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

FORM 10-Q

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

For the quarterly period ended March 31, 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 001-39990

ANGION BIOMEDICA CORP

(Exact name of registrant as specified in its charter)

Delaware	**11-3430072**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
51 Charles Lindbergh Boulevard Uniondale, New York	**11553**
(Address of Principal Executive Offices)	**(Zip Code)**

(415) 655-4899

Registrant's telephone number, including area code

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.01	ANGN	The Nasdaq Global Select Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting 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 Act). Yes ☐ No ☒

The number of shares of the issuer’s common stock outstanding as of May 13, 2022 was 29,958,840.

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Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Any statements contained in this Quarterly Report on Form 10-Q that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “positioned,” “seek,” “should,” “target,” “will,” “would,” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the potential benefits, activity, effectiveness and safety of our product candidates;
- the success and timing of our preclinical studies and clinical trials, including the timing and availability of data from such clinical trials;
- the primary endpoints to be utilized in our clinical trials;
- the scope, progress, expansion, and costs of developing and commercializing our product candidates;
- our dependence on existing and future collaborators for commercializing product candidates in the collaboration;
- our receipt and timing of any milestone payments or royalties under any existing or future research collaboration and license agreements or arrangements;
- the potential effects of the COVID-19 pandemic on our business and operations, results of operations and financial performance;
- the potential adverse effects of any regional armed conflicts on our business and operations, results of operations and financial performance;
- the size and growth of the potential markets for our product candidates and the ability to serve those markets;
- our expectations regarding our expenses and revenue, the sufficiency of our cash resources, and needs for additional financing;
- regulatory developments in the United States and other countries;
- the rate and degree of market acceptance of any future products;
- the implementation of our business model and strategic plans for our business and product candidates, including additional indications which we may pursue;
- our expectations regarding competition;
- our anticipated growth strategies;
- the performance of third-party manufacturers;
- our ability to establish and maintain development partnerships;
- our expectations regarding federal, state, and foreign regulatory requirements;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- the successful development for our sales and marketing capabilities;
- the hiring and retention of key scientific or management personnel; and
- the anticipated trends and challenges in our business and the market in which we operate.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this Quarterly Report on Form 10-Q.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We discuss these risks in greater detail in “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our management’s beliefs and assumptions only as of the date of this Quarterly Report on Form 10-Q. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business and the markets for certain drugs, including data regarding the estimated size of those markets, their projected growth rates and the incidence of certain medical conditions. Information that is based on estimates, forecasts, projections or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by third parties, industry, medical and general publications, government data and similar sources. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

Trademarks

This Quarterly Report on Form 10-Q includes trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included in this Quarterly Report on Form 10-Q are the property of their respective owners.

Part I FINANCIAL INFORMATION

Item 1. Financial Statements

ANGION BIOMEDICA CORP.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)
(unaudited)

	March 31, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 73,002	$ 88,756
Grants receivable	—	806
Prepaid expenses and other current assets	3,237	1,685
Total current assets	76,239	91,247
Property and equipment, net	419	451
Operating lease right-of-use assets	3,790	3,986
Investments in related parties	732	723
Other assets	78	106
Total assets	**$ 81,258**	**$ 96,513**
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 3,433	$ 4,710
Accrued expenses	5,242	3,219
Operating lease liabilities, current	918	894
Financing obligation, current	60	58
Deferred revenue, current	653	2,301
Warrant liability	75	114
Total current liabilities	10,381	11,296
Operating lease liabilities, noncurrent	3,236	3,475
Financing obligation, noncurrent	219	235
Other liabilities, noncurrent	220	—
Total liabilities	14,056	15,006
Commitments and contingencies (Note 9)		
Stockholders' equity		
Common stock, $0.01 par value per share; 300,000,000 and 300,000,000 shares authorized, 29,959,425 and 29,959,060 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	300	300
Additional paid-in capital	296,476	296,445
Accumulated other comprehensive loss	(199)	(103)
Accumulated deficit	(229,375)	(215,135)
Total stockholders' equity	67,202	81,507
Total liabilities and stockholders' equity	**$ 81,258**	**$ 96,513**

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

ANGION BIOMEDICA CORP.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2022	**2021**
Revenue:		
Contract revenue	$ 1,648	$ 371
Total revenue	1,648	371
Operating expenses:		
Research and development	11,667	14,298
General and administrative	4,466	6,012
Total operating expenses	16,133	20,310
Loss from operations	**(14,485)**	**(19,939)**
Other income (expense)		
Change in fair value of warrant liability	39	(3,519)
Change in fair value of convertible notes	—	(7,469)
Change in fair value of Series C convertible preferred stock	—	(3,592)
Foreign exchange transaction (loss) gain	111	(53)
Earnings from equity method investment	9	55
Interest income (expense), net	86	(2,170)
Total other income (expense)	245	(16,748)
Net loss	**(14,240)**	**(36,687)**
Other comprehensive income:		
Foreign currency translation adjustment	(96)	46
Comprehensive loss	**$ (14,336)**	**$ (36,641)**
Net loss per common share, basic and diluted	$ (0.48)	$ (1.56)
Weighted average common shares outstanding, basic and diluted	29,959,251	23,443,851

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

ANGION BIOMEDICA CORP.
Condensed Consolidated Statements of Stockholders' Equity (Deficit)
(in thousands, except share amounts)
(unaudited)

	Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2021	29,959,060	$ 300	—	$ —	$ 296,445	$ (103)	$ (215,135)	$ 81,507
Issuance of common stock upon net settlement of restricted stock units and performance stock units	365	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	31		—	31
Foreign currency translation adjustment	—	—	—	—	—	(96)	—	(96)
Net loss	—	—	—	—	—	—	(14,240)	(14,240)
Balance as of March 31, 2022	29,959,425	$ 300	—	$ —	$ 296,476	$ (199)	$ (229,375)	$ 67,202

	Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2020	15,632,809	$ 156	(316,088)	$ (1,846)	$ 72,136	$ (333)	$ (160,562)	$ (90,449)
Issuance of common stock upon initial public offering, net of issuance costs, discount, and commissions of $9.3 million	5,750,000	58	—	—	82,657	—	—	82,715
Issuance of common stock upon Concurrent Private Placement, net of issuance costs of $0.7 million	1,562,500	16	—	—	24,234	—	—	24,250
Conversion of convertible preferred stock into common stock upon initial public offering	2,234,640	22	—	—	35,732	—	—	35,754
Conversion of convertible notes into common stock upon initial public offering	3,636,189	36	—	—	58,143	—	—	58,179
Conversion of convertible notes prior to initial public offering	33,978	—	—	—	460	—	—	460
Net exercise of warrants upon initial public offering	844,335	9	—	—	13,500	—	—	13,509
Exercise of broker warrants	47,188	—	—	—	—	—	—	—
Exercise of warrants	107,038	1	—	—	679	—	—	680
Exercise of stock options	155	—	—	—	1	—	—	1
Issuance of common stock upon vesting of restricted stock units and performance stock units	204,774	2	—	—	11	—	—	13
Return of common stock to pay withholding taxes on restricted stock	—	—	(77,060)	(1,145)	—	—	—	(1,145)
Stock-based compensation	—	—	—	—	5,117	—	—	5,117
Foreign currency translation adjustment	—	—	—	—	—	46	—	46
Net loss	—	—	—	—	—	—	(36,687)	(36,687)
Balance as of March 31, 2021	30,053,606	$ 300	(393,148)	$ (2,991)	$ 292,670	$ (287)	$ (197,249)	$ 92,443

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

ANGION BIOMEDICA CORP.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Three Months Ended March 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (14,240)	$ (36,687)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	32	6
Amortization of right-of-use assets	196	149
Amortization of debt issuance costs	—	1,884
Stock-based compensation	31	5,117
Change in fair value of convertible notes	—	7,469
Change in fair value of Series C convertible preferred stock	—	3,592
Change in fair value of warrant liability	(39)	3,519
Earnings from equity method investment	(9)	(67)
Distribution from equity investment	—	12
Changes in operating assets and liabilities:		
Grants receivable	806	—
Prepaid expenses and other current assets	(1,515)	2,667
Other assets	28	(38)
Accounts payable	(1,323)	1,112
Accrued expenses	2,023	(769)
Lease liabilities	(215)	(146)
Deferred revenue	(1,648)	(371)
Other liabilities, noncurrent	220	—
Net cash used in operating activities	(15,653)	(12,551)
Cash flows from investing activities:		
Purchases of fixed assets	—	(41)
Net cash used in investing activities	—	(41)
Cash flows from financing activities:		
Net proceeds from issuance of common stock upon initial public offering and Concurrent Private Placement, net of discount and commissions	—	110,560
Payment of deferred offering costs	—	(1,665)
Taxes paid related to net share settlement upon vesting of restricted stock awards	—	(1,145)
Proceeds from RSU settlement	—	13
Payment of financing obligation	(14)	—
Exercise of warrants	—	680
Exercise of stock options	—	1
Net cash provided by (used in) financing activities	(14)	108,444
Effect of foreign currency on cash	(87)	(3)
Net increase (decrease) in cash and cash equivalents	(15,754)	95,849
Cash and cash equivalents at the beginning of the period	88,756	34,607
Cash and cash equivalents at the end of the period	**$ 73,002**	**$ 130,456**
Supplemental disclosure of noncash investing and financing activities:		
Conversion of convertible notes into common stock upon initial public offering	$ —	$ 58,179
Conversion of Series C preferred stock into common stock upon initial public offering	$ —	$ 35,754
Net exercise of warrants upon initial public offering	$ —	$ 13,509
Right-of-use assets obtained in exchange for operating lease liabilities	$ —	$ 618
Conversion of convertible notes into common stock prior to initial public offering	$ —	$ 460
Deferred offering costs in accrued expenses or accounts payable	$ —	$ 1,408
Fixed assets purchased in accrued expenses or accounts payable	$ —	$ 55

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

ANGION BIOMEDICA CORP.
Notes to Unaudited Interim Condensed Consolidated Financial Statements

Note 1—Description of the Business and Financial Condition

Angion Biomedica Corp. ("Angion" or, the "Company") is a clinical biopharmaceutical company focused on the discovery, development and commercialization of novel small molecule therapeutics to address acute organ injuries and fibrotic diseases. The Company was incorporated in Delaware in 1998.

Initial Public Offering and the Concurrent Private Placement

On February 9, 2021, the Company's registration statement on Form S-1 (File No. 333-252177) relating to its initial public offering ("IPO") of common stock became effective. The IPO closed on February 9, 2021 at which time the Company issued 5,750,000 shares of its common stock at a price to the public of $16.00 per share, which included the full exercise by the underwriters of their option to purchase an additional 750,000 shares of common stock. In addition to the shares being sold in the IPO, the Company sold an additional 1,562,500 shares of its common stock at the public offering price of $16.00 per share to entities affiliated with Vifor International, Ltd., an existing stockholder (the "Concurrent Private Placement") for gross proceeds of $25.0 million.

The IPO and Concurrent Private Placement generated aggregate net proceeds of approximately $107.0 million, after deducting the underwriting discounts and commissions, private placement fee and offering expenses payable by the Company.

In connection with the closing of the IPO, all outstanding shares of convertible preferred stock and outstanding convertible notes automatically converted into shares of common stock. Subsequent to the closing of the IPO, there were no shares of convertible preferred stock outstanding and there were no convertible notes outstanding. In connection with the closing of the IPO, the Company restated its Restated Certificate of Incorporation to change the authorized capital stock to 300,000,000 shares designated as common stock, and 10,000,000 shares designated as preferred stock, with a par value of $0.01 per share and $0.01 per share, respectively.

Reduction in Force

On January 4, 2022, the Company announced a reduction in force impacting somewhat less than half of its employees. The Company's decision to engage in this reduction resulted from an assessment of its internal resources needs, given the results of the Phase 3 study of ANG-3777 in patients at risk for delayed graft function (DGF) would likely not support a regulatory approval in that population and the Phase 2 study in CSA-AKI would not support a Phase 3 trial in that indication. This reduction was a cost-cutting measure across the organization to support the Company's 2022 primary focus on the clinical development of its investigational asset ANG-3070, a highly selective, oral tyrosine kinase receptor inhibitor in development as a treatment for fibrotic diseases, particularly in the kidney and lung, as well as advancing preclinical assets to IND-enabling studies. In connection with the reduction in force, the Company incurred termination costs, which include severance, benefits, and related costs of approximately $3.2 million, of which $2.7 million was research and development expense and $0.5 million was general and administrative expense. The Company paid $1.1 million during the three months ended March 31, 2022 and expects to pay the remaining $2.1 million, of which $1.9 million is included in accrued expenses, and $0.2 million is included in other liabilities, noncurrent, on or before September 2023.

Liquidity and Capital Resources

Since inception, the Company has devoted substantially all of its efforts and financial resources to conducting research and development activities, including drug discovery and pre-clinical studies and clinical trials, establishing and maintaining its intellectual property portfolio, organizing and staffing the Company, business planning, raising capital and providing general and administrative support for these operations. The Company has incurred losses from operations and negative cash flows from operating activities since inception and expects to continue to incur substantial losses for the next several years as it continues to fully develop and, if approved, commercialize its product candidates. As of March 31, 2022, the Company had $73.0 million in cash and cash equivalents and an accumulated deficit of $229.4 million.

The planned expansion of the Company's clinical and discovery programs will require significant funds. Management expects to continue to incur significant expenses and to incur operating losses for the foreseeable future. The Company has evaluated and concluded there are no conditions or events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern for a period of one year following the date these condensed consolidated financial statements are issued and believes its existing cash and cash equivalents will be sufficient to meet the projected operating requirements well into 2023.

Note 2—Summary of Significant Accounting Policies

Basis of Presentation

The Company's condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”) and include the accounts of the Company, its wholly owned subsidiary, Angion Biomedica Europe Limited, which was dissolved on March 16, 2021, and its wholly owned subsidiary, Angion Pty Ltd., which was established on August 22, 2019. The Company established Angion Pty Ltd., an Australian subsidiary, for the purpose of qualifying for research credits for studies conducted in Australia. All significant intercompany balances and transactions have been eliminated in consolidation. Certain prior period amounts reported in our condensed consolidated financial statements and accompanying notes have been reclassified to conform to the current period presentation.

The Company’s remaining significant accounting policies are described in Note 2 to its consolidated financial statements for the year ended December 31, 2021, included in its Annual Report on Form 10-K. There have been no material changes to the Company’s significant accounting policies during the three months ended March 31, 2022.

Unaudited Interim Financial Information

The condensed consolidated financial statements of the Company included herein have been prepared, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission (the “SEC”). The interim unaudited condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements as of and for the year ended December 31, 2021 and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company’s consolidated financial position, results of operations and comprehensive loss, and cash flows. The condensed consolidated balance sheet as of December 31, 2021 was derived from the audited financial statements as of that date. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted from this Quarterly Report, as is permitted by such rules and regulations. Accordingly, these condensed consolidated financial statements should be read in conjunction with the financial statements and notes thereto included in the Company’s Annual Report on Form 10-K as filed with the SEC on March 30, 2022. The results for any interim period are not necessarily indicative of results for any future period.

Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker (“CODM”) in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business as one operating segment.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that 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 revenue and expenses during the reporting period. On an ongoing basis, management evaluates its estimates, including those related to the useful lives of long-lived assets, the measurement of stock-based compensation, accruals for research and development activities, income taxes and revenue recognition. The Company bases its estimates on historical experience and on other relevant assumptions that are reasonable under the circumstances. Actual results could materially differ from those estimates.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Cash and cash equivalents are financial instruments potentially subject to concentrations of credit risk. The Company's cash and cash equivalents are deposited in accounts at large financial institutions, and amounts may exceed federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risk on its cash balances due to the financial position of the depository institution in which those deposits are held.

Additionally, the Company established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity.

The Company maintains its cash equivalents in securities and money market funds with original maturities less than three months.

The Company has no financial instruments with off-balance sheet risk of loss.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less to be cash equivalents. As of March 31, 2022 and December 31, 2021, the Company’s cash equivalents were held in institutions in the United States and include deposits in a money market fund which were unrestricted as to withdrawal or use.

Fair Value Measurement

Certain assets and liabilities are carried at fair value under GAAP. Fair value is determined using the principles of ASC 820, *Fair Value Measurement*. Fair value is described as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value hierarchy prioritizes and defines the inputs to valuation techniques as follows:

Level 1: Observable inputs such as quoted prices in active markets.

Level 2: Inputs are observable for the asset or liability either directly or through corroboration with observable market data.

Level 3: Unobservable inputs.

The inputs used to measure the fair value of an asset or a liability are categorized within levels of the fair value hierarchy. The fair value measurement is categorized in its entirety in the same level of the fair value hierarchy as the lowest level input that is significant to the measurement.

The Company's cash and cash equivalents, accounts payable and accrued expenses are carried at cost, which approximates fair value due to the short-term nature of these instruments.

Revenue

The Company does not have any products approved for sale and has not generated any revenue from product sales. The Company’s revenue to date has been primarily derived from government funding consisting of U.S. government grants and contracts and revenue under its license agreements.

Contract Revenue

The Company accounts for revenue earned from contracts with customers under Accounting Standards Update (“ASU”) No. 2014-09, Revenue from Contracts with Customers (Topic 606) (“ASC 606”). Under ASC 606, the Company recognizes revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements within the scope of ASC 606, the Company performs the following five steps:

(1) Identify the contract(s) with a customer;

(2) Identify the performance obligations in the contract;

(3) Determine the transaction price;

(4) Allocate the transaction price to the performance obligations in the contract; and

(5) Recognize revenue when (or as) the Company satisfies a performance obligation.

At contract inception, the Company assesses the goods or services promised within each contract, whether each promised good or service is distinct, and determines those that are performance obligations. The Company then recognizes as revenue the amount of the transaction price allocated to the respective performance obligation when or as the performance obligation is satisfied.

The Company enters into agreements under which it may obtain upfront payments, milestone payments, royalty payments and other fees. Promises under these arrangements may include research licenses, research services, including selection campaign research services for certain replacement targets, the obligation to share information during the research and the participation of alliance managers and in joint research committees, joint patent committees and joint steering committees. The Company assesses these promises within the context of the agreements to determine the performance obligations.

Licenses of Intellectual Property: If a license to its intellectual property is determined to be distinct from the other promises or performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring proportional performance for purposes of recognizing revenue from non-refundable, upfront payments. The Company evaluates the measure of proportional performance each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone payments: The Company evaluates the probability of whether regulatory and development milestones will be reached and estimates the amounts to be included in the transaction price using the most likely amount method. The Company evaluates factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the particular milestone in making this assessment. If it is probable a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. At the end of each reporting period, the Company re-evaluates the probability of achievement of milestones and any related constraint, and if necessary, adjust the estimate of the overall transaction price.

Sales-based milestones and royalties: For sales-based royalties, including milestone payments based on the level of sales, the Company determines whether the sole or predominant item to which the royalties relate is a license. When the license is the sole or predominant item to which the sales-based royalty relates, the Company recognize revenue at the later of: (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any sales-based royalty revenue resulting from any license agreement.

Deferred revenue, which is a contract liability, represents amounts received by the Company for which the related revenues have not been recognized because one or more of the revenue recognition criteria have not been met. The current portion of deferred revenue represents the amount expected to be recognized within one year from the consolidated balance sheet date based on the estimated performance period of the underlying performance obligation. The noncurrent portion of deferred revenue represents amounts expected to be recognized after one year from the condensed consolidated balance sheet date through the end of the performance period of the performance obligation.

Grant Revenue

The Company concluded the Company's government grants are not within the scope of ASC Topic 606 as they do not meet the definition of a contract with a customer. The Company has concluded the grants meet the definition of a contribution and are non-reciprocal transactions, and has also concluded Subtopic 958-605, Not-for-Profit-Entities-Revenue Recognition, does not apply, as the Company is a business entity and the grants are with governmental agencies.

In the absence of applicable guidance under GAAP, the Company developed a policy recognizing grant revenue when the allowable costs are incurred and the right to payment is realized.

The Company believes this policy is consistent with the overarching premise in ASC Topic 606, to ensure revenue recognition reflects the transfer of promised goods or services to customers in an amount reflecting the consideration the Company expects to be entitled to in exchange for those goods or services, even though there is no exchange as defined in ASC Topic 606. The Company believes the recognition of revenue as costs are incurred and amounts become realizable is analogous to the concept of transfer of control of a service over time under ASC Topic 606.

Research and Development

Research and development costs include, but are not limited to, payroll and personnel expenses, laboratory supplies, preclinical studies, compound manufacturing costs, consulting costs and allocated overhead, including rent, equipment, depreciation and utilities. Research and development costs may be offset by research and development refundable tax rebates received by our wholly-owned Australian subsidiary.

The Company has agreements with various Contract Research Organizations (“CROs") and third-party vendors. Research and development accruals of amounts due to the CRO are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development provided, but not yet invoiced, are included in accrued expenses on the condensed consolidated balance sheet. Payments made to CROs under such arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets until the services are rendered. The Company makes judgments and estimates in determining the accrued expenses balance in each reporting period. As actual costs become known, the Company adjusts its accrued expenses. For the three months ended March 31, 2022 and 2021, the Company has not experienced any material differences between accrued costs and actual costs incurred.

Advertising Costs

Advertising costs are expensed as incurred. For the three months ended March 31, 2022 and 2021, advertising costs were not material.

Net Loss Per Share

Basic net loss per share of common stock is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net loss per share excludes the potential impact of common stock options, warrants and unvested shares of restricted stock and restricted stock units because their effect would be anti-dilutive due to the Company's net loss. Since the Company had net losses for the three months ended March 31, 2022 and 2021, basic and diluted net loss per common share are the same.

Recently Issued Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326) Measurement of Credit Losses on Financial Instruments (ASU No. 2016-13), which requires an entity to utilize a new impairment model known as the current expected credit loss (“CECL”) model to estimate its lifetime “expected credit loss” and record an allowance that, when deducted from the amortized cost basis of the financial assets and certain other instruments, including but not limited to, available-for-sale debt securities. Credit losses relating to available-for-sale debt securities will be recorded through an allowance for credit losses rather than as a direct write-down to the security. As an emerging growth company, ASU No. 2016-13 is effective for the Company for fiscal years beginning after December 15, 2022, with early adoption permitted. The Company is currently evaluating the impact of the adoption of ASU No. 2016-13 on its condensed consolidated financial statements.

Note 3—Revenue and Deferred Revenue

Contract Revenue

The Company's contract revenue has been generated from payments received pursuant to a license agreement (the "Vifor License") with Vifor International, Ltd. ("Vifor Pharma"), with headquarters located in Switzerland. The Company recognized revenue from upfront payments over the term of its estimated period of performance using a cost-based input method under Topic 606. The Company expects to continue recognizing revenue from upfront payments related to the Vifor License using the cost-based input method.

Vifor License Agreement

In November 2020, the Company entered into a license agreement with Vifor Pharma, granting Vifor Pharma global rights (excluding China, Taiwan, Hong Kong and Macau) to develop, manufacture and commercialize ANG-3777 in all therapeutic, prophylactic and diagnostic uses for renal indications, including forms of acute kidney injury (AKI), and congestive heart failure (collectively, the Renal Indications). Pursuant to the Vifor License, the Company received $60.0 million in upfront and equity payments, including $30.0 million in up-front cash received in November 2020, and a $30.0 million equity investment, $5.0 million of which was a convertible note that subsequently converted into common stock with the IPO and $25.0 million of which was received in the Concurrent Private Placement with the Company's IPO. The Company is also eligible to receive post-approval milestones of up to approximately $260.0 million and sales-related milestones of up to $1.585 billion, providing a total potential deal value of up to $1.905 billion (subject to certain specified reductions and offsets), plus tiered royalties on net sales of ANG-3777 at royalty rates of up to 40%. Under the Vifor License, the Company is responsible for executing a pre-specified clinical development plan designed to obtain regulatory approvals of ANG-3777 for delayed graft function (DGF) and AKI associated with cardiac surgery involving cardiopulmonary bypass (CSA-AKI). Based on the ANG-3777 clinical trial data disclosed in the fourth quarter of 2021, the Company does not expect to receive any additional clinical, post-approval, or sales milestones, or royalties, as it does not intend to continue to pursue the clinical development plan for ANG-3777 set forth in the Vifor License.

On October 26, 2021, the Company announced that its Phase 3 trial of ANG-3777 in DGF did not achieve its primary endpoint and the data from the Phase 3 trial was not expected to provide sufficient evidence to support an indication in the studied DGF population. On December 9, 2021, the Company announced its Phase 2 trial of ANG-3777 in CSA-AKI did not achieve its primary endpoint and the data from the Phase 2 trial was not expected to provide sufficient evidence to support a Phase 3 trial in the studied CSA-AKI population. Angion and Vifor continue to analyze data from the CSA-AKI trial. The Company does not intend to continue the clinical development plan for ANG-3777 set forth in the Vifor License, which had included a Phase 3 study in CSA-AKI and a Phase 4 confirmatory study in DGF. Based on the ANG-3777 clinical trial data disclosed in the fourth quarter of 2021, the Company does not expect to receive any additional clinical, post-approval, or sales milestones, or royalties, as it does not intend to continue to pursue the current clinical development plan for ANG-3777 set forth in the Vifor License. In 2022, the Company and Vifor Pharma continue to work to complete the planned analyses of the results of the clinical trials announced in the fourth quarter of 2021 and to discuss the future of the collaboration based upon such analyses.

Vifor Pharma may terminate the Vifor License at its sole discretion upon the earlier of (i) the acceptance for filing of an NDA covering products incorporating ANG-3777 filed with the FDA (after completion of the relevant Phase 3 clinical trial for such products), or (ii) the third anniversary of the effective date of the Vifor License. Both the Company and Vifor Pharma may terminate the Vifor License in its entirety if the other is in material breach of the Vifor License and has not cured the breach (if curable) within 60 days, or 90 days for incurable breach. In certain circumstances, in the event of the Company's material breach of the Vifor License, Vifor Pharma may terminate the Vifor License with respect to certain major markets. In addition, both parties have the right to terminate the Vifor License upon insolvency of the other party.

The Company identified the following performance obligations in the Vifor License based upon the clinical development plan for ANG-3777: (1) the global license (excluding greater China), (2) the development services, including the clinical development services including a post-approval confirmatory study, the technical development services and regulatory services and (3) the required participation on Joint Committees for coordination and oversight. The Company determined that the license is not capable of being distinct due to the specialized nature of the development services to be provided by the Company, and, accordingly, this promise was combined with the development services and participation in the joint committees as one single performance obligation.

In order to determine the transaction price, the Company evaluated all the payments to be received during the duration of the contract. Certain milestones and additional fees were considered variable consideration, which were not included in the transaction price at contract inception. The Company determined the transaction price at the inception of the Vifor License was $15.0 million, which represents 50% of the $30.0 million upfront payment due to the potential setoff defined in the contract. The Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

Based on the ANG-3777 clinical trial data disclosed in the fourth quarter of 2021 and the Company's decision to discontinue the current clinical development plan for ANG-3777 DGF as described above, the Company adjusted the transaction price to include an additional $15.0 million in previously constrained variable consideration. The Company also reassessed the performance period as the Company is currently closing out the planned analyses from both trials. The Company plans to fully conclude these analyses by the end of December 2022 and complete its performance obligation under the Vifor License. As a result, the Company revised the total estimated costs for completion of the performance obligation to reflect the winding down of ANG-3777-related studies by December 2022.

Using the cost-based input method, the Company recognizes revenue based on actual costs incurred as a percentage of total estimated costs as the Company completes its performance obligation. The cumulative effect of revisions to estimated costs to complete the Company's performance obligation will be recorded in the period in which changes are identified and amounts can be reasonably estimated. These actual costs consist primarily of internal full time equivalent (FTE) efforts and third-party contract costs related to the Vifor License.

For the three months ended March 31, 2022 and 2021, the Company recognized contract revenue related to the Vifor License of $1.6 million and $0.4 million, respectively. As of March 31, 2022 and December 31, 2021, $0.7 million and $2.3 million, respectively, was recorded as deferred revenue, current, on the condensed consolidated balance sheets related to the Vifor License.

Note 4—Fair Value Measurements

The following tables present the Company's financial assets and liabilities measured at fair value on a recurring basis and their assigned levels within the fair value hierarchy (in thousands):

	March 31, 2022			
	Level 1	Level 2	Level 3	Total
Money market funds[1]	$ 70,843	$ —	$ —	$ 70,843
Total assets	$ 70,843	$ —	$ —	$ 70,843
Warrant liabilities	$ —	$ —	$ 75	$ 75
Total liabilities	$ —	$ —	$ 75	$ 75

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
Money market funds[1]	$ 87,252	$ —	$ —	$ 87,252
Total assets	$ 87,252	$ —	$ —	$ 87,252
Warrant liabilities	—	—	114	114
Total liabilities	$ —	$ —	$ 114	$ 114

(1) Included in cash and cash equivalents on the condensed consolidated balance sheets. This balance includes cash requirements settled on a nightly basis.

There were no transfers made among the three levels in the fair value hierarchy during periods presented.

The following table presents a summary of changes in the fair value of the Company's common stock warrant liability (in thousands):

	March 31, 2022	December 31, 2021
Balance, beginning of the period	$ 114	$ 10,704
Net exercise of warrants	—	(13,509)
Change in fair value	(39)	2,919
Balance, end of the period	$ 75	$ 114

The fair value of the warrants issued by the Company has been estimated using a variant of the Black Scholes option pricing model. The underlying equity included in the Black Scholes option pricing model was valued based on the equity value implied from sales of preferred and common stock at each measurement date. The fair value of the warrants was impacted by the model selected as well as assumptions surrounding unobservable inputs including the underlying equity value, expected volatility of the underlying equity, risk free interest rate and the expected term.

The Company records the change in the fair value of common stock warrants in change in fair value of warrant liability in the condensed consolidated statements of operations.

The fair value of the common stock warrant liability was estimated using the following assumptions:

	March 31, 2022	December 31, 2021
Weighted average strike price	$7.60	$7.60
Contractual term (years)	6.4	6.7
Volatility (annual)	119.0%	124.0%
Risk-free rate	2.4%	1.4%
Dividend yield (per share)	0.0%	0.0%

Note 5—Balance Sheet Components

Property and Equipment, Net

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

	March 31, 2022	December 31, 2021
Equipment	$ 866	$ 866
Furniture and fixtures	34	34
Leasehold improvements	68	68
Total property and equipment	968	968
Less: accumulated depreciation	(549)	(517)
Property and equipment, net	$ 419	$ 451

Depreciation expense for each of the three months ended March 31, 2022 and 2021 was immaterial.

Prepaid and Other Current Assets

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

	March 31, 2022	December 31, 2021
Angion Pty tax credit receivable	$ 21	$ 781
Prepaid insurance	2,625	275
Security deposit	131	131
Other	460	498
Total prepaid and other current assets	$ 3,237	$ 1,685

Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2022	December 31, 2021
Accrued compensation	$ 1,250	$ 2,023
Accrued restructuring	1,899	—
Accrued direct research costs	1,642	764
Accrued operating expenses	451	432
Total accrued expenses	$ 5,242	$ 3,219

Note 6—Stockholders' Equity

Common Stock

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are not entitled to receive dividends, unless declared by the board of directors.

Note 7—Stock-Based Compensation

2015 Plan

In June 2019, the Company approved an Amended and Restated 2015 Equity Incentive Plan (the "2015 Plan") permitting the granting of incentive stock options, non-statutory stock options, restricted stock and other stock-based awards. Following the effectiveness of the 2021 Equity Incentive Plan ("2021 Plan"), the Company ceased making grants under the 2015 Plan. However, the 2015 Plan continues to govern the terms and conditions of the outstanding awards granted under it. Shares of common stock subject to awards granted under the 2015 Plan that cease to be subject to such awards by forfeiture or otherwise after the termination of the 2015 Plan will be available for issuance under the 2021 Plan.

2021 Plan

On January 25, 2021, the Company's board of directors approved the 2021 Plan which permits the granting of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards to employees, directors, officers and consultants. On January 25, 2021, shares of common stock equal to 11% of the post-IPO capitalization were authorized for issuance under the 2021 Plan. The 2021 Plan provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2022, by the lesser of 5% of the Company's common stock outstanding on the immediately preceding December 31, or such lesser number of shares as determined by the Company's board of directors.

Stock Options

The fair value of each employee and non-employee stock option grant was estimated on the date of grant using the Black-Scholes option-pricing model based on the following assumptions:

	Three Months Ended March 31,	
	2022	2021
Risk-free interest rate	1.7%	0.7%
Expected dividend yield	0.0%	0.0%
Expected term in years	5.9	6.0
Expected volatility	71.8%-72.5%	73.8%-86.8%

Each of these inputs is subjective and generally requires significant judgment.

Expected Term—The expected term represents the period the Company's stock-based awards are expected to be outstanding and is determined using the simplified method, which is based on the mid-point between the contractual term and vesting period.

Volatility—The Company determines volatility based on the historical volatilities of comparable publicly traded life science companies over a period equal to the expected term because it does not have sufficient trading history for its common stock price. The comparable companies were chosen based on the similar size, stage in the life cycle, or area of specialty. The Company will continue to apply this process until a sufficient amount of historical information regarding volatility on its own stock becomes available.

Risk-Free Interest Rate—The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award.

Dividend Yield—The Company has never paid and has no plans to pay any dividends on its common stock. Therefore, the Company has used an expected dividend yield of zero.

Fair Value of Common Stock—For periods prior to the IPO, the Company determined the estimated fair value of its common stock using the Subject Company Transaction Method which includes the back-solve and scenario-based methods (Probability Weighted Expected Return Method) to arrive at estimated fair values. Subsequent to the IPO, the fair value was based on the closing price of the Company's common stock on the grant date.

The following table summarizes information and activity related to the Company's stock options:

	Number of Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Total Intrinsic Value (in thousands)
Outstanding as of December 31, 2021	4,230,162	$ 8.92	8.4	$ —
Options granted	2,188,700	1.93		
Options forfeited	(391,106)	11.14		
Options exercised	—	—		
Options expired	(212,909)	9.26		
Outstanding as of March 31, 2022	5,814,847	$ 6.13	8.0	$ 406
Options vested and exercisable	2,554,368	$ 7.43	6.0	$ —

The aggregate intrinsic value in the above table is calculated as the difference between the estimated fair value of the Company's common stock price and the exercise price of the stock options. The weighted average grant date fair value per share for the stock option grants during the three months ended March 31, 2022 and 2021 was $1.19 and $8.86, respectively. As of March 31, 2022, the total unrecognized compensation related to unvested stock option awards granted was $5.9 million, which the Company expects to recognize over a weighted-average period of approximately 3.0 years.

Restricted Stock Units (RSUs)

The following table summarizes information and activity related to the Company's RSUs:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value Per Share
Outstanding at December 31, 2021	17,504	$ 9.51
Granted	—	$ —
Vested	(365)	$ 9.51
Outstanding at March 31, 2022	17,139	$ 9.51
Vested as of March 31, 2022	365	$ 9.51

Performance-based Restricted Stock Units (PSUs)

The Company had 556,530 PSUs outstanding that were granted in June 2019. Vesting of the PSUs is dependent upon the satisfaction of both a service condition and a performance condition, an initial public offering or a change of control, as defined in the 2015 Plan. As the IPO occurred in February 2021, the performance condition was met and 185,510 PSUs vested and were released upon the closing of the IPO. Another 185,510 PSUs vested and were released in June 2021 upon the second anniversary of the grants. As of March 31, 2022, the Company had 185,510 PSUs outstanding.

Stock-based Compensation Expense

The following table summarizes total stock-based compensation expense recorded in the condensed consolidated statements of operations (in thousands):

	Three Months Ended March 31,	
	2022	2021
Research and development	$ (448)	$ 2,543
General and administrative	479	2,574
Total	$ 31	$ 5,117

The decrease in total stock-based compensation expense for the three months ended March 31, 2022 is primarily due to the reversal of expense upon the forfeiture of awards in connection with the reduction in force event that occurred on January 4, 2022. See Note 1 for additional information.

Employee Stock Purchase Plan

In January 2021, the board of directors of the Company approved the Employee Stock Purchase Plan (the “ESPP”). The ESPP was effective on the date immediately prior to the effectiveness of the Company's registration statement relating to the IPO. A total of 390,000 shares of common stock were initially reserved for issuance under the ESPP. The ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2022, by the lesser of 1% of the Company’s common stock outstanding on the immediately preceding December 31, or such lesser number of shares as determined by the Company’s board of directors. The offering period and purchase period will be determined by the board of directors. As of March 31, 2022, 390,000 shares under the ESPP remain available for purchase and no offerings have been authorized.

Note 8—Warrants

As of March 31, 2022 and December 31, 2021, outstanding warrants to purchase the Company's common stock consisted of the following:

	Classification	Exercise Price	Expiration Date	March 31, 2022	December 31, 2021
Warrants issued with Conversion of Notes to Common Stock	Equity	$ 8.03	8/31/23	232,287	232,287
Warrants issued with Units in the Equity Offering	Equity	$ 8.03	8/31/23	875,034	875,034
Broker Warrants issued with Equity Offering	Equity	$ 0.01	8/31/25	1,297	1,297
Consultant Warrants	Liability	$ 7.60	8/31/28	39,505	39,505
Total Warrants				1,148,123	1,148,123

In accordance with ASC 815, the warrants classified as liabilities are recorded at fair value at the issuance date, with changes in the fair value recognized in the condensed consolidated statements of operations at the end of each reporting period. Refer to Note 4 for changes in the fair value recognized during the periods reported.

In accordance with ASC 815, the warrants classified as equity do not meet the definition of a derivative and are classified in stockholders' equity in the condensed consolidated balance sheets.

There was no warrant activity during the three months ended March 31, 2022.

Note 9—Commitments and Contingencies

Operating Leases

The Company leases office and laboratory space in Uniondale, New York from NovaPark, a related party, under an agreement classified as an operating lease expiring on June 20, 2026. The Company's lease does not require any contingent rental payments, impose any financial restrictions, or contain any residual value guarantees. Variable expenses generally represent the Company's share of the landlord's operating expenses, including management fees. The Company does not act as a lessor or have any leases classified as financing leases.

The Company leased office space in Fort Lee, New Jersey, comprising approximately 2,105 square feet for approximately $0.1 million per year, under a non-cancelable operating lease through March 31, 2022. However, this arrangement is excluded from the calculation of lease liabilities and right of use assets as its term is less than one year. The lease was subject to charges for common area maintenance and other costs. The Company did not renew the New Jersey lease and it expired on March 31, 2022.

In July 2020, the Company entered into a lease for office furniture in San Francisco, California set to expire in July 2025, with an immaterial annual lease payment.

In February 2021, the Company entered into a lease for clinical and regulatory space in Newton, Massachusetts (the “Newton lease”), comprising approximately 6,157 square feet for approximately $0.2 million per year, under a non-cancelable operating lease through June 30, 2024. Pursuant to the Newton lease, the Company had four months of free rent starting from February 15, 2021 to June 14, 2021. The Company has one option to extend the term of the lease for three years with nine months’ notice.

The following table summarizes the components of the Company's operating lease costs (in thousands):

	Three Months Ended March 31,	
	2022	2021
Operating lease cost	$ 413	$ 273
Variable lease cost	52	130
Short-term lease cost	6	39
Total operating lease cost	$ 471	$ 442

The following table summarizes quantitative information about the Company's operating leases (dollars in thousands):

	Three Months Ended March 31,	
	2022	2021
Operating cash flows from operating leases	$ 323	$ 267
Right-of-use assets exchanged for operating lease liabilities	$ —	$ 618
Weighted-average remaining lease term—operating leases (in years)	3.7	4.0
Weighted-average discount rate—operating leases	9.4 %	8.0 %

As of March 31, 2022, maturities of lease liabilities were as follows (in thousands):

Year Ended December 31,	Amounts
2022 (remaining nine months)	$ 968
2023	1,305
2024	1,209
2025	1,104
2026	516
Total	5,102
Less present value discount	(948)
Operating lease liabilities	$ 4,154

Financing obligation

In 2021, the Company entered into an immaterial sale and leaseback arrangement with a third-party financing institution as a financing mechanism to fund certain of its capital expenditures primarily related to operating equipment, whereby the physical asset is sold concurrent with an agreement to lease the asset back. The initial leaseback term is 42 months starting from November 2021. The arrangement includes a renewal option as well as a repurchase option at fair value with a cap at the end of the term. The arrangement does not qualify as an asset sale as control of the equipment did not transfer to the third party and is accounted for as a failed sale-leaseback. Therefore, the Company accounts for the arrangement as a financing transaction and records the proceeds received as a financing obligation. The leased assets are included in property and equipment, net on the condensed consolidated balance sheets and are subject to depreciation.

The following table summarizes quantitative information about the Company's financing obligation for the three months ended March 31, 2022 (dollars in thousands):

Cash flow information:	
Payments of financing obligation	
Operating cash flows from financing obligation	$ 10
Financing cash flows from financing obligation	$ 14
Other information:	
Weighted-average remaining lease term (in years)	3.0
Weighted-average discount rate (in percent)	1.1 %
Carrying value of leased asset included in Property and Equipment, net	$ 254
Depreciation associated with the leased asset	$ 15

As of March 31, 2022, maturities of financing obligation were as follows (in thousands):

Year Ended December 31,	Amounts
2022 (remaining nine months)	$ 71
2023	94
2024	94
2025	31
Total	290
Less present value discount	(11)
Financing obligation	$ 279

Litigation

The Company is not a party to any material legal proceedings and is not aware of any pending or threatened claims. From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities.

Indemnification

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

Note 10—Income Taxes

The Company’s income tax provision was immaterial and the effective tax rate was 0% in each of the three months ended March 31, 2022 and 2021. The difference between the Company's effective tax rate of 0% and the U.S. federal statutory tax rate of 21% is primarily due to net operating losses in this period which are offset by the corresponding valuation allowance. The Company has provided a full valuation allowance against its net deferred tax assets as it is more likely than not such assets would not be realized.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not some portion or all of the deferred tax assets will not be realized. The ultimate realization of the deferred tax assets is dependent upon the generation of future taxable income in which those temporary differences become deductible. Based on the available objective evidence, management believes it is more likely than not the net deferred tax assets at March 31, 2022 will not be realizable. Accordingly, management has maintained a full valuation allowance against its net deferred tax assets at March 31, 2022. Each reporting period, management evaluates the need for a valuation allowance on the Company’s deferred tax assets by jurisdiction and adjust the Company’s estimates as more information becomes available.

The Company is required to recognize the financial statement effects of a tax position when it is more likely than not, based on the technical merits, the position will be sustained upon examination. Tax years starting from 2015 and forward are subject to examination by the U.S. federal and state tax authorities. These years are open due to net operating losses and tax credits remain unutilized from such years. The Company's policy is to recognize interest expense and penalties related to income tax matters as a component of income tax expense. As of March 31, 2022, there were no accruals for interest and penalties related to uncertain tax positions.

Note 11—Employee Benefit Plan

Employee Benefit Plan

The Company sponsors a retirement savings plan intended to qualify for favorable tax treatment under Section 401(a) of the Code, and contains a cash or deferred feature intended to meet the requirements of Section 401(k) of the Code. Participants may make pre-tax and certain after-tax (Roth) salary deferral contributions to the plan from their eligible earnings up to the statutorily prescribed annual limit under the Code. Participants who are 50 years of age or older may contribute additional amounts based on the statutory limits for catch-up contributions. Participant contributions are held in trust as required by law. No minimum benefit is provided under the plan. An employee's interest in his or her salary deferral contributions is 100% vested when contributed. Contributions, subject to established limits, are matched at a dollar for dollar rate up to 3% of an individual's earnings and fifty cents on the dollar on the next 4-5% of earnings.

Note 12—Net Loss Per Share

The following table sets forth the computation of the Company's basic and diluted net loss per share attributable to common stockholders, which excludes shares which are legally outstanding but subject to repurchase by the Company (in thousands, except share and per share data):

	Three Months Ended March 31,	
	2022	2021
Numerator		
Net loss attributable to common stockholders	$ (14,240)	$ (36,687)
Denominator:		
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	29,959,251	23,443,851
Net loss per share attributable to common stockholders, basic and diluted	$ (0.48)	$ (1.56)

The table below provides potentially dilutive securities not included in the calculation of the diluted net loss per share because to do so would be anti-dilutive:

	Three Months Ended March 31,	
	2022	2021
Shares issuable upon exercise of stock options	5,814,847	4,428,897
Shares issuable upon the exercise of warrants	1,148,123	1,171,614
Unvested shares under restricted stock unit grants	202,650	37,440
Unvested shares under restricted stock grants	—	10,938
Total	7,165,620	5,648,889

Note 13—Related Party Transactions

On February 25, 2022, the Company entered into a Separation Agreement with Itzhak D. Goldberg, M.D., who formerly served as Executive Chairman and Chief Scientific Officer and currently serves as a director and Chairman Emeritus on the Company's board of directors. Pursuant to the terms of the Separation Agreement, Dr. Goldberg will receive severance benefits of approximately $1.1 million. Under the 2015 Plan and 2021 Plan, Dr. Goldberg will continue to vest his PSUs and stock options and exercisability of his options, so long as he remains in continuous service with the Company as a director on the board of directors or otherwise.

On March 1, 2022, the Company entered into a Separation Agreement with Elisha Goldberg, former employee and son of Itzhak D. Goldberg, M.D. Pursuant to the terms of the Separation Agreement, Mr. Goldberg will receive severance benefits of approximately $0.5 million. Mr. Goldberg will also have the right to exercise any vested stock options he may have received under the 2015 Plan or 2021 Plan until December 31, 2022, which extended the exercise period by 11 months.

Ohr Investment

In a series of investments in November 2013 and July 2017, the Company invested a total of $150,000 to acquire a membership interest in Ohr Cosmetics, LLC (“Ohr”), an affiliated company.

The Company owns, and the family of the Company's Chairman Emeritus owns, approximately 2.4% and 81.3%, respectively, of the membership interests in Ohr. The Chairman Emeritus' son is the manager of Ohr.

In November 2013, the Company granted Ohr an exclusive worldwide license, with the right to sublicense, under the Company's patent rights covering one of the Company's CYP26 inhibitors, ANG-3522, for the use in treating conditions of the skin or hair. Sublicensees may not grant further sublicenses under the Company's patent rights other than to affiliates of such sublicensees and entities with which sublicensees are collaborating for the research, development, manufacture and commercialization of the products. Ohr will pay the Company a royalty at a rate in the low single digits on gross revenue of products incorporating ANG-3522, and milestone payments potentially totaling up to $9.0 million based on achievement of sales milestones. Royalties and milestone payments will be paid until the later of 15 years from the first commercial sale of a licensed product or the last to expire licensed patent rights. The royalty rate is subject to adjustments under certain circumstances. The Company believes the Ohr License was made on terms no less favorable to the Company than those the Company could obtain from unaffiliated third parties.

No revenue from this license agreement was recognized for the periods presented.

NovaPark Investment and Lease

As of March 31, 2022, the Company had a 10% interest in NovaPark. Members of the Company's Chairman Emeritus’ immediate family own a majority of the membership interests of NovaPark. The Company accounts for its aggregate 10% investment in NovaPark under the equity method.

The following table provides the activity for the NovaPark investment for the three months ended March 31, 2022, and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Beginning balance	$ 723	$ 672
Earnings from equity method investment	9	67
Distribution from NovaPark	—	(12)
Ending balance	$ 732	$ 727

The Company rents office and laboratory space in Uniondale, New York from NovaPark under a lease expiring June 20, 2026. The Company recorded rent expense for fixed lease payments of $0.3 million in each of the three months ended March 31, 2022 and 2021. The Company recorded rent expense for variable expenses related to the lease of $0.1 million for the three months ended March 31, 2022 and 2021. See Note 9.

Convertible Notes

In connection with the IPO in February 2021, Victor Ganzi, Gilbert Omenn and Karen Wilson, directors of the Company, and Raj Venkatesan, brother of the Chief Executive Officer and director of the Company, converted all their outstanding convertible notes into an aggregate of 149,500 shares of common stock with a conversion price of $11.57. As of March 31, 2022, there were no convertible notes outstanding.

Series C Convertible Preferred Stock

In connection with the IPO in February 2021, Jay Venkatesan, M.D., the Chief Executive Officer and director of the Company converted all his outstanding preferred stock into an aggregate of 165,094 shares of common stock with a conversion price of $11.57 per share. As of March 31, 2022, there were no shares of convertible preferred stock outstanding.

Consultant Fees

Angion paid consulting fees under an agreement with the wife of the Company's Chairman Emeritus for Company management services. Consultant fees paid to the wife were immaterial in each of the three months ended March 31, 2022 and 2021. This consultant agreement was terminated in February 2022.

Other

Dr. Michael Yamin, a former member of the board of directors of the Company, is a Scientific Advisor for Pearl Cohen Zedek Latzer Baratz LLP (Pearl Cohen). During the three months ended March 31, 2022 and 2021, the Company paid Pearl Cohen an immaterial amount in legal fees, respectively.

In January 2018, the Company also entered into a consulting agreement with Dr. Yamin pursuant to which he agreed to provide consulting services to the Company in the areas of biomedical research and development. Consultant fees paid to Dr. Yamin were immaterial in in each of the three months ended March 31, 2022 and 2021. Dr. Yamin resigned from the Company's board of directors in March 2020. Dr. Yamin's resignation was not due to any disagreement with the Company, the board or management of the Company.

Note 14—Subsequent Event

On May 12, 2022, the Company was notified by the U.S. Food and Drug Administration (FDA) of the acceptance of an Investigational New Drug (IND) application supporting the clinical development of ANG-3070 in idiopathic pulmonary fibrosis (IPF) and clearance to begin a Phase 1b study of ANG-3070 in patients with IPF. Topline data from this Phase 1b study are expected in 2022.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2021. In addition to the historical financial information, this discussion contains forward-looking statements involving risks, assumptions and uncertainties, such as statements of our plans, objectives, expectations, intentions, forecasts and projections. Our actual results and the timing of selected events could differ materially from those discussed in these forward-looking statements as a result of several factors, including those set forth under the section of this Quarterly Report on Form 10-Q titled "Risk Factors," which you should carefully to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled "Forward-Looking Statements" at the beginning of this report.

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of novel small molecule therapeutics to address chronic and progressive fibrotic diseases. Our goal is to transform the treatment paradigm for patients suffering from these potentially life-threatening conditions for which there are no approved medicines or where existing approved medicines have limitations. Our lead product candidate, ANG-3070, is a highly selective oral tyrosine kinase receptor inhibitor (TKI) in development as a treatment for fibrotic diseases, particularly in the kidney and lung. Enrollment is ongoing in "JUNIPER," a dose-finding Phase 2 trial of ANG-3070 in primary proteinuric kidney diseases (PPKD) and we expect to file an IND in idiopathic pulmonary fibrosis (IPF) by the end of 2022. We are also continuing to develop our preclinical programs. Our ROCK2 program is targeted towards the treatment of fibrotic diseases. Our CYP11B2 program is targeted towards diseases related to aldosterone synthase dysregulation.

Prior to January 2022, our lead product was ANG-3777, a hepatocyte growth factor (HGF) mimetic we were evaluating in multiple indications of acute organ injury, including delayed graft function (DGF) and for the treatment of AKI associated with cardiac surgery involving cardiopulmonary bypass (CSA-AKI). In 2021, we also studied ANG-3777 in patients with severe COVID-19 related pneumonia at high risk for acute respiratory distress syndrome (ARDS). On October 26, 2021, we announced the Phase 3 trial of ANG-3777 in DGF did not achieve its primary endpoint and the data were not expected to be sufficient evidence to support an indication in the studied DGF population. On December 9, 2021, we announced the Phase 2 trial of ANG-3777 in CSA-AKI did not achieve its primary endpoint. We do not intend to continue the clinical development plan for ANG-3777 set forth in the Vifor License, which had included a Phase 3 study in CSA-AKI and a Phase 4 confirmatory study in donor kidney transplant patients who were at risk for developing DGF, given we do not believe the earlier Phase 2 and Phase 3 clinical trial results in the respective indications support a regulatory approval. We have no funds budgeted for additional clinical trials for ANG-3777.

On May 12, 2022, we were notified by the U.S. Food and Drug Administration (FDA) of the acceptance of an Investigational New Drug (IND) application supporting the clinical development of ANG-3070 in idiopathic pulmonary fibrosis (IPF) and clearance to begin a Phase 1b study of ANG-3070 in patients with IPF. Topline data from this Phase 1b study are expected in 2022.

We do not have any products approved for sale and have not generated any revenue from product sales since our inception and do not expect to generate revenue from product sales unless we successfully develop, and we or our collaborators, commercialize our product candidates, which we do not expect to occur for several years, if ever. Our net losses were $14.2 million and $36.7 million for the three months ended March 31, 2022 and 2021, respectively. As of March 31, 2022, we had an accumulated deficit of $229.4 million. We expect to continue to incur net losses for the foreseeable future. As we seek to advance ANG-3070 in clinical trials and our other product candidates through preclinical development, our expenses and operating losses may increase over time.

In addition, if we seek regulatory approval for any of our wholly-owned product candidates or those for which we retain the right to commercialize in the future, we would need to incur additional expenses as we expand our clinical, regulatory, quality, manufacturing and commercialization capabilities, incur significant commercialization expenses for marketing, sales, manufacturing and distribution if we obtain marketing approval for such product candidates.

We rely on third parties in the conduct of our preclinical studies and clinical trials and for manufacturing and supply of our product candidates. We have no internal manufacturing capabilities, and we expect to continue to rely on third parties, many of whom are single-source suppliers, for our preclinical study and clinical trial materials. In addition, we do not yet have a marketing or sales organization or commercial infrastructure. Accordingly, we will incur significant expenses to develop a marketing and sales organization and commercial infrastructure in advance of generating any product sales of wholly-owned product candidates or those for which we retain the right to commercialize.

Furthermore, we will need to make continued investment in development studies, registration activities and the development of commercial support functions including quality assurance and safety pharmacovigilance before we will be in a position to sell any of our product candidates, if approved.

The Initial Public Offering and Concurrent Private Placement

The Initial Public Offering ("IPO") and Concurrent Private Placement, which both closed on February 9, 2021, generated aggregate net proceeds of approximately $107.0 million, after deducting the underwriting discounts and commissions, private placement fee and offering expenses payable by us.

Reduction in Force

On January 4, 2022, we announced a reduction in force impacting less than half of our employees. Our decision to engage in this reduction resulted from an assessment of our internal resources needs, given the results of the Phase 3 study of ANG-3777 in patients at risk for DGF would likely not support a regulatory approval in that population and the Phase 2 study in CSA-AKI would not support a Phase 3 trial in that indication. This reduction was a cost-cutting measure across the organization to support our 2022 primary focus on the clinical development of our investigational asset ANG-3070, a highly selective, oral tyrosine kinase receptor inhibitor in development as a treatment for fibrotic diseases, particularly in the kidney and lung, as well as advancing preclinical assets to IND-enabling studies. In connection with the reduction in force, we incurred termination costs, which include severance, benefits and related costs, of approximately $3.2 million, of which $1.1 million were paid during the three months ended March 31, 2022. We expect to pay the remaining $2.1 million on or before September 2023.

COVID-19 Update

The COVID-19 pandemic has placed strains on the providers of healthcare services, including the healthcare institutions where we conduct our clinical trials. These strains have resulted in institutions prohibiting the initiation of new clinical trials and enrollment in existing trials and restricting the on-site monitoring of clinical trials. We also follow FDA guidance on clinical trial conduct during the COVID-19 pandemic, including the remote monitoring of clinical data.

The global pandemic of COVID-19 continues to rapidly evolve. The extent to which COVID-19 may continue impact our business, including our clinical trials, and financial condition will depend on future developments, which are highly uncertain due to the continuing emergence of new variants and cannot be predicted with confidence, such as the ultimate duration of the pandemic and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

At this time, we do not expect any disruption in our supply chain of drugs necessary to conduct our clinical trials, and we believe we will be able to supply the drug needs of our clinical trials in 2022. However, we are continuing to evaluate our clinical supply chain in light of the COVID-19 pandemic.

License, Collaboration and Grant Agreements

License Agreement with Vifor Pharma

In November 2020, we granted Vifor Pharma, an exclusive, global (excluding Greater China), royalty-bearing license, for the commercialization of ANG-3777 in all Renal Indications, beginning with DGF and CSA-AKI. The Vifor License also grants Vifor Pharma exclusive rights, with a right to sublicense subject to our consent for certain specified conditions, to develop and manufacture ANG-3777 for commercialization in Renal Indications worldwide (excluding Greater China) in cooperation with us or independently. We retain the right to develop and commercialize combination therapy products combining ANG-3777 with our other proprietary molecules, subject to Vifor Pharma's right of first negotiation with respect to global (excluding Greater China) rights to such combination therapy products in the Renal Indications.

Pursuant to the Vifor License and specifically based upon the clinical development plan for ANG-3777 set forth in the Vifor License, we are entitled to receive $80 million in upfront and near-term clinical milestone payments, including $30 million in up-front cash received in November 2020, and a $30 million equity investment comprising a $5 million convertible note subsequently converting into common stock with the IPO and $25 million of which was received in the Concurrent Private Placement with our IPO.

We are also eligible to receive post-approval milestones of up to approximately $260 million and sales-related milestones of up to $1.585 billion, providing a total potential deal value of up to $1.925 billion (subject to certain specified reductions and offsets), plus tiered royalties on net sales of ANG-3777 at royalty rates of up to 40%. Under the Vifor License, we are responsible for executing a pre-specified clinical development plan designed to obtain regulatory approvals of ANG-3777 for DGF and CSA-AKI. For the three months ended March 31, 2022 and 2021, we recognized license revenue related to the Vifor License of $1.6 million and $0.4 million, respectively. As of March 31, 2022 and December 31, 2021, we recorded $0.7 million and $2.3 million, respectively, as deferred revenue, current on the condensed consolidated balance sheet related to the Vifor License.

On October 26, 2021, we announced the Phase 3 trial of ANG-3777 in DGF did not achieve its primary endpoint and the data were not expected to be sufficient evidence to support an indication in the studied DGF population. On December 14, 2021, we announced the Phase 2 trial of ANG-3777 in CSA-AKI did not achieve its primary endpoint. The Vifor License includes additional milestone and royalty objectives related to the clinical development plan for ANG-3777, which had included a Phase 3 study for CSA-AKI and a Phase 4 confirmatory study in DGF. We do not expect to receive any clinical, post-approval, or sales milestones, or royalties, as we do not intend to continue to pursue the current clinical development plan for ANG-3777. In 2022, we and Vifor Pharma continue to work to complete the planned analyses of the results of the clinical trials announced in the fourth quarter of 2021 and to discuss the future of the collaboration based upon such analyses.

Components of Results of Operations

The following discussion summarizes the key factors our management believes are necessary for an understanding of our financial statements.

Revenue

We do not have any products approved for sale and have not generated any revenue from product sales. Our revenue to date primarily has been derived from government funding consisting of U.S. government grants and contracts, and revenue under our license agreements, specifically the Vifor License.

Grant Revenue

Our grants and contracts reimburse us for direct and indirect costs relating to the grant projects and also provide us with a pre-negotiated profit margin on total direct and indirect costs of the grant award, excluding subcontractor costs, after giving effect to directly attributable costs and allowable overhead costs. Funds received from grants and contracts are generally deemed to be earned and recognized as revenue as allowable costs are incurred during the grant or contract period and the right to payment is realized.

Contract Revenue

Our license agreements comprise elements of upfront license fees, milestone payments based on development and royalties based on net product sales. The timing of our operating cash flows may vary significantly from the recognition of the related revenue. Income from upfront payments is recognized when we satisfy the performance obligations in the contract, which can result in recognition at either a point in time or over the period of continued involvement. Other revenue, such as milestone payments, are recognized when achieved.

Our revenue to date has been generated from payments received pursuant to the Vifor License Agreement. We recognize revenue from upfront payments over the term of our estimated period of performance using a cost-based input method under Topic 606, *Revenue from Contracts with Customers*.

In addition to receiving an upfront payment, we may also be entitled to milestones and other contingent payments upon achieving predefined objectives. If a milestone is considered probable of being reached, and if it is probable that a significant revenue reversal would not occur, the associated milestone amount would also be included in the transaction price. We expect any license revenue we generate from any future collaboration partners, will fluctuate in the future as a result of the timing and amount of upfront, milestones and other collaboration agreement payments and other factors.

Operating Expenses

Cost of Grant Revenue

Our cost of grant revenue primarily relates to personnel-related costs and expenses for grant projects.

Research and Development Expenses

To date, our research and development expenses have primarily related to discovery efforts and preclinical and clinical development of our product candidates. We recognize research and development expenses as they are incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

Our research and development expenses consist primarily of:

- personnel costs, including salaries, payroll taxes, employee benefits and stock-based compensation, for personnel in research and development functions;
- costs associated with medical affairs activities;
- fees paid to consultants, clinical testing sites and contract research organizations (CROs), including in connection with our preclinical studies and clinical trials, and other related clinical trial fees, such as for investigator grants, patient screening, laboratory work, clinical trial database management, clinical trial material management and statistical compilation, analysis and reporting;
- contracted research and license agreement fees with no alternative future use;
- costs related to acquiring, manufacturing and maintaining clinical trial materials and laboratory supplies;
- depreciation of equipment and facilities;
- legal expenses related to clinical trial agreements and material transfer agreements; and
- costs related to preparation of regulatory submissions and compliance with regulatory requirements.

Other than with respect to reimbursable expenses required to be recorded under our government grants and contracts, we do not allocate our expenses by product candidates. A significant amount of our direct research and development expenses include payroll and other personnel expenses for our departments supporting multiple product candidate research and development programs and, other than as specified above, we do not record research and development expenses by product. However, research and development expenses were primarily driven by expenses relating to the development of ANG-3070 and ANG-3777 during the three months ended March 31, 2022, and the development of ANG-3777 during the three months ended March 31, 2021. Of our total research and development expenses for the three months ended March 31, 2022 and 2021, 59% and 54%, respectively, of such expenses were from external third-party sources and the remaining 41% and 46%, respectively, were from internal sources.

We expect our research and development expenses to be slightly lower in the near term even though we will continue the development of our product candidates and continue to invest in research and development activities. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time consuming, and successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs of the efforts necessary to complete the remainder of the development of any of our clinical or preclinical product candidates or the period, if any, in which material net cash inflows from these product candidates may commence. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our ongoing, as well as any additional, clinical trials and other research and development activities;
- future preclinical and clinical trial results;
- obtaining market access and reimbursement approvals; and
- the timing and receipt of any regulatory approvals.

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

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related expenses, such as salaries, payroll taxes, employee benefits and stock-based compensation, for personnel in executive, operational, finance and human resources functions. Other significant general and administrative expenses include facilities costs, insurance costs, and accounting and legal services and expenses associated with obtaining and maintaining patents. A portion of the general and administrative expenses are reimbursed through the overhead rates contained in our grants with the U.S. Government.

We expect our general and administrative expenses to be generally consistent in the near term to support our continued research and development activities. We also expect to generally maintain our current level of expenses associated with operating as a public company, including expenses related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with the rules and regulations of the SEC and standards applicable to companies listed on a national securities exchange, insurance expenses, investor relations activities and other administrative and professional services.

Other Income (Expense)

Convertible Notes Recorded at Fair Value

We elected the fair value option for recognition of our convertible notes. Our convertible notes were subject to re-measurement each reporting period with gains and losses reported through our condensed consolidated statements of operations. All of our convertible notes were converted into shares of our common stock upon the closing of our IPO.

Liability Classified Series C Convertible Preferred Stock Recorded at Fair Value

Our Series C convertible preferred stock included settlement features resulting in classification as a liability. The initial carrying value of the Series C convertible preferred stock was accreted to the settlement value, the fair value of the securities to be issued upon the conversion of the Series C Preferred Stock. The discount to the settlement value was accreted to interest expense using the effective interest method. During 2020, certain of the convertible notes were exchanged for Series C convertible preferred stock. As the exchange was accounted for as a modification, the Series C convertible preferred stock exchanged for the convertible notes (the Exchanged Series C Shares) was recorded at fair value. The Exchanged Series C Shares were subject to re-measurement each reporting period with gains and losses reported through our condensed consolidated statements of operations. All shares of our Series C convertible preferred stock converted into common stock upon the closing of our IPO.

Warrant Liability

We have accounted for certain of our freestanding warrants to purchase shares of our common stock as liabilities measured at fair value, in accordance with ASC 815, *Derivatives and Hedging*. The warrants are subject to re-measurement at each reporting period with gains and losses reported through our condensed consolidated statements of operations.

Foreign Exchange Transaction Gain

Foreign currency transaction gains, primarily related to intercompany loans, are recorded as a component of other income (expense) in our condensed consolidated statements of operations.

Earnings in Equity Method Investment

Earnings in equity method investment represents our 10% interest in NovaPark accounted for under the equity method.

Interest Income

Interest income consists of interest earned on our cash and cash equivalents.

Results of Operations

Comparison of the Three Months Ended March 31, 2022 and 2021

The following table summarizes our results of operations for the periods indicated:

	Three Months Ended March 31,			
	2022	2021	$ Change	% Change
	(In thousands, except percentages)			
Revenue:				
Contract revenue	$ 1,648	$ 371	$ 1,277	344%
Total revenue	1,648	371	1,277	344%
Operating expenses:				
Research and development	11,667	14,298	(2,631)	(18)%
General and administrative	4,466	6,012	(1,546)	(26)%
Total operating expenses	16,133	20,310	(4,177)	(21)%
Loss from operations	(14,485)	(19,939)	5,454	(27)%
Other income (expense), net	245	(16,748)	16,993	101%
Net loss	**$ (14,240)**	**$ (36,687)**	**$ 22,447**	

Contract Revenue

Contract revenue increased by $1.3 million for the three months ended March 31, 2022 compared to the same period in 2021. Since Angion does not intend to continue the clinical development plan for ANG-3777 currently set forth in Angion's license agreement with Vifor International, Ltd, which had included a Phase 3 study in cardiac surgery associated with cardiopulmonary bypass (CSA-AKI) and a Phase 4 confirmatory study in delayed graft function (DGF), Angion performed a reassessment of the performance period and estimated costs for the completion of the performance obligations. This accelerated the revenue recognition related to the upfront payment received by Angion from Vifor Pharma when the license agreement with Vifor Pharma was entered into in 2020.

We do not expect to receive any further substantial revenues under the Vifor License and we expect the remaining unearned revenue under the Vifor License to be recognized by the end of 2022.

Research and Development Expenses

Research and development expenses decreased by $2.6 million, or 18%, for the three months ended March 31, 2022 compared to the same period in 2021. The decrease in research and development expenses was primarily due to a net decrease of $4.4 million in personnel-related expenses during the three months ended March 31, 2022 and a decrease of $2.9 million in CRO expenses from decreased clinical trial activities, primarily related to the completion of ANG-3777 trials, offset by severance-related charges of $2.7 million (see Note 1 to the condensed consolidated financial statements for additional information) and an increase of $2.0 million in CRO and CMO expenses from increased clinical and non-clinical trial activities, primarily related to the development of ANG-3070.

General and Administrative Expenses

General and administrative expenses decreased by $1.5 million, or 26%, for the three months ended March 31, 2022 compared to the same period in 2021. The decrease in general and administrative expenses was primarily due to a net decrease of $2.3 million in personnel-related expenses during the three months ended March 31, 2022, offset by severance-related charges of $0.5 million (see Note 1 to the condensed consolidated financial statements for additional information) and an increase of $0.3 million in business insurance expense.

Other Income (Expense)

Other income (expense) increased by $17.0 million for the three months ended March 31, 2022 compared to the same period in 2021. The increase is primarily due to a decrease in expense of $14.6 million from the change in fair value related to our warrant liability, convertible notes, and Series C convertible preferred stock for which we elected the fair value option as most of these instruments were no longer outstanding after our IPO. There was also a decrease of $2.2 million in interest expense, primarily related to $2.2 million of amortization of debt issuance costs from the issuance of Series C convertible preferred stock issued during the three months ended March 31, 2021.

Liquidity and Capital Resources

Sources and Uses of Liquidity

We have incurred losses and negative cash flows from operations since inception, and we anticipate we will incur losses for at least the next several years. To date, we have not generated any revenue from product sales. We have funded our operations primarily through the receipt of grants, the sale of debt and equity securities, and proceeds from license agreements. As of March 31, 2022, we had $73.0 million of cash and cash equivalents and an accumulated deficit of $229.4 million, compared to $88.8 million of cash and cash equivalents and an accumulated deficit of $215.1 million as of December 31, 2021.

Future Cash Needs and Funding Requirements

Based on our current operating plan, we believe our cash and cash equivalents will be sufficient to fund our planned operations for at least 12 months following the issuance date of our condensed consolidated financial statements and well into 2023. However, we have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of biotechnology products, we are unable to estimate the exact amount of our operating capital requirements. The amount and timing of our future funding requirements will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of researching and developing ANG-3070 or any other product candidates, and conducting preclinical studies and clinical trials;
- the outcome of our ongoing and future clinical trials, including our Phase 2 clinical trial of ANG-3070 in patients with PPKD;
- whether we are able to take advantage of any FDA expedited development and approval programs for any of our product candidates;
- the extent to which COVID-19 may impact our business, including our clinical trials and financial condition;
- the willingness of the FDA and foreign regulatory authorities to accept the results of our completed, ongoing, and planned clinical trials and preclinical studies and other work, as the basis for review and approval of ANG-3070;
- the outcome, costs and timing of seeking and obtaining and maintaining FDA and any foreign regulatory approvals;
- the number and characteristics of product candidates that we pursue, including our product candidates in preclinical development;
- the ability of our product candidates to progress through clinical development successfully;
- our need to expand our research and development activities, including to conduct additional clinical trials;
- market acceptance of our product candidates, including physician adoption, market access, pricing and reimbursement;
- the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies;
- our ability to maintain, expand 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 the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire additional personnel, including management, clinical development, medical and commercial personnel;
- the effect of competing technological, market developments and government policy;
- the costs associated with being a public company, including our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- the costs associated with securing and establishing commercialization and manufacturing capabilities, as well as those associated with packaging, warehousing and distribution;

- the costs associated with being a commercial company with approved products for sale, including our obligation to meet applicable healthcare laws and regulations and implement robust compliance programs;
- the economic and other terms, timing of and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future and timing and amount of payments thereunder; and
- the timing, receipt and amount of sales and general commercial success of any future approved products, if any.

Until such time as we or our collaborators can generate significant revenue from sales of ANG-3070 or any other product candidate, if ever, we expect to finance our operations through public or private equity offerings or debt financings or other sources of capital, including collaborations, licenses, credit or loan facilities, receipt of research contributions or grants, tax credit revenue or a combination of one or more of these funding sources. Adequate funding may not be available to us on acceptable terms, or at all. To the extent we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences adversely affecting the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through additional collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. 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 commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

Summary Statement of Cash Flows

The following table sets forth a summary of our net cash flow activity for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Net cash provided by (used in)		
Operating activities	$ (15,653)	$ (12,551)
Investing activities	—	(41)
Financing activities	(14)	108,444
Effect of foreign currency on cash	(87)	(3)
Net increase (decrease) in cash	$ (15,754)	$ 95,849

Operating activities

For the three months ended March 31, 2022, net cash used in operating activities was $15.7 million, which primarily consisted of a net loss of $14.2 million, partially offset by net non-cash charges of $0.2 million and a use of cash from the change in net operating assets and liabilities of $1.6 million. The net non-cash charges were primarily related to the amortization of operating lease right-of-use assets of $0.2 million. The use of cash due to the change in net operating assets and liabilities was due to a decrease in deferred revenue of $1.6 million due to revenue recognized in the period, an increase of $1.5 million in prepaid expenses and other current assets primarily due to the prepayment of business insurance, and a decrease of $1.3 million in accounts payable due to the payment of CRO invoices, partially offset by an increase of $2.0 million in accrued expenses due to timing of invoices, and an increase of $0.2 million in other liabilities, noncurrent, for accrued severance, and a decrease of $0.8 million in grants receivable due to the fulfillment of the grant contract with the U.S. Department of Defense.

For the three months ended March 31, 2021, net cash used in operating activities was $12.6 million, which primarily consisted of a net loss of $36.7 million, partially offset by net non-cash charges of $21.7 million and a change in net operating assets and liabilities of $2.5 million. The net non-cash charges were primarily related to a change in fair value of $14.6 million in convertible notes, Series C preferred stock and warrant liabilities, stock-based compensation expense of $5.1 million and amortization of debt issuance costs of $1.9 million. The provision of cash due to the change in net operating assets and liabilities was due to a decrease of $2.7 million in prepaid expenses and other current assets and an increase of $1.1 million in accounts payable due to our overall growth, partially offset by a decrease in $0.8 million in accrued expenses due to timing of invoices and a decrease in deferred revenue of $0.4 million due to revenue recognized in the period.

Investing activities

For the three months ended March 31, 2022, no cash was provided by or used in investing activities, and for the three months ended March 31, 2021, net cash used in investing activities was $41,000, primarily related to purchases of fixed assets for research activities.

Financing activities

For the three months ended March 31, 2022, net cash used in financing activities was immaterial.

For the three months ended March 31, 2021, net cash provided by financing activities was $108.4 million, primarily due to net proceeds of $110.6 million from the IPO and Concurrent Private Placement and $0.7 million from the exercise of warrants, partially offset by the payment of the deferred offering costs of $1.7 million and taxes paid related to net share settlement upon vesting of restricted stock awards of $1.1 million.

Critical Accounting Policies and Significant Judgements and Estimates

Our condensed consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States (“U.S. GAAP”). The preparation of our condensed consolidated financial statements and related disclosures requires us to make estimates and judgments affecting the reported amounts of assets, liabilities, costs and expenses. We base our estimates on historical experience, known trends and events and various other factors 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 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.

Our critical accounting policies are described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Use of Estimates” in our Annual Report on Form 10-K for the year ended December 31, 2021, which was filed with the SEC on March 30, 2022. During the three months ended March 31, 2022, except as described in Note 1 to the unaudited interim condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, there were no material changes to our critical accounting policies from those previously disclosed.

Emerging Growth Company and Smaller Reporting Company Status

We are a smaller reporting company and an emerging growth company, as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay the adoption of new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for emerging growth companies include presentation of only two years of audited financial statements in a registration statement for an initial public offering, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to Sarbanes-Oxley Act of 2002, as amended (Sarbanes-Oxley) an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements.

We have elected to use the extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that (i) we are no longer an emerging growth company or (ii) we affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our condensed consolidated financial statements may not be comparable to companies that comply with new or revised accounting standards as of public company effective dates.

We will remain an emerging growth company until the earliest of (i) December 31, 2026, (ii) the last day of our first fiscal year in which we have total annual gross revenue of $1.07 billion or more, (iii) the date on which we are deemed to be a “large accelerated filer,” as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (Exchange Act), which means the market value of equity securities held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter and (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company” and/or “non-accelerated filer” which may allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply for a period of time with the auditor attestation requirements of Section 404 of Sarbanes-Oxley, and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our President and Chief Executive Officer and our Chief Financial Officer, our principal executive officer and principal accounting and financial officer, respectively, have evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of March 31, 2022.

Disclosure controls and procedures are controls and other procedures designed to ensure information required to be disclosed in our reports filed or submitted under 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 controls and procedures designed to ensure information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our President and Chief Executive Officer and our Chief Financial Officer, to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures, our President and Chief Executive Officer and our Chief Financial Officer concluded our disclosure controls and procedures were not effective as of March 31, 2022 due to the material weaknesses in our internal control over financial reporting described below. In light of this fact, our management has performed additional analyses, reconciliations, and other post-closing procedures and has concluded that, notwithstanding the material weaknesses in our internal control over financial reporting, the condensed consolidated financial statements for the periods covered by and included in this Quarterly Report on Form 10-Q fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with U.S. GAAP.

Changes in Internal Control Over Financial Reporting

Except for the changes in connection with the ongoing remediation of the previously identified material weakness discussed below, there has been no change in our internal control over financial reporting during the quarter ended March 31, 2022, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

In connection with the preparation of our consolidated financial statements, we identified control deficiencies in the design and operation of our internal control over financial reporting that constituted material weaknesses. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

The material weaknesses identified in our internal control over financial reporting related to (i) insufficient resources with knowledge and expertise in U.S. GAAP to properly evaluate certain complex transactions, including debt instruments and equity instruments; and (ii) insufficient financial reporting and close controls to ensure that incurred expenses are accrued at period end and deliverables from third party contractors are reviewed for accuracy.

During 2021, we took a number of actions to remediate these material weaknesses, including:

- engaging SEC compliance and technical accounting consultants to assist in evaluating transactions for conformity with U.S. GAAP;
- hiring additional finance and accounting personnel to augment accounting staff and to provide more resources for complex accounting matters and financial reporting; and
- strengthening our financial reporting and close relating to incurred expenses by ensuring our data capture procedures are clearly defined and that responsible personnel, including supervisory personnel, have adequate training regarding the process and expectation.

We are still in the process of implementing these controls. We intend to continue to take steps to remediate the material weaknesses through formalizing documentation of policies and procedures and further evolving our accounting processes. While we believe these efforts will improve our internal control over financial reporting, the design and implementation of our remediation is ongoing and will require validation and testing of the design and operating effectiveness of our internal controls over a sustained period of financial reporting cycles. The actions we are taking are subject to ongoing senior management review, as well as audit committee oversight. We will not be able to conclude whether the steps we are taking will fully remediate the material weaknesses in our internal control over financial reporting until we have completed our remediation efforts and subsequent evaluation of their effectiveness.

Inherent Limitation on the Effectiveness Over Financial Reporting

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable and not absolute assurances. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but there can be no assurance such improvements will be sufficient to provide us with effective internal control over financial reporting.

Part II OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently a party to any material legal proceedings. From time to time, we may be involved in legal proceedings or subject to claims incident to the ordinary course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information in this Quarterly Report on Form 10-Q, including our condensed *consolidated financial statements and related notes, before deciding whether to invest in shares of our common stock. Many of the following risks and uncertainties are, and will be, exacerbated by the COVID-19 pandemic and any worsening of the global business and economic environment as a result. The occurrence of any of the adverse developments described in the following risk factors could materially and adversely harm our business, financial condition, results of operations or prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.*

Risk Factors Summary

The following is a summary of the principal factors causing an investment in our company to be speculative or risky:

Risks Relating to Our Financial Position and Need for Additional Capital

- We are a clinical-stage biopharmaceutical company with no products approved for sale and we have not generated any product revenue to date, which makes it difficult to assess our future viability.
- To achieve our goals we will require substantial additional funding, for which capital may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our clinical trials or operations.

Risks Relating to the Development and Regulatory Approval of Our Product Candidates

- COVID-19 could adversely impact our business, including our clinical trials and financial condition.
- Product development and regulatory approval involve a lengthy and expensive process with uncertain outcomes. We cannot be certain ANG-3070 or any of our other product candidates will receive or maintain regulatory approval and, without regulatory approval, we and our collaborators will not be able to market our product candidates.
- Delays or difficulties in the commencement, enrollment and completion of clinical trials could result in increased costs to us and delay or limit our ability to obtain regulatory approval for ANG-3070 and our other product candidates.
- Clinical failure can occur at any stage of clinical development, and the results of earlier clinical trials are not necessarily predictive of future results.
- Our clinical trials could be disrupted by the uncertainty of war due to the aggressive actions taken by Russia which, if this occurs, could delay our ability to complete our clinical trials.
- Even if we successfully complete ongoing and planned clinical trials of one or more of our product candidates, the product candidates may fail for other reasons.
- Our product candidates may have undesirable side effects which may delay or halt clinical development or prevent marketing approval or, if approval is received, require them to be taken off the market, require them to include safety warnings, or otherwise limit their sales.
- Clinical trials of our product candidates may not uncover all possible adverse effects that patients may experience or be indicative of the effect of our product candidates post approval in the general population.

- Due to the significant resources required for the development and commercialization of our product candidates, we must prioritize development of certain product candidates and/or certain disease indications. We may expend our limited resources on product candidates or indications that do not yield a successful product and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.
- Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.
- If manufacturers obtain approval for generic versions of our products or product candidates, our business will be materially harmed.

Risks Relating to Collaborations and Commercialization of Our Product Candidates

- If we are able to develop and obtain regulatory approval for any of our product candidates, our business will be materially harmed if we are unable to successfully commercialize such approved products.
- If we fail to develop market opportunities for ANG-3070 or any future products are smaller than we believe they are, our potential to generate revenue may be adversely affected, and our business may suffer.

Risks Relating to Our Business and Strategy

- We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.
- We currently depend on single third-party suppliers for the manufacture and supply of drug substance and potential future commercial product supplies for our product candidates, and any performance failure on the part of our supplier could delay the development and potential commercialization of our product candidates.
- We depend on third-party contractors for a substantial portion of our operations and may not be able to control their work as effectively as if we performed these functions ourselves. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize our product candidates, if approved.

Risks Relating to Our Intellectual Property

- It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If our patent position and potential regulatory exclusivity do not adequately protect our product candidates, others could compete against us more directly, which would harm our business, possibly materially.
- If we do not obtain protection under the Hatch-Waxman Act and similar legislation outside of the United States by extending the patent terms and obtaining data exclusivity for our product candidates, our business may be materially harmed.
- We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.
- We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our product candidates.

Risks Relating to Our Common Stock

- Our stock price may be volatile and you may not be able to resell shares of our common stock at or above the price you paid.
- We identified material weaknesses in our internal control over financial reporting and we may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements. If we fail to remediate any material weaknesses or if we otherwise fail to establish and maintain effective control over financial reporting, our ability to accurately and timely report our financial results could be adversely affected.

Risks Relating to Our Financial Position and Need for Additional Capital

We are a clinical-stage biopharmaceutical company with no products approved for sale and we have not generated any product revenue to date, which makes it difficult to assess our future viability.

We are a clinical-stage biopharmaceutical company. Drug development is a highly speculative undertaking and involves a substantial degree of risk. We have not yet submitted any product candidates for approval or received approval of any product candidate by regulatory authorities in any jurisdiction, including the United States Food and Drug Administration (FDA). We do not expect to generate revenue from product sales unless we, or we and our collaborators, obtain approval and commercialize our product candidates, which we do not expect to occur for several years, if ever. We expect to continue to incur net losses for the foreseeable future, and we expect our expenses and operating losses to increase substantially as we advance ANG-3070 and our other product candidates through clinical and preclinical development, seek regulatory approval for ANG-3070 or any of our other product candidates, and continue to incur expenses to protect our intellectual property, maintain our general and administrative support functions, including hiring additional personnel, and incur costs associated with operating as a public company.

In addition, while we have a license agreement with Vifor Pharma relating to ANG-3777 that contemplates upfront, regulatory and commercial milestone payments as well as royalties on sales of ANG-3777, we do not intend to continue the clinical development plan for ANG-3777 set forth in the Vifor License, which had included a Phase 3 study for CSA-AKI and a Phase 4 confirmatory study in DGF. Thus, it is unlikely we will receive any substantial revenue stream from milestone or royalty payments under the license agreement.

If we are unable to enroll our clinical trials for ANG-3070 or if ANG-3070 or any of our other product candidates fail in ongoing clinical trials or do not gain regulatory approval, we may never generate revenue or become profitable.

To achieve our goals we will require substantial additional funding, for which capital may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our clinical trials or operations.

We have invested and will continue to invest a significant portion of our efforts and financial resources in research and development activities. We are currently in the process of advancing ANG-3070 through a Phase 2 dose-finding clinical trial in 100 patients with Primary Proteinuria Kidney Diseases (PPKDs), specifically FSGS and IgAN patients, in the United States, Georgia, Bulgaria, Lithuania, Spain, Australia and Italy, and other product candidates through preclinical and potential clinical development. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We will require substantial additional future capital to complete clinical development, including additional clinical studies, and seek regulatory approval for ANG-3070 for any indication as well as to conduct the research, clinical and regulatory activities necessary to bring our other product candidates to market. Regulatory authorities in the United States and elsewhere could also require we perform additional preclinical studies or clinical trials to receive or maintain regulatory approval of our product candidates, including ANG-3070, and our expenses would further increase beyond what we currently expect. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development of such product candidates as well as the costs of commercializing any of our wholly-owned product candidates and those for which we retain the right to commercialize.

We estimate our current cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements well into 2023. We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of biotechnology products, we are unable to estimate the exact amount of our operating capital requirements. The amount and timing of our future funding requirements will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of researching and developing ANG-3070 or other product candidates, and conducting preclinical studies and clinical trials;
- the outcome of our ongoing and future clinical trials, including our ANG-3070 Phase 2 clinical trial in PPKD;
- whether we are able to take advantage of any FDA expedited development and approval programs for any of our product candidates;

- the extent to which COVID-19 may impact our business, including our clinical trials and financial condition;
- the willingness of the FDA and foreign regulatory authorities to accept the results of our ongoing ANG-3070 Phase 2 clinical trial, as well as our other completed and planned clinical trials and preclinical studies and other work;
- the number and characteristics of product candidates we pursue, including our product candidates in preclinical development;
- the ability of our product candidates to progress through clinical development successfully;
- our need to expand our research and development activities, including to conduct additional clinical trials;
- the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies;
- our ability to maintain, expand 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 the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire additional personnel, including management, clinical development, medical and commercial personnel;
- the costs associated with being a public company, including our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- the costs associated with securing and establishing manufacturing capabilities, as well as those associated with packaging, warehousing and distribution; and
- the economic and other terms, timing of and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future and the timing and amount of payments thereunder.

Until such time we can generate sufficient revenue from sales of ANG-3070 or any other product candidate, if ever, we expect to finance our operations through public or private equity offerings, debt financings or other sources of capital, including collaborations, licenses, credit or loan facilities, receipt of research contributions or grants, tax credits or a combination of one or more of these funding sources. Adequate funding may not be available to us on acceptable terms, or at all. This may be particularly true if global capital markets continue to experience extreme volatility due to the COVID-19 pandemic or armed conflict. To the extent we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences adversely affecting the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements including covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through additional collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. 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 commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

Risks Relating to the Development and Regulatory Approval of Our Product Candidates

COVID-19 could adversely impact our business, including our clinical trials and financial condition.

We have been and continue to be subject to risks related to public health crises such as the global pandemic associated with COVID-19. As COVID-19 continues to persist around the globe, we may continue to experience disruptions that could severely impact our business and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials, including our ANG-3070 Phase 2 study in PPKD with clinical sites in Eastern Europe, namely Georgia, Lithuania, Bulgaria and Italy;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or

interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;

- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in receiving authorizations from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials, such as investigational drug product used in our clinical trials;
- changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- interruptions or delays in preclinical studies due to restricted or limited operations at our research and development laboratory facilities or at our third-party clinical research organizations;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and refusal of the FDA to accept data from clinical trials in affected geographies outside the United States.

We are continuing to evaluate the impact of the COVID-19 restrictions on our expected pace of enrollment, as such impacts could delay the timing of topline results in our ongoing clinical trials.

The global pandemic of COVID-19 continues to evolve. The extent to which COVID-19 may impact our business, including our clinical trials, and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the geographic spread of the disease and its variants, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

Product development and regulatory approval involve a lengthy and expensive process with uncertain outcomes. We cannot be certain ANG-3070 or any of our other product candidates will receive or maintain regulatory approval and, without regulatory approval, we and our collaborators will not be able to market our product candidates.

We currently have no products approved for sale, and we cannot guarantee we will ever have approved products we or our collaborators can market and sell. The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulation by regulatory authorities, including the FDA in the United States and other regulatory authorities in other foreign countries, with regulations differing from country to country. We are not permitted to market our product candidates in the United States or elsewhere until we receive regulatory approval and/or marketing authorization, such as approval of an NDA from the FDA. We have not submitted any marketing applications for any of our product candidates.

New drug marketing applications must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. Such marketing applications must also include significant information regarding the chemistry, manufacturing, and controls for the product. Obtaining approval of our product candidates will be a lengthy, expensive, and uncertain process, and we may not be successful. Specifically, the review processes of the FDA and foreign regulatory authorities can take years to complete, and approval is never guaranteed. Even if a product is approved, the FDA or foreign regulatory authorities may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming additional clinical trials or reporting as conditions of approval. The FDA or foreign regulatory authorities also may not approve our product candidates with the labeling we believe is necessary or desirable for the successful commercialization of such product candidates. Obtaining regulatory approval for marketing of a product candidate in one country does not ensure we will be able to obtain regulatory approval in any other country.

The FDA or any foreign regulatory authorities can delay, limit or deny approval of our product candidates for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory authority any of our product candidates are safe and effective for the requested indication;
- the FDA's or the applicable foreign regulatory authority's disagreement with our trial protocols or the interpretation of data from preclinical studies or clinical trials;
- our inability to demonstrate the clinical and other benefits of any of our product candidates outweigh any safety or other perceived risks;
- the FDA's or the applicable foreign regulatory authority's requirement for additional preclinical studies or clinical trials;
- the FDA's or the applicable foreign regulatory authority's non-approval of the formulation, labeling or specifications of any of our product candidates;
- the FDA's or the applicable foreign regulatory authority's failure to approve our manufacturing processes and facilities or the facilities of third-party manufacturers upon which we rely; or
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory authorities to significantly change in a manner rendering our clinical data insufficient for approval.

We cannot predict whether our ongoing or future clinical trials of our product candidates will be successful, or whether regulators will agree with our conclusions regarding the preclinical studies and clinical trials we have conducted to date or we conduct in the future. Accordingly, we may never receive approval of ANG-3070 or any of our other product candidates, or be authorized to market and sell our product candidates to customers. If we are unable to obtain approval from regulatory authorities for ANG-3070 or any of our other product candidates, we may not be able to generate sufficient revenue to become profitable or to continue our operations.

Delays or difficulties in the commencement, enrollment and completion of clinical trials could result in increased costs to us and delay or limit our ability to obtain regulatory approval for ANG-3070 and our other product candidates.

Delays in the commencement, enrollment, and completion of clinical trials could increase our product development costs or limit the regulatory approval of our product candidates. We are currently enrolling patients in our Phase 2 clinical trial of ANG-3070 for PPKD. Delays in any of our clinical trials may increase the amount of additional funding we will require to complete these trials. The commencement, enrollment, and completion of clinical trials can be delayed, challenged or suspended for a variety of reasons, including but not limited to:

- severity of the disease under investigation;
- inability to obtain sufficient funds required for a clinical trial;
- inability to obtain Institutional Review Board (IRB) approval at participating institutions;
- our ability to effectively manage the clinical research organizations (CROs) we have engaged to conduct of our clinical trials;
- the extent to which COVID-19 may impact our clinical trials and our or our CROs' ability to monitor such trials;
- the extent to which the Russian invasion of Ukraine may impact our clinical trials and our or our CROs' ability to monitor such trials;
- availability and efficacy of approved medications or competing product candidates in development for the disease under investigation;
- the patient eligibility criteria defined in the protocol;
- the ability to attract and retain patients and the general willingness of patients to enroll, consent and complete participation in the trial;
- the extent to which there is competition for patients to enroll in clinical trials;
- the size of the patient population required for analysis of the trial's primary endpoint or endpoints;
- clinical holds, other regulatory objections to commencing or continuing a clinical trial, or the inability to obtain regulatory approval to commence a clinical trial in countries requiring such approvals;
- discussions with the FDA or foreign regulatory authorities regarding the scope or design of our clinical trials;
- severe or unexpected drug-related adverse effects experienced by patients; and
- inability to timely manufacture sufficient quantities of the product candidate and other clinical supplies required for a clinical trial.

Changes in regulatory requirements and related guidance related to regulatory approval may also occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of our clinical trials. Furthermore, if we are required to conduct additional clinical trials or other preclinical studies of our product candidates beyond those contemplated, our ability to obtain or maintain regulatory approval of these product candidates and generate revenue from their sales would be similarly harmed**.**

Clinical failure can occur at any stage of clinical development, and the results of earlier clinical trials are not necessarily predictive of future results.

Clinical failure can occur at any stage of our clinical development. For example, in the fourth quarter of 2021, we disclosed the results of the ANG-3777 Phase 3 clinical trial for delayed graft function (DGF) and AKI associated with cardiac surgery involving cardiopulmonary bypass (CSA-AKI), neither of which met their primary endpoints despite the existence of encouraging pre-clinical and clinical data for ANG-3777 established prior to initiating such studies. Clinical trials may produce negative or inconclusive results, and we or our collaborators may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to various interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Success in preclinical studies and early clinical trials does not ensure subsequent clinical trials will generate the same or similar results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in Phase 3 registration trials, even after seeing promising results in earlier clinical trials or pre-clinical studies.

In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We have limited experience in designing clinical trials as we have never previously completed a Phase 3 registration trial with results sufficient to obtain regulatory approval or submitted an NDA to the FDA or a marketing application to any foreign regulatory authority, and we may be unable to design and execute a clinical trial to support regulatory approval. Further, clinical trials of potential products often reveal it is not practical or feasible to continue development efforts.

Furthermore, our ability to show statistical significance in our clinical trials may be affected by factors beyond our control. This could result in the need for additional clinical trials prior to submission of an NDA to the FDA or other marketing applications to foreign regulatory authorities.

There can also be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in composition of the patient populations, adherence to the dosing regimen and other trial protocols, differences in drug lot manufacturing, and the rate of dropout among clinical trial participants. We do not know whether any preclinical or clinical trials we or any of our existing or future collaborators may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates.

If ANG-3070 or our other product candidates are the subject of clinical trial failures or are found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for them and our business would be harmed.

Our clinical trials could be disrupted by the uncertainty of war due to the aggressive actions taken by Russia which, if this occurs, could delay our ability to complete our clinical trials.

We are currently in the process of advancing ANG-3070 through a Phase 2 clinical trial in 100 patients with Primary Proteinuria Kidney Diseases (PPKD), specifically FSGS and IgAN patients, including trial sites in Georgia, Bulgaria and Lithuania. In late February 2022, Russia initiated significant military action against Ukraine, and given the proximity of Georgia, Bulgaria and Lithuania to Russia there may be significant uncertainty and unrest in these countries which could impair or delay the progress of our clinical trials in those countries. Further, in response to the Russian invasion of Ukraine, the U.S. and certain other countries imposed significant sanctions and trade actions against Russia, and the U.S. and certain other countries could impose further sanctions, trade restrictions and other retaliatory actions should the conflict continue or worsen.

It is not possible to predict the broader consequences of the conflict, including related geopolitical tensions, and the measures and retaliatory actions taken by the U.S. and other countries in respect thereof, as well as any counter measures or retaliatory actions by Russia in response, is likely to cause regional instability, geopolitical shifts and could materially adversely affect global trade, currency exchange rates, regional economies and the global economy. In particular, while it is difficult to anticipate the impact of any of the foregoing on our clinical trials or our business, the conflict and actions taken in response to the conflict could increase our costs, disrupt our supply chain, impair the progress of our clinical trials, impair our ability to raise additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition and results of operations.

Even if we successfully complete ongoing and planned clinical trials of one or more of our product candidates, the product candidates may fail for other reasons.

Even if we successfully complete the clinical trials for one or more of our product candidates, such product candidates may fail for other reasons, including the possibility the product candidates will:

- fail to receive the regulatory approvals required to market them as drugs;
- be subject to proprietary rights held by others requiring the negotiation of a license agreement prior to marketing;
- be difficult or expensive to manufacture on a commercial scale;
- have adverse side effects that make their use less desirable;
- not achieve reimbursement or sales levels sufficient for continued marketing; or
- fail to compete with product candidates or other treatments commercialized by our competitors.

If we are unable to receive and maintain the required regulatory approvals, secure our intellectual property rights, maintain an acceptable safety profile or fail to compete with our competitors' products, our business, financial condition, and results of operations could be materially and adversely affected.

Our product candidates may have undesirable side effects which may delay or halt clinical development or prevent marketing approval or, if approval is received, require them to be taken off the market, require them to include safety warnings, or otherwise limit their sales.

The results of our clinical trials of our product candidates may show such product candidates led to patient safety concerns or undesirable or unacceptable side effects, creating risk to the patient which is deemed to outweigh the potential benefits of treatment to that patient. Unforeseen side effects from any of our product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. Any such event could interrupt, delay or halt such clinical trials, resulting in the denial of regulatory approval by the FDA and other regulatory authorities or result in restrictive label warnings, if approved. In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the Government Accounting Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion, or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

ANG-3070 is a tyrosine kinase inhibitor (TKI). TKIs are widely used across a range of indications. Depending on their specific targets, TKIs have been associated with several near and long-term side effects. They have been most extensively used in cancer where cardiopulmonary toxicity, myelosuppression, and gastrointestinal toxicity have been key side effects in addition to several others. TKIs have also been studied in fibrosis, with nintedanib being approved for IPF. Nintedanib has been associated with several side effects including severe liver injuries, arterial thromboembolic events and gastrointestinal disorders including diarrhea, nausea and vomiting, and risk of bleeding. Pirfenidone, with an unknown mechanism of action, has also been approved in IPF and has been associated with elevated liver enzymes, diarrhea, nausea vomiting, photosensitivity and rash.

While we believe the preliminary safety and pharmacokinetic data from our Phase 1 healthy-volunteer study in Australia support the conduct of our ongoing Phase 2 clinical trial in PPKD and additional clinical trials, there can be no assurance similar or unforeseen side effects will not occur during future clinical trials. The range and potential severity of possible side effects from systemic therapies can be significant.

If any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require the addition of labeling statements or specific warnings, including “Black Box” warnings if the FDA views the possible side effects as very severe;
- we may be required to change instructions regarding the way the product is administered, conduct additional clinical trials, or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- regulatory authorities may require us to take our approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us or any potential future collaborators from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which, in turn, could delay or prevent us from generating significant revenues from the sale of our products.

Clinical trials of our product candidates may not uncover all possible adverse effects patients may experience or be indicative of the effect of our product candidates post approval in the general population.

Clinical trials are conducted in representative samples of the potential patient population, which may have significant variability. By design, clinical trials are based on a limited number of subjects and are of limited duration of exposure to the product, to determine whether the product candidate demonstrates the substantial evidence of efficacy and safety necessary to obtain regulatory approval. As with the results of any statistical sampling, we cannot be sure any evidence of efficacy will be repeated in the general population or all side effects of our product candidates may be uncovered. It may be the case only with a significantly larger number of patients exposed to the product candidate for a longer duration may a more complete safety and efficacy profile be identified Further, even larger clinical trials may not identify rare serious adverse events, and the duration of such studies may not be sufficient to identify when those events may occur particularly for adverse events or safety risks could occur over time, such as the development and diagnosis of cancer. Other products have been approved by the regulatory authorities for which safety concerns have been uncovered following approval. Such safety concerns have led to labeling changes, restrictions on distribution through use of a REMS, or withdrawal of products from the market, and any of our product candidates may be subject to similar risks.

Patients treated with our products, if approved, may experience previously unreported adverse reactions, and it is possible the FDA or other regulatory authorities may ask for additional safety data as a condition of, or in connection with, our efforts to obtain approval of our product candidates. If safety problems occur or are identified after our products, if any, reach the market, we may make the decision or be required by regulatory authorities to amend the labeling of our products, recall our products, or even withdraw approval for our products.

Due to the significant resources required for the development and commercialization of our product candidates, we must prioritize development of certain product candidates and/or certain disease indications. We may expend our limited resources on product candidates or indications that do not yield a successful product and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We plan to develop a pipeline of product candidates to treat potentially life-threatening acute organ injuries and fibrotic diseases. However, due to the significant resources required for the development of our product candidates, we must focus on specific indications and decide which product candidates to pursue and the amount of resources to allocate to each. For instance, in 2022, we plan to identify a lead candidate in one or more of our pre-clinical programs, but not in all such programs. Our primary focus is on advancing ANG-3070 in PPKD through our ongoing Phase 2 dose-finding study in that population and filing an IND to support the clinical development of ANG-3070 in IPF.

Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect of certain programs may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities.

If we make incorrect determinations regarding the viability or market potential of any of our programs or product candidates or misread trends in the biopharmaceutical industry, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain development and commercialization rights.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include: the U.S. federal Anti-Kickback Statute; U.S. federal civil and criminal false claims laws, including the civil False Claims Act; the federal fraud provision of the U.S. federal Health Insurance Portability and Accountability Act of 1996 (HIPAA); HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH; the FDCA; the U.S. Physician Payments Sunshine Act; federal consumer protection and unfair competition laws; analogous U.S. state laws and regulations, including state anti-kickback and false claims laws; and similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our current internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom are compensated in the form of stock options for consulting services provided, may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our 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, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business and our ability to sell our products may be materially harmed.

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

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (Affordable Care Act), was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Since its enactment, there have been judicial, executive branch and congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. For example, legislation informally titled the Tax Cuts and Jobs Acts (TCJA) was enacted, which, among other things, removed penalties for not complying with the individual mandate to carry health insurance. On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Thus, the Affordable Care Act will remain in effect in its current form. It is possible that the Affordable Care Act will be subject to judicial or congressional challenges in the future. It is unclear how such challenges or the health reform measures of the Biden administration will affect the Affordable Care Act or our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments, will remain in effect through 2031, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. In addition, on January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, including hospitals, and an increase in the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain.

We expect other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. In July 2021, the Biden administration released an executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at prescription drugs. In response to Biden’s executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices outlining principles for drug pricing reform and setting out a variety of potential legislative policies Congress could pursue to advance these principles. No legislation or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of other reform initiatives. Individual states in the United States have become increasingly aggressive in implementing regulations designed to contain pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

We rely on single-source third party contract manufacturing organizations to manufacture and supply our product candidates, and if the FDA or foreign regulatory authorities do not approve these manufacturing facilities or if these organizations fail to perform, our ability to conduct clinical trials and obtain regulatory approval our product candidates may be harmed.

We do not own facilities for clinical and commercial manufacturing of our product candidates, including ANG-3070, and we rely upon third-party contract manufacturing organizations to manufacture and supply product candidates for our clinical trials and we will rely in such manufacturers to meet commercial demand. Currently, we rely on and have agreements with a single third-party contract manufacturer to supply the drug substance for ANG-3070 and to manufacture all clinical trial supplies of ANG-3070.

Additionally, the facilities at which ANG-3070 or any of our other product candidates are manufactured must be the subject of a satisfactory inspection before the FDA or the regulators in other jurisdictions approve the product candidate manufactured at that facility. We are completely dependent our third-party vendors for compliance with the current Good Manufacturing Practice requirements (cGMPs). requirements of United States and non-United States regulators for the manufacture of our active ingredients, drug products, and finished products.

If our manufacturers cannot successfully manufacture material conforming to our specifications and cGMPs of any applicable governmental agency, our product candidates will not be approved or, if already approved, may be subject to recalls or demands by regulatory agencies to stop selling the product until manufacturing issues are resolved.

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

- the possibility we are unable to enter into a manufacturing agreement with a third party to manufacture our product candidates;
- the possible breach of the manufacturing agreements by the third parties because of factors beyond our control; and
- the possibility of termination or nonrenewal of the agreements by the third parties before we are able to arrange for a qualified replacement third-party manufacturer.

Any of these factors could delay the development or approval of our product candidates, cause us to incur higher costs or prevent us from developing our product candidates successfully. Furthermore, if the supply chain for our clinical trial materials is interrupted or if any of our contract manufacturers fail to deliver the required clinical trial supplies on a timely basis and at commercially reasonable prices and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality and on a timely basis, we may be unable to supply our clinical trial programs with clinical trial materials which could delay our programs and increase our costs. For instance, we are conducting our ongoing Phase 2 of ANG-3070 in certain countries in Eastern Europe, namely Georgia, Bulgaria, and Lithuania. If our supply chain in the region is interrupted for any reason, including the current war in Ukraine, the dosing of patients in our Phase 2 clinical trial could be slowed, delayed or stopped. Further, such challenges could be compounded by the COVID-19 pandemic.

Changes in structure of or funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel, the maintenance of regulatory review timelines, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. The lack of appropriate funding or appropriate resource for the FDA, could have material adverse effect on our ability to develop ANG-3070 and our product candidates.

We have conducted and may continue to conduct future clinical trials outside of the United States. The FDA and other regulatory authorities may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We are enrolling or plan to enroll patients in our Phase 2 clinical trial of ANG-3070 for PPKD in Georgia, Australia, Lithuania, Bulgaria, Spain, Italy and potentially other jurisdictions under separate clinical trial applications in such jurisdictions. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, the FDA requires the clinical trial to have been conducted in accordance with GCPs, and the FDA must be able to validate the data from the clinical trial through an onsite inspection if it deems such inspection necessary. In addition, when clinical trials are conducted only at sites outside of the United States, such trials may not be subject to IND review, meaning the FDA may not provide advance comment on the clinical protocols for the trials, and therefore there is an additional potential risk that the FDA could determine the study design or protocol for a non-U.S. clinical trial was inadequate, which would likely require additional clinical trials in order to seek FDA approval. If the FDA does not accept data from our clinical trials of ANG-3070 and any future product candidates conducted outside the United States, it would likely result in the need for additional clinical trials, which would be costly and time consuming and delay or permanently halt our development of ANG-3070 and any future product candidates.

Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- patient monitoring and compliance;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research;
- diminished protection of intellectual property in some countries, and
- operational risks resulting from war and conflict certain countries or in proximity to the countries in which we are conducting our clinical trials.

If manufacturers obtain approval for generic versions of our products or product candidates, our business will be materially harmed.

In our industry, much of an innovative product's commercial value is realized while it has patent protections and market exclusivity. When market exclusivity expires generic versions of the product can be approved and marketed, and there can be substantial decline in the innovative product's sales.

Market exclusivity for our products is based upon patent rights and certain regulatory forms of exclusivity. If we are unable to secure or maintain our exclusivities, we may face generic competition that could materially impede our ability to effectively commercialize our products, including be reducing the price we can charge and reducing our market share. ANG-3070 and our other product candidates are protected by a number of granted and pending patent applications, and may be entitled to certain regulatory exclusivities if approved.

In some countries, patent protections for our products may not exist because certain countries did not historically offer the right to obtain specific types of patents or we did not file patents in those markets. Also, the patent environment is unpredictable and the validity and enforceability of patents cannot be predicted with certainty.

Specifically, with regard to the potential for generic entry in the United States, under the U.S. Food, Drug and Cosmetic Act (FDCA) the FDA can approve an Abbreviated New Drug Application (ANDA) for a generic version of an approved branded drug without the ANDA applicant undertaking the clinical testing necessary to obtain approval to market a new drug. Generally, in place of such clinical studies, an ANDA applicant needs only to submit data demonstrating that its product has the same active ingredient(s), strength, dosage form, route of administration and that it is bioequivalent to the approved product.

The FDCA requires an ANDA applicant certify either that its generic product does not infringe any of the patents listed by the owner of the branded drug in the Orange Book or that those patents are not enforceable. This process is known as a paragraph IV certification. Upon notice of a paragraph IV certification, a patent owner or NDA holder has 45 days to bring a patent infringement suit in federal district court against the company seeking ANDA approval of a product covered by one of the owner's patents. If this type of suit is commenced, the FDCA provides a 30-month stay on the FDA's approval of the competitor's application.

If the litigation is resolved in favor of the ANDA applicant or the challenged patent expires during the 30-month stay period, the stay is lifted and the FDA may thereafter approve the application based on the standards for approval of ANDAs. Once an ANDA is approved by the FDA, the generic manufacturer may market and sell the generic form of the branded drug in competition with the branded medicine.

The ANDA process can result in generic competition if the patents at issue are not upheld or if the generic competitor is found not to infringe the owner's patents. If this were to occur with respect to any of our product candidates after approval, our business could be materially harmed.

Risks Relating to Collaborations and Commercialization of Our Product Candidates

If we are able to develop and obtain regulatory approval for any of our product candidates, our business will be materially harmed if we are unable to successfully commercialize such approved products.

Even if we receive regulatory approval of any product candidate, including ANG-3070, it is uncertain whether we will be able to successfully commercialize such product. Our marketing of any approved product will be limited to the product's approved use and potentially subject to other limitations as set forth in its approved prescribing information and package insert. Accordingly, we cannot ensure any of our future approved products will be successfully developed, approved or commercialized. If we are unable to successfully commercialize our future approved products, we may not be able to generate sufficient revenue to operate our business. In particular, the future commercial success of any approved product is subject to a number of risks, including the following:

- the emergence of unknown side effects causing an approved drug to be taken off the market;
- the receipt of market acceptance by physicians, hospitals, payers and patients;
- our ability to obtain meaningful pricing and reimbursement for any approved product, and
- our ability to obtain, maintain or enforce our patents and other intellectual property rights related to our approved products.

Our existing collaborations as well as additional collaboration arrangements we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our product candidates.

We have licensed certain rights with respect to ANG-3777 to Vifor Pharma, and in the future we may seek additional collaboration arrangements for the commercialization, or potentially for the development, of certain of our product candidates depending on the merits of retaining development and/or commercialization rights for ourselves as compared to entering into collaboration arrangements.

The success of our existing and any future collaboration arrangements, will depend heavily our ability with our collaborators to develop and obtain approval of the any licensed product or product candidate and on the efforts and activities of our collaborators. For instance, in November 2020 we entered into a license agreement (the Vifor License) with Vifor International, Ltd. (Vifor Pharma), granting Vifor Pharma global rights (excluding Greater China) to develop, manufacture and commercialize ANG-3777 in all therapeutic, prophylactic and diagnostic uses for renal indications and congestive heart failure. Pursuant to the Vifor License, we are eligible to receive certain clinical, post-approval, or sales milestone payments, and/or royalties, based upon the clinical development plan for ANG-3777 set forth in Vifor License. However, based upon clinical trial results for ANG-3777 disclosed in the fourth quarter of 2021 we do not expect to receive any such payments as we do not intend to continue to pursue the current clinical development plan for ANG-3777 set forth in the Vifor License, which had included a Phase 3 study for CSA-AKI and a Phase 4 confirmatory study in DGF.

Further, our dependence on collaborative arrangements subjects us to a number of risks, including the risk we may never receive substantial economic benefit from the arrangements, we may not be able to control the amount and timing of resources our collaborators may devote to the product candidates; our collaborators may experience financial difficulties; business combinations or significant changes in a collaborator's business strategy may also adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement; and collaboration arrangements may be terminated or allowed to expire, which would delay the development and may increase the cost of developing our product candidates. Any of these outcomes could harm our business.

Additionally, to the extent we decide to enter into additional collaboration agreements in the future, we may face significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to prudently manage our existing collaborations or to enter new ones should we chose to do so. The terms of new collaborations or other arrangements that we may establish may not be favorable to us.

If we fail to develop market opportunities for ANG-3070 or any future products, or market opportunities are smaller than we believe they are, our potential to generate revenue may be adversely affected, and our business may suffer.

The precise incidence and prevalence for all the conditions we currently or may intend to address with ANG-3070 or any future product candidates are unknown. Our projections of both the number of people who have the diseases we target, as well as the subset of people with these diseases who have the potential to benefit from treatment with ANG-3070 or any future product candidates, are based on our beliefs and estimates.

These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics or market research, and may prove to be incorrect. Further, new trials may change the estimated incidence or prevalence of these diseases. The total addressable market across ANG-3070 and any future product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each of ANG-3070 and any future product candidates approved for sale for these indications, the availability of alternative treatments and the safety, convenience, cost and efficacy of ANG-3070 and any future product candidates relative to such alternative treatments, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

Risks Relating to Our Business and Strategy

We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors in the United States, Europe, and other jurisdictions, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical and generic drug companies, and universities and other research institutions. Many of our competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients, and manufacturing pharmaceutical products. These companies also have significantly greater research, sales, and marketing capabilities and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds potentially making the product candidates we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA approval or discovering, developing, and commercializing drugs for kidney, heart, liver, lung and other diseases we are targeting before we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. In addition, many universities and private and public research institutes may become active in our target disease areas.

With respect to ANG-3070, Tarpeyo® (budesonide) from Calliditas was granted accelerated approved by the FDA for IgAN, one form of PPKD. Reata Pharmaceuticals has filed an NDA with the FDA for approval of bardoxolone methyl in Alport disease, another form of PPKD. Phase 3 programs in PPKD include Atrasentan from Chinook Pharmaceuticals (IgAN, FSGS, Alport), Iptacopan from Novartis (IgAN), Narsoplimab from Omeros (IgAN), Sibeprenlimab from Visterra/Otsuka Pharmaceuticals (IgAN), Sparsenten from Travere Therapeutics (IgAN, FSGS), and DMX-200 from Dimerix (FSGS). There are two approved therapies, pirfenidone (Esbriet®, sold by Roche/Genentech) for IPF and nintedanib (OFEV®, sold by Boehringer-Ingleheim) for IPF and SSc-ILD. Corporate Phase 3 clinical programs potentially competitive with ANG-3070 in IPF include pamrevlumab from Fibrogen, Treprostinil from United Therapeutics, and PRM-151 from Roche/Genentech.

With respect to competition for our ROCK2 inhibitor, netarsudil ophthalmic solution from Aerie Pharmaceuticals, Inc. was first approved by the FDA in 2017 as a topical agent for reducing intraocular pressure in patients with open-angle glaucoma and ocular hypertension. Other competition in clinical development include Kadmon Holdings, Inc.'s belumosudil (KD025), a ROCK2 inhibitor with reduced selectivity against ROCK1, in the clinic for several indications, including chronic graft versus host disease, systemic sclerosis and IPF. CXC007 from Redx Pharma and GV101 from Graviton Biotherapeutics are in Phase 1 trials. We are also aware of other ROCK2 inhibitors in preclinical development.

Regarding competition for our CYP11B2 inhibitor, CIN-107 from CinCor Pharma is in multiple Phase 2 trials for resistant hypertension, uncontrolled hypertension, and primary aldosteronism. MLN-101 from Mineralis is in Phase 2 trials for patients with uncontrolled hypertension. PB6440 from PhaseBio is preparing for Phase 1 trials in 2022 in treatment resistant hypertension.

We believe our ability to successfully compete will depend on, among other things:

- our ability to recruit and enroll patients for our clinical trials;
- our ability to design and successfully execute appropriate clinical trials;
- our ability to gain and to maintain positive relationships with regulatory authorities;
- the efficacy, safety, and reliability of our product candidates;
- the speed at which we develop our product candidates;
- our ability to commercialize and market any of our product candidates receiving regulatory approval;
- the pricing of our products;
- adequate levels of reimbursement by government entities and by private health insurance plans;
- our ability to protect intellectual property rights and regulatory exclusivities related to our products;
- our ability to manufacture and sell commercial quantities of any approved products to the market; and
- acceptance of our product candidates by downstream customers, including physicians, other healthcare providers, pharmacists, and patients.

If our competitors market products more effective, safer, or less expensive than our products or product candidates, or if any, or these products reach the market sooner we may not achieve commercial success. In addition, the biopharmaceutical industry is characterized by rapid technological change. It may be difficult for us to stay abreast of the rapid changes in each area of research and development. If we fail to stay at the forefront of change, we may be unable to compete effectively. Products developed by our competitors may render our product candidates or products obsolete, less competitive or not economical.

We currently depend on single third-party suppliers for the manufacture and supply of drug substance and potential future commercial product supplies for our product candidates, and any performance failure on the part of our supplier could delay the development and potential commercialization of our product candidates.

We cannot be certain our drug substance supplier will continue to provide us with sufficient quantities of drug substance, our manufacturers will be able to produce sufficient quantities of drug product incorporating such drug substance, to satisfy our anticipated specifications and quality requirements, or such quantities can be obtained at pricing necessary to sustain acceptable pharmaceutical margins for any of our product candidates, if approved. Our current dependence on a single supplier for our drug substance and the challenges we may face in obtaining adequate supply of drug substance involves several risks, including limited control over pricing, availability, quality and delivery schedules, and such risks may be heightened as a result of the COVID-19 pandemic. Any supply interruption in drug substance or drug product could materially harm our ability to complete our development program for such indications. In addition, any supply interruption in drug substance or drug product could materially harm our ability to complete our other development programs or satisfy commercial demand, if approved, until a new source of supply, if any, could be identified and qualified. For instance, we are conducting our ongoing Phase 2 of ANG-3070 in certain countries in Eastern Europe, namely Georgia, Bulgaria, and Lithuania. If our supply chain in the region is interrupted for any reason, including the current war in Ukraine, the dosing of patients in our Phase 2 clinical trial could be slowed, delayed or stopped. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of our product candidates, including limiting supplies necessary for clinical trials and regulatory approvals, which would have a material adverse effect on our business.

Moreover, our current supplier of drug substance may not have the capacity to manufacture drug substance in the quantities that we believe will be sufficient to meet our future clinical needs or, in the case of any of our wholly-owned product candidates and those for which we retain the right to commercialize, anticipated market demand or to enable us to achieve the economies of scale necessary to reduce the manufacturing cost of applicable drug substance. While we are currently engaged in discussions with a potential second supplier for clinical and commercial drug substance, such negotiations may not lead to a definitive agreement on acceptable terms, or at all, which could have a material adverse effect on our business.

With respect to any of our wholly-owned product candidates and those for which we retain the right to commercialize, we expect that we will be able to develop a supply chain with multiple suppliers and significantly decrease our cost of goods within the first several years of commercialization following the receipt of any approvals. However, if our contract manufacturer for drug substance is unable to source, or we are unable to purchase, sufficient quantities of materials necessary for the production of the drug substance for such product candidates, the ability of such product candidates to reach their market potential or to be timely launched, would be delayed or suffer from a shortage in supply, which would impair our ability to generate revenue from sales. If there is a disruption to our contract manufacturers' or suppliers' relevant operations, we could have no other means of producing drug substance until they restore the affected facilities or we or they procure alternative manufacturing facilities. Additionally, any damage to or destruction of our contract manufacturers' or suppliers' facilities or equipment may significantly impair our ability to manufacture drug substance for our product candidates on a timely basis.

We depend on third-party contractors for a substantial portion of our operations and may not be able to control their work as effectively as if we performed these functions ourselves. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize our product candidates, if approved.

We outsource substantial portions of our operations to third-party service providers, including the conduct of preclinical studies and clinical trials, collection and analysis of data, and manufacturing. Our agreements with third-party service providers and CROs are on a study-by-study and project-by-project basis. Typically, we may terminate the agreements with notice and are responsible for the supplier's previously incurred costs.

In addition, any CRO we retain will be subject to the FDA's and EMA's regulatory requirements and similar standards outside of the United States and Europe, and we do not have direct control over compliance with these regulations by these providers. Consequently, if these providers do not adhere to applicable governing practices and standards, the development and commercialization of our product candidates could be delayed or stopped, which could severely harm our business and financial condition.

Because we have relied on third parties, our internal capacity to perform these functions is limited to contractual oversight. Outsourcing these functions involves the risk third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. This challenge has been made more difficult by the COVID-19 pandemic and resulting shelter-in-place and stay-at-home restrictions, which are driving greater dependency on electronic monitoring of trial sites. Such monitoring can be less reliable and creates additional exposure to data privacy and cybersecurity issues. Additionally, the facilities at which any of our product candidates are manufactured must be the subject of a satisfactory inspection before the FDA or the regulators in other jurisdictions approve the product candidate manufactured at that facility. We are completely dependent our third-party vendors for compliance with cGMP requirements of United States and non-United States regulators for the manufacture of our finished products. If our manufacturers cannot successfully manufacture material conforming to our specifications and cGMPs of any applicable governmental agency, our product candidates will not be approved or, if already approved, may be subject to recalls or demands by regulatory agencies to stop selling the product until manufacturing issues are resolved. In addition, our third-party service providers and CROs that perform nonclinical studies and clinical trials on our behalf must comply with applicable Good Laboratory Practice (GLP) requirements for animal testing and GCP requirements for clinical trials, where any failure to comply with such requirements could result in the FDA or other regulatory authorities refusing to accept data obtained in violation of such requirements and possibly initiating other enforcement action against us and our contractors.

We and our consultants monitor our third parties for performance and adherence to protocols. We have had to replace clinical sites because of poor enrollment. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties (including sensitive data such as personal information or clinical data), which could increase the risk this information will be misappropriated or compromised in connection with a security breach, cyber-attack or other security incident. There are a limited number of third-party service providers specializing in or having the expertise required to achieve our business objectives.

Identifying, qualifying, and managing performance of third-party service providers can be difficult, time consuming, and cause delays in our development programs. We currently have a relatively small number of employees, which limits the internal resources we have available to identify and monitor third-party service providers. To the extent we are unable to identify, retain, and successfully manage the performance of third-party service providers in the future, our business may be adversely affected, and we may be subject to the imposition of civil or criminal penalties if their conduct of clinical trials violates applicable law.

We will need to maintain a good relationship with our employees to maintain our operations. A deterioration in our relationships with our employees could have an adverse impact on our business.

On January 4, 2022, we announced a reduction in force impacting somewhat less than half of our employees. Our decision to engage in this reduction results from an assessment of our internal resources needs given the results of the Phase 3 study of ANG-3777 in patients at risk for DGF would likely not support a regulatory approval in that population and the results from a Phase 2 trial in CSA-AKI would not support a Phase 3 trial in the indication. This reduction was a cost-cutting measure across the organization to support our 2022 primary focus on the clinical development of its investigational asset ANG-3070, a highly selective, oral tyrosine kinase receptor inhibitor in development as a treatment for fibrotic diseases, particularly in the kidney and lung, as well as advancing preclinical assets to IND-enabling studies. This may cause substantial uncertainty as to job security for the rest of our employees. Maintaining good relationships with our employees and operating effectively and efficiently across our organization are crucial to our operations and our success. If we are unable to successfully maintain such relationships or manage the uncertainty as a result of the reduction in the number of our employees, and the complexity of operations, our business may be adversely affected.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants.

We may not be able to attract or retain qualified management, finance, scientific, clinical, and commercial personnel and consultants due to the intense competition for qualified personnel and consultants among biotechnology, pharmaceutical, and other businesses. If we are not able to attract and retain necessary personnel and consultants to accomplish our business objectives, we may experience constraints significantly impeding the achievement of our development objectives, our ability to raise additional capital, and our ability to implement our business strategy.

We are highly dependent upon our senior management, particularly our Chief Executive Officer, Dr. Jay Venkatesan, as well as on the development, regulatory, commercialization, and business development expertise of the rest of our senior management and other senior personnel across preclinical, clinical, translational medicine, legal, and regulatory affairs. If we lose one or more of our executive officers or key employees or consultants, our ability to implement our business strategy successfully could be seriously harmed. Any of our executive officers, key employees, or consultants may terminate their employment and/or engagement with us at any time. Replacing executive officers, key employees, and consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of, and commercialize products successfully. Competition to hire and retain employees and consultants from this limited pool is intense, and we may be unable to hire, train, retain, or motivate these additional key personnel and consultants. Our failure to retain key personnel or consultants could materially harm our business.

We have scientific and clinical advisors and consultants who assist us in formulating and implementing our research, development, and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities limiting their availability to us and typically they will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies competitive with ours.

We expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.

We are a clinical -stage biopharmaceutical company that has been operating since 1998. Our operations to date have been limited to researching and developing product candidates, including conducting preclinical studies and clinical trials. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market.

Our financial condition and operating results are expected to significantly fluctuate from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include, but are not limited to:

- the timing and cost of, and level of investment in, research, development, including the needs for additional clinical trials, and, if approved, commercialization activities relating to our product candidates, which may change from time to time;
- delay in or the success of our clinical trials through all phases of clinical development, including our ongoing clinical trials of ANG-3070;
- potential adverse events associated with our product candidates potentially delaying or preventing approval or causing an approved drug to be taken off the market;
- any delays in regulatory review and approval by regulatory authorities of our product candidates in clinical development, including ANG-3070;
- our ability to obtain additional funding to develop our product candidates;
- our ability to commercialize and obtain market acceptance and reimbursement for our approved products; and
- our dependency on third-party manufacturers to manufacture and distribute our products and key ingredients.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for a product candidate and may have to limit its commercialization.

The use of our product candidates in clinical trials and the sale of any products for which we may obtain marketing approval expose us to the risk of product liability claims. Product liability claims may be brought against us or our collaborators by participants enrolled in our clinical trials, patients, healthcare providers, or others using, administering, or selling our products. If we cannot successfully defend ourselves against any such claims, we would incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- decreased demand for our product candidates and loss of revenues;
- impairment of our business reputation;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

We have obtained limited product liability insurance coverage for our clinical trials in the United States and in selected other jurisdictions where we are conducting clinical trials. Our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to product liability. Large judgments have been awarded in class action lawsuits based on drugs with unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash resources and adversely affect our business.

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

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, employment benefits liability, business automobile, workers' compensation, products liability, malicious invasion of our electronic systems, and clinical trials (U.S. and foreign), and directors' and officers', employment practices and fiduciary liability insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

Under the terms of the government grant funding we have received, the government may compel us to license to a third party, or suspend, terminate or withhold grant funding.

A significant amount of our discovery and initial clinical research has been funded principally by United States government grants and contracts. As with all other pharmaceutical research programs supported in part by federal research dollars, conducting research under federal grants required us to grant the U.S. government a nonexclusive, nontransferable, irrevocable, paid-up license for the government to practice or have the invention practiced on its behalf throughout the world. Under certain circumstances, the government can require the grantee to license a third party, or the government may take title and grant a license itself, known as march-in rights, which may occur if the invention is not brought to practical use within a reasonable time, if health or safety issues arise, if public use of the invention is in jeopardy, or if other legal requirements are not satisfied. Although, to our knowledge, the U.S. government has never forced a grantee to license a third party or taken title and granted a license itself, these march-in rights are available to the government, and we cannot assure you that the government will not exercise such rights in the future.

Under the terms and conditions of the government grant funding, we are obligated to comply with various reporting requirements and to take certain administrative actions. Material noncompliance with the terms and conditions of the grant funding may result in one or more enforcement actions by the grant agency. These enforcement actions include denying funds for the cost of funded activities, suspending the grant in whole or in part, pending corrective action, and withholding further grant awards. The grant agency may also terminate the grant for cause, or take other legally available remedies.

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

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset a portion of future taxable income, if any, until such unused losses expire, if ever. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change,” generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a rolling three-year period, the corporation's ability to use its pre-change net operating loss carryforwards (NOLs) and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. We have not performed an analysis to assess whether an ownership change has occurred. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise become unavailable to offset future income tax liabilities. Under the TCJA, as modified by the Coronavirus Aid, Relief and Economic Security Act (the CARES Act), the amount of post-2017 NOLs that are permitted to deduct from U.S. federal income taxes for tax years beginning after December 31, 2020 is limited to 80% of our taxable income in such year, where taxable income is determined without regard to the NOL deduction itself. The TCJA, as modified by the CARES Act, generally eliminates the ability to carry back any NOLs to prior taxable years for tax years beginning after December 31, 2020, while allowing post-2017 unused NOLs to be carried forward indefinitely without expiration. Additionally, state NOLs generated in one state cannot be used to offset income generated in another state. For these reasons, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes.

Any claims relating to improper handling, storage or disposal of hazardous materials used in our business could be costly and delay our research and development efforts.

Our research and development activities involve the controlled use of potentially harmful hazardous materials, including volatile solvents and chemicals causing cancer. Our operations also produce hazardous waste products. We face the risk of contamination or injury from the use, storage, handling or disposal of these materials. We are subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations could be significant, and current or future environmental regulations may impair our research, development or production efforts. If one of our employees were accidentally injured from the use, storage, handling, or disposal of these materials, the medical costs related to their treatment would be covered by our workers' compensation insurance policy. However, we do not carry specific hazardous waste insurance coverage and our general liability insurance policy specifically excludes coverage for damages and fines arising from hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be subject to criminal sanctions or fines or be held liable for damages, our operating licenses could be revoked, or we could be required to suspend or modify our operations and our research and development efforts.

Risks Relating to Our Intellectual Property

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If our patent position and potential regulatory exclusivity do not adequately protect our product candidates, others could compete against us more directly, which would harm our business, possibly materially.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current and future product candidates, and their methods of manufacture and use. Our ability to stop 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 and/or trade secrets that cover these activities. The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States or in many jurisdictions outside of the United States. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be issued in relevant jurisdictions from our present or future patent filings, or those we license from third parties, and further cannot predict the extent to which we will be able to enforce such issued claims in jurisdictions important to our business. If any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

It is possible others have filed, and in the future may file, patent applications covering products and technologies similar, identical or competitive to ours, or are otherwise important to our business. We cannot be certain any patent filings owned by a third party will not have priority over patent applications filed or in-licensed by us, or we or our licensors will not be involved in interference, opposition or invalidity proceedings before United States or foreign patent offices. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, and/or could allow third parties to commercialize our technology or products and compete directly with us, without payment to us. Furthermore, third-party filings may issue as patents infringed by our manufacture or commercialization of our products. Licenses may not be available to such third party patents, and challenges to their validity or infringement may be expensive and may not succeed. If the breadth or strength of protection provided by our patents and patent applications is threatened, or if we are perceived or found to infringe intellectual property rights of others, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates, and could impede or preclude our ability to commercialize our products.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. We may become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, any of which could limit our ability to stop others from using or commercializing similar or identical technology and products, and/or limit the duration of the patent protection of our technology and products.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we might not have been the first to make the inventions covered by our pending patent applications or patents;
- others may be able to develop a product similar to, or better than, ours in a way that is not covered by the claims of our patents;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- any patents that we have or obtain may not provide us with any competitive advantages;
- patents have limited term and geographic scope; we may not be able to secure patents that last long enough and are in relevant jurisdictions to effectively limit competition;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

Without patent protection for our compounds, pharmaceutical compositions, or formulations of our product candidates, our ability to stop others from using or selling our product, or other competitive products including our compounds, may be limited.

If the patent applications we hold or have in-licensed with respect to present or future product candidates fail to issue, if their breadth and/or strength of protection is limited or challenged, or if they fail to provide meaningful exclusivity for present or future product candidates, it could dissuade companies from collaborating with us to develop future candidates and threaten our ability to commercialize future commercial products. Any such outcome could have a materially adverse effect on our business.

We may also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or feasible. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators, and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If we do not obtain protection under the Hatch-Waxman Act and similar legislation outside of the United States by extending the patent terms and obtaining data exclusivity for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, if any, one or more of our United States patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process.

However, we may not be granted an extension of patent term because, for example, of failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than what we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our product candidates approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates, and have not yet begun the process of applying to register trademarks for our product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications or otherwise challenge our use of the trademarks. In the event our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks, and we may not have adequate resources to enforce our trademarks.

In addition, any proprietary name we propose to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

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

The United States has enacted and implemented wide-ranging patent reform legislation. 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. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the Federal Courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce patents we have obtained or licensed, or we might obtain or license in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies enforcing them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents we have obtained or licensed or we may obtain or license in the future.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

If we choose to go to court to stop another party from using the inventions claimed in any patents we obtain, that individual or company has the right to ask the court to rule such patents are invalid or should not be enforced against that third party. These lawsuits are expensive, would consume time and resources and would divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents. In addition, there is a risk the court will decide such patents are not valid and we do not have the right to stop the other party from using the inventions.

There is also a risk, even if the validity of such patents is upheld, the court will refuse to stop the other party on the grounds such other party's activities do not infringe our patents. In addition, the United States Supreme Court has recently modified some tests used by the USPTO in granting patents over the past 20 years, which may decrease the likelihood we will be able to obtain patents and increase the likelihood of challenge of any patents we obtain or license.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our product candidates.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. We cannot guarantee our products or product candidates, or their manufacture or use, will not infringe third-party patents. Furthermore, a third party may claim we or our manufacturing or commercialization collaborators are using inventions covered by the third party's patent rights. It is also possible a third party might allege our products or product candidates, or their manufacture or use, incorporate or rely on trade secrets improperly received from the third party. A third party alleging violations of their intellectual property rights may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. Defense of such claims, regardless of their merit, are costly and could affect our results of operations and divert the attention of managerial and scientific personnel.

There is a risk a court would decide we or our commercialization collaborators are infringing the third party's intellectual property rights and would order us or our collaborators to stop relevant activities. In that event, we or our commercialization collaborators may not have a viable way to avoid the infringement and may need to halt commercialization of the relevant product. In addition, there is a risk a court will order us or our collaborators to pay the other party damages for having infringed the other party's intellectual property rights. In the future, we may agree to indemnify our commercial collaborators against certain intellectual property infringement claims brought by third parties. The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform.

If we are sued for patent or other intellectual property (e.g., trade secret, trademark, etc.) infringement, we could incur significant costs, and delays in our product development or commercialization.

For example, in order to prevail in a suit alleging patent infringement, we would need to demonstrate our products or methods either do not infringe the claims of the relevant patent or the patent claims are invalid, and we may not be able to do this. Proving invalidity of a patent is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming.

We cannot be certain others have not filed patent applications or obtained issued patents for technology that we need to use to commercialize our products, at least because:

- some patent applications in the United States may be maintained in secrecy until the patents are issued;
- patent applications in the United States are typically not published until 18 months after the priority date;
- even published patent applications and patents may be difficult or impossible to identify if their records in available databases are incomplete or inaccurate, or are in a language that is not readily amendable to searching in English; and
- publications in the scientific literature often lag behind actual discoveries.

Our most advanced programs are currently in clinical trials. Patent laws of various jurisdictions, including the United States, exempt clinical trial activities, and most or all preclinical work, from patent infringement. These exemptions expire when clinical work is completed and application for a commercialization license (e.g., a New Drug Application) is submitted to a relevant regulatory authority (e.g., the FDA). Accordingly, we cannot be confident that third parties will not allege patent infringement with respect to our existing products or programs merely because they have not yet done so.

Our competitors may have filed, and may in the future file, patent applications covering technology like ours. Any such patent application may have priority over our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a United States patent application on inventions similar to ours, we may have to participate in an interference or derivation proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our United States patent position with respect to such inventions, and granting such position to the third party, so we may need to seek a license from such third party to continue our use of the technologies, which license might not be available, or might impose significant costs.

Other countries have similar laws permitting secrecy of patent applications and may be entitled to priority over our applications in such jurisdictions.

In addition, we may be subject to claims we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

We may not have sufficient resources to bring actions alleging intellectual property infringement to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates. Furthermore, even if we are successful in proceedings relating to alleged intellectual property infringement or misappropriation, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us.

Some of our competitors may be able to sustain the costs of complex litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to the USPTO and non-United States patent agencies. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, 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. In such an event, our competitors might be able to enter the market and this circumstance could have a material adverse effect on our business.

Risks Relating to Our Common Stock

Our stock price may be volatile and you may not be able to resell shares of our common stock at or above the price you paid.

The trading price of our common stock could be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed in this “Risk Factors” section of this report and others such as:

- results from, and any delays in, our clinical trials for ANG-3070;
- results of clinical trials of our competitors' products;
- competition from existing products or new products that may emerge;
- announcements by academic, guideline publishers or other third parties challenging the fundamental premises underlying our approach to treating PPKDs like FSGS and IgAN, or IPF;
- failure or discontinuation of any of our research and development programs;
- manufacturing setbacks or delays of or issues with the supply of the materials for ANG-3070;
- announcements relating to future licensing, collaboration or development agreements;
- sales of our common stock by or announcements relating to our existing collaborators, including Vifor Pharma;
- acquisitions and sales of new products, technologies or businesses;
- quarterly variations in our results of operations or those of our future competitors;
- changes in earnings estimates or recommendations by securities analysts;
- announcements by us or our competitors of new products, significant contracts, commercial relationships, acquisitions or capital commitments;
- developments with respect to intellectual property rights;
- our commencement of, or involvement in, litigation;
- changes in financial estimates or guidance, including our ability to meet our future revenue and operating profit or loss estimates or guidance;
- any major changes in our board of directors or management;
- new legislation in the United States or relevant foreign jurisdictions relating to the sale or pricing of pharmaceuticals;
- FDA or other U.S. or foreign regulatory actions affecting us or our industry;
- product liability claims or other litigation or public concern about the safety of ANG-3070;
- market conditions in the pharmaceutical and biotechnology sectors; and
- general economic conditions in the United States and abroad.

In addition, the stock markets in general, and the markets for pharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If we were to become involved in securities litigation, we could incur substantial costs and resources and the attention of our management could be diverted from the operation of our business.

An active, liquid and orderly market for our common stock may not be sustained.

Our common stock is currently listed on the Nasdaq Global Select Market under the symbol “ANGN”. The price for our common stock may vary and an active or liquid market in our common stock may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses, applications, or technologies using our shares as consideration.

If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

We may, from time to time, issue additional shares of common stock at a discount from the current trading price of our common stock, including pursuant to our 2021 Incentive Award Plan and 2021 Employee Stock Purchase Plan. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

We identified material weaknesses in our internal control over financial reporting and we may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements. If we fail to remediate any material weaknesses or if we otherwise fail to establish and maintain effective control over financial reporting, our ability to accurately and timely report our financial results could be adversely affected.

We have identified control deficiencies in the design and operation of our internal control over financial reporting that constituted material weaknesses. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

The material weaknesses identified in our internal control over financial reporting related to (i) insufficient resources with knowledge and expertise in U.S. GAAP to properly evaluate certain complex transactions, including debt instruments and equity instruments; and (ii) insufficient financial reporting and close controls to ensure that incurred expenses are accrued at period end and deliverables from third party contractors are reviewed for accuracy. We have taken a number of actions to remediate these material weaknesses, including engaging SEC compliance and technical accounting consultants to assist in evaluating transactions for conformity with U.S. GAAP; hiring additional finance and accounting personnel to augment accounting staff and to provide more resources for complex accounting matters and financial reporting; and strengthening our financial reporting and close relating to incurred expenses by ensuring our data capture procedures are clearly defined and that responsible personnel, including supervisory personnel, have adequate training regarding the process and expectation.

However, we are still in the process of implementing these processes and controls and we cannot assure you that these measures will be sufficient to remediate the material weaknesses that have been identified or prevent future material weaknesses or significant deficiencies from occurring.

If we are unable to successfully remediate the existing material weaknesses in our internal control over financial reporting, or discover additional material weaknesses in the future, the accuracy and timing of our financial reporting, and our stock price, may be adversely affected and we may be unable to maintain compliance with the applicable stock exchange listing requirements.

We are an "emerging growth company" and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an "emerging growth company," as defined in Jumpstart Our Business Act of 2012, (JOBS Act), and we intend to take advantage of certain exemptions from various reporting requirements 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, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and obtaining stockholder approval of any golden parachute payments not previously approved.

In addition, as an "emerging growth company," the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. We have elected to use this extended transition period under the JOBS Act. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards applicable to public companies, which may make comparison of our financials to those of other public companies more difficult. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply for a period of time with the auditor attestation requirements of Section 404, and reduced disclosure obligations regarding executive compensation in this report and our periodic reports and proxy statements.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company or smaller reporting company.

We have completed and may in the future complete related party transactions that were not and may not be conducted on an arm's length basis.

We have in the past and continue to be party to certain transactions with certain entities affiliated with Dr. Goldberg, director and Chairman Emeritus on our Board, as well as certain of his immediate family members. For instance, in November 2013, we granted Ohr Cosmetics, LLC (Ohr), an affiliated company, an exclusive worldwide license, with the right to sublicense, under our patent rights covering one of our CYP26 inhibitors, ANG-3522, for the use in treating conditions of the skin or hair. We own, and the family of Dr. Goldberg owns, approximately 2.4% and 80.6%, respectively, of the membership interests in Ohr. Dr. Goldberg's son is the manager of Ohr.

In addition, we rent office and laboratory space in Uniondale, New York from NovaPark LLC (NovaPark), an affiliated company, under a lease that expires on June 20, 2026. The space we rent is part of an approximately 110,000-square-foot general laboratory and development facility (NovaPark Facility) for biological and chemistry research owned by NovaPark. We own, and Dr. Goldberg and Rina Kurz, Dr. Goldberg's spouse, own 10%, 45% and 45%, respectively, of the membership interests in NovaPark.

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

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

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;

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

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

Our amended and restated certificate of incorporation and amended and restated bylaws provide for an exclusive forum in the Court of Chancery of the State of Delaware for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation and amended and restated bylaws also 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 against us or any of our directors, officers, employees or agents and arising under the Securities Act. Nothing in our amended and restated certificate of incorporation or amended and restated bylaws precludes stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive-forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

General Risk Factors

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

The global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including most recently as a result of the COVID-19 pandemic and the Russian invasion of Ukraine. Such volatility and disruptions have caused and may continue to cause severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

Our business could be affected by litigation, government investigations and enforcement actions.

We currently operate in a number of jurisdictions in a highly regulated industry and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the United States. or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, privacy, anti-kickback, anti-bribery, securities, commercial, employment, and other claims and legal proceedings which may arise from conducting our business. Any determination our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief, and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Legal proceedings, government investigations and enforcement actions can be expensive and time consuming. An adverse outcome resulting from any such proceeding, investigations or enforcement actions could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business and results of operations.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures, reckless and/or negligent conduct or unauthorized activities violating (i) the laws and regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (ii) manufacturing standards, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad and (iv) laws requiring the true, complete and accurate reporting of financial information or data. 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 restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations.

Additionally, we are subject to the risk a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government-funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations, any of which could have a negative impact on our business, financial condition, results of operations and prospects.

If we engage in an acquisition, reorganization or business combination, we will incur a variety of risks potentially adversely affecting our business operations or our stockholders.

From time to time we have considered, and we will continue to consider in the future, strategic business initiatives intended to further the expansion and development of our business. These initiatives may include acquiring businesses, technologies, or products or entering into a business combination with another company. If we pursue such a strategy, we could, among other things:

- issue equity securities dilutive to our current stockholders' percentage ownership;
- incur substantial debt straining our operations;
- spend substantial operational, financial, and management resources to integrate new businesses, technologies, and products;
- assume substantial actual or contingent liabilities;
- reprioritize our development programs and even cease development and commercialization of our product candidates; or
- merge with, or otherwise enter into a business combination with, another company in which our stockholders would receive cash and/or shares of the other company on terms certain of our stockholders may not deem desirable.

Although we intend to evaluate and consider acquisitions, reorganizations, and business combinations in the future, we have no agreements or understandings with respect to any acquisition, reorganization, or business combination at this time.

Security breaches, cyber-attacks, or other disruptions or incidents could expose us to liability and affect our business and reputation.

We are increasingly dependent on our information technology systems and infrastructure for our business. We, our collaborators and our service providers collect, store, and transmit sensitive information including intellectual property, proprietary business information, clinical trial data and personal information in connection with our business operations. The secure maintenance of this information is critical to our operations and business strategy. Some of this information could be an attractive target of criminal attack by third parties with a wide range of motives and expertise, including organized criminal groups, “hacktivists,” patient groups, disgruntled current or former employees, nation-state and nation-state supported actors and others. Cyber-attacks are of ever-increasing levels of sophistication, and despite our security measures, our information technology and infrastructure may be vulnerable to such attacks or may be breached, including due to employee error or malfeasance. We have implemented information security measures to protect our systems, proprietary information and sensitive data, including the personal information of clinical trial participants against the risk of inappropriate and unauthorized external use and disclosure and other types of compromise. However, despite these measures, and due to the ever changing information cyber-threat landscape, we cannot guarantee these measures will be adequate to detect, prevent or mitigate security breaches and other incidents and we may be subject to data breaches through cyber-attacks, malicious code (such as viruses and worms), phishing attacks, social engineering schemes, and insider theft or misuse. Any such breach could compromise our networks and the information stored there could be accessed, modified, destroyed, publicly disclosed, lost or stolen. If our systems become compromised, we may not promptly discover the intrusion. Like other companies in our industry, we have experienced attacks to our data and systems, including malware and computer viruses. Any security breach or other incident, whether real or perceived, would cause us to lose product sales if any, and suffer reputational damage and loss of customer confidence. Such incidents could result in costs to respond to, investigate and remedy such incidents, notification obligations to affected individuals, government agencies, credit reporting agencies and other third parties, legal claims or proceedings, and liability under our contracts with other parties and federal and state laws that protect the privacy and security of personal information.

If a security breach, cyber-attack, or other disruption is the result of state-sponsored activities, it may be considered an “act-of-war”, potentially making us ineligible for reimbursement under our insurance policies covering such attacks. Any one of these events could cause our business to be materially harmed and our results of operations would be adversely impacted.

The occurrence of natural disasters, including a tornado, an earthquake, or fire, or any material failure, weakness, interruption, cyber-attack, security incident, war or any other catastrophic event, could disrupt our operations or the operations of third parties who provide vital support functions to us, which could have a material adverse effect on our business, results of operations, and financial condition.

We and the third-party service providers on which we depend for various support functions, such as data storage, are vulnerable to damage from catastrophic events, such as power loss, natural disasters, terrorism, physical theft, power loss, war, state-sponsored attacks, telecommunications failure and similar unforeseen events beyond our control, as well as from internal and external security breaches, malware and viruses, denial or degradation of service attacks, ransomware, cyber events and other disruptive problems. Such events could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition, and prospects.

If a natural disaster, power outage, security incident or other event occurred that prevented us from using all or a significant portion of our offices or other facilities, damaged critical infrastructure such as our data storage facilities, financial systems, or manufacturing resource planning and quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event.

We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. In addition, the failure of our systems to operate effectively, maintenance problems, upgrading or transitioning to new platforms, or a breach in security could result in delays and reduce efficiency in our operations. Remediation of such problems could result in significant, unplanned capital investments.

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

We are subject to numerous and varying data privacy and security laws, regulations and standards, and our failure to comply could result in penalties and reputational damage.

We are subject to domestic and foreign laws and regulations concerning data privacy, information security and the protection of personal information including health information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business and is expected to increase our compliance costs and exposure to liability. In the United States, numerous federal and state laws and regulations, including state security breach notification laws, federal and state health information privacy laws (including HIPAA), and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of personal information. Each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues for us. For example, the California Consumer Privacy Act (CCPA) went into effect January 1, 2020. The CCPA, among other things, imposes new data privacy obligations on covered companies and provides expanded privacy rights to California residents, including the right to access, delete and opt out of certain disclosures of their information. The CCPA provides for civil penalties for violations, as well as a private right of action with statutory damages for certain data breaches, which may increase the frequency and likelihood of data breach litigation. Although the law includes limited exceptions, including for “protected health information” maintained by a covered entity or business associate, such exceptions may not apply to all of our operations and processing activities. Further, the California Privacy Rights Act (CPRA), recently passed in California. The CPRA imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also creates a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. In addition, the CCPA has prompted a number of proposals for new federal and state privacy legislation that, if passed, could increase our potential liability, increase our compliance costs and adversely affect our business.

If we fail to comply with applicable laws and regulations we could be subject to penalties or sanctions, including criminal penalties if we knowingly obtain or disclose individually identifiable health information in a manner that is not authorized or permitted by HIPAA or applicable state laws.

We are also or may become subject to rapidly evolving data protection laws, rules and regulations in foreign jurisdictions, including Canada, Australia, Brazil, Georgia and Europe. For example, the European Union General Data Protection Regulation (GDPR) governs certain collection and other processing activities involving personal data about individuals in the European Economic Area and the United Kingdom. Among other things, the GDPR imposes requirements regarding the security of personal data, the rights of data subjects to access and delete personal data, requires having lawful bases on which personal data can be processed and transferred outside of the European Economic Area, requires changes to informed consent practices, and requires more detailed notices for clinical trial participants and investigators. In addition, the GDPR imposes substantial fines for breaches and violations (up to the greater of €20 million or 4% of our annual global revenue). The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR. Relatedly, following the United Kingdom's withdrawal from the European Economic Area and the European Union, and the expiry of the transition period, companies will have to comply with the GDPR and the GDPR as incorporated into United Kingdom national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk.

Compliance with U.S. and foreign privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or in some cases, impact our or our partners' or suppliers' ability to operate in certain jurisdictions. Each of these constantly evolving laws can be subject to varying interpretations. If we fail to comply with any such laws, rules or regulations, we may face government investigations and/or enforcement actions, fines, civil or criminal penalties, private litigation or adverse publicity that could adversely affect our business, financial condition and results of operations.

U.S. tax legislation and future changes to applicable U.S. tax laws and regulations may have a material adverse effect on our business, financial condition and results of operations.

Changes in laws and policy relating to taxes may have an adverse effect on our business, financial condition and results of operations. For example, the U.S. government enacted significant tax reform legislation in 2017, which, as modified by the CARES Act, contains, certain provisions which may adversely affect us. Changes include, but are not limited to, a federal corporate income tax rate decrease to 21% for tax years beginning after December 31, 2017, a reduction to the maximum deduction allowed for net operating losses generated in tax years after December 31, 2017, eliminating carrybacks of net operating losses for tax years beginning after December 31, 2020, providing for indefinite carryforwards for losses generated in tax years after December 31, 2017, imposing significant additional limitations on the deductibility of interest, allowing for the accelerated expensing of capital expenditures, and putting into effect the migration from a “worldwide” system of taxation to a largely territorial system. The legislation is unclear in many respects and may continue to be subject to potential amendments, technical corrections, interpretations and implementing regulations by the Treasury and Internal Revenue Service, any of which may mitigate or increase certain adverse effects of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation. Generally, future changes in applicable U.S. tax laws and regulations, or their interpretation and application could have an adverse effect on our business, financial condition and results of operations.

We may be subject to claims our employees have wrongfully used or disclosed alleged trade secrets of their former employers. If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be significantly diminished.

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 seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. We may also be subject to claims former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims.

There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, validity or enforceability of, or right to use, valuable intellectual property. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

The laws of some foreign countries do not protect proprietary rights to the same extent as do the laws of the United States, and we may encounter significant problems in securing and defending our intellectual property rights outside the United States.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain countries. The legal systems of certain countries, particularly certain developing countries, do not always favor the enforcement of patents, trade secrets, and other intellectual property rights, particularly those relating to pharmaceutical products, which could make it difficult for us to stop infringement of our patents, misappropriation of our trade secrets, or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our intellectual property rights in foreign countries could result in substantial costs, divert our efforts and attention from other aspects of our business, and put our patents in these territories at risk of being invalidated or interpreted narrowly, or our patent applications at risk of not being granted, and could provoke third parties to assert claims against us. We may not prevail in all legal or other proceedings we may initiate and, if we were to prevail, 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.

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

Use of Proceeds from the Initial Public Offering

On February 9, 2021, we closed our Initial Public Offering of 5,750,000 shares of our common stock at a public offering price of $16.00 per share, which includes the full exercise by the underwriters of their option to purchase an additional 750,000 shares of common stock. All of the shares of common stock issued and sold in our IPO were registered under the Securities Act pursuant to registration statements on Form S-1, as amended (Registration No. 333-252177), which was declared effective by the SEC on February 4, 2021. Aggregate net proceeds to Angion were $85.6 million, after deducting underwriting discounts and commissions of $6.4 million. None of the underwriting discounts and commissions or offering expenses were incurred or paid, directly or indirectly, to any of our directors or officers or their associates or to persons owning 10% or more of our common stock or to any of our affiliates.

The Initial Public Offering and Concurrent Private Placement, which both closed on February 9, 2021, generated aggregate net proceeds of approximately $107.0 million, after deducting the underwriting discounts and commissions, private placement fee and estimated offering expenses of $10.0 million. As of March 31, 2022, we have used approximately $66.0 million of the aggregate net proceeds from our IPO.

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on February 5, 2021 pursuant to Rule 424(b)(4), except that given the clinical trial data on ANG-3777 reported in the fourth quarter of 2021, we no longer intend to use the proceeds for the clinical development of ANG-3777. There are no funds budgeted for additional clinical trials of ANG-3777.

Recent Sales of Unregistered Securities

There were no unregistered securities sold in three months ended March 31, 2022.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation	8-K	2/09/2021	3.1	
3.2	Amended and Restated Bylaws	8-K	2/09/2021	3.2	
4.1	Reference is made to exhibits 3.1 through 3.2.				
4.2	Form of Common Stock Certificate.	S-1/A	2/01/2021	4.2	
4.3	Form of Warrant to Purchase Common Stock.	S-1	1/15/2021	4.3	
4.4	Registration Rights Agreement, dated as of March 31, 2020, by and among Angion Biomedica Corp. and the investors party thereto.	S-1	1/15/2021	4.6	
10.1	Separation Agreement, dated February 25, 2022, by and between Angion Biomedica Corp. and Itzhak D. Goldberg	10-K	3/30/2022	10.7(a)	
10.2	Separation Agreement, dated March 1, 2022, by and between Angion Biomedica Corp. and Elisha Goldberg	10-K	3/30/2022	10.8(b)	
10.3	Third Amendment dated March 17, 2022 to Consulting Agreement, dated June 3, 2020, as amended, by and between Angion Biomedica Corp. and Gregory S. Curhan.	10-K	3/30/2022	10.11(c)	
10.4	2022 Compensation Decisions with Executive Officers	8-K	3/04/2022	Item 5.02	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1^	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2^	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101.INS	XBRL Instance Document.				X
101.SCH	XBRL Taxonomy Extension Schema Document.				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.				X
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).				X

† Portions of this exhibit have been omitted in accordance with Item 601(b)(10) of Regulation S-K.

^ The certification that accompanies this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, is not deemed “filed” by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

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.

ANGION BIOMEDICA CORP.

By: /s/ JAY R. VENKATESAN, M.D.

Jay R. Venkatesan, M.D.
President and Chief Executive Officer and Director (Principal Executive Officer)

Date: May 16, 2022

ANGION BIOMEDICA CORP.

By: /s/ GREGORY S. CURHAN

Gregory S. Curhan
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: May 16, 2022

Exhibit 31.1

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

I, Jay R. Venkatesan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Angion Biomedica Corp.;

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. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

ANGION BIOMEDICA CORP.

By: /s/ JAY R. VENKATESAN, M.D.

Jay R. Venkatesan, M.D.
President and Chief Executive Officer and Director (Principal Executive Officer)

Date: May 16, 2022

Exhibit 31.2

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

I, Gregory S. Curhan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Angion Biomedica Corp.;

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. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

ANGION BIOMEDICA CORP.

By: /s/ Gregory S. Curhan

Gregory S. Curhan

Interim Chief Financial Officer (Principal Financial and Accounting Officer)

Date: May 16, 2022

Exhibit 32.1

CERTIFICATIONS PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. SECTION 1350)

The undersigned officers of Angion Biomedica Corp. (the Company) certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Quarterly Report on Form 10-Q of the Company for the period ended September 30, 2021 (the Quarterly Report), as filed with the Securities and Exchange Commission, 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 this Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

ANGION BIOMEDICA CORP.

By: /s/ JAY R. VENKATESAN, M.D.

Jay R. Venkatesan, M.D.
President and Chief Executive Officer and Director (Principal Executive Officer)

Date: May 16, 2022

Exhibit 32.2

CERTIFICATIONS PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. SECTION 1350)

The undersigned officers of Angion Biomedica Corp. (the Company) certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Quarterly Report on Form 10-Q of the Company for the period ended September 30, 2021 (the Quarterly Report), as filed with the Securities and Exchange Commission, 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 this Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

ANGION BIOMEDICA CORP.

By: /s/ Gregory S. Curhan

Gregory S. Curhan
Interim Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: May 16, 2022