thousand of salaries and benefits, and $126 thousand of patent fees. In addition, there was an increase related to directors and officers liability insurance of $1.3 million, including $634 thousand associated with a tail policy related to the Transaction.

Other Income (Expense), Net

For the nine months ended September 30, 2022, total other expense, net was primarily comprised of a $6.6 million expense related to stock issuance costs which exceeded gross proceeds received from the Transaction and Maxim Private Placement and a $1.0 million expense related to issuance costs associated with the Purchase Agreement, as well as a $590 thousand loss from payments related to a business email compromise fraud which resulted in a diversion of the Company's capital to unknown parties which was partially offset by $164 thousand of insurance proceeds for a net loss of $426 thousand. These expenses were partially offset by a $2.0 million decrease in fair value of the Company's derivative warrant liabilities which were assumed in the Transaction.

For the nine months ended September 30, 2021, total other income, net primarily consisted of a $161 thousand gain on debt extinguishment resulting from forgiveness of the Company's notes payable issued under the Paycheck Protection Program which was established as part of the Coronavirus Aid, Relief and Economic Security Act and is administered by the U.S. Small Business Administration, offset by $77 thousand change in fair value of convertible notes.

Three Months Ended September 30, 2022 Compared with Three Months Ended September 30, 2021

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

	Three Months Ended September 30,		Change	
	2022	2021	Dollar	Percentage
Revenue	$ 234,922	$ 87,767	$ 147,155	168 %
Cost of revenue	60,963	48,364	12,599	26 %
Operating expenses:				
Research and development	394,800	263,620	131,180	50 %
General and administrative	2,314,554	689,483	1,625,071	236 %
Total operating expenses	2,709,354	953,103	1,756,251	184 %
Loss from operations	(2,535,395)	(913,700)	(1,621,695)	177 %
Other (expense) income, net	(541,446)	—	(541,446)	100 %
Net loss and comprehensive loss	$ (3,076,841)	$ (913,700)	$ (2,163,141)	237 %

Revenue

Revenue was $235 thousand for the three months ended September 30, 2022, compared to $88 thousand for the three months ended September 30, 2021. The increase of $147 thousand is primarily related to research activities performed under customer contracts.

Cost of Revenue

Cost of revenue was $61 thousand for the three months ended September 30, 2022, compared to $48 thousand for the three months ended September 30, 2021. The increase of $13 thousand is primarily related to higher direct labor costs incurred during the three months ended September 30, 2022, due to an increase in research activities performed under customer contracts which had more favorable margins compared with the prior period.

Research and Development Expenses

The following table sets forth our research and development expenses for the three months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		Change	
	2022	2021	Dollar	Percentage
Employee related	$ 233,848	$ 169,016	$ 64,832	38 %
Occupancy and facility related	44,132	41,128	3,004	7 %
Lab supplies and materials	42,951	46,436	(3,485)	(8)%
Other	73,869	7,040	66,829	949 %
Total research and development expense	$ 394,800	$ 263,620	$ 131,180	50 %

Research and development expenses were $395 thousand for the three months ended September 30, 2022, compared to $264 thousand for the three months ended September 30, 2021. The overall increase of $131 thousand is primarily related to expansion of research and development activities and higher employee related expenses, including salaries and benefits, of $65 thousand and other miscellaneous expenses, including consulting expenses of $62 thousand.

General and Administrative Expenses

General and administrative expenses were $2.3 million for the three months ended September 30, 2022, compared to $689 thousand for the three months ended September 30, 2021. The increase of $1.6 million is primarily related to increases in expenses in connection with the Company's growth and costs associated with transitioning to a public company. These increases include $530 thousand of salaries and benefits, $364 thousand of accounting fees, and $193 thousand of legal fees. In addition, there was an increase related to directors and officers liability insurance of $371 thousand. These increases were partially offset by a decrease in recruiting fees of $114 thousand.

Other Income (Expense), Net

For the three months ended September 30, 2022, total other expense, net is primarily comprised of a $1.0 million loss related to issuance costs associated with the Purchase Agreement. This expense was partially offset by a $500 thousand decrease in fair value of the Company's derivative warrant liabilities which were assumed in the Transaction.

There was no other income (expense), net for the three months ended September 30, 2021.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We do not have any products approved for sale and have not generated any revenue from product sales. As of September 30, 2022, we have generated revenue from research agreements with various partners. Our ability to generate revenue sufficient to achieve profitability will depend heavily on the successful development and eventual licensing and/or commercialization of one or more of our current or future pipeline programs as well as continued successful execution of pharmaceutical research collaborations and subsequent execution of collaboration programs. Our net loss was $15.0 million for the nine months ended September 30, 2022. As of September 30, 2022, we had an accumulated deficit of $31.9 million. We expect to continue to incur significant expenses for at least the next several years as we continue to develop our technology platform and conduct research and development activities on our pipeline programs. In addition, we expect our expenses to significantly increase as our pipeline programs advance into clinical development and eventual regulatory approval stages. If we obtain marketing approval for any of our pipeline programs, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. As of September 30, 2022, the Company has not engaged in any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on the Company's financial condition, results of operations or cash flows.

We will receive up to an aggregate of $127.0 million if all of the outstanding Public and Private Placement Warrants are exercised to the extent such warrants are exercised for cash. However, we will only receive such proceeds if and when the warrant holders exercise the Public and Private Placement Warrants, and we believe the likelihood that warrant holders will exercise their warrants, and therefore the amount of cash proceeds that we would receive, is dependent upon the market price of Comera common stock. The closing price of Comera common stock on Nasdaq on September 30, 2022 was $1.61, which is $9.89 below the exercise price of all of the Public Warrants and Private Placement Warrants. If the market price for Comera common stock does not increase from the current level, it is unlikely that any of the Public Warrants or Private Placement Warrants will be exercised.

We may also receive proceeds from sales under the purchase agreement (the "Purchase Agreement") dated August 31, 2022 with Arena Business Solutions Global SPC II, Ltd. ("Arena"). Under the terms and subject to the conditions of the Purchase Agreement, the Company has the right, but not the obligation, to sell to Arena, and Arena is obligated to purchase up to $15.0 million of the Company's common stock, subject to increase at the Company's option to $30.0 million of the Company's common stock. Actual sales of shares of the Company's common stock to Arena may occur from time to time and will depend on a variety of factors, including, among others, market conditions, the trading price of our common stock and determinations made by us as to the appropriate sources of funding for us and our operations. The net proceeds that we may receive under the Purchase Agreement cannot be determined at this time, since it will depend on the frequency and prices at which we sell shares of our common stock to Arena, our ability to meet the conditions of the Purchase Agreement and the other limitations, terms and conditions of the Purchase Agreement.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaboration agreements, government and other third-party funding, strategic alliances, licensing arrangements or marketing and distribution arrangements. 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 government and other third-party funding, collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, pipeline programs or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or pipeline programs that we would otherwise prefer to develop and market ourselves.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

We do not believe the cash and cash equivalents on hand as of September 30, 2022 of $2.7 million will be sufficient to fund our operations for the next twelve months from the date the condensed consolidated financial statements are issued. We will be required to raise additional capital to continue to fund operations and capital expenditures. Such funding may not be available on acceptable terms, or at all. If we are unable to access additional funds when needed, we may not be able to continue operations or we may be required to delay, scale back or eliminate some or all of our ongoing research and development efforts and other operations. Our ability to access capital when needed is not assured and, if not achieved on a timely basis, will materially harm our business, financial condition and results of operations. These uncertainties create substantial doubt about our ability to continue as a going concern.

Cash Flows

The following table sets forth the sources and uses of cash, cash equivalents, and restricted cash for the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,	
	2022	2021
Net cash used in operating activities	$ (7,924,004)	$ (2,154,408)
Net cash used in investing activities	(28,607)	(11,464)
Net cash provided by financing activities	4,111,825	10,279,675
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (3,840,786)	$ 8,113,803

Operating Activities

During the nine months ended September 30, 2022, net cash used in operating activities was $8.5 million which consisted of a $15.0 million net loss, partially offset by $5.6 million of adjustments to reconcile net loss to cash used in operating activities and $939 thousand of changes in operating assets and liabilities. Our adjustments to reconcile net loss to cash used in operating activities were primarily comprised of $6.6 million related to issuance costs which exceeded gross proceeds received from the Transaction and Maxim Private Placement and $650 thousand related to noncash Purchase Agreement issuance costs, partially offset by $2.0 million decrease in fair value of the derivative warrant liabilities. The net cash inflows associated with changes in operating assets and liabilities was primarily due to increases of $1.0 million in accounts payable and $380 thousand in accrued expenses and other current liabilities, partially offset by increases of $294 thousand in accounts receivable and $157 thousand in prepaid expenses and other current assets.

During the nine months ended September 30, 2021, net cash used in operating activities was $2.2 million which consisted of a $3.4 million net loss and partially offset by $1.1 million of adjustments to reconcile net loss to cash used in operating activities and $220 thousand of changes in operating assets and liabilities. Our adjustments to reconcile net loss to cash used in operating activities were primarily comprised of $1.1 million of stock-based compensation expense and $77 thousand of change in fair value of convertible notes, partially offset by $161 thousand of gain on debt extinguishment. The net cash inflows associated with changes in operating assets and liabilities was primarily due to an increase of $130 thousand in accounts payable and decrease of $110 thousand in accounts receivable.

Investing Activities

The cash outflows from investing activities for the nine months ended September 30, 2022 and 2021 related to the purchase of property and equipment.

Financing Activities

Financing activities during the nine months ended September 30, 2022 related to $3.3 million of net proceeds received from the Transaction and Maxim Private Placement, $749 thousand of proceeds from the Purchase Agreement, and $660 thousand of proceeds from the exercise of stock options, and partially offset by $605 thousand of repayments under our insurance premium financing arrangement.

Financing activities during the nine months ended September 30, 2021 related to $9.3 million of proceeds from the issuance of preferred stock, $750 thousand of proceeds from the issuance of convertible notes, and $180 thousand of proceeds from the exercise of stock options.

Known Trends, Events and Uncertainties

In March 2020, COVID-19 was declared a global pandemic by the World Health Organization and continues to present a substantial public health and economic challenge around the world. The COVID-19 pandemic has created significant economic uncertainty and volatility in the credit and capital markets and has caused global inflationary and supply chain pressures. As a result, we may not be able to raise sufficient capital to commercialize our current and future product candidates. The length of time and full extent to which the COVID-19 pandemic may directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain, subject to change and difficult to predict.

We plan to continue to closely monitor the ongoing impact of the COVID-19 pandemic on our employees and our other business operations. In an effort to provide a safe work environment for our employees, we have, among other things, limited employees in our office and lab facilities to those where on-site presence is needed for their job activities, implemented various social distancing measures in our offices and labs, and are providing personal protective equipment for our employees present in our office and lab facilities. We continue to monitor the impact and effects of the COVID-19 pandemic and our response to it, and we expect to continue to take actions as may be required or recommended by government authorities or as we determine are in the best interests of our employees and other business partners in light of the pandemic.

Other than as discussed above and elsewhere in this report, we are not aware of any trends, events or uncertainties that are likely to have a material effect on our financial condition.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in company reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Our Chief Executive Officer and Chief Financial Officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of September 30, 2022, have concluded that, based on such evaluation, our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

As previously disclosed, in February 2022, we became aware that we had been a victim of a criminal fraud commonly referred to as "business email compromise fraud." The incident involved impersonation of one of our senior personnel through unauthorized access to his email account which resulted in a diversion of funds to unknown parties and a loss of $726,000, of which we were able to recover insurance proceeds of $300,000 to partially offset the loss. We retained TCG Technologies to assist in our cyber investigation and remedial measures. In response to the incident, and with the support of TCG, we conducted a review of our corporate information technology and email policies and implemented additional security and training measures during the quarters ended June 30, 2022 and September 30, 2022, including: (i) full penetration testing (PEN testing) of our network, (ii) enacting multi-factor authorization (MFA) protocols, (iii) implementing an employee education program, (iv) enhancing the segregation of duties within the finance and accounting team, (v) adding additional financial and accounting resources, (vi) improving our current network and (vii) implementing banking software system controls. Other than the implementation of these changes, there were no changes in our internal control over

financial reporting that occurred during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations of the Effectiveness of Internal Controls

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the internal control system are met. Because of the inherent limitations of any internal control system, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may be involved in litigation that arises through the normal course of business. As of the date of this filing, we are not aware of any material legal proceedings to which we or any of our subsidiaries is a party or to which any of our property is subject, nor are we aware of any such threatened or pending litigation or any such proceedings known to be contemplated by governmental authorities.

We are not aware of any material proceedings in which any of our directors, officers, or affiliates or any registered or beneficial stockholder of more than 5% of our common stock, or any associate of any of the foregoing, is a party adverse to or has a material interest adverse to, us or any of our subsidiaries.

Item 1A. Risk Factors.

Our business faces significant risks and uncertainties. Certain factors may have a material adverse effect on our business prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in or incorporated by reference into this Quarterly Report on Form 10-Q and our other public filings with the SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

Risk Factor Summary

This summary briefly states the principal risks and uncertainties facing our business that could affect our common stock, which are only a select portion of those risks. A more complete statement of those risks and uncertainties is set forth immediately following this summary, which is qualified in its entirety by that more complete statement. You should carefully read the entire statement and "Risk Factors" when considering the risks and uncertainties as part of your evaluation of an investment in our common stock.

- We do not have, and may never have, any products approved for commercial sale and may never become profitable.
- Our success depends on our ability to respond and adapt to changes in the drug development industry, including payer, medical practice, medical provider and prescriber behavior.
- We will require substantial additional funding to finance our operations. If we are unable to raise additional capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations.
- We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern.
- We have never successfully completed the regulatory approval process for any of our product candidates and may be unable to do so for any product candidates we acquire or develop.
- Drug development is a lengthy, expensive and uncertain process. The results of preclinical studies and clinical trials are not always predictive of future results. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.
- Our current or future product candidates may cause adverse or other undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following regulatory approval, if obtained.
- We may experience fluctuations in our operating results, which could make our future operating results difficult to predict or cause its operating results to fall below analysts' and investors' expectations.
- Our success depends on broad market acceptance of our products if approved, which we may never achieve.
- The COVID-19 pandemic, or a similar pandemic, epidemic, or outbreak of an infectious disease, inflation, supply chain and interest rate pressures, foreign currency exchange rate fluctuations, the ongoing conflict between Russia and Ukraine and other macroeconomic and geopolitical events may materially and adversely affect our business and financial results and could cause a disruption to the development of our product candidates.
- Our success depends on our ability to retain key members of management team and on our ability to hire, train, retain and motivate new employees.

- If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.
- We expect to enter into in-license agreements under which we will acquire rights to use, develop, manufacture and/or commercialize certain of our product candidates. If these collaborations are not successful, our business could be adversely affected.
- We may seek to establish additional collaborations, and, if we are not able to establish them on commercially reasonable terms, or at all, we may have to alter our development and commercialization plans.
- We may be required to pay certain milestones and royalties under our license or collaboration agreements with third-party licensors or collaborators.
- We may rely on third parties to conduct our future clinical trials of product candidates, in the U.S. and other jurisdictions. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.
- We contract with third parties for the manufacture of our product candidates for preclinical development, clinical testing, and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- The manufacture of biologics is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide a supply of current product candidates or any future product candidates for clinical trials or products for patients, if approved, could be delayed or prevented.
- The third parties upon whom we rely for the supply of the active pharmaceutical ingredients and drug product to be used in the preclinical testing and clinical trials for our product candidates are currently our sole source of supply, and the loss of any of these suppliers could significantly harm our business.
- If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates or if the scope of the intellectual property protection obtained is not sufficiently broad or we are delayed in bringing product candidates to market such that those products have a shorter period of patent exclusivity than expected, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired.
- Intellectual property litigation and administrative patent office patent validity challenges in one or more countries could cause us to spend substantial resources and distract our personnel from their normal responsibilities.
- We may seek priority review designation for one or more of our product candidates, but it might not receive such designation, and even if it does, such designation may not lead to a faster regulatory review or approval process.
- Accelerated approval by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive regulatory approval.
- 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 post-market study requirements, marketing and labeling restrictions, and even recall or market withdrawal if unanticipated safety issues are discovered following approval. In addition, we may be subject to penalties or other enforcement action if we fail to comply with regulatory requirements.
- We are subject to cybersecurity risks and experienced a diversion of funds through a business email compromise fraud, resulting in a total loss of $726 thousand before we became aware of the matter in February 2022, of which $300 thousand was recovered by insurance proceeds.
- Our management has limited experience in operating a public company.
- There may be sales and issuances of a substantial amount of our common stock, including sales, if any, that may be made to Arena pursuant to the Purchase Agreement, and these sales and issuances could dilute the interest of our stockholders and cause the price of our securities to fall.

Risks Related to Our Financial Status, Business Model and Growth Plans

We are a preclinical stage biotechnology company and do not currently have, and may never have, any products approved for commercial sale and have not, and may never, generate revenue from product sales or become profitable.

To become profitable and grow our revenue, we must develop and eventually commercialize a product or products with significant market potential. This will require us to be successful in a range of challenging activities, including establishing our business model and key third-party relationships with payers, completing preclinical studies and clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing, selling those products for which we may obtain marketing approval and satisfying any post-marketing requirements.

We are a preclinical stage biotechnology company and currently do not have any products approved for commercial sale have not, and may never, generate revenue from product sales or become profitable. We cannot guarantee that we will ever receive necessary regulatory approvals to commercialize any products. Our ability to become profitable depends upon our ability to generate revenue from services and product sales or execute other business arrangements. Our current product candidates are in various early stages of development and we do not expect to generate any revenue from the sale of approved products in the near future. We do not expect to generate significant additional revenue unless and until we obtain regulatory approval of, and begin to sell, one or more of our products, if approved. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- successfully complete internal preclinical validation of our pipeline programs and their respective product candidates;
- obtain rights from third parties to utilize third party cell lines or to develop these internally;
- successfully complete our ongoing and planned preclinical and clinical studies for our pipeline programs;
- timely file and gain acceptance of investigational new drug applications for our programs in order to commence planned clinical trials or future clinical trials;
- successfully enroll subjects in, and complete, our ongoing and planned clinical trials;
- obtain data and other development support from our third-party contractors and collaborators;
- initiate and successfully complete all safety and efficacy studies required to obtain U.S. and foreign regulatory approval for our product candidates, and additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates;
- successfully demonstrate to the satisfaction of the U.S. Food and Drug Administration (“FDA”), the European Medicines Agency (“EMA”), or similar foreign regulatory authorities the safety, efficacy, purity and potency, and acceptable risk to benefit profile of our product candidates or any future product candidates;
- successfully manage the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates, if any;
- obtain the timely receipt of necessary marketing approvals from the FDA, EMA and similar foreign regulatory authorities;
- establish commercial manufacturing capabilities or make arrangements with third-party manufacturers for clinical supply and commercial manufacturing;
- obtain and maintain patent and trade secret protection or regulatory exclusivity for our product candidates;
- launch commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- obtain and maintain acceptance of the products, if and when approved, by patients, the medical community and third-party payers;
- position our product candidates to effectively compete with other therapies;
- obtain and maintain healthcare coverage and adequate reimbursement for our products;
- hire additional clinical, regulatory and scientific personnel;
- enforce and defend intellectual property rights and claims; and
- maintain a continued acceptable safety profile of our products following approval.

Due to the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenues, or the extent of any losses. We may never succeed in these activities and, even if we succeed in commercializing one or more of our product candidates, we may never generate revenue that is significant enough to achieve profitability on any product candidate. If we do achieve profitability, we may not be able to sustain or increase profitability on a

quarterly or annual basis and we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. Our failure in any of the above activities could jeopardize our revenue growth and profitability and could decrease the value of our securities and impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

Our business model is untested and may never be successful or generate sufficient growth to sustain profitability.

We are building a pipeline of innovative new biologic product candidates aimed at transforming essential biologic medicines from intravenous to subcutaneous forms, or to produce improved versions of current subcutaneous biologics. Leveraging our proprietary SQore™ technology platform and excipient library of over 200 compounds — primarily well-established biological products, most with known toxicology profiles — we intend to continue partnering with biopharmaceutical companies to develop their assets into new or improved subcutaneous formulations while advancing our own novel pipeline programs. Although our products are in the preclinical stage and none are approved for sale, we believe that we are also positioned to be able to develop biosimilar versions of currently approved products. However, each aspect our business model is untested in the biopharmaceutical industry, and any of the assumptions underlying our expectations may be incorrect. There can be no assurance that our assumptions are correct or that, if correct, our strategy will succeed.

Our business model may never be successful or generate sufficient growth to sustain profitability. Our competitors or new market entrants may adopt similar or otherwise more favorable products and strategies, leading to significant price competition and/or reducing or eliminating our competitive advantage, each of which could adversely affect our revenues.

Our business model requires us to scale our pipeline through drug engineering collaborations, in-licensing or otherwise acquiring additional product candidates, and developing such product candidates, which we may be unable to successfully achieve or maintain.

Our business model requires us to scale through the development or acquisition of many additional product candidates, which we may be unable to achieve or maintain. Our business model requires that we continually review, evaluate and consider potential development and acquisitions of additional product candidates and that we evaluate and enter into collaborations with partners for our SQore™ platform. In such evaluations, we will be required to make difficult judgments regarding the potential value of such additional product candidates or collaboration partners. We may not be successful in identifying attractive opportunities and our research and development agreements with partners may not evolve into collaborations for our SQore™ platform. Even if we are successful in identifying attractive opportunities, we may not successfully execute development or acquisition of such opportunities on terms acceptable to us. We may also experience increased competition for attractive assets from other pharmaceutical companies, many of which have significantly more resources than we do. We may also experience additional challenges in the acquisition of certain assets, including but not limited to geopolitical considerations when acquiring assets from outside the United States.

Even if we are successful in acquiring additional product candidates, we may not successfully integrate them into our existing operations or derive the anticipated benefits of such acquisitions, which may result in the investment of our capital resources without realizing the expected returns on such investments. Given our limited resources, we may also forego acquisition of product candidates that later prove to have greater commercial potential. Product candidates that we acquire will also be subject to the risks and uncertainties associated with developing product candidates. The time and effort involved in attempting to identify acquisition candidates and consummate acquisitions may also divert the attention of members of our management from the operations of our company.

In addition, we may not be successful in our efforts to identify, engineer, or develop additional product candidates in the future either internally or through our current or future collaboration partners. Research programs to identify new product candidates require substantial technical, financial and human resources. Product candidates that we develop internally through our own efforts or with our partners may be more expensive to discover, develop or manufacture than we expect, which could require us to adjust our pricing model, or de-emphasize internal development efforts in the near or long-term. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including our inability to design such product candidates with the properties that we desire. Potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. We may also be limited in our ability to pursue multiple indications with one product, due to financial or other resource constraints, development issues or regulatory obstacles. Even if we are able to pursue multiple indications, we may not be able to do so as quickly or successfully as our competitors, which may affect our ability to gain market acceptance across multiple indications for any one product. If we are unable to identify suitable additional candidates for development or acquisition, our opportunities to successfully develop and commercialize therapeutic products will be limited.

Failure to manage our growth effectively could cause our business to suffer and have an adverse effect on our ability to execute our business strategy, as well as operating results and financial condition.

As of September 30, 2022, we had 11 full-time employees and 1 part-time employee. As we continue development of our product candidates, as well as function as a public company, we will need to expand our financial, development, regulatory, manufacturing, commercial and other capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various collaborators, suppliers, and other third parties. Future growth will impose significant added responsibilities on members of our management. Our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to these growth activities, including identifying, recruiting, integrating, maintaining, and motivating additional employees, managing our research and development efforts effectively, including the clinical trials and the FDA's or comparable foreign regulatory authorities' review process for our product candidates, while complying with our contractual obligations to contractors and other third parties and improving our operational, financial and management controls, reporting systems and procedures. Our future financial performance and our ability to develop and commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company or could disrupt our operations.

Our success depends on our ability to respond and adapt to changes in the drug development industry, including payer, medical practice, medical provider and prescriber behavior. We may be unsuccessful in achieving acceptance or changing prescribing or purchasing habits of healthcare system participants.

Our success and future growth largely depend on our ability to increase awareness of our offerings, and on the willingness of healthcare system participants, assuming that our products are approved for sale, to purchase our products — all of which are preclinical and not approved for sale — for the treatment of patients. To effectively market our products, we must educate healthcare system participants about the benefits of our offerings. We cannot assure you that we will be successful in changing prescribing or purchasing habits of healthcare system participants or that we will achieve broad market education or awareness among healthcare system participants. Even if we are able to raise awareness among healthcare system participants, they may be slow in changing their habits and may be hesitant to use our products for a variety of reasons, including but not limited to:

- lack of experience with our company, products, and concerns that we are relatively new to the industry;
- perceived health, safety or quality risks associated with the use of new products;
- competition and negative selling efforts from competitors, including competing offerings and price matching programs;
- concerns that our product candidates are not as safe or effective as first-to-market medicines, including because clinical development of our product candidates in some cases will have been performed by third parties; and
- pre-existing or intractable prescribing habits among doctors or guidelines among payers that limit products like ours from gaining market share.

If we are unsuccessful in changing prescribing or purchasing habits of healthcare system participants, our business, financial condition and results of operations would be adversely affected.

We may be unable to continue to attract and retain third-party collaborators, including collaboration partners and licensors, or may fail to do so in an effective manner. Our collaborations with third-party collaborators are also subject to certain risks.

Our success depends in part on our ability to effectively attract third-party collaborators and retain our existing collaborators, across several strategic areas, including acquiring additional product candidates, and conducting research collaborations. We have made significant investments related to attracting, acquiring and retaining third-party collaborators but cannot assure you that our efforts will be effective or that benefits realized from our partnerships with any new third-party collaborators will ultimately exceed the costs incurred in attracting, acquiring or retaining such collaborators. If we are unable to attract or retain third-party collaborators, our business, financial condition and results of operations would be adversely affected.

Our collaborations with third-party business collaborators are also subject to a number of risks, including but not limited to:

- adverse decisions by a third party regarding the amount and timing of resource expenditures for the development and commercialization of product candidates;
- possible disagreements as to the timing, nature and extent of development plans, including clinical trials or regulatory approval strategy;
- delays or non-performance by our collaborators in performance of their contractual obligations, including delivery of data to us;

- lack of alignment between specifications for products and specifications that have or might be approved by regulatory authorities;
- the right of a third-party business collaborator to terminate its agreement with us on limited notice upon the occurrence of certain defined events;
- loss of significant rights if we fail to meet our obligations under a collaboration agreement;
- withdrawal of support by a third-party business collaborator following change of that collaborator's corporate strategy or due to competing priorities;
- changes in key management personnel at a third-party business collaborator that are members of the collaboration's various operating committees; and
- possible disagreements with a third-party business collaborator regarding a collaboration agreement or ownership of proprietary rights, including with respect to inventions discovered under the applicable collaboration agreement.

Due to these factors and other possible disagreements with a third-party collaborator, including potential disputes over intellectual property ownership or timely access to clinical data, we may be delayed or prevented from developing, manufacturing or commercializing product candidates or we may become involved in litigation or arbitration, which would be time consuming and expensive.

We may consider strategic alternatives in order to maximize stockholder value, including financings, strategic alliances, licensing arrangements, acquisitions or the possible sale of our business. We may not be able to identify or consummate any suitable strategic alternatives and any consummated strategic alternatives may have an adverse impact on our product candidates.

We may consider all strategic alternatives that may be available to us to maximize stockholder value, including financings, strategic alliances, licensing arrangements, acquisitions or the possible sale of our business. We currently have no agreements or commitments to engage in any specific strategic transactions, and our exploration of various strategic alternatives may not result in any specific action or transaction. If we do engage in a strategic transaction, our business objectives may change depending upon the nature of the transaction. Furthermore, if we determine to engage in a strategic transaction, we cannot predict the impact that such strategic transaction might have on our operations or the prices of our securities. We also cannot predict the impact on securities prices if we fail to enter into a transaction.

In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process is expensive and time-consuming. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort, third parties may not view our product candidates as having sufficient potential, or for other reasons. Any delays in entering into a strategic partnership related to our product candidates could delay the development and commercialization of our product candidates, which would harm our business prospects, financial condition and results of operations.

Risks Related to Our Financial Position, Capital Requirements and Limited Operating History

We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern.

We do not believe the cash and cash equivalents on hand as of September 30, 2022 of $2.7 million will be sufficient to fund our operations and capital expenditure requirements for the next twelve months from the date the condensed consolidated financial statements are issued. We will be required to raise additional capital to continue to fund operations and capital expenditures. Such funding may not be available on acceptable terms, or at all. If we are unable to access additional funds when needed, we may not be able to continue operations or we may be required to delay, scale back or eliminate some or all of our ongoing research and development efforts and other operations. Our ability to access capital when needed is not assured and, if not achieved on a timely basis, will materially harm our business, financial condition and results of operations. These uncertainties create substantial doubt about our ability to continue as a going concern.

Additional information regarding our ability to continue as a going concern can be found in Note 2 to the Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q under the heading "Risks and Uncertainties."

We will require substantial additional funding to finance our operations. If we are unable to raise additional capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations.

As of September 30, 2022, we had cash and cash equivalents of $2.7 million. We are a preclinical stage biotechnology company and do not currently have any products approved for commercial sale. We believe that we will need to raise substantial additional capital to fund our continuing operations and the development and commercialization of our current product candidates and future

product candidates. Our business or operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. We will need to raise additional capital before we can progress any of our product candidates into a pivotal clinical trial. We expect to finance our subsequent cash needs through public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements or any combination of these approaches. In addition, we may need to accelerate the growth of our sales capabilities and distribution beyond what is currently envisioned, and this would require additional capital.

However, we may not be able to secure funding when we need it or on favorable terms and we may not be able to raise sufficient funds to commercialize our current and future product candidates we intend to develop. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide, including the trading price of common stock, resulting from the ongoing COVID-19 pandemic. Our future capital requirements will depend on many factors, including:

- the timing, scope, progress, results and costs of research and development, testing, screening, manufacturing, preclinical development and clinical trials;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform field efficacy studies for our product candidates, require more studies than those that we currently expect or change their requirements regarding the data required to support a marketing application;
- the costs of future commercialization activities, including product manufacturing, marketing, sales, royalties and distribution, for any of our product candidates for which we receive marketing approval;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements 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;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract, hire and retain skilled personnel;
- the revenue, if any, received from commercial sales, or sales to foreign governments, of our product candidates for which we may receive marketing approval;
- the costs to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing of any patents or other intellectual property rights;
- the costs of operating as a public company;
- macro-economic factors, including inflation, supply chain issues and a shortage in the labor market that have impacted local and global economies; and
- the impact of the COVID-19 pandemic, which may exacerbate the magnitude of the factors discussed above.

Although we entered into the Purchase Agreement with Arena in August 2022, the number of shares of common stock we decide to sell to Arena under the Purchase Agreement will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell all, some or none of the shares of common stock that may be available to us to sell to Arena pursuant to the Purchase Agreement and, depending on market liquidity at the time, resales of those shares by Arena may cause the public trading price of our common stock to decrease. Because the purchase price per share to be paid by Arena for the shares of common stock that we may elect to sell to Arena under the Purchase Agreement, if any, will fluctuate based on the market prices of the common stock during the applicable period for each sale made pursuant to the Purchase Agreement, if any, it is not possible for us to predict prior to any such sales the number of shares of common stock that will ultimately sell to Arena under the Purchase Agreement, the purchase price per share that Arena will pay for the shares purchased from us under the Purchase Agreement, or the aggregate gross proceeds that we will receive from those purchases from Arena under the Purchase Agreement, if any.

Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. We cannot be certain that additional funding will be available on acceptable terms, or at all. We have limited committed sources of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. Our license agreements may also be terminated if we are unable to meet the payment obligations or milestones under the agreements. We could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on

unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

Our PPP Loan was forgiven, but we may still be subject to audit and any resulting adverse audit findings of non-compliance could result in the repayment of a portion or all of the PPP Loan and may restrict our flexibility in operating our business or otherwise adversely affect our results of operations.

On April 24, 2020, the Company executed a promissory note pursuant to which it received proceeds of $161 thousand under the Paycheck Protection Program ("PPP Loan") established under the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), as amended by the Paycheck Protection Program Flexibility Act of 2020 in response to the COVID-19 pandemic and is administered by the U.S. Small Business Administration (the "SBA"). We received total proceeds of $161,000 from the PPP Loan. Under the terms of the program, the Company could apply for and be granted forgiveness for all or a portion of the loan, with such forgiveness to be determined, subject to limitations, based on the use of the loan proceeds for payment of payroll costs and any payments of mortgage interest, rent and utilities. The Company applied for forgiveness on November 23, 2020. On January 7, 2021, the Company received notice that forgiveness of all amounts due had been approved.

The U.S. Department of the Treasury has announced that it will conduct audits for PPP Loans that exceed $2,000 for a period of six years after forgiveness. Should we be audited or reviewed by the U.S. Department of the Treasury or the SBA, such audit or review could result in the diversion of management's time and attention and cause us to incur significant costs. If we were to be audited and receive an adverse outcome in such an audit, we could be required to return the full amount of the PPP Loans and may potentially be subject to civil and criminal fines and penalties. If it is subsequently determined that the PPP Loans must be repaid, we may be required to use a substantial portion of our available cash and/or cash flows from operations to pay interest and principal on the PPP Loans, and any future repayment of such loans, would adversely impact our operations and financial results.

Macroeconomic pressures in the markets in which we operate, including, but not limited to, the effect of the COVID-19 pandemic may alter the ways in which we conduct our business operations and manage our financial capacities.

To varying degrees, the ways in which we conduct our business operations and manage our financial capacities are influenced by macroeconomic conditions that affect companies directly involved in or providing services related to the drug and biological product development. For example, real GDP growth, business and investor confidence, the COVID-19 pandemic, inflation, employment levels, oil prices, interest rates, tax rates, availability of consumer and business financing, housing market conditions, foreign currency exchange rate fluctuations, costs for items such as fuel and food and other macroeconomic trends can adversely affect not only our decisions and ability to engage in research and development and clinical trials, but also those of our management, employees, third-party contractors, manufacturers and suppliers, competitors, stockholders and regulatory authorities. The ongoing military conflict between Russia and Ukraine has created extreme volatility in the global capital markets and is expected to have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs. In addition, higher inflation and macro turmoil and uncertainty could also adversely affect our customers, which could reduce demand for our products.

Economic uncertainty may adversely affect our access to capital, cost of capital and ability to execute our business plan as scheduled.

Generally, worldwide economic conditions remain uncertain. Access to capital markets is critical to our ability to operate. Traditionally, biotechnology companies have funded their research and development expenditures through raising capital in the equity markets. Declines and uncertainties in these markets in the past have severely restricted raising new capital and have affected companies' ability to continue to expand or fund existing research and development efforts. We require significant capital for research and development for our product candidates and clinical trials. The general economic and capital market conditions, both in the U.S. and worldwide, have been volatile and at times have adversely affected our access to capital and increased the cost of capital. For example, the ongoing military conflict between Russia and Ukraine, the possibility of a wider European or global conflict, global sanctions imposed in response thereto and the possibility of a global energy crisis resulting therefrom, has created extreme volatility in the global capital markets and is expected to have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If global capital markets deteriorate, including as a result of political unrest or war, it may make any necessary financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. If economic conditions become worse, our future cost of equity or debt capital and access to the capital markets could be adversely affected. If we are unable to access the capital markets on favorable terms, our ability to execute our business plan as scheduled would be compromised. Moreover, we rely and intend to rely on third-parties, including clinical research organizations, contract manufacturing organizations and other important

vendors and consultants. Global economic conditions may result in a disruption or delay in the performance of our third-party contractors and suppliers. If such third-parties are unable to adequately satisfy their contractual commitments to us in a timely manner, our business could be adversely affected.

Our limited operating history and our evolving business make it difficult to evaluate our future prospects and the risks and challenges we may encounter.

Our predecessor, Legacy Comera, was formed in January 2014. Our limited operating history and our evolving business make it difficult to evaluate and assess the success of our business to date, our future prospects and the risks and challenges that we may encounter. These risks and challenges include our ability to:

- accurately forecast our revenue and plan our expenses;
- successfully introduce new products and services;
- successfully compete with current and future competitors;
- successfully expand our business in existing markets and enter new markets and geographies;
- comply with existing and new laws and regulations applicable to our business and the industry in which we operate;
- anticipate and respond to macroeconomic changes as well as changes in the markets and geographies in which we operate;
- maintain and enhance the value of our reputation and brand;
- maintain and expand our relationships with partners and payers;
- successfully execute on our sales and marketing strategies;
- hire, integrate and retain talented people at all levels of our organization;
- expand through future acquisitions and successfully identify and integrate acquired entities;
- successfully in-license or acquire other products and technologies and the terms of these transactions;
- pursue viable product candidates across a variety of indications and disease areas;
- successfully prepare, file, prosecute, maintain, expand, defend and enforce patent claims related to our programs; and
- effectively manage our growth.

If we fail to address the risks and difficulties that we face, including those associated with the challenges listed above as well as those described elsewhere in this "Risk Factors" section, our business, financial condition, results of operations and prospects could be adversely affected. Further, because we have limited historical financial data and our business continues to evolve, any predictions about our future revenue and expenses may not be as accurate as they would be if we had a longer operating history, operated a more predictable business or operated in a less regulated industry. We have encountered and will continue to encounter multiple risks and uncertainties that are frequently experienced by growing companies with limited operating histories and evolving business that operate in rapidly changing, highly regulated and competitive industries. If our assumptions regarding these risks and uncertainties, which we use to plan and operate our business, are incorrect or change, or if we do not address these risks successfully, our results of operations could differ materially from our expectations and our business, financial condition and results of operations could be adversely affected.

Risks Related to the Discovery, Development and Regulatory Approval of Our Product Candidates

We have never successfully completed the regulatory approval process for any of our product candidates and we may be unable to do so for any product candidates we acquire or develop.

We have not yet demonstrated our ability to successfully complete clinical trials, obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Our product candidates are still in preclinical development and may never advance to clinical development. If we are required to conduct additional preclinical studies or clinical trials of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining regulatory approval for our product candidates;
- not obtain regulatory approval at all;

- obtain regulatory approval for indications or patient populations that are not as broad as intended or desired;
- continue to be subject to post-marketing testing requirements; or
- experience having the product removed from the market after obtaining regulatory approval.

Our failure to complete the regulatory approval process for one or more of our product candidates, or if the results of trials and testing result in delays, limitations, requirements, withholding or withdrawal in connection with the regulatory approval process, our business, financial condition and results of operations would be adversely affected.

Drug development is a lengthy, expensive and uncertain process. The results of preclinical studies and clinical trials are not always predictive of future results. If our preclinical studies and clinical trials are not sufficient to support regulatory approval of any of our product candidates, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of such product candidate.

Currently, all our product candidates are in preclinical development. It is impossible to predict when or if any of our product candidates will receive regulatory approval. Before obtaining regulatory approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety, purity and potency of our biological product candidates in humans to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities. Clinical testing is expensive, difficult to design and implement, can take many years to complete and the outcomes are uncertain. A failure of one or more clinical trials can occur at any stage of testing. Our preclinical studies may not be successful, which will limit our ability to execute on our business model effectively.

Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe that the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA, EMA or comparable regulatory authorities. The FDA or other regulatory authorities may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or they may object to elements of our clinical development program, requiring their alteration. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their product candidates. Furthermore, the outcome of preclinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are not as positive as we expect or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs.

In addition, even if the clinical trials are successfully completed, preclinical and clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA, EMA or comparable foreign regulatory authorities will interpret the results as we do, and more clinical trials could be required before we submit our product candidates for approval. To the extent that the results of the clinical trials are not satisfactory to the FDA, EMA or comparable foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional clinical trials in support of potential approval of our product candidates.

Any preclinical studies or clinical trials that we may conduct may not demonstrate the safety, efficacy, purity or potency necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety, efficacy, purity or potency of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for such product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be delayed in or prevented from obtaining marketing approval.

Additionally, some of the clinical trials we conduct may be open-label in study design and may be conducted at a limited number of clinical sites on a limited number of patients. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most

typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Moreover, patients selected for early clinical trials often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label clinical trial may not be predictive of future clinical trial results when studied in a controlled environment with a placebo or active control.

Our current or future product candidates may cause adverse or other undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following regulatory approval, if obtained.

Undesirable side effects caused by any of our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, EMA or comparable foreign regulatory authorities. In our planned and future clinical trials of our product candidates, we may observe a more unfavorable safety and tolerability profile than was observed in earlier-stage testing of these candidates.

We may also observe additional safety or tolerability issues with our product candidates in ongoing or future clinical trials. Many compounds that initially showed promise in clinical or earlier-stage testing have later been found to cause undesirable or unexpected side effects that prevent further development of the compound. Results of future clinical trials of our product candidates could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics, despite a favorable tolerability profile observed in earlier-stage testing.

If unacceptable side effects arise in the development of our product candidates, we, the FDA, EMA or comparable foreign regulatory authorities, the institutional review boards ("IRBs"), or independent ethics committees at the institutions in which our trials are conducted, could suspend, limit or terminate our clinical trials, or the independent safety monitoring committee could recommend that we suspend, limit or terminate our trials, or the FDA, EMA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-emergent side effects that are deemed to be drug-related could delay recruitment of clinical trial subjects or may cause subjects that enroll in our clinical trials to discontinue participation in our clinical trials. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may need to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in harm to patients that receive our product candidates. Any of these occurrences may adversely affect our business, financial condition and prospects significantly.

Moreover, clinical trials of our product candidates will likely be conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects.

We may incur additional costs or experience delays in initiating or completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

We may experience delays in initiating or completing our preclinical studies or clinical trials for various reasons, including as a result of delays in obtaining, or failure to obtain, the FDA's clearance to initiate clinical trials under future investigational new drug applications ("INDs"). Additionally, we cannot be certain that preclinical studies or clinical trials for our product candidates will not require redesign, will enroll an adequate number of subjects on time, or will be completed on schedule, if at all. We may experience numerous unforeseen events during, or as a result of, preclinical studies and clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including the following:

- we may receive feedback from regulatory authorities that require us to modify the design or implementation of our preclinical studies or clinical trials or to delay or terminate a clinical trial;
- regulators or IRBs or ethics committees may delay or may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective clinical research organizations ("CROs"), the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- preclinical studies or clinical trials of our product candidates may fail to show safety, efficacy, purity or potency, or otherwise produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials, or we may decide to abandon product research or development programs;
- preclinical studies or clinical trials of our product candidates may not produce differentiated or clinically significant results;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls, be unable to provide us with sufficient product supply to conduct or complete preclinical studies or clinical trials, fail to meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators or IRBs or ethics committees may require us or our investigators to, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our clinical trials are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- clinical trials of our product candidates may be delayed due to complications associated with the evolving COVID-19 pandemic;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs or ethics committees to suspend or terminate the trials, or reports may arise from preclinical or clinical testing of other therapies that raise safety or efficacy concerns about our product candidates;
- collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate;
- the FDA may require us to conduct clinical trials comparing our product candidates against the current standard of care in the U.S.; and
- the FDA may refuse to file a Biologics License Application ("BLA") or New Drug Application ("NDA") within 60 days of our submission if it is incomplete or insufficient.

We could encounter delays if a clinical trial is suspended or terminated by us or our partners, by the IRBs of the institutions at which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination or clinical hold due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, adverse findings upon an inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA may disagree with our clinical trial design or our interpretation of data from clinical trials or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials.

Our product development costs will also increase if we experience delays in testing or regulatory approvals. We do not know whether any of our future clinical trials will begin as planned, or whether any of our current or future clinical trials will need to be restructured or will be completed on schedule, if at all. Significant preclinical study or clinical trial delays, including those caused by the COVID-19 pandemic, also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may significantly harm our business, operating results, financial condition and prospects.

We may investigate our product candidates in combination with other therapies, which exposes us to additional risks.

We may investigate our product candidates in combination with one or more other approved or unapproved therapies to treat medical conditions. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or comparable foreign regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies we use in combination with

our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially.

Risks Related to Our Business Operations and Industry

We may experience fluctuations in our operating results, which could make our future operating results difficult to predict or cause our operating results to fall below analysts' and investors' expectations.

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

- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- our ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts;
- our ability to obtain marketing approval for our product candidates, and the timing and scope of any such approvals we may receive;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on the difficulty of manufacture, quantity of production and the terms of our agreements with manufacturers;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;
- the level of demand for our product candidates should they receive approval, which may vary significantly;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete with our product candidates;
- general market conditions or extraordinary external events, such as recessions or the COVID-19 pandemic;
- the changing and volatile U.S. and global economic conditions, including increasing interest rates and inflation; and
- future accounting pronouncements or changes in our accounting policies.

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

Our success depends on broad market acceptance of our products if approved, which we may never achieve.

Our proposed product candidates may include new versions of existing approved intravenous biological products, with reduced viscosity and other features designed to allow our products to be administered by subcutaneous injection; new improved versions of existing subcutaneous biologics; or biosimilar versions of existing subcutaneous biologics. Thus, the success of our product candidates will depend primarily on our products demonstrating advantages over the existing products in terms of safety, efficacy, convenience, or other factors. If FDA and other regulatory authorities does not approve our products with labeling that allows us to promote such advantages, we may not be able to compete with the existing reference biologic products. Even if our current product candidates and any future product candidates are approved by the appropriate regulatory authorities for marketing and sale with desirable labeling regarding advantages of our products, they still may not gain acceptance among physicians, patients, third-party payers, and others in the medical community. If any product candidates for which we obtain regulatory approval do not gain an adequate level of market acceptance, we may not generate significant revenue and may not grow or maintain profitability. Market acceptance of our current product candidates and any future product candidates by the medical community, patients and third-party payers will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients, and patients may be reluctant to switch, from existing therapies even when new and potentially more effective or safer treatments enter the market. Physicians and healthcare providers earn revenue from intravenous infusion procedures and may be reluctant to switch patients to products that allow in-home self-administration. If public perception is influenced by claims that the use of our products is

unsafe, our products, once approved, may not be accepted by the general public or the medical community. Future adverse events could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our product candidates.

Efforts to educate the medical community and third-party payers on the benefits of our current product candidates and any future product candidates may require significant resources and may not be successful. If our current product candidates or any future product candidates are approved but do not achieve an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. The degree of market acceptance of any of our current product candidates and any future product candidates will depend on a number of factors, including:

- our ability to obtain regulatory approval of labeling to support our products' advantages over competing products with the same active molecule used for the same indication(s);
- the efficacy of our current product candidates and any future product candidates;
- the prevalence and severity of adverse events associated with our current product candidates and any future product candidates or those products with which they may be co-administered;
- the clinical indications for which our product candidates are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the product's FDA-approved labeling or those of comparable foreign regulatory authorities, including potential limitations or warnings for our current product candidates and any future product candidates that may be more restrictive than other competitive products;
- changes in the standard of care for the targeted indications for our current product candidates and any future product candidates, or in applicable clinical practice guidelines, any of which could reduce the marketing impact of any claims that we could make following FDA approval or approval by comparable foreign regulatory authorities, if obtained;
- the relative convenience and ease of administration of our current product candidates and any future product candidates and any products with which they are co-administered;
- the cost of treatment compared with the economic and clinical benefit of alternative treatments or therapies;
- the availability of adequate coverage or reimbursement by third party payers;
- the price concessions required by third-party payers to obtain coverage;
- the willingness of patients to pay out-of-pocket in the absence of adequate coverage and reimbursement;
- the extent and strength of our marketing and distribution of our current product candidates and any future product candidates;
- the cost, safety, efficacy, and other potential advantages over, and availability of, alternative treatments already used or that may later be approved;
- distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities with respect to our current product candidates and any future product candidates or to which we agree as part of a Risk Evaluation and Mitigation Strategy ("REMS") or voluntary risk management plan;
- the timing of market introduction of our current product candidates and any future product candidates, as well as competitive products;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the extent and strength of our third-party manufacturer and supplier support;
- the actions of companies that market any products with which our current product candidates and any future product candidates may be co-administered;
- the approval of other new products;
- adverse publicity about our current product candidates and any future product candidates or any products with which they are co-administered, or favorable publicity about competitive products; and
- potential product liability claims.

We may not be successful in addressing these or other factors that might affect the market acceptance of our product candidates. Failure to achieve widespread market acceptance of our product candidates would materially harm our business, operating results, financial condition and prospects.

We operate in an intensely competitive market that includes companies with greater financial, technical and marketing resources than us.

The development and commercialization of new products in the biopharmaceutical and related industries is highly competitive and characterized by rapidly advancing technologies and a strong emphasis on intellectual property. We face substantial competition from many different sources, including pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions across various components of our product and service offerings.

Our competitors include divisions of large pharmaceutical companies and biotechnology companies of various sizes. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Any product candidate that we successfully develop and commercialize will compete with currently approved therapies and new therapies that may become available in the future from segments of the pharmaceutical, biotechnology and other related markets. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety, convenience and cost of our products. We believe principal competitive factors to our business include, among other things, the scalability of our pipeline and business, our innovative technology, and our access to, and ability to raise capital.

Many of the companies that we compete against or which we may compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and marketing approved products than we do. These companies will also be able to efficiently develop and market products in multiple indications or disease areas faster than we can. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our strategy.

Our commercial opportunity could be reduced or eliminated if our competitors engage in more extensive research and development efforts, undertaking more impactful marketing campaigns, adopt more aggressive pricing strategies, which may allow them to increase their market share or generate revenue more effectively than we do. Also, some of our current competitors have, and potential competitors may have, longer operating histories, greater brand recognition, greater global infrastructures, greater resources and technical capabilities, significantly greater financial, marketing and other resources and larger customer bases than we do. In addition, our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient than any products that we may develop. Our competitors may also obtain FDA or other regulatory approval for their products sooner than we may obtain approval for ours and for multiple indications in parallel, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, level of competition, and availability of reimbursement from government and other third-party payers.

From time to time, stockholders, competitors and activist investors may attempt to influence us, which could adversely affect our operations, financial condition and the value of our stock.

Market participants, such as our direct and indirect competitors and activist stockholders, may propose a variety of actions for our company, including seeking to acquire a controlling stake in our company, engaging in proxy solicitations, involving themselves in the governance and strategic direction of our company, or otherwise attempting to effect changes at our company. Campaigns by stockholders to effect changes at publicly-traded companies are sometimes led by investors seeking to increase short-term stockholder value through actions such as financial restructuring, increased debt, special dividends, stock repurchases, or sales of assets or the entire company or changes to our business strategy. Such campaigns can be led by stockholders that have interests that are different from the majority of our stockholders and our board, and may not be in the best interests of the company. Responding to proxy contests and other actions by stockholders can be costly and time-consuming, could disrupt our operations and divert the attention of our board of directors and senior management from the pursuit of our business strategies, and otherwise adversely affect our operations, financial condition and the value of our securities.

The COVID-19 pandemic, or a similar pandemic, epidemic, or outbreak of an infectious disease, may materially and adversely affect our business and our financial results and could cause a disruption to the development of our product candidates.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. The coronavirus pandemic is evolving, and has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. The extent to which the coronavirus impacts our operations or those of our third-party partners, including our preclinical studies or clinical trial operations, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that will emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. The continued spread of COVID-19 globally could adversely impact our preclinical or clinical trial operations, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. For example, similar to other biopharmaceutical companies, we or our collaborators may experience delays in initiating studies, protocol deviations, enrolling clinical trials, or dosing of patients in clinical trials as well as in activating new trial sites. COVID-19 may also affect employees of third-party contract research organizations located in affected geographies that we or our collaborators rely upon to carry out clinical trials. Any negative impact COVID-19 has to patient enrollment or treatment or the execution of our product candidates could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and have a material adverse effect on our financial results.

Our employees, agents, contractors, consultants, and vendors as well as our license, research and collaboration partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We cannot provide assurance that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, consultants, commercial partners, and vendors that would violate the law or regulation of the jurisdictions in which we operate, including, without limitation, healthcare, employment, foreign corrupt practices, environmental, competition, and patient privacy and other privacy laws and regulations. Such improper actions could subject us to civil or criminal investigations and monetary and injunctive penalties, and could adversely impact our ability to conduct business, operating results, and reputation. We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners, and vendors. Misconduct by these parties could include intentional, reckless, and/or negligent conduct that fails to comply with the laws enforced by the FDA and comparable foreign regulatory authorities, fails to provide true, complete and accurate information to the FDA and comparable foreign regulatory authorities, fails to comply with manufacturing standards, fails to comply with healthcare fraud and abuse laws in the United States and similar foreign laws, or fails to report financial information or data accurately or to 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 also 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, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause 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. These laws and regulations may impact, among other things, proposed and future sales, marketing, and education programs. 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 government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If our operations are found to be in violation of any of the laws and regulations that may apply to us, we may be subject to the imposition of civil, criminal, and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid, and other federal and state healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment.

Negative media coverage could adversely affect our business and commitments to self-regulation may subject us to investigations and litigation.

The healthcare industry receives a high degree of media coverage in the United States. Unfavorable publicity regarding, for example, the healthcare industry, litigation or regulatory activity, our offerings and products, medication pricing, pricing structures in place amongst the industry participants, our data privacy or data security practices or our revenue could adversely affect our

reputation. Such negative publicity also could have an adverse effect on our ability to attract and retain collaborators, partners, or employees, and result in decreased revenue, which would adversely affect our business, financial condition and results of operation.

In addition, commitments to self-regulation in the healthcare industry may subject us to investigation by government or self-regulatory bodies, government or private litigation, and harm our reputation, brand, business, operating results and financial condition.

Our success depends on our ability to retain key members of our management team and on our ability to hire, train, retain and motivate new employees.

Our success depends on the skills, experience and performance of key members of our senior management team. The individual and collective efforts of these and other members of our senior management team will be important as we continue to develop product candidates, establish strategic partnerships and build out our operations. The loss or incapacity of existing members of our executive management team could adversely affect our operations if we experience difficulties in hiring qualified successors. Our executive officers have signed employment agreements with us, but their service is at-will and may end at any point in time.

Our research and development initiatives and laboratory operations depend on our ability to attract and retain highly skilled scientists, technicians and engineers. We may not be able to attract or retain qualified scientists, clinical personnel, technicians or engineers in the future due to the competition for qualified personnel among life science and technology businesses. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. We may have difficulties locating, recruiting or retaining qualified personnel across functions that we deem critical to our success. Recruiting, training and retention difficulties can limit our ability to support our research and development and commercialization efforts. All of our employees are at-will, which means that either we or the employee may terminate their employment at any time.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development, regulatory and commercialization strategy. Our consultants and advisors may provide services to other organizations and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. The loss of the services of one or more of our current consultants or advisors might impede the achievement of our research, development, regulatory and commercialization objectives.

Our reliance on third parties heightens the risks we face.

We rely on suppliers, vendors and partners for certain key aspects of our business, including support for information technology systems and certain human resource functions. We do not control these partners, but we depend on them in ways that may be significant to us. If these parties fail to meet our expectations or fulfill their obligations to us, we may fail to receive the expected benefits. In addition, if any of these third parties fails to comply with applicable laws and regulations in the course of its performance of services for us, there is a risk that we may be held responsible for such violations as well. This risk is particularly serious in emerging markets, where corruption is often prevalent and where the third parties that we may come to rely on do not have internal compliance resources comparable to our own. Any such failures by third parties, in emerging markets or elsewhere, could adversely affect our business, reputation, financial condition or results of operations.

We rely on, and intend to continue to rely on third parties to conduct our preclinical testing, research and clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.

We have been relying on third parties for our preclinical studies, and we expect to continue to rely on third parties, such as CROs, contract manufacturers of clinical supplies, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials and to conduct some aspects of our research and preclinical testing. These third parties may terminate their engagements with us at any time. If these third parties do not successfully carry out their duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If we are required to enter into alternative arrangements, it could delay our product development activities.

Our reliance on third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and other international regulatory authorities require us to comply with GCP standards 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. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, available at www.clinicaltrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our securities. We will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an emerging growth company, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. We believe that any disclosure controls and procedures or internal 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. 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.

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 or insufficient disclosures due to error or fraud may occur and not be detected.

Risks Related to Our Strategic Agreements and Relationships with Third Parties

We expect to enter into in-license agreements under which we acquire rights to use, develop, manufacture and/or commercialize product candidates. If these collaborations are not successful, our business could be adversely affected.

In the future, we expect to seek and form strategic alliances, create joint ventures or collaborations, or enter into acquisitions or licensing arrangements with third parties that we believe will complement or augment our existing technologies and product candidates. We may not realize the benefits of any acquisitions, in-licenses or strategic alliances that we enter into. These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. As a result, we may not be able to realize the benefits of such future acquisitions or in-licenses if we are unable to successfully integrate them into our operations and company culture. Following a strategic transaction or license, we may not achieve the revenue or specific net income that justifies such transaction or such other benefits that led us to enter into the arrangement. If we breach our obligations under these agreements, we may be required to pay damages, lose our rights to these programs or both, which would adversely affect our business and prospects.

Any collaborations we enter into may pose several risks, including the following:

- Collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- Collaborators may not perform their obligations as expected;
- The clinical trials conducted as part of these collaborations may not be successful;

- Collaborators may not pursue development and/or commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- Collaborators may delay or provide insufficient funding for development efforts or undertake efforts that create questions of safety and efficacy regarding or related programs, and they may not provide us with the necessary data and support needed to facilitate our planned development and regulatory strategy;
- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- Product candidates developed in collaboration with us may be viewed by collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- Disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any programs or product candidates, may cause delays or termination of the research, development, manufacture or commercialization of such programs or product candidates, may lead to additional responsibilities for us with respect to such programs or product candidates or may result in litigation or arbitration, any of which would be time-consuming and expensive;
- Collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- Disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;
- Collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- Collaborations may be terminated and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If our collaborations do not result in the successful development and commercialization of products, or if one of any future collaborators terminates its agreement with us, we may not receive any milestone or royalty payments under the collaboration. If we do not receive the payments we expect under these agreements, our development of product candidates could be delayed and we may need additional resources to develop our product candidates. All of the risks relating to product development, regulatory approval and commercialization summarized and described in this report also apply to the activities of our collaborators.

In addition, if any collaborator terminates its agreement with us, we may find it more difficult to attract new collaborators and our reputation among the business and financial communities could be adversely affected.

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

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us.

We may also be restricted under collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

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

We may be required to pay certain milestones and royalties under our license or collaboration agreements with third-party licensors or collaborators.

Under our future license or collaboration agreements, we may be required to pay milestones, royalties and other payments based on our revenues, including revenues from product sales, and these milestones and royalty payments could adversely affect the overall profitability of any products that we may seek to commercialize. In order to maintain our rights under these agreements, we may need to meet certain specified milestones in the development of our product candidates. Further, our licensors (or their licensors), licensees or other strategic collaborators may dispute the terms, including amounts, that we are required to pay under the respective license or collaboration agreements. If these claims result in a material increase in the amounts that we are required to pay to our licensors or collaborators, or in a claim of breach of the license, our ability to research, develop and obtain approval of product candidates or to commercialize our products could be significantly impaired.

We may rely on third parties to conduct our future clinical trials of our product candidates, in the U.S. and other jurisdictions. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We do not have the ability to independently conduct clinical trials. We expect to rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct or otherwise support clinical trials for our product candidates. We may also rely on academic and private non-academic institutions to conduct and sponsor clinical trials relating to our product candidates. We will not control the design or conduct of the investigator-sponsored trials, and it is possible that the FDA or non-U.S. regulatory authorities will not view these investigator-sponsored trials as providing adequate support for future clinical trials, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results.

Such arrangements will likely provide us certain information rights with respect to the investigator-sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from the investigator-sponsored trials. However, we would not have control over the timing and reporting of the data from investigator-sponsored trials, nor would we own the data from the investigator-sponsored trials. If we are unable to confirm or replicate the results from the investigator-sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development of our product candidates. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data proves to be inadequate compared to the first-hand knowledge we might have gained had the investigator-sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourselves may be adversely affected.

We, our principal investigators and our CROs are required to comply with regulations, including Good Clinical Practices ("GCPs"), for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we, our principal investigators or our CROs fail to comply with applicable GCPs, 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 before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our future clinical trials will comply with GCPs. In addition, our clinical trials must be conducted with product candidates produced under current Good Manufacturing Practice ("cGMP") regulations. Our failure or the failure of our principal investigators or CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process, significantly

increase our expenditures and could also subject us to enforcement action. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Many of our current and planned clinical trials are conducted by CROs and we expect CROs will conduct all of our future clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, are outside of our direct control. Our reliance on third parties to conduct future clinical trials also results in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

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

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

If any of our relationships with these third-party principal investigators or CROs terminate, we may not be able to enter into arrangements with alternative CROs. If principal investigators or CROs do not successfully carry out their contractual obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such principal investigators or CROs are associated with may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

We contract with third parties for the manufacture of our product candidates for preclinical development, clinical testing, and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently own or operate, nor do we have any plans to establish in the future, any manufacturing facilities or manufacturing personnel. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical development and clinical testing, as well as for the commercial manufacture of our products if any of our product candidates receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

The facilities used by our contract manufacturers to manufacture our product candidates must be inspected by the FDA pursuant to pre-approval inspections that will be conducted after we submit our marketing applications to the FDA. We do not control the manufacturing process of, and will be completely dependent on, our contract manufacturers for compliance with cGMPs in connection with the manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to pass regulatory inspections and/or maintain regulatory compliance for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it finds deficiencies or withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

If any contract manufacturing organization ("CMO"), with whom we contract fails to perform its obligations, we may be forced to enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In such scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

Further, our failure, or the failure of our third party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, if approved, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our product candidates.

We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

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

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

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying and qualifying any such replacement.

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

The manufacture of biologics is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide a supply of our current product candidates or any future product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.

Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies to handle living cells. Each lot of an approved biologic must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturers, 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 harm our business.

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 good

manufacturing practices, lot consistency and timely availability of raw materials. Even if we obtain marketing approval for any of our current product candidates or any future product candidates, there is no assurance that our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial 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, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

The third parties upon whom we rely for the supply of the active pharmaceutical ingredients and drug product to be used the preclinical testing and clinical trials for our product candidates are currently our sole source of supply, and the loss of any of these suppliers could significantly harm our business.

The active pharmaceutical ingredients ("API") and drug product we may use in all of our product candidates are currently supplied to us from single-source suppliers. Our ability to successfully develop our product candidates, and to ultimately supply our commercial products in quantities sufficient to meet the market demand, depends in part on our ability to obtain the API and drug product for these products in accordance with regulatory requirements and in sufficient quantities for clinical testing and commercialization. We are also unable to predict how changing global economic conditions or potential global health concerns such as the COVID-19 pandemic will affect our third-party suppliers and manufacturers. Any negative impact of such matters on our third-party suppliers and manufacturers may also have an adverse impact on our results of operations or financial condition.

For all of our product candidates, we intend to identify and qualify additional manufacturers to provide such API and drug product prior to submission of an application for approval with the FDA, EMA or other applicable regulatory authority. We are not certain, however, that our single-source suppliers will be able to meet our demand for their products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

Establishing additional or replacement suppliers for the API and drug product used in our product candidates, if required, may not be accomplished quickly. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory inspection or approval, which could result in further delay. While we seek to maintain adequate inventory of the API and drug product used in our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain such API and drug product from alternate sources at acceptable prices in a timely manner could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

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

Until such time, if ever, as we can generate substantial revenue, we expect to finance our cash needs through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. Our future need for additional funding depends on many factors, including:

- the scope, progress, results and costs of researching and developing our current product candidates, as well as other additional product candidates we may develop and pursue in the future;
- the timing of, and the costs involved in, obtaining marketing approvals for our product candidates and any other additional product candidates we may develop and pursue in the future;
- the number of future product candidates that we may pursue and their development requirements;
- the costs of commercialization activities for our product candidates, to the extent such costs are not the responsibility of any current or future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of regulatory approval, revenue, if any, received from commercial sales of our product candidates or any other additional product candidates we may develop and pursue in the future;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- our ability to establish collaboration arrangements for the development of our product candidates on favorable terms, if at all;

- our headcount growth and associated costs as we expand our research and development and establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- the costs of operating as a public company.

The terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our securities to decline. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest may be diluted, and the terms of those securities may include liquidation or other preferences that may adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, acquiring, selling or licensing intellectual property rights, and making capital expenditures, declaring dividends or other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to meet certain milestones in connection with debt financing and the failure to achieve such milestones by certain dates may force us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us which could have a material adverse effect on our business, operating results and prospects.

We also could be required to seek funds through arrangements with additional collaborators. If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates, grant licenses on terms that may not be favorable to us or grant rights to develop and market our product candidates that we would otherwise prefer to develop and market ourselves, any of which may have a material adverse effect on our business, operating results and prospects.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates or if the scope of the intellectual property protection obtained is not sufficiently broad or we are delayed in bringing product candidates to market such that those products have a shorter period of patent exclusivity than we expect, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired.

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection in the United States and other countries for our current and future product candidates, as well as for their respective compositions, formulations, methods used to manufacture them, and methods of treatment, in addition to successfully defending these patents against third-party challenges. We seek to protect our proprietary and intellectual property position by, among other methods, filing patent applications in the United States and abroad related to our proprietary technology, inventions, and improvements that are important to the development and implementation of our business. Our ability to stop unauthorized third parties from making, using, selling, offering to sell, or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. The degree of patent protection we require to successfully commercialize our current and future product candidates may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our current or future product candidates. In addition, if the breadth or strength of protection provided by our patent applications or any patents we may own or in-license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, in jurisdictions outside the United States, a license may not be enforceable unless all the owners of the intellectual property agree or consent to the license. Accordingly, any actual or purported co-owner of our patent rights could seek monetary or equitable relief requiring us to pay it compensation for, or refrain from, exploiting these patents due to such co-ownership.

Furthermore, patents have a limited lifespan. In the United States, and most other jurisdictions in which we have undertaken patent filings, the natural expiration of a patent is generally 20 years after it is filed, assuming all maintenance fees are paid. Various extensions may be available, on a jurisdiction-by-jurisdiction basis; however, the life of a patent, and thus the protection it affords, is limited. In the United States, depending upon the timing, duration, and specifics of any FDA marketing approval of a product

candidate, the patent term of a patent that covers an FDA-approved product may be eligible for limited patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, permits a patent term extension of up to five (5) years beyond the expiration of the patent. While, in the future, if and when our product candidates receive FDA approval, we expect to apply for patent term extensions on patents directed to those candidates, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. We may not be granted an extension 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 the relevant patents, or otherwise failing to satisfy applicable requirements. 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. As a result, patents we may own or in-license may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing drugs similar or identical to our current or future product candidates, including generic versions of such drugs.

Other parties have developed technologies that may be related or competitive to our own, and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our own patent applications or issued patents, with respect to either the same compounds, methods, formulations or other subject matter, in either case that we may rely upon to dominate our patent position in the market. 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 at least 18 months after the earliest priority date of patent 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 patents we may own or in-license patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights cannot be predicted with any certainty.

In addition, the patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Further, with respect to certain pending patent applications covering our current or future product candidates, prosecution has yet to commence. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the relevant patent office(s) may be significantly narrowed by the time they issue, if they ever do. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Even if we acquire patent protection that we expect should enable us to establish and/or maintain a competitive advantage, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We may become involved in post-grant proceedings such as opposition, derivation, reexamination, *inter partes* review, post-grant review, or interference proceedings challenging our patent rights or the patent rights of others from whom we may in the future obtain licenses to such rights, in the U.S. Patent and Trademark Office (the "USPTO") the European Patent Office (the "EPO"), or in other countries. In addition, we may be subject to a third-party submission to the USPTO, the EPO, or elsewhere, that may reduce the scope or preclude the granting of claims from our pending patent applications. Competitors may allege that they invented the inventions claimed in our issued patents or patent applications prior to us, or may file patent applications before we do. Competitors may also claim that we are infringing their patents and that we therefore cannot practice our technology as claimed under our patents or patent applications. Competitors may also contest our patents by claiming to an administrative patent authority or judge that the invention was not patent-eligible, was not original, was not novel, was obvious, and/or lacked inventive step, and/or that the patent application filing failed to meet relevant requirements relating to description, basis, enablement, and/or support. In litigation, a competitor could claim that our patents, if issued, are not valid or are unenforceable for a number of reasons. If a court or administrative patent authority agrees, we would lose our protection of those challenged patents.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we generally require all of our employees, consultants and advisors and any other third parties who have access to our proprietary know-how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy.

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 or identical technology and drugs, without payment to us, or could limit the duration of the patent protection covering our technology and current and future product candidates. Such challenges may also result in our inability to manufacture or commercialize our current and future product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if they are unchallenged, our issued patents and our pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent patents we may own or in-license by developing similar or alternative technologies or drugs in a non-infringing manner. For example, a third-party may develop a competitive drug that provides benefits similar to one or more of our current or future product candidates but that has a different composition or dosage that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our current or future product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our current and future product candidates could be negatively affected, which would harm our business, operating results, financial condition and prospects.

Furthermore, even if we are able to issue patents with claims of valuable scope in one or more jurisdictions, we may not be able to secure such claims in all relevant jurisdictions, or in a sufficient number to meaningfully reduce competition. Our competitors may be able to develop and commercialize their products, including products identical to ours, in any jurisdiction in which we are unable to obtain, maintain, or enforce such patent claims.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, deadlines, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements. We may miss a filing deadline for patent protection on these inventions.

The USPTO and foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after issuance of any patent. In addition, periodic maintenance fees, renewal fees, annuity fees and/or various other government fees are required to be paid periodically. While an inadvertent lapse can, in some cases, be cured by payment of a late fee, or by other means in accordance with the applicable rules, there are situations in which 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. Noncompliance events that could result in abandonment or lapse of a patent include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market with similar or identical products or platforms, which could have a material adverse effect on our business prospects and financial condition.

If our trademarks and trade names for our products or company name are not adequately protected in one or more countries where we intend to market our products, we may delay the launch of product brand names, use different trademarks or tradenames in different countries, or face other potentially adverse consequences to building our product brand recognition.

Our trademarks or trade names may be challenged, infringed, diluted, circumvented or declared generic or determined to be infringing on other marks. We intend to rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During the trademark registration process, we may receive Office Actions from the USPTO or from comparable agencies in foreign jurisdictions objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. 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/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademark applications or registrations, and our trademark applications or registrations may not survive such proceedings. If we are unable to obtain a registered trademark or establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

If we are unable to adequately protect and enforce our trade secrets, our business and competitive position would be harmed.

In addition to the protection afforded by patents we may own or in-license, we seek to rely on trade secret protection, confidentiality agreements, and partnership and license agreements to protect proprietary know-how that may not be patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes or our business processes that involve proprietary know-how, information, or technology that may not be covered by patents. Although we

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, trade secrets can be difficult to protect and we have limited control over the protection of trade secrets used by our collaborators and suppliers. We cannot be certain that we have or will obtain these agreements in all circumstances and we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary information.

Moreover, any of these parties might breach the agreements and intentionally or inadvertently disclose our trade secret information and we may not be able to obtain adequate remedies for such breaches. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights and trade secrets to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property and trade secrets to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could adversely affect our business, financial condition, results of operations and future prospects.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If we choose to go to court to stop a third-party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them from using that technology or information to compete with us.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. In the case of employees, the proprietary information and inventions assignment agreements with employees provide that the employees shall assign and transfer, and will assign and transfer, to us the rights, title, and interest in all inventions that (a) relate to our business or that of our affiliates, our customers or suppliers, or any of the products or services being researched, developed or sold by us or our affiliates; (b) result from tasks assigned by us; or (c) result from the use of our premises or personal property. Although we require all of our employees to assign their inventions 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 have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may initiate, become a defendant in, or otherwise become party to lawsuits to protect or enforce our intellectual property rights, which could be expensive, time-consuming, and unsuccessful.

There is considerable patent and other intellectual property litigation in the pharmaceutical and biotechnology industries. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and product candidates, including interference proceedings, post grant review, inter parties review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions such as oppositions before the European Patent Office.

Competitors may infringe any patents we may own or in-license. In addition, any patents we may own or in-license also may become involved in inventorship, priority, validity or unenforceability disputes. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke such parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property. In addition, in a patent infringement proceeding, such parties could counterclaim that the patents we or our licensors have asserted are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may institute such claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter parties review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings).

We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, in an infringement proceeding, a court may decide that one or more of any patents we may own or in-license is not valid or is unenforceable or that the other party's use of our technology that may be patented falls under the safe harbor to patent infringement under 35 U.S.C. § 271(e)(1). There is also the risk that, even if the validity of these patents is upheld, the court may refuse to stop the other party from using the technology at issue on the grounds that any patents we may own or in-license do not cover the technology in question or that such third-party's activities do not infringe our patent applications or any patents we may own or in-license.

Even if we believe that third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of misappropriation, infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold these third-party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any technology or product candidate covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Conversely, an adverse result in any litigation or defense proceedings could put one or more of any patents we may own or in-license at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing.

Post-grant proceedings provoked by third-parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to our patent applications or any patents we may own or in-license. These proceedings are expensive and an unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. In addition to potential USPTO post-grant proceedings, we may become a party to patent opposition proceedings in the EPO, or similar proceedings in other foreign patent offices or courts where our patents may be challenged. The costs of these proceedings could be substantial, and may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result in a post-grant challenge proceeding may result in the loss of our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our business. Litigation or post-grant proceedings within patent offices may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our securities.

We may not be able to detect infringement against any patents we may own or in-license. Even if we detect infringement by a third-party of any patents we may own or in-license, we may choose not to pursue litigation against or settlement with the third-party. If we later sue such third-party for patent infringement, the third-party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us to enforce any patents we may own or in-license against such third-party.

Intellectual property litigation and administrative patent office patent validity challenges in one or more countries could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. The risks of being involved in such litigation and proceedings may increase if and as our product candidates near commercialization and as we gain the greater visibility associated with being a public company. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our securities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, patient support or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. As noted above, some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development collaborations that would help us commercialize

our current or future product candidates, if approved. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

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

We may be unable to obtain patent or other intellectual property protection for our current or future product candidates or our future products, if any, in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

We may not be able to pursue patent coverage of our current or future product candidates in all countries. Filing, prosecuting and defending patents on current or future product candidates in all countries throughout the world would be prohibitively expensive, and 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. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our current or future product candidates and in jurisdictions where we do not have any issued patents our patent applications or other intellectual property rights may not be effective or sufficient to prevent them from competing. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines.

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

Many countries 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. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents we may own or license that are relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

If we fail to comply with our obligations in any agreements under which we may license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We may from time to time be party to license, funding and collaboration agreements with third parties to advance our research or allow commercialization of current or future product candidates. Such agreements may impose numerous obligations, such as development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patent prosecution, enforcement and other obligations on us and may require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. If we fail to comply with such obligations, our counterparties might therefore terminate the license, funding or collaboration agreements or require us to grant them certain rights, thereby removing or limiting our ability to develop and commercialize products and technologies covered by these agreements.

Any termination of these may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under those agreements, including our rights to important intellectual property or technology, which could harm our ability to commercialize our current or future product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Additionally, these and other license agreements may not provide exclusive rights to use the licensed 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 drugs in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products

and technology in fields of use and territories not included in enforcement, and defense of patents and patent applications directed to the technology that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our drugs that are the subject of such licensed rights could be adversely affected.

We may need to obtain additional licenses from others to advance our research or allow commercialization of our therapeutic candidates. It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all, or such licenses may be non-exclusive. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several 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 obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, therapeutic candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and therapeutic candidates, which could harm our business, financial condition, results of operations, and prospects significantly.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents and patent applications we in-licensed. If other third parties have ownership 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 have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property rights of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our current or future product candidates, and what activities satisfy those diligence obligations;
- the priority of invention of any patented technology; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners.

In addition, the agreements under which we may license intellectual property or technology from third parties 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 technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we may license prevent or impair our ability to maintain future licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected current or future product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

We may be subject to claims that our employees or consultants have wrongfully used or disclosed alleged trade secrets.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees or consultants have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we could lose valuable intellectual property rights or personnel, which could

adversely impact our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Any granted patents we may own or in-license covering our product candidates or other valuable technology could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the USPTO and the EPO. A patent asserted in a judicial court could be found invalid or unenforceable during the enforcement proceeding. Administrative or judicial proceedings challenging the validity of our patents or individual patent claims could take months or years to resolve.

If we or our licensors or strategic partners initiate legal proceedings against a third-party to enforce a patent covering one of our current or future product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third-party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of patentable subject matter, lack of written description, lack of novelty, obviousness, or non-enablement. 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, in the process of obtaining the patent during patent prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post grant review and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in revocation or amendment to our patent applications or any patents we may own or in-license in such a way that they no longer cover our current or future product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, any rights we may have from our patent applications or any patents we may own or in-license, allow third parties to commercialize our current or future product candidates or other technologies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our or our future licensors' priority of invention or other features of patentability with respect to our patent applications and any patents we may own or in-license. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our current or future product candidates and other technologies. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our future licensing partners and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our current or future product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and current or future product candidates.

Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. If we are unsuccessful in any such proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the current or future product candidates we may develop. The loss of exclusivity or the narrowing of our patent application claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could have a material adverse effect on our business, results of operations, financial condition and prospects.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or Leahy-Smith Act, signed into law on September 16, 2011, could increase the uncertainties and costs surrounding the prosecution of our owned and potential future in-licensed patent applications and the maintenance, enforcement or defense of our owned and potential future in-licensed 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, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent

at USPTO-administered post-grant proceedings, including post-grant review, inter parties review, and derivation proceedings. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a "first-inventor-to-file" system. The first-inventor-to-file provisions, however, only became effective on March 16, 2013. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, operating results, financial condition and prospects.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

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

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

Intellectual property rights do not guarantee commercial success of current or future product candidates or other business activities. Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights, whether owned or in-licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third-party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- patent applications that we own or may in-license may not lead to issued patents;
- patents, should they issue, that we may own or in-license, may not provide us with any competitive advantages, may be narrowed in scope, or may be challenged and held invalid or unenforceable;

- others may be able to develop and/or practice technology, including excipients that are similar to the chemical compositions of our current or future product candidates, that is similar to our technology or aspects of our technology but that is not covered by the claims of any patents we may own or in-license, should any patents issue;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we, or our licensors or collaborators, might not have been the first to make the inventions covered by a patent application that we own or may in-license;
- we, or our licensors or collaborators, might not have been the first to file patent applications covering a particular invention;
- others may independently develop similar or alternative technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not be able to obtain and/or maintain necessary licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property;
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third-party may subsequently file a patent covering such trade secrets or know-how;
- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

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

Risks Related to Government Regulation

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or 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.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In short, the foreign regulatory approval process involves all of the risks associated with FDA approval. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we may intend to charge for our products will also be subject to approval.

Our product candidates may be subject to government price controls in certain jurisdictions that may affect our revenue.

There has been heightened governmental scrutiny in the United States, China, the European Union, Japan and other jurisdictions of pharmaceutical pricing practices in light of the rising cost of prescription drugs. In the United States, such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal 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. At the federal level, Congressional leadership and the Biden administration have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly enacted 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.

Outside of the United States, 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 product. 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. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

We may seek priority review designation for one or more of our product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster regulatory review or approval process.

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for some of our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily result in an expedited regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

Accelerated approval by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive regulatory approval.

We may seek accelerated approval of our current or future product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition and provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality ("IMM"), that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA requires that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product, if approved. Even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate FDA approval.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability under the FDCA, the False Claims Act, or other federal or state laws. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, if approved. In particular, in August 2021 the FDA finalized a rule clarifying its position on the types of evidence it will consider when determining a medical product's intended use. In the final rule, the FDA declined to narrow its interpretation of evidence of intended use to a firm's promotional claims and indicated its intent to look broadly at any relevant evidence to establish intended use. While the FDA permits the dissemination of truthful and non-misleading information about an approved product, a manufacturer may not promote a product for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we are found to have promoted such off-label uses, intentionally or unintentionally, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees, corporate integrity agreements or permanent injunctions under which specified promotional conduct must be changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

The FDA, the EMA and other regulatory authorities may implement additional regulations or restrictions on the development and commercialization of our product candidates, and such changes can be difficult to predict.

The FDA, the EMA and regulatory authorities in other countries have each expressed interest in further regulating biotechnology products. Agencies at both the federal and state level in the United States, as well as the U.S. Congressional committees and other governments or governing agencies, have also expressed interest in further regulating the biotechnology industry. Such action may delay or prevent commercialization of some or all of our product candidates. Adverse developments in clinical trials of products conducted by others may cause the FDA or other oversight bodies to change the requirements for approval of any of our product candidates. These regulatory review agencies and committees and the new requirements or guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory agencies and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all.

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 post-market study requirements, marketing and labeling restrictions, and even recall or market withdrawal if unanticipated safety issues are discovered following approval. In addition, we may be subject to penalties or other enforcement action if we fail to comply with regulatory requirements.

If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion, monitoring, and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and listing, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product. The FDA may also require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Later 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;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- clinical trial holds;
- fines, warning letters or other regulatory enforcement action;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose

any regulatory approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Healthcare legislative reform discourse and potential or enacted measures may have a material adverse impact on our business and results of operations and legislative or political discussions surrounding the desire for and implementation of pricing reforms may adversely impact our business.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the ACA was enacted. Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA. It is unclear how other healthcare reform measures of the Biden administrations or other efforts, if any, to challenge repeal or replace the ACA, will impact our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

At a federal level, President Biden signed an Executive Order on July 9, 2021 affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs the U.S. Department of Health and Human Services ("HHS") to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. On September 25, 2020, the HHS's Centers for Medicare & Medicaid Services ("CMS") stated that drugs imported by states under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates would have been calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. However, on August 6, 2021 CMS announced a proposed rule to rescind the Most Favored Nations rule. Additionally, on December 2, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. On November 30, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Further, implementation of these changes and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees are currently under review by the Biden administration and may be amended or repealed. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that it will continue to seek new legislative measures to control drug costs. The effect of these legislative and executive activities on our business model and operations is currently unclear.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We are subject to federal and state laws and regulations related to privacy, data protection, information security and consumer protection across different markets where we conduct our business. Our actual or perceived failure to comply with such obligations could harm our business.

We are subject to laws and regulations related to, among other things, privacy, data protection, information security and consumer protection across different markets were we conduct our business in those markets. Such laws and regulations are constantly evolving and changing and are likely to remain uncertain for the foreseeable future. Our actual or perceived failure to comply with such obligations could have an adverse effect on our business, operating results and financial operations. For example, on June 28, 2018, California enacted the California Consumer Privacy Act ("CCPA"), which took effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers, increases the privacy and security obligations of entities handling certain personal information, requires new disclosures to California individuals and affords such individuals new abilities to opt out of certain sales of personal information, and provides for civil penalties for violations as well as a private right of action for data breaches that is expected to increase data breach litigation. Additionally, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") and its implementing regulations, and as amended again by the Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules published in January 2013 (commonly referred to as the "Final HIPAA Omnibus Rule"), imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the Final HIPAA Omnibus Rule. There are European and other foreign law equivalents of each of such laws with similar requirements. Complying with these numerous, complex, and often changing regulations is expensive and difficult, and failure to comply with any privacy laws or data security laws or any security incident or breach involving the misappropriation, loss or other unauthorized processing, use or disclosure of sensitive or confidential patient, consumer or other personal information, whether by us, one of our collaborators or another third party, could adversely affect our business, financial condition, and results of operations, 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.

European data collection is also governed by restrictive regulations governing the use, processing and cross-border transfer of personal information. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the European Union (the "EU"), including personal health data, is subject to the EU General Data Protection Regulation ("GDPR"), which imposes strict requirements for processing the personal data of individuals within the European Economic Area (the "EEA"). The GDPR is directly applicable in each EU member state and is extended to the EEA. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR implements more stringent operational requirements than its predecessor legislation. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. For example, the GDPR applies extraterritorially, requires us to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which we can process personal data, makes it harder for us to obtain valid consent for collecting and processing personal data (including data from clinical trials), requires the appointment of data protection officers when sensitive personal data, such as health data, is processed on a large scale, provides more robust rights for data subjects, introduces mandatory data breach notification through the EU, imposes additional obligations on us when contracting with service providers and requires us to adopt appropriate privacy governance, including policies, procedures, training, and data audit. The GDPR provides that EEA countries may establish their own laws and regulations limiting the processing of personal data, including genetic, biometric, or health data, which could limit our ability to use and share personal data or could cause our costs to increase. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. For example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union ("CJEU"). The CJEU upheld the adequacy of the Standard Contractual Clauses ("SCCs"), a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. New SCCs were adopted by the European Commission on June 4, 2021, replacing the 2001, 204, and 2010 SCCs that were previously in use. Use of the SCCs must nonetheless now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain.

We cannot assure you that our third-party service providers with access to our or our customers', suppliers', trial patients' and employees' personally identifiable and other sensitive or confidential information will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, 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, results of operations, and financial condition. 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, use, storage, and transmission of such information. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our internal computer systems, or those used by our contractors or consultants, may fail or experience security breaches or other unauthorized or improper access.

Despite the implementation of security measures, our internal computer systems, and those of our contract research organizations ("CROs") and other third parties on which we rely, are vulnerable to privacy and information security incidents, such as data breaches, damage from computer viruses and unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication, electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased.

In February 2022, we became aware that we had been a victim of a criminal fraud commonly referred to as "business email compromise fraud." The incident involved impersonation of one of our senior personnel through unauthorized access to his email account which resulted in a diversion of funds to unknown parties and a loss of $136,000 for the year ended December 31, 2021. Subsequent to December 31, 2021, as part of the same incident, an additional $590,000 was diverted, resulting in a total loss of $726,000 before we became aware of the problem. We notified federal law enforcement (FBI) and the relevant bank involved, which are working with us to recover the amount lost. At this time, we have recovered insurance proceeds of $300,000 to partially offset the loss. We retained TCG Technologies to assist in our cyber investigation and remedial measures. Based on our investigation to date, the incident was financially motivated and impacted a single email account. In response to the incident, we conducted a review of our corporate information technology and email policies and are implementing additional security and training measures, including full penetration test (PEN test) of our network, enacted multi-factor authorization (MFA) protocols, implemented an employee education program, and implementing improvements to current network.

Although we did not experience any interruptions in our operations or material disruption of our development programs or business operations, the incidents have been a distraction to our management and any future incidents could interrupt our operations or materially disrupt our development programs. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, our ability to commercialize products depends on third parties to conduct clinical trials and manufacture products, and similar events relating to their computer systems could also have a material adverse effect on our business.

Unauthorized disclosure of sensitive or confidential data, including personally identifiable information, whether through a breach of computer systems, systems failure, employee negligence, fraud or misappropriation, or otherwise, or unauthorized access to or through our information systems and networks, whether by our employees or third parties, could result in negative publicity, legal liability and damage to our reputation. Unauthorized disclosure of personally identifiable information could also expose us to sanctions for violations of data privacy laws and regulations around the world. To the extent that any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

As we become more dependent on information technologies to conduct our operations, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, may increase in frequency and sophistication. These threats pose a risk to the security of our systems and networks, the confidentiality and the availability and integrity of our data and these risks apply both to us, and to third parties on whose systems we rely for the conduct of our business. Because the techniques used to obtain unauthorized access, disable or degrade service or sabotage systems change frequently and often are not recognized until launched against a target, we and our partners may be unable to anticipate these techniques or to implement adequate preventative measures. Further, we do not have any control over the operations of the facilities or technology of our cloud and service providers. Our systems, servers and platforms and those of our service providers may be vulnerable to computer viruses or physical or electronic break-ins that our or their security measures may not detect. Individuals able to circumvent such security measures may misappropriate our confidential or proprietary information, disrupt our operations, damage our computers or otherwise impair our reputation and business. We may need to expend significant resources and make significant capital investment to protect against security breaches or to mitigate the impact of any such breaches. There can be no assurance that we or our third-party providers will be successful in preventing cyber-attacks or successfully mitigating their effects. To the extent that any disruption or security breach

were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our future product candidates could be delayed.

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

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

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

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Risks Related to the Company

We will continue to incur increased costs as a result of operating as a public company, and our management is devoting substantial time to new compliance initiatives.

We will incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an emerging growth company, as defined in Section 2(a) of the Securities Act. As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules adopted, and to be adopted, by the SEC and Nasdaq. 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 and to make some activities more time consuming and costly. The increased costs will increase the Company's net loss. For example, these rules and regulations could make it more difficult and more expensive for us to obtain and maintain director and officer liability insurance and as a result, we may be forced to accept reduced policy limits or incur substantially higher costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs it may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or as executive officers.

Management has limited experience in operating a public company.

Our executive officers have limited experience in the management of a publicly traded company. Our management team may not successfully or effectively manage its transition to a public company that will be subject to significant regulatory oversight and reporting obligations under federal securities laws. Their limited experience in dealing with the increasingly complex laws pertaining to public companies could be a significant disadvantage in that it is likely that an increasing amount of their time may be devoted to these activities which will result in less time being devoted to the management and growth of the company. We may not have adequate personnel with the appropriate level of knowledge, experience, and training in the accounting policies, practices or internal controls over financial reporting required of public companies in the U.S. The development and implementation of the standards and controls necessary for us to achieve the level of accounting standards required of a public company in the U.S. may require costs greater than expected. It is possible that we will be required to expand its employee base and hire additional employees to support our operations as a public company, which will increase its operating costs in future periods.

There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq.

Our common stock and warrants are listed on Nasdaq. There can be no assurance that we will continue to meet Nasdaq's listing standards. If we do not, we and our stockholders could face significant material adverse consequences:

- a limited availability of market quotations for its securities;
- reduced liquidity for its securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for its securities;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as "covered securities." If our common stock remains listed on Nasdaq, it will be considered a covered security. Although the states are preempted from regulating the sale of our securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. While we are not aware of a state, other than the State of Idaho, having used these powers to prohibit or restrict the sale of securities issued by blank check companies, certain state securities regulators view blank check companies unfavorably and might use these powers, or threaten to use these powers, to hinder the sale of securities of blank check companies in their states. Further, if we were not listed on Nasdaq, our securities would not be covered securities and we would be subject to regulation in each state in which it offers its securities.

If we fail to maintain effective internal controls over financial reporting, the price of our securities may be adversely affected.

We are required to maintain appropriate internal controls over financial reporting. Failure to maintain those controls could adversely affect our public disclosures regarding our business, financial condition or results of operations. In addition, management's assessment of internal controls over financial reporting may identify weaknesses and conditions that need to be addressed in our internal controls over financial reporting, or other matters that may raise concerns for investors. Any actual or perceived weaknesses and conditions that need to be addressed in our internal controls over financial reporting, or disclosure of management's assessment of our internal controls over financial reporting, may have an adverse impact on the price of our securities.

Our failure to timely and effectively implement controls and procedures required by Section 404(a) ("Section 404(a)") of the Sarbanes-Oxley Act could have a material adverse effect on our business, operating results and financial condition.

We are required to provide management's attestation on internal controls pursuant to the requirements of Section 404 of the Sarbanes-Oxley Act. The standards required for a public company under Section 404(a) are significantly more stringent than those that were required of Legacy Comera as a privately-held company. Management may not be able to effectively and timely implement controls and procedures that adequately respond to the increased regulatory compliance and reporting requirements. If we are not able to implement the additional requirements of Section 404(a) in a timely manner or with adequate compliance, it may not be able to assess whether its internal controls over financial reporting are effective or may result in a finding that there is a material weakness in our internal controls over financial reporting, which may subject it to adverse regulatory consequences and could harm investor confidence and the market price of our securities.

A market for our securities may not continue, which would adversely affect the liquidity and price of our securities.

The price of our common stock and warrants has fluctuated and may continue to fluctuate significantly due to the market's reaction to the Transaction and general market and economic conditions. An active trading market for our common stock and warrants may never develop or, if developed, it may not be sustained. In addition, the price of our common stock and warrants can vary due to general economic conditions and forecasts, our general business condition and the release of its financial reports. If its securities are not listed on, or become delisted from, Nasdaq for any reason, and are quoted on the OTC Bulletin Board, an inter-dealer automated quotation system for equity securities that is not a national securities exchange, the liquidity and price of its securities may be more limited than if it were quoted or listed on Nasdaq or another national securities exchange. You may be unable to sell your Company securities unless a market can be established or sustained.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business, or our market, or if they change their recommendations regarding our common stock adversely, then the price and trading volume of our common stock or warrants could decline.

The trading market for our common stock and warrants will be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market, or our competitors. Securities and industry analysts do not currently, and may never, publish research on us. If no securities or industry analysts commence coverage of our company, our common stock and warrant price and trading volume would likely be negatively impacted. If any of the analysts who may cover us change their recommendation regarding our common stock and warrants adversely, or provide more favorable relative recommendations about the Company's competitors, the price of our common stock and warrants would likely decline. If any analyst who may cover us fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause the price or trading volume of common stock or warrants to decline.

The JOBS Act permits "emerging growth companies" like us to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies.

We currently qualify as an "emerging growth company" as defined in Section 2(a)(19) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). As such, we take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as it continues to be an emerging growth company, including the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act. As a result, our stockholders may not have access to certain information they deem important. We will remain an emerging growth company until the earlier of: (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of the Transaction, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common equity that is held by non-affiliates equals or exceeds $700.0 million as of the end of the prior fiscal year's second fiscal quarter; and (2) the date on which we have issued more than $1.00 billion in non-convertible debt securities during the prior three-year period.

We cannot predict if investors will find our common stock and warrants less attractive because it relies on these exemptions. If some investors find our common stock or warrants less attractive as a result, there may be a less active trading market and share price for our common stock or warrants may be more volatile. Once we cease to qualify as an emerging growth company, we will incur increased legal, accounting and compliance costs associated with Section 404 of the Sarbanes-Oxley Act.

We may issue additional shares of common stock or shares of preferred stock under our amended and restated certificate of incorporation, which would dilute the interest of our stockholders.

Our amended and restated certificate of incorporation authorizes the issuance of 150,000,000 shares of common stock, and 1,000,000 shares of preferred stock, in each case, par value $0.0001 per share, which includes shares of common stock issuable under an employee incentive plan. The issuance of additional common stock or preferred stock:

- may significantly dilute the equity interest of current stockholders, who will not have preemption rights in respect of such an issuance;
- could cause a change in control if a substantial number of shares of common stock are issued, which may affect, among other things, our ability to use our net operating loss carry forwards, if any, and could result in the resignation or removal of our present officers and directors; and
- may adversely affect prevailing market prices for our common stock and/or warrants.

Additionally, pursuant to the Purchase Agreement entered into with Arena in August 2022, Arena has committed to purchase up to $15.0 million of our common stock, subject to increase to $30.0 million at our option. Depending on market liquidity at the time of such sales, if any, resales of those shares by Arena may cause the public trading price of our common stock to decrease and could cause additional substantial dilution to our stockholders.

Our amended and restated certificate of incorporation contain anti-takeover provisions that could adversely affect the rights of our stockholders.

Our amended and restated certificate of incorporation contain provisions to limit the ability of others to acquire control of us or cause us to engage in change-of-control transactions, including, among other things:

- provisions that authorize its board of directors, without action by its stockholders, to issue additional shares of common stock and preferred stock with preferential rights determined by its board of directors;
- provisions that permit only a majority of its board of directors, the chairperson of the board of directors or the chief executive officer to call stockholder meetings and therefore do not permit stockholders to call special meetings of the stockholders;
- provisions limiting stockholders' ability to act by written consent; and
- a staggered board whereby our directors are divided into three classes, with each class subject to retirement and re-election once every three years on a rotating basis.

These provisions could have the effect of depriving our stockholders of an opportunity to sell their common stock at a premium over prevailing market prices by discouraging third parties from seeking to obtain control of our company in a tender offer or similar transaction. With its staggered board of directors, at least two annual or special meetings of stockholders will generally be required in order to effect a change in a majority of its directors. Our staggered board of directors can discourage proxy contests for the election of its directors and purchases of substantial blocks of its shares by making it more difficult for a potential acquirer to gain control of its board of directors in a relatively short period of time.

Our amended and restated certificate of incorporation provide, subject to limited exceptions, that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for certain stockholder litigation matters, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or stockholders.

Our amended and restated certificate of incorporation provide that unless we consent in writing to the selection of an alternative forum, and subject to applicable jurisdictional requirements, the sole and exclusive forum for (1) any derivative action or proceeding brought on behalf of the Company, (2) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer, employee, agent or shareholder of the Company to the Company or the Company's shareholders, (3) any action asserting a claim arising pursuant to any provision of the DGCL, the Company's amended and restated certificate of incorporation, or (4) any action asserting a claim governed by the internal affairs doctrine shall be the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware lacks jurisdiction over such action or proceeding, then the United States District Court for the District of Delaware or another court of the State of Delaware). Our amended and restated certificate of incorporation also provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction.

The 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 our directors, officers, or other employees, which may discourage such lawsuits against us and our directors, officers, and other employees. Alternatively, if a court were to find the choice of forum provision contained in the amended and 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, results of operations, and financial condition.

Additionally, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. As noted above, our Articles provide that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Accordingly, there is uncertainty as to whether a court would enforce such provision. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the forum provisions in our Articles.

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

Our share price may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities litigation, including class action litigation. We may be the target of this type of litigation in the future. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could have a material adverse effect on our business, financial condition, and results of operations. Any adverse determination in litigation could also subject the Company to significant liabilities.

Because we have no current plans to pay cash dividends on our common stock for the foreseeable future, you may not receive any return on investment unless you sell our common stock for a price greater than that which you paid for it.

We may retain future earnings, if any, for future operations, expansion and debt repayment and have no current plans to pay any cash dividends for the foreseeable future. Any decision to declare and pay dividends in the future will be made at the discretion of our board of directors and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions and other factors that our board of directors may deem relevant. In addition, our ability to pay dividends may be limited by covenants of any existing and future outstanding indebtedness we or our subsidiaries incur. As a result, you may not receive any return on an investment in our common stock unless you sell our common stock for a price greater than that which you paid for it.

General Risk Factors

Our business is subject to the risks of earthquakes, fires, floods and other natural catastrophic events, global pandemics and interruptions by man-made problems, such as terrorism or war. Material disruptions of our business or information systems resulting from these events could adversely affect its operating results.

A significant natural disaster, such as an earthquake, fire, flood, hurricane or significant power outage or other similar events, such as infectious disease outbreaks or pandemic events, including the ongoing COVID-19 pandemic, could have an adverse effect on our business and operating results. The ongoing COVID-19 pandemic may have the effect of heightening many of the other risks described in this "Risk Factors" section, such as the demand for our products, its ability to achieve or maintain profitability and its ability to raise additional capital in the future. In addition, natural disasters, acts of terrorism or war could cause disruptions in our remaining manufacturing operations, our or our customers' or channel partners' businesses, suppliers' or the economy as a whole. We also rely on information technology systems to communicate among its workforce and with third parties. Any disruption to our communications, whether caused by a natural disaster or by manmade problems, such as power disruptions, could adversely affect our business. We do not have a formal disaster recovery plan or policy in place and do not currently require that our suppliers' partners have such plans or policies in place. To the extent that any such disruptions result in delays or cancellations of orders or impede our suppliers' ability to timely deliver product components, or the deployment of our products, our business, operating results and financial condition would be adversely affected.

Interruption or failure of our information technology and communications systems could impact ability to effectively provide its products and services.

We plan to include services and functionality that utilize data connectivity to monitor performance and timely capture opportunities to enhance performance and functionality. The availability and effectiveness of our services depend on the continued operation of information technology and communications systems. Our systems will be vulnerable to damage or interruption from, among others, physical theft, fire, terrorist attacks, natural disasters, power loss, war, telecommunications failures, viruses, denial or degradation of service attacks, ransomware, social engineering schemes, insider theft or misuse or other attempts to harm our systems. We utilize reputable third-party service providers or vendors for all of its data other than its source code, and these providers could also be vulnerable to harms similar to those that could damage our systems, including sabotage and intentional acts of vandalism causing potential disruptions. Some of our systems will not be fully redundant, and our disaster recovery planning cannot account for all eventualities. Any problems with our third-party cloud hosting providers could result in lengthy interruptions in our business. In addition, our services and functionality are highly technical and complex technology which may contain errors or vulnerabilities that could result in interruptions in our business or the failure of its systems.

We are subject to cybersecurity risks to operational systems, security systems, infrastructure, and customer data processed by us or third-party vendors or suppliers and any material failure, weakness, interruption, cyber event, incident or breach of security could prevent us from effectively operating its business.

We are at risk for interruptions, outages and breaches of: operational systems, including business, financial, accounting, product development, data processing or production processes, owned by us or our third-party vendors or suppliers; facility security systems, owned by us or our third-party vendors or suppliers; in-product technology owned by us or our third-party vendors or suppliers; or customer or driver data that we process or our third-party vendors or suppliers process on our behalf. Such cyber incidents could materially disrupt operational systems; result in loss of funds, intellectual property, trade secrets or other proprietary or competitively sensitive information; compromise certain information of customers, employees, suppliers, drivers or others; or jeopardize the security of our facilities. A cyber incident could be caused by disasters, insiders (through inadvertence or with malicious intent) or malicious third parties (including nation-states or nation-state supported actors) using sophisticated, targeted methods to circumvent firewalls, encryption and other security defenses, including hacking, fraud, trickery or other forms of deception.

In February 2022, we became aware that we had been a victim of a criminal fraud commonly referred to as "business email compromise fraud." The incident involved impersonation of one of our senior personnel through unauthorized access to his email account which resulted in a diversion of funds to unknown parties and a loss of $136,000 for the year ended December 31, 2021. Subsequent to December 31, 2021, as part of the same incident, an additional $590,000 was diverted, resulting in a total loss of $726,000, before we became aware of the problem. We notified federal law enforcement (FBI) and the relevant bank involved, which are working with us to recover the amount lost. At this time, we have recovered insurance proceeds of $300,000 to partially offset the loss. We retained TCG Technologies to assist in our cyber investigation and remedial measures. Based on our investigation to date, the incident was financially motivated and impacted a single email account. In response to the incident, we conducted a review of our corporate information technology and email policies and are implementing additional security and training measures, including full penetration test (PEN test) of our network, enacted multi-factor authorization (MFA) protocols, implemented an employee education program, and implementing improvements to current network.

The techniques used by cyber attackers change frequently and may be difficult to detect for long periods of time. Although we maintain information technology measures designed to protect itself against intellectual property theft, data breaches and other cyber incidents, such measures will require updates and improvements, and we cannot guarantee that such measures will be adequate to detect, prevent or mitigate cyber incidents. The implementation, maintenance, segregation and improvement of these systems requires significant management time, support and cost. Moreover, there are inherent risks associated with developing, improving, expanding and updating current systems, including the disruption of our data management, procurement, production execution, finance, supply chain and sales and service processes. These risks may affect our ability to manage our data and inventory, procure parts or supplies or produce, sell, deliver and service our products, adequately protect intellectual property or achieve and maintain compliance with, or realize available benefits under, applicable laws, regulations and contracts. We cannot be sure that the systems upon which we rely, including those of its third-party vendors or suppliers, will be effectively implemented, maintained or expanded as planned. If we do not successfully implement, maintain or expand these systems as planned, its operations may be disrupted, its ability to accurately and timely report its financial results could be impaired, and deficiencies may arise in its internal control over financial reporting, which may impact our ability to certify our financial results. Moreover, our proprietary information or intellectual property could be compromised or misappropriated and its reputation may be adversely affected. If these systems do not operate as we expect them to, we may be required to expend significant resources to make corrections or find alternative sources for performing these functions.

A significant cyber incident could impact production capability, harm our reputation, cause us to breach our contracts with other parties or subject us to regulatory actions or litigation, any of which could materially affect our business, prospects, financial condition and operating results. In addition, as was the case with the fraud discovered in February 2022, our insurance coverage for cyber-attacks may not be sufficient to cover all the losses we may experience as a result of a cyber-incident.

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

Options to purchase an aggregate of 364,200 shares of the Company's common stock at an exercise price of $2.77 per share were issued pursuant to the 2022 Plan on August 9, 2022. The offer, sale and issuance of the securities described herein were deemed to be exempt from registration either under Rule 506 promulgated under the Securities Act or under Section 4(a)(2) of the Securities Act in that the transactions were between an issuer and its employee and did not involve any public offering within the meaning of Section 4(a)(2). The recipient of such securities was an executive officer and they received the securities under our equity incentive plan.

As previously disclosed in the Company's Current Report on Form 8-K filed on August 31, 2022, the Company entered into a purchase agreement (the "Purchase Agreement") with Arena Business Solutions Global SPC II, Ltd. ("Arena"), pursuant to which Arena committed to purchase up to $15.0 million (the "Commitment Amount") of the Company's common stock, at the Company's direction from time to time, subject to the satisfaction of the conditions in the Purchase Agreement. The Commitment Amount is subject to increase, at the Company's option, to $30.0 million of common stock. During the three months ended September 30, 2022,

we (i) issued an aggregate of 296,181 shares of common stock to Arena as commitment fee shares, with an aggregate value of $650,000 based on a price per share equal to the simple average daily VWAP of the common stock during the ten trading days immediately preceding the date on which the SEC declared the registration statement covering the resale of the shares of common stock to be sold to Arena effective as previously reported, and (ii) sold an aggregate of 420,000 shares of common stock to Arena pursuant to the Purchase Agreement at a weighted-average price of $1.78 per share for aggregate consideration of $0.7 million. The purchase price of the shares sold to Arena was equal to 96% of the simple average of the daily VWAP of our common stock immediately preceding the time of sale, as computed under the Purchase Agreement. The issuances of the shares of the Company's common stock described herein were deemed to be exempt from registration under Section 4(a)(2) of the Securities Act as a sale to an "accredited investor" as defined in Rule 501(a) of the Securities Act.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description
2.1	Business Combination Agreement, dated as of January 31, 2022, among the Registrant, OTR Acquisition Corp., CLS Sub Merger 1 Corp., CLS Sub Merger 2 Corp. and Comera Life Sciences, Inc. (incorporated by reference to Exhibit 2.1 to the Quarterly Report on Form 10-Q filed by the Registrant with the SEC on August 15, 2022).
2.2	First Amendment to Business Combination Agreement, dated as of May 19, 2022 among the Registrant, OTR Acquisition Corp., CLS Sub Merger 1 Corp., CLS Sub Merger 1 Corp. and Comera Life Sciences, Inc. (incorporated by reference to Exhibit 2.2 to the Current Report on Form 8-K filed by the Registrant with the SEC on May 25, 2022).
3.1	Amended and Restated Certificate of Incorporation of the Registrant of the Registrant (incorporated by reference to Exhibit 3.1 to the Quarterly Report on Form 10-Q filed by the Registrant with the SEC on August 15, 2022).
3.2	Certificate of Designation of the Series A Convertible Perpetual Preferred Stock (incorporated by reference to Exhibit 3.3 to the Current Report on Form 8-K filed by the Registrant with the SEC on May 25, 2022).
3.3	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.3 to the Quarterly Report on Form 10-Q filed by the Registrant with the SEC on August 15, 2022).
10.1	Purchase Agreement, dated August 31, 2022, between the Registrant and Arena Business Solutions Global SPC II, Ltd. (incorporated by reference to exhibit 10.1 to the Current Report on Form 8-K filed by the Registrant with the SEC on August 31, 2022).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

SIGNATURES

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

COMERA LIFE SCIENCES HOLDINGS, INC.

Date: November 14, 2022

By: /s/ Jeffrey S. Hackman
Name: Jeffrey S. Hackman
Title: Chairman, President and Chief Executive Officer
(Principal Executive Officer)

Date: November 14, 2022

By: /s/ Michael Campbell
Name: Michael Campbell
Title: Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jeffrey Hackman, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q (this "report") of Comera Life Sciences Holdings, Inc. (the "registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) [Omitted];
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to affect adversely the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2022

By: /s/ Jeffrey S. Hackman

Jeffrey S. Hackman

Chairman, President and Chief Executive Officer

(*Principal Executive Officer*)

Exhibit 31.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael Campbell, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q (this "report") of Comera Life Sciences Holdings, Inc. (the "registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) [Omitted];
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to affect adversely the registrant's ability to record, process, summarize and report financial information; and
    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2022

By: /s/ Michael Campbell

Michael Campbell

Executive Vice President and Chief Financial Officer

(*Principal Financial Officer and Principal Accounting Officer*)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Comera Life Sciences Holdings, Inc. (the "Company") for the period ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned Chairman, President and Chief Executive Officer of the Company, certifies, to the best knowledge and belief of the signatory, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

/s/ Jeffrey S. Hackman

Jeffrey S. Hackman

Chairman, President and Chief Executive Officer

(*Principal Executive Officer*)

Date: November 14, 2022

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Comera Life Sciences Holdings, Inc. (the "Company") for the period ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned Executive Vice President and Chief Financial Officer of the Company, certifies, to the best knowledge and belief of the signatory, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

/s/ Michael Campbell

Michael Campbell

Executive Vice President and Chief Financial Officer

(*Principal Financial Officer and Principal Accounting Officer*)

Date: November 14, 2022