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

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**FORM 10-Q**

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

For the quarterly period ended March 31, 2021

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 001-04321

**ANGION BIOMEDICA CORP**  
(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**51 Charles Lindbergh Boulevard Uniondale,  
New York**

(Address of Principal Executive Offices)

**11-3430072**

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

**11553**

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

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

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

The number of shares of the issuer's common stock outstanding as of May 14, 2021 was 29,663,194.

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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;
- our and our collaborators' ability to obtain and maintain regulatory approval of ANG-3777 and any other product candidates we may develop, and the labeling under any approval we may obtain;
- 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 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 for 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 (unaudited)

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

	March 31, 2021	December 31, 2020
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 130,456	\$ 34,607
Prepaid expenses and other current assets	3,042	7,690
Total current assets	133,498	42,297
Property and equipment, net	246	156
Right of use assets	4,541	4,072
Investments in related parties	877	822
Other assets	38	—
<b>Total assets</b>	<b>\$ 139,200</b>	<b>\$ 47,347</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities		
Accounts payable	\$ 6,690	\$ 5,578
Accrued expenses	4,092	6,665
Lease liability—current	780	611
Deferred revenue—current	3,792	3,942
Warrant liability	714	10,704
Convertible promissory notes payable at fair value	—	51,170
Series C convertible preferred stock at amortized cost	—	26,001
Series C convertible preferred stock at fair value	—	2,518
Other short-term debt	895	260
Total current liabilities	16,963	107,449
Lease liability—noncurrent	4,150	3,847
Deferred revenue—noncurrent	25,644	25,865
Other long-term debt	—	635
Total liabilities	46,757	137,796
Commitments and contingencies—Note 11		
Stockholders' equity (deficit)		
Common stock, \$0.01 par value per share; 300,000,000 authorized shares; 30,053,606 and 15,632,809 shares issued as of March 31, 2021 and December 31, 2020, respectively; 29,660,458 and 15,316,721 shares outstanding as of March 31, 2021 and December 31, 2020, respectively	300	156
Treasury stock, 393,148 and 316,088 shares outstanding as of March 31, 2021 and December 31, 2020, respectively	(2,991)	(1,846)
Additional paid-in capital	292,670	72,136
Accumulated other comprehensive loss	(287)	(333)
Accumulated deficit	(197,249)	(160,562)
Total stockholders' equity (deficit)	92,443	(90,449)
<b>Total liabilities and stockholders' equity (deficit)</b>	<b>\$ 139,200</b>	<b>\$ 47,347</b>

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

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

	Three Months Ended March 31,	
	2021	2020
<b>Revenue:</b>		
Contract revenue	\$ 371	\$ —
Grant revenue	—	865
Total revenue	371	865
<b>Operating expenses:</b>		
Cost of grant revenue	—	383
Research and development	14,298	9,596
General and administrative	6,012	3,455
Total operating expenses	20,310	13,434
<b>Loss from operations</b>	<b>(19,939)</b>	<b>(12,569)</b>
<b>Other income (expense)</b>		
Change in fair value of warrant liability	(3,519)	(292)
Change in fair value of convertible notes	(7,469)	(454)
Change in fair value of Series C convertible preferred stock	(3,592)	—
Foreign exchange transaction (loss) gain	(53)	245
Earnings from equity method investment	55	28
Interest income (expense), net	(2,170)	(180)
Total other income (expense)	(16,748)	(653)
<b>Net loss</b>	<b>(36,687)</b>	<b>(13,222)</b>
<b>Other comprehensive income:</b>		
Foreign currency translation adjustment	46	149
<b>Comprehensive loss</b>	<b>\$ (36,641)</b>	<b>\$ (13,073)</b>
Net loss per common share, basic and diluted	\$ (1.56)	\$ (0.91)
Weighted average common shares outstanding, basic and diluted	23,443,851	14,462,823

*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 (Deficit)
	Shares	Amount	Shares	Amount				
<b>Balance as of December 31, 2019</b>	14,758,718	\$ 148	(312,164)	\$ (1,810)	\$ 63,531	\$ —	\$ (80,455)	\$ (18,586)
Issuance of broker warrants	—	—	—	—	151	—	—	151
Exercise of broker warrants	58,415	1	—	—	—	—	—	1
Exercise of stock options	192,872	1	—	—	(2)	—	—	(1)
Stock-based compensation	—	—	—	—	832	—	—	832
Foreign currency translation adjustment	—	—	—	—	—	149	—	149
Net loss	—	—	—	—	—	—	(13,222)	(13,222)
<b>Balance as of March 31, 2020</b>	<u>15,010,005</u>	<u>\$ 150</u>	<u>(312,164)</u>	<u>\$ (1,810)</u>	<u>\$ 64,512</u>	<u>\$ 149</u>	<u>\$ (93,677)</u>	<u>\$ (30,676)</u>

	Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Other Comprehensive loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
<b>Balance as of December 31, 2020</b>	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 IPO	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)
<b>Balance as of March 31, 2021</b>	<u>30,053,606</u>	<u>\$ 300</u>	<u>(393,148)</u>	<u>\$ (2,991)</u>	<u>\$ 292,670</u>	<u>\$ (287)</u>	<u>\$ (197,249)</u>	<u>\$ 92,443</u>

*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,	
	2021	2020
<b>Cash flows from operating activities</b>		
Net loss	\$ (36,687)	\$ (13,222)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	6	27
Amortization of right of use assets	149	144
Amortization of debt issuance costs	1,884	157
Stock-based compensation	5,117	832
Change in fair value of convertible notes	7,469	454
Change in fair value of Series C convertible preferred stock	3,592	—
Change in fair value of warrant liability	3,519	292
Earnings from equity investment	(67)	(28)
Distribution from equity investment	12	—
Changes in operating assets and liabilities:		
Grants receivable	—	(140)
Prepaid expenses and other current assets	2,667	(366)
Other assets	(38)	—
Accounts payable	1,112	1,445
Accrued expenses	(769)	1,824
Lease liabilities	(146)	(152)
Deferred revenue	(371)	—
Net cash used in operating activities	(12,551)	(8,733)
<b>Cash flows from investing activities</b>		
Purchase of fixed assets	(41)	(20)
Net cash used in investing activities	(41)	(20)
<b>Cash flows from financing activities</b>		
Proceeds from issuance of convertible notes and warrants	—	3,051
Net Proceeds from issuance of common stock upon IPO and Concurrent Private Placement, net of discount and commissions	110,560	—
Proceeds from issuance of Series C convertible preferred stock, net of issuance costs	—	885
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	—
Exercise of broker warrants	—	(1)
Exercise of warrants	680	—
Exercise of stock options	1	1
Net cash provided by financing activities	108,444	3,936
Effect of foreign currency on cash	(3)	233
Net increase (decrease) in cash and cash equivalents	95,849	(4,584)
Cash and cash equivalents at the beginning of the period	34,607	5,571
<b>Cash and cash equivalents at the end of the period</b>	<b>\$ 130,456</b>	<b>\$ 987</b>
<b>Supplemental disclosure of noncash investing and financing activities:</b>		
Conversion of convertible notes into common stock upon IPO	\$ 58,179	\$ —
Conversion of Series C preferred stock into common stock upon IPO	\$ 35,754	\$ —
Net exercise of warrants upon IPO	\$ 13,509	\$ —
Accrued interest premium for Series C convertible preferred stock	\$ —	\$ 7
Right of use assets exchanged for operating lease liabilities	\$ 618	\$ 525
Conversion of convertible notes into common stock prior to IPO	\$ 460	\$ —
Deferred offering costs in accrued expenses or accounts payable	\$ 1,408	\$ 153
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 late-stage 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.

**Forward Stock Split**

On January 25, 2021, the board of directors of the Company approved an amendment to the Company's certificate of incorporation to effect a forward stock split ("Forward Split") of shares of the Company's common stock on a one-for-1.55583 basis, which was effected on February 1, 2021. All references to common stock, convertible preferred stock, warrants to purchase common stock, stock options, RSAs, RSUs, PSUs, per share amounts and related information contained in the condensed consolidated financial statements have been retroactively adjusted to reflect the effect of the forward stock split for all periods presented. No fractional shares of the Company's common stock were issued in connection with the Forward Split. Any fractional share resulting from the Forward Split was rounded down to the nearest whole share, and any stockholder entitled to fractional shares as a result of the Forward Split will receive a cash payment in lieu of receiving fractional shares.

**Initial Public Offering and the Concurrent Private Placement**

On February 9, 2021, the Company closed its Initial Public Offering ("IPO") of 5,750,000 shares of 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. Aggregate net proceeds to Angion were \$85.6 million, after deducting underwriting discounts, commissions and offering expenses of \$6.4 million. In addition to the shares being sold in the IPO, Angion 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 aggregate net proceeds of \$24.3 million, after deducting a 3% private placement agent fee of \$0.7 million. Subsequent to the closing of the IPO, all of the 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.

**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, 2021, the Company had \$130.5 million in cash and cash equivalents and an accumulated deficit of \$197.2 million. Prior to its IPO completed in February 2021, the Company has funded its operations through United States government grants, the issuance of convertible notes (see Note 6), sales of convertible preferred stock and common stock (see Notes 7) and warrants (see Note 10) and licensing agreements (see Note 12).

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 believes that its existing cash and cash equivalents will be sufficient to meet the projected operating requirements for at least 12 months from the date of issuance of its financial statements. The Company has evaluated and concluded there are no conditions or events, considered in the aggregate, that raise substantial

**ANGION BIOMEDICA CORP.**  
**Notes to Consolidated Financial Statements (Continued)**

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.

**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.

The Company's remaining significant accounting policies are described in Note 2 to its consolidated financial statements for the year ended December 31, 2020, 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, 2021.

***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, 2020 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, 2020 was derived from financial statements audited by Moss Adams LLP, independent public accountants, 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, 2021. 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 that are potentially subject to concentrations of credit risk. The Company's cash and cash equivalents are deposited in accounts at large financial institutions, and amounts

**ANGION BIOMEDICA CORP.**  
**Notes to Consolidated Financial Statements (Continued)**

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, 2021 and December 31, 2020, 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.

### ***Deferred Offering Costs***

Deferred offering costs consist of legal and accounting fees incurred through the balance sheet date that are directly related to the Company's IPO and have been reflected as issuance costs upon the completion of the offering. As of December 31, 2020, \$2.0 million of deferred offering costs were included in prepaid expenses and other current assets in the condensed consolidated balance sheets. Subsequent to the closing of the IPO, \$2.8 million of deferred costs previously included in prepaid expenses and other current assets was netted with additional paid in capital in the condensed consolidated balance sheets.

### ***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.

### ***Convertible Notes Payable at Fair Value***

As permitted under ASC 825, *Financial Instruments* ("ASC 825"), the Company has elected the fair value option for recognition of its convertible notes. In accordance with ASC 825, the Company recognizes these convertible notes at fair value with changes in fair value recognized in the condensed consolidated statements of operations. The fair value option may be applied instrument by instrument, but it is irrevocable. As a result of applying the fair value option, direct costs and fees related to the convertible notes were recognized in general and administrative expense in earnings as incurred and not deferred. The estimated fair value of the convertible notes is determined by utilizing a present value cash flow model and the values of the equity underlying the conversion options were estimated using company equity values implied from the Subject Company Transaction Method which

**ANGION BIOMEDICA CORP.**  
**Notes to Consolidated Financial Statements (Continued)**

includes the back-solve and scenario-based methods (Probability Weighted Expected Return Method). See Note 4. Accrued interest for the notes has been included in the change in fair value of convertible notes in the condensed consolidated statements of operations. All outstanding convertible notes were converted into common stock upon the close of the IPO on February 9, 2021 and no balances remained outstanding as of March 31, 2021. See Note 6.

**Convertible Preferred Stock**

Series C convertible preferred stock includes settlement features that result in liability classification. The initial carrying value of the Series C convertible preferred stock is 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 is accreted to interest expense using the effective interest method. During 2020, certain 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 that was exchanged for the convertible notes was recorded at fair value and are subject to re-measurement at each reporting period with gains and losses reported through the Company's condensed consolidated statements of operations. All outstanding shares of convertible preferred stock were converted into common stock upon the close of the Company's IPO on February 9, 2021. See Note 7. As of March 31, 2021, there was no convertible preferred stock outstanding.

**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 Topic 606"). Under ASC Topic 606, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC Topic 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 entity satisfies a performance obligation.

At contract inception, the Company assess 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 that is 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

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**Notes to Consolidated Financial Statements (Continued)**

customer is able to use and benefit from the license. For licenses that are 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 whether the regulatory and development milestones are considered probable of being reached and estimate 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 that 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, we determine 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 through the end of the performance period of the performance obligation.

#### **Grant Revenue**

The Company concluded that 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 that the grants meet the definition of a contribution and are non-reciprocal transactions, and has also concluded that 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 for the recognition of 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 that revenue recognition reflects the transfer of promised goods or services to customers in an amount that reflects the consideration that 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.

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

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**Notes to Consolidated Financial Statements (Continued)**

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, 2021 and 2020, 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, 2021 or 2020, advertising costs were not significant.

**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 convertible preferred stock, 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, 2021 and 2020, basic and diluted net loss per common share are the same.

**Recently Adopted Accounting Pronouncements**

In August 2020, the FASB issued ASU No. 2020-06, Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, which simplifies accounting for convertible instruments by removing major separation models required under current U.S. GAAP. ASU No. 2020-06 removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2021. Early adoption is permitted for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The Company adopted this standard as of January 1, 2021, which did not have material impact on its condensed consolidated financial statements and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740)-Simplifying the Accounting for Income Taxes (ASU 2019-12), which is intended to simplify accounting for income taxes. It removes certain exceptions to the general principles in Topic 740 and amends existing guidance to improve consistent application. ASU 2019-12 is effective for the Company for fiscal years beginning after December 15, 2020, including interim periods therein. The Company adopted this standard as of January 1, 2021, which did not have material impact on its condensed consolidated financial statements and related disclosures.

In January 2020, the FASB issued ASU No. 2020-01, Investments-Equity Securities (Topic 321), Investments-Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815)-Clarifying the Interactions between Topic 321, Topic 323, and Topic 815 (a consensus of the Emerging Issues Task Force). This update clarifies whether an entity should consider observable transactions that require it to either apply or discontinue the equity method of accounting for the purposes of applying the measurement alternative and how to account for certain forward contracts and purchased options to purchase securities. For public entities, this guidance is effective for fiscal years beginning after December 15, 2020. The Company adopted this standard as of January 1, 2021, which did not have material impact on its condensed consolidated financial statements and related disclosures.

In March 2020, the FASB issued ASU No. 2020-04, Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting. The amendments in this ASU provide optional expedients and exceptions for applying GAAP to contracts, hedging relationships, and other transactions affected by reference rate reform if certain criteria are met. The amendments in this ASU apply only to contracts, hedging relationships, and other transactions that reference LIBOR or another reference rate expected to be discontinued because of reference rate reform. LIBOR is expected to be phased out by 2021. The amendments in this ASU are effective as of



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March 12, 2020 through December 31, 2022. The Company adopted this standard as of January 1, 2021, which did not have material impact on its condensed consolidated financial statements and related disclosures.

In October 2020, the FASB issued ASU No. 2020-10, Codification Improvements. ASU 2020-10 provides amendments to a wide variety of topics in the FASB's Accounting Standards Codification, which applies to all reporting entities within the scope of the affected accounting guidance. ASU 2020-10 is effective for the Company for fiscal years beginning after December 15, 2020, including interim periods therein. The Company adopted this standard as of January 1, 2021, which did not have material impact on its condensed consolidated financial statements and related disclosures.

***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**

***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***

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"), headquartered in Switzerland. We recognized revenue from upfront payments over the term of our estimated period of performance using a cost-based input method under Topic 606. We expect to continue recognizing revenue from upfront payments related to the Vifor License using the cost-based input method for the foreseeable future.

**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 is entitled to receive \$80.0 million in upfront and near-term clinical milestone payments, including \$30.0 million in upfront cash that was received in November 2020, and a \$30.0 million equity investment, \$5.0 million of which was convertible note and subsequently converted into common stock upon the IPO and \$25.0 million of which was received in the Concurrent Private Placement with our 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 \$1.925 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, the Company is responsible for executing a pre-specified clinical development plan designed to obtain regulatory

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approvals of ANG-3777 for delayed graft function (DGF) and AKI associated with cardiac surgery involving cardiopulmonary bypass (CSA-AKI).

The Vifor License will continue until the expiration of the last royalty term for a licensed product in the licensed territory, unless earlier terminated. The royalty term for a licensed product is, on a country-by-country basis, shall start with the first commercial sale of such licensed product in such country and expire at the latest of (i) expiration of all licensed patents covering the composition of matter of such licensed product or method of use for such licensed product that has obtained regulatory approval in such country, (ii) expiration of all regulatory and data exclusivity applicable to such licensed product in such country, or (iii) the tenth (10th) anniversary of the date of the first commercial sale of such licensed product in such country.

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 we 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 our 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: (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 as of March 31, 2021. The Company determined that the transaction price at the inception of the Vifor License is \$15.0 million, which is 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. The transaction price is recognized as license revenue using the cost-based input method over the estimated performance period of approximately seven years. The performance period represents the estimated timing of completion of the identified performance obligation.

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, 2021 and 2020, the Company recognized contract revenue related to the Vifor License of \$0.4 million and zero, respectively. As of March 31, 2021, \$29.4 million was recorded as deferred revenue, of which \$3.8 million was current, on the condensed consolidated balance sheets related to the Vifor License.



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**Notes to Consolidated Financial Statements (Continued)**

**Note 4—Fair Value Measurements**

The following table classifies the Company's financial assets and liabilities measured at fair value on a recurring basis into the fair value hierarchy as of March 31, 2021 and December 31, 2020 (in thousands):

	Fair Value Measured at March 31, 2021			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets included in:				
Cash and cash equivalents—Money market securities <sup>(1)</sup>	\$ 1	\$ —	\$ —	\$ 1
<b>Total fair value</b>	<b>\$ 1</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 1</b>
Liabilities included in:				
Warrants	\$ —	\$ —	\$ 714	\$ 714
<b>Total fair value</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 714</b>	<b>\$ 714</b>

	Fair Value Measured at December 31, 2020			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets included in:				
Cash and cash equivalents—Money market securities <sup>(1)</sup>	\$ 1	\$ —	\$ —	\$ 1
<b>Total fair value</b>	<b>\$ 1</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 1</b>
Liabilities included in:				
Convertible notes	\$ —	\$ —	\$ 51,170	\$ 51,170
Warrants	—	—	10,704	10,704
Series C convertible preferred stock	—	—	2,518	2,518
<b>Total fair value</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 64,392</b>	<b>\$ 64,392</b>

(1) Included in cash and cash equivalents on the condensed consolidated balance sheets.

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**Notes to Consolidated Financial Statements (Continued)**

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

The following table presents changes in Level 3 liabilities measured at fair value (in thousands):

	Warrant Liability	Convertible Notes	Series C Convertible Preferred Stock at Fair Value	Total
<b>Balance—December 31, 2019</b>	\$ 5,794	\$ 5,848	\$ —	\$ 11,642
Issuance of convertible notes and warrants	—	36,223	—	36,223
Exchange of outstanding convertible notes for Series C convertible preferred stock	—	(2,254)	2,254	—
Change in fair value	4,910	11,353	264	16,527
<b>Balance—December 31, 2020</b>	10,704	51,170	2,518	64,392
Conversion of convertible notes into common stock	—	(58,639)	—	(58,639)
Conversion of convertible Series C convertible preferred stock into common stock	—	—	(6,110)	(6,110)
Net exercise of warrants	(13,509)	—	—	(13,509)
Change in fair value	3,519	7,469	3,592	14,580
<b>Balance—March 31, 2021</b>	\$ 714	\$ —	\$ —	\$ 714

Both observable and unobservable inputs were used to determine the fair value of positions that the Company has classified within the Level 3 category. Unrealized gains and losses associated with liabilities within the Level 3 category include changes in fair value that were attributable to both observable (e.g., changes in market interest rates) and unobservable (e.g., changes in unobservable long-dated volatilities) inputs.

The Company used an option model to measure the fair value of the Notes (on conversion date). The values of the equity underlying the conversion options in the model were estimated using equity values implied from sales of convertible preferred stock. The fair value of the Notes was impacted by the model selected as well as assumptions surrounding unobservable inputs. Key unobservable inputs include the expected volatility of the underlying equity, and the timing of an expected liquidity event.

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.

**Convertible Notes**

The fair value adjustment during the three months ended March 31, 2021 is based on the final settlement amount using a conversion price of \$11.57 per share on February 9, 2021. Subsequent to the closing of the IPO, there were no convertible notes outstanding.

**Series C Preferred Stock**

The fair value adjustment during the three months ended March 31, 2021 is based on the final settlement amount using a conversion price of \$11.57 per share on February 9, 2021. Subsequent to the closing of the IPO, there were no shares of convertible preferred stock outstanding.

**Warrant Liability**

The fair value adjustment for the net exercise of warrants with an exercise price of \$6.43 during the three months ended March 31, 2021 is based on the final settlement amount using the IPO price on February 9, 2021.

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**Notes to Consolidated Financial Statements (Continued)**

Subsequent to the closing of the IPO, there were 39,505 warrants outstanding issued to various consultants as a liability.

A summary of the weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring the Company's warrant liabilities that are categorized within Level 3 of the fair value hierarchy as of March 31, 2021 and December 31, 2020 was as follows:

	March 31, 2021	December 31, 2020
Strike price	\$ 8.02	\$ 0.01
Contractual term (years)	2.2	4.9
Volatility (annual)	86.8 %	86.8 %
Risk-free rate	0.7 %	0.1 %
Dividend yield (per share)	0.0 %	0.0 %

**Note 5—Balance Sheet Components**

***Property and Equipment, Net***

The Company's property and equipment, net was comprised of the following (in thousands):

	March 31, 2021	December 31, 2020
Equipment	\$ 463	\$ 512
Furniture and fixtures	164	27
Leasehold improvements	51	43
Total property and equipment	678	582
Less: accumulated depreciation	(432)	(426)
Property and equipment, net	<u>\$ 246</u>	<u>\$ 156</u>

Depreciation expense for the three months ended March 31, 2021 and 2020 was \$6 thousand and \$27 thousand, respectively.

***Prepaid and Other Current Assets***

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

	March 31, 2021	December 31, 2020
Deferred Offering costs	\$ —	\$ 1,978
Convertible note receivable	—	5,000
Angion Pty tax	—	352
Prepaid insurance	2,343	—
Security deposit	91	—
Other	608	360
Total prepaid and other current assets	<u>\$ 3,042</u>	<u>\$ 7,690</u>

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**Notes to Consolidated Financial Statements (Continued)**

**Accrued Expenses**

Accrued expenses were comprised of the following (in thousands):

	March 31, 2021	December 31, 2020
Accrued compensation	\$ 2,100	\$ 3,154
Accrued direct research costs	894	1,321
Accrued operating expenses	1,090	707
Accrued interest	8	1,483
Total accrued expenses	<u>\$ 4,092</u>	<u>\$ 6,665</u>

**Note 6—Convertible Notes Payable**

During 2020, the Company issued \$31.2 million in aggregate principal amount of convertible notes (the "2020 Notes"). During 2019, the Company issued \$5.3 million of convertible notes to various investors, all of which are due approximately one year from the date of issuance (the "2019 Notes"). The 2019 Notes and the 2020 Notes (collectively referred as the "Additional Convertible Notes") bore interest at a rate of 12% per annum, had a one-year term and the right to convert at the lesser of a 20% discount to the share price and \$11.57 per share. In addition, in December 2020, the Company issued Vifor Pharma a convertible promissory note in aggregate principal amount of \$5.0 million, with interest accruing at 2%, on substantially similar terms, but with a maturity date of three years and a conversion price of \$11.57 per share (the "Vifor Convertible Note"). The Company received \$5.0 million cash from Vifor Pharma in January 2021. As of December 31, 2020, the \$5.0 million convertible note was recorded as convertible note receivable which was included in other current assets on the condensed consolidated balance sheet.

The Company has elected the fair value option for recognition of the 2019 Notes, the 2020 Notes and the Vifor Convertible Note. As such, the 2019 Notes, the 2020 Notes and the Vifor Convertible Note are recognized at estimated fair value with changes in fair value recognized in the condensed consolidated statements of operations. Accrued interest for the notes has been included in the change in fair value of convertible notes in the condensed consolidated statements of operations.

In connection with the issuance of the 2020 Notes, the Company issued equity-classified broker warrants to purchase 214,305 shares of common stock, at an exercise price of \$0.01, with an initial fair value of \$1.7 million which has been recorded as general and administrative expenses. The Company issued broker warrants to purchase 40,087 shares of common stock at an exercise price of \$0.01 in connection with the issuance of the 2019 Notes.

In July and August 2020, the Company exchanged (the "Note Exchange") \$7.0 million in aggregate principal amount of the 2019 Notes and the 2020 Notes for \$7.5 million in aggregate principal amount of new convertible notes (the "New 2020 Notes"). The increase in \$0.5 million was the accrued interest balance for the 2019 Notes and the 2020 Notes upon the Note Exchange. The New 2020 Notes bear interest at a rate of 12% per annum and have a one-year term from the date of the exchange and the right to convert at a 20% discount of the share price, with a price cap of \$11.57 per share, from certain qualified financings. The Note Exchange was recognized as a modification, with changes to fair value accounted for on a prospective basis. As the Company had elected the fair value option for the 2019 Notes and 2020 Notes, the changes in fair value from the modification were included in change in fair value of convertible notes in the condensed consolidated statements of operations.

In August 2020, the Company exchanged (the "Series C Exchange") \$1.9 million in aggregate principal amount of the 2019 Notes and the 2020 Notes, with a fair value of \$2.3 million for 3,042 shares of Series C convertible preferred stock at \$642.75 per share, or \$2.0 million. The increase of \$0.1 million was the accrued interest balance for the 2019 Notes and the 2020 Notes upon this exchange. See Note 7.

**Conversion of Convertible Notes Payable**

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**Notes to Consolidated Financial Statements (Continued)**

In January 2021, the Company issued 33,978 shares of common stock upon the conversion of certain of the outstanding 2020 Notes. In connection with the IPO in February 2021, with an IPO price of \$16.00 per share, the remaining outstanding Additional Convertible Notes and Vifor Convertible Note were converted into 3,636,189 shares of the Company's common stock based on a conversion price of \$11.57 per share. There were no convertible notes outstanding as of March 31, 2021.

**Note 7— Series C Convertible Preferred Stock**

In January 2020, the Company filed an Amended and Restated Certificate of Incorporation, authorizing 12,000 shares of Series C convertible preferred stock (the "Series C Preferred Stock") with 12% per annum cumulative dividends unless the Company fails to redeem any outstanding Series C Preferred Stock in full on the redemption date, then the dividend will increase to 15% per annum until the Series C Preferred Stock has been fully redeemed. Unless earlier converted, the Series C Preferred Stock shall be redeemed on the earlier of: (i) the first anniversary of its issuance date, (ii) the date of a change in control, as defined, or (iii) the date of the occurrence of an event of default, as defined. Each share of Series C Preferred Stock and all accrued and unpaid dividends, at the option of the holders of Series C Preferred Stock, may be converted in whole or in part into equity shares of the Company issued in a future financing at 80% of the fair value of the shares issued in such financing.

In July 2020, the Company filed an Amended and Restated Certificate of Incorporation, increasing the authorized number of shares of Series C Preferred Stock to 40,000 shares of Series C convertible preferred stock and included a cap price of \$11.57 per share on the conversion price of the Series C convertible preferred stock into equity shares of the Company issued in a future financing.

In 2020, the Company issued 34,928 shares of Series C Preferred Stock at \$642.75 per share for gross proceeds of \$22.3 million. In conjunction with the IPO, the Company paid fees to third parties aggregating \$2.2 million and issued equity-classified warrants to brokers to purchase 178,982 shares of common stock at an exercise price of \$0.01 with an initial fair value of \$1.4 million. The initial recognition of the warrant liability, direct fees and settlement premium of \$5.6 million resulted in a discount of \$9.3 million.

Based on management's assessment of the predominant settlement features of the Series C Preferred Stock, the instrument is recognized as a liability in accordance with ASC 480, Distinguishing Liabilities from Equity. The initial carrying value of the Series C Preferred Stock is accreted to the settlement value, which is the fair value of the securities to be issued upon the conversion of the Series C Preferred Stock. The discount to the settlement value is accreted to interest expense using the effective interest method.

In August 2020, the Company exchanged \$1.9 million in aggregate principal amount of the 2019 Notes and the 2020 Notes, with a fair value of \$2.3 million into 3,042 shares of Series C convertible preferred stock (the "Exchanged Series C Shares"). The Series C Exchange is accounted for as a modification, thus upon the date of the Series C Exchange the fair value of \$2.3 million of the exchanged 2019 Notes and the 2020 Notes has been included in Series C convertible preferred stock in the condensed consolidated balance sheets. As the Company had elected the fair value option for the 2019 Notes and the 2020 Notes exchanged in the Series C Exchange, the Exchanged Series C Shares will be recognized at fair value pursuant to the prior fair value option election. Changes in the fair value of Series C convertible preferred stock will be recorded in the condensed consolidated statements of operations.

The following table summarizes the aggregate values recorded for the Series C Preferred Stock as of December 31, 2020 (in thousands):

	At issuance	December 31, 2020
<b>Series C convertible preferred stock recorded at amortized cost</b>		
Principal	\$ 22,308	\$ 22,308
Settlement premium	5,577	5,577
Unamortized discounts and fees	(9,250)	(1,884)
Net carrying amount	<u>\$ 18,635</u>	<u>\$ 26,001</u>
<b>Series C convertible preferred stock recorded at fair value</b>		
Series C convertible preferred stock issued in exchange for convertible notes		2,254
Change in fair value of Series C convertible preferred stock exchanged for convertible notes		264
Total Series C convertible preferred stock		<u>\$ 28,519</u>

### **Conversion of Series C Convertible Preferred Stock**

In connection with the IPO in February 2021, with an initial public offering price of \$16.00 per share, all Series C convertible preferred stock outstanding plus accrued dividends were automatically converted into an aggregate of 2,234,640 shares of common stock on February 9, 2021 with a conversion price of \$11.57 per share. There were no shares of convertible preferred stock outstanding as of March 31, 2021.

## **Note 8—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.

On February 9, 2021, in connection with the IPO, the Company filed a restated Certificate of Incorporation, which, among other things, restated the number of shares of all classes of stock that the Company had authority to issue to 310,000,000 shares, of which (i) 300,000,000 shares shall be a class designated as common stock, par value \$0.01 per share, and (ii) 10,000,000 shares shall be a class designated as undesignated preferred stock, par value \$0.01 per share.

### **Treasury Stock**

At March 31, 2021 and December 31, 2020, the balance on the treasury stock was approximately \$3.0 million and \$1.8 million, respectively.

## **Note 9—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, with annual increases, up to a maximum of 60,000,000 shares of common stock were authorized for issuance under the 2021 Plan.

### Stock Options

The fair value of each employee and non-employee stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company determines 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. The Company was a private company as of February 4, 2021 and lacked company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies. Due to the lack of historical exercise history, the expected term of the Company's stock options for employees has been determined utilizing the "simplified" method for awards. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. 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. Expected dividend yield is zero based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future. Subsequent to the IPO on February 5, 2021, the Company determines the fair value and exercise price using the market closing price of the Company's common stock on the date of grant.

The following assumptions were used to estimate the fair value of stock option awards:

	Three Months Ended March 31,	
	2021	2020
Risk-free interest rate	0.7%	0.7%
Expected dividend yield	—	—
Expected term in years	5.99	5.92
Expected volatility	73.8%-86.8%	70.8%-86.8%

The following table summarizes information activity related to our share option plans:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Total Intrinsic Value (in thousands)
Outstanding as of December 31, 2020	3,479,731	\$ 6.97	8.4	\$ 15,140
Options granted	956,321	15.94		—
Options forfeited	(6,809)	7.93		—
Options exercised	(155)	7.77		—
Options expired	(191)	7.77		—
Outstanding as of March 31, 2021	4,428,897	\$ 8.90	8.5	\$ 26,268
Options vested and exercisable	1,949,595	\$ 6.43	7.6	\$ 15,699

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, 2021 and 2020 was \$8.86 and \$6.12, respectively. As of March 31, 2021, the total unrecognized compensation related to unvested stock option awards granted was \$11.3 million, which the Company expects to recognize over a weighted-average period of approximately 2.8 years.

### Restricted Stock and Restricted Stock Units

The Company's RSA and RSU activity was as follows:

	Shares of Restricted Stock	Weighted Average Grant Date Fair Value Per Share	Restricted Stock Units	Weighted Average Grant Date Fair Value Per Share
Outstanding at December 31, 2020	14,585	\$ 6.05	74,144	\$ 6.50
Released	(3,647)	6.05	(19,264)	6.33
Outstanding at March 31, 2021	<u>10,938</u>	<u>\$ 6.05</u>	<u>54,880</u>	<u>\$ 8.16</u>
Vested as of March 31, 2021	<u>—</u>		<u>17,440</u>	<u>\$ 8.70</u>

#### **Performance-based Restricted Stock Units**

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 Company recorded \$2.8 million of stock-based compensation expense using the accelerated attribution method as the performance condition was satisfied in the first quarter of 2021. As of March 31, 2021, the Company had 371,020 PSUs outstanding.

The following table summarizes the total stock-based compensation expense for the stock options, RSUs, RSAs and compensation issued in shares recorded in the condensed consolidated statements of operations (in thousands):

	Three Months Ended March 31,	
	2021	2020
Research and development	\$ 2,543	\$ 438
General and administrative	2,574	394
Total	<u>\$ 5,117</u>	<u>\$ 832</u>

#### **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 offering period and purchase period will be determined by the Board of Directors. As of March 31, 2021, 390,000 shares under the ESPP remain available for purchase and no offerings had been authorized.



## Note 10—Warrants

As of March 31, 2021 and December 31, 2020, the outstanding warrants to purchase the Company's common stock were comprised of the following:

	Classification	Exercise Price	Expiration Date	Warrants at	Warrants at
				March 31, 2021	December 31, 2020
Warrants issued with 2015 Notes	Liability	\$ 6.43	7/5/28	—	388,396
Warrants issued with 2016 Notes	Liability	\$ 6.43	7/5/28	—	538,933
Warrants issued with 2017 Notes	Liability	\$ 6.43	7/5/28	—	79,265
Warrants issued with 2018 Notes	Liability	\$ 6.43	7/5/28	—	498,567
Warrants issued with Conversion of Notes to Common Stock	Equity	\$ 8.03	8/31/28	232,287	238,779
Warrants issued with Units in the Equity Offering	Equity	\$ 8.03	8/31/28	898,525	907,860
Broker Warrants issued with Equity Offering	Equity	\$ 0.01	8/31/25	1,297	48,485
Consultant Warrants	Liability	\$ 7.60	8/31/28	39,505	39,506
<b>Total Warrants</b>				<b>1,171,614</b>	<b>2,739,791</b>

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. During the three months ended March 31, 2021 and 2020, the increase in the fair value of the warrants of \$3.5 million and \$0.3 million, respectively, are recognized in change in fair value of warrant liability in the condensed consolidated statements of operations.

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

The Company's warrant activity for the three months ended March 31, 2021 was as follows:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
<b>Balance—December 31, 2020</b>	2,739,791	\$ 7.00	4.9
Exercised	(1,565,265)	7.71	
Returned/cancelled	(2,912)	8.03	
<b>Balance—March 31, 2021</b>	<b>1,171,614</b>	<b>\$ 8.02</b>	<b>2.2</b>

### Conversion of Warrants

In February 2021, all warrants outstanding issued with 2015 Notes, 2016 Notes, 2017 Notes, and 2018 Notes with a \$6.43 exercise price were net exercised into an aggregate of 844,335 shares of common stock upon the IPO with a conversion price of \$11.57 per share.

## Note 11—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 that expires 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 leases 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 is subject to charges for common area maintenance and other costs.

In July 2020, the Company entered into a lease for office furniture in San Francisco, California set to expire in July 2025, with an annual lease payment of approximately \$13 thousand.

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 has 4 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 3 years with 9 months' notice.

The following table provides the components of the Company's rent expense (in thousands):

	Three Months Ended March 31,	
	2021	2020
Operating leases		
Operating lease cost	\$ 273	\$ 288
Variable cost	130	92
Operating lease expense	403	380
Short-term lease rent expense	39	61
Total rent expense	\$ 442	\$ 441

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

	Three Months Ended March 31,			
	2021		2020	
Operating cash flows from operating leases	\$	267	\$	296
Right-of-use assets exchanged for operating lease liabilities	\$	618	\$	525
Weighted-average remaining lease term—operating leases (in years)		4.0		5.8
Weighted-average discount rate—operating leases		8.0 %		11.0 %

As of March 31, 2021, maturities of lease liabilities were as follows (in thousands):

Years Ended December 31,	Amounts
2021 (remaining nine months)	\$ 911
2022	1,069
2023	1,303
2024	1,209
2025	1,104
Thereafter	516
Total	6,112
Less present value discount	(1,182)
Operating lease liabilities	\$ 4,930

### **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.

### **Paycheck Protection Program**

In April 2020, the Company received funds in the amount of \$0.9 million pursuant to a loan under the Paycheck Protection Program of the 2020 CARES Act ("PPP") administered by the Small Business Association. The loan has an interest rate of 1.0% and a term of 24 months. No payments are due for the first 16 months, although interest accrues, and monthly payments are due over the next 8 months to retire the loan plus accrued interest. Funds from the loan may only be used for certain purposes, including payroll, benefits, rent and utilities, and a portion of the loan used to pay certain costs may be forgivable, all as provided by the terms of the PPP. The loan is evidenced by a promissory note, which contains customary events of default relating to, among other things, payment defaults and breaches of representations and warranties. The Company may prepay the loan at any time prior to maturity with no prepayment penalties.

## **Note 12—Significant Agreements**

### ***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 the Renal Indications. For the three months ended March 31, 2021 and 2020, the Company recognized contract revenue related to the Vifor License of \$0.4 million and zero, respectively. As of March 31, 2021, \$29.4 million was recorded as deferred revenue, of which \$3.8 million was current, on the condensed consolidated balance sheets related to the Vifor License. See Note 3.

## **Note 13—Income Taxes**

The Company's income tax provision was \$800 and the effective tax rate was 0% in each of the three months ended March 31, 2021 and 2020. 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 that such assets would not be realized.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that 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 that the net deferred tax assets at March 31, 2021 will not be realizable. Accordingly, management has maintained a full valuation allowance against its net deferred tax assets at March 31, 2021. Each reporting period, management evaluates the need for a valuation allowance on our deferred tax assets by jurisdiction and adjust our 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, that 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, 2021, there were no accruals for interest and penalties related to uncertain tax positions.

## **Note 14—Employee Benefit Plan**

### ***Employee Benefit Plan***

The Company sponsors a retirement savings plan that is intended to qualify for favorable tax treatment under Section 401(a) of the Code, and contains a cash or deferred feature that is 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 15—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,	
	2021	2020
<b>Numerator</b>		
Net loss attributable to common stockholders	\$ (36,687)	\$ (13,222)
<b>Denominator:</b>		
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	23,443,851	14,462,823
Net loss per share attributable to common stockholders, basic and diluted	\$ (1.56)	\$ (0.91)

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,	
	2021	2020
Shares issuable upon exercise of stock options	4,428,897	2,835,689
Shares issuable upon the exercise of warrants	1,171,614	3,029,850
Shares issuable upon conversion of the convertible notes <sup>(1)</sup>	—	391,946
Non-vested shares under restricted stock unit grants	37,440	38,895
Non-vested shares under restricted stock grants	10,938	29,171
Total	5,648,889	6,325,551

- (1) The number of shares issuable upon conversion of the 2019 Notes and 2020 Notes has been estimated using the Company's common stock fair value at March 31, 2020, discounted by 20%.

## Note 16—Related Party Transactions

### 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 Executive Chairman owns approximately 2.4% and 81.3%, respectively, of the membership interests in Ohr. The Executive Chairman's 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 that the Ohr License was made on terms no less favorable to the Company than those that 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, 2021, the Company had a 10% interest in NovaPark. Members of the Company's Executive Chairman's 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, 2021 and 2020 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Beginning balance	\$ 672	\$ 849
Earnings from equity method investment	67	28
Distribution from NovaPark	(12)	—
Ending balance	\$ 727	\$ 877

The Company rents office and laboratory space in Uniondale, New York from NovaPark under a lease that expires 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, 2021 and 2020. The Company recorded rent expense for variable expenses related to the lease of \$0.1 million for the three months ended March 31, 2021 and 2020. See Note 11.

### ***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, 2021, 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 stocks into an aggregate of 165,094 shares of common stock with a conversion price of \$11.57 per share. As of March 31, 2021, there were no convertible preferred stocks outstanding.

### ***Consultant Fees***

Angion pays consulting fees under an agreement with the wife of the Executive Chairman of the Company for Company management services. Consultant fees paid to the wife were approximately \$37 thousand and \$29 thousand in each of the three months ended March 31, 2021 and 2020.

### ***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, 2021 and 2020, the Company paid Pearl Cohen approximately zero and \$17 thousand 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. Pursuant to the terms of the consulting agreement, Dr. Yamin, in his capacity as a consultant, received \$27 thousand and \$9 thousand during the three months ended March 31, 2021 and 2020, respectively. 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 17—Subsequent Events**

On April 29, 2021, the Company and Vifor Pharma issued a joint press release announcing completion of enrollment in AKI-002-15, the Phase 2 trial of ANG-3777 in acute kidney injury associated with cardiac surgery involving cardiopulmonary bypass.

## 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 our Annual Report on Form 10-K for the year ended December 31, 2020. In addition to the historical financial information, this discussion contains forward-looking statements that involve risk, 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" and elsewhere in this report. You should carefully read the section of this Quarterly Report on Form 10-Q titled "Risk Factors" 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 of this report titled "Special Note Regarding Forward-Looking Statements."*

### Overview

We are a late-stage biopharmaceutical company focused on the discovery, development and commercialization of novel small molecule therapeutics to address acute organ injuries and 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-3777, is a hepatocyte growth factor (HGF) mimetic that we are currently evaluating in multiple acute organ injuries and related indications, including acute kidney injury (AKI) and injuries to other major organs, such as the lungs, central nervous system (CNS) and heart. Within AKI, we are currently evaluating ANG-3777's ability to improve kidney function and reduce the severity of transplant-associated AKI, also known as delayed graft function (DGF), in patients at risk for kidney dysfunction, as well as for the treatment of AKI associated with cardiac surgery involving cardiopulmonary bypass (CSA-AKI). We are also evaluating ANG-3777 for indications within acute lung injury (ALI), with our primary focus on acute respiratory distress syndrome (ARDS), as well as acute CNS injuries. We are advancing multiple programs for the treatment of fibrotic diseases, leading with ANG-3070, a tyrosine kinase inhibitor (TKI), and our inhibitor of rho kinase 2 (ROCK2). We also continue to develop other preclinical product candidates, including our CYP11B2 (aldosterone synthase) inhibitors, which we are investigating for the purpose of targeting aldosterone-related fibrotic diseases.

In our lead ANG-3777 clinical development program, we recently completed enrollment of the Phase 2 trial in cardiac surgery-associated acute kidney injury (CSA-AKI) and in the Phase 2 trial in Brazil in patients with acute lung injury associated with COVID-19 pneumonia who are at high risk of progressing to Acute Respiratory Distress Syndrome (ARDS).

Since our inception, we have devoted substantially all of our efforts and financial resources to conducting research and development activities, including drug discovery and pre-clinical studies and clinical trials, establishing and maintaining our intellectual property portfolio, organizing and staffing our business, business planning, raising capital and providing general and administrative support for these operations. Prior to 2014, our efforts were primarily focused on researching a number of pathways related to serious organ diseases and applying our medicinal chemistry expertise towards creating potential therapeutics to address the unmet medical needs of patients. During this time period, our operations were funded primarily through the receipt of U.S. government grants and contracts. In 2014, we began raising capital through the sale of debt and equity securities as well as licenses, and since that time have significantly expanded our operations, with a focus on advancing our lead product candidate, ANG-3777, into and through multiple clinical programs and accelerating our other development programs, including our second product candidate, ANG-3070.

From our inception through March 31, 2021, we have received an aggregate of \$292.9 million in funding, which includes approximately net proceeds of \$110.6 million from the IPO and Concurrent Private Placement, approximately \$68.8 million from U.S. government grants, and contracts and aggregate gross proceeds of \$113.5 million through the issuance and sale of our debt and equity securities. As of March 31, 2021, we had cash and cash equivalents of \$130.5 million.

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. In addition, a significant portion of our future revenue and cash resources is expected to be derived from our license



agreement with Vifor Pharma and, to a lesser extent, our license agreement with Sinovant. Our net losses were \$36.7 million and \$13.2 million for the three months ended March 31, 2021 and 2020, respectively. As of March 31, 2021, we had an accumulated deficit of \$197.2 million. 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-3777, ANG-3070 and our other product candidates through clinical trials and preclinical development, and as we seek regulatory approval for ANG-3777, ANG-3070 or any of our other product candidates. In addition, if we seek approval for any of our wholly-owned product candidates or those for which we retain the right to commercialize, we expect 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. Finally, we expect to incur increased expenses to protect our intellectual property and expand our general and administrative support functions, including hiring additional personnel, as well as incur additional costs associated with operating as a public company. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical development activities, other research and development activities and pre-commercialization activities.

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.

### **COVID-19 Update**

A novel strain of coronavirus SARS-CoV-2 and the resulting disease, coronavirus disease 2019 (COVID-19), were first reported in Wuhan, China in December 2019, and subsequently declared a pandemic by the World Health Organization. COVID-19 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, enrollment in existing trials and restricting the on-site monitoring of clinical trials. For example, our Phase 3 registration trial of ANG-3777 to improve kidney function and reduce the severity of DGF, patient enrollment between February 2020 and when we completed enrollment was impacted by public safety restrictions related to the COVID-19 pandemic. Our Phase 2 clinical trial of ANG-3777 in patients at risk for developing AKI following cardiac surgery involving cardiopulmonary bypass was similarly impacted. We also follow FDA guidance on clinical trial conduct during the COVID-19 pandemic, including the remote monitoring of clinical data.

Numerous state and local jurisdictions have imposed, and others in the future may impose, "shelter-in-place" orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. Starting in mid-March 2020, the governor of California, where our corporate operations are based, issued "shelter-in-place" or "stay at home" orders restricting non-essential activities, travel and business operations for an indefinite period of time, subject to certain exceptions for necessary activities. Similar orders and restrictions have been imposed in New York and Massachusetts, and such orders or restrictions have resulted in our office closing, work stoppages, slowdowns and delays, travel restrictions and cancellation of events, among other effects, thereby negatively impacting our operations. We are supporting our employees by utilizing remote work, leveraging virtual meeting technology and encouraging employees to follow local guidance.

The global pandemic of COVID-19 continues to rapidly 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 ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions 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 given our drug inventories, and we believe we will be able to supply the drug needs of our clinical trials in 2021. 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, we are entitled to receive \$80.0 million in upfront and near-term clinical milestone payments, including \$30 million in upfront cash that we received in November 2020, a \$30.0 million equity investment and \$20.0 million due upon enrolling the first patient in a Phase 3 trial of ANG-3777 for CSA-AKI. In December 2020, we issued Vifor Pharma a convertible promissory note in aggregate principal amount of \$5.0 million as part of the equity investment with a maturity date of three years, 2% interest and a conversion price of \$11.57 per share, which was automatically converted into shares of our common stock upon the consummation of our initial public offering on February 9, 2021, and one or more entities affiliated with Vifor Pharma purchased \$25.0 million of shares of our common stock in the Concurrent Private Placement at a price per share equal to the initial public offering price, \$16.00 per share. We are also eligible to receive post-approval milestones of up to approximately \$260.0 million. Further, we are eligible to receive milestone payments based upon global net sales: in the United States, the milestone payments range from \$100 million to \$450 million, based upon annual U.S. net sales tiers between \$300 million and \$1 billion, and outside the United States, the milestone payments range from \$75 million to \$200 million, based upon annual net sales tiers between \$250 million and \$550 million. In aggregate, we are eligible for sales milestone payments totaling \$1.585 billion and a total potential deal value of up to \$1.925 billion (subject to certain reductions and offsets). We are also eligible to receive tiered royalties on global net sales of ANG-3777 at royalty rates of 10% for annual U.S. net sales below \$100 million, mid-teens to low twenties for annual U.S. net sales between \$100 million and \$500 million and 40% for annual U.S. net sales above \$500 million. Outside the United States, we are eligible to receive tiered royalties on annual ex-U.S. net sales of ANG-3777 at royalty rates of 10% for annual ex-U.S. net sales below \$50 million, mid-teens to low twenties for annual ex-U.S. net sales between \$50 million and \$250 million and 40% for annual ex-U.S. net sales above \$250 million. Such milestones and royalties are subject to certain specified reductions and offsets. We recognized revenue of \$0.4 million for the upfront cash payment during three months ended March 31, 2021 as contract revenue. We had deferred revenue under this agreement of \$29.4 million at March 31, 2021.

Under the Vifor License, we retain responsibility at our own cost for executing a pre-specified clinical development plan, which has been designed to obtain regulatory approvals of ANG-3777 for the DGF and CSA-AKI indications in the United States, the European Union, Switzerland and the United Kingdom. The plan includes the completion of our ongoing and currently planned clinical trials and other clinical development activities in such indications. We will be responsible for regulatory interactions and filings relating to such indications in the United States, and Vifor Pharma will be responsible for such matters outside the United States. We will share equally with Vifor Pharma the cost of related post-approval clinical development activities for such indications. We will conduct drug substance and drug product development for ANG-3777 for DGF and CSA-AKI until production scale at our cost. Prior to the first regulatory approval of ANG-3777 for DGF or CSA-AKI in the United States or the European Union, Vifor Pharma will assume responsibility of the commercial manufacture of ANG-3777 for such indications in accordance with a supply agreement to be negotiated in good faith between Vifor Pharma and us. In addition, Vifor Pharma will be solely responsible at its own cost for the commercialization of DGF and CSA-AKI indications and any other Renal Indications, both within and outside of the United States (excluding Greater China). Pursuant to the Vifor License, we expect to collaborate with Vifor Pharma through the operation of joint governance committees, with each party having final determination authority in their respective areas of responsibility and other specific matters, subject to certain exceptions.

The Vifor License will continue until the expiration of the last royalty term for a licensed product in the licensed territory, unless earlier terminated. The royalty term for a licensed product is, on a country-by-country basis, shall start with the first commercial sale of such licensed product in such country and expire at the latest of (i) expiration of all licensed patents covering the composition of matter of such licensed product or method of use for such licensed product that has obtained regulatory approval in such country, (ii) expiration of all regulatory and data

exclusivity applicable to such licensed product in such country, or (iii) the tenth (10th) anniversary of the date of the first commercial sale of such licensed product in such country.

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 we 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 our 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.

## **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.

#### *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 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. As of March 31, 2021, we recognized 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. We expect to continue recognizing revenue from upfront payments related to the Vifor License Agreement using the cost-based input method in the foreseeable future.

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 that any license revenue we generate from our current license agreement, and 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 that support 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-3777 and ANG-3070 during the three months ended March 31, 2021 and 2020. Of our total research and development expenses for the three months ended March 31, 2021 and 2020, 54% and 72%, respectively, of such expenses were from external third-party sources and the remaining 46% and 28%, respectively, were from internal sources.

We expect our research and development expenses to increase substantially for the foreseeable future as we 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 that will be 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 that 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, 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 that our general and administrative expenses will increase in the future to support our continued research and development activities, pre-commercial preparation activities for ANG-3777 and, if any future product candidate receives marketing approval, commercialization activities. We also anticipate incurring additional expenses associated with operating as a public company, including increased 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, additional insurance expenses, investor relations activities and other administrative and professional services.

#### **Other Income (Expense)**

##### *Convertible Notes Recorded at Fair Value*

We have elected the fair value option for recognition of our convertible notes. Our convertible notes are subject to re-measurement each reporting period with gains and losses reported through our condensed consolidated statements of operations. All outstanding convertible notes were converted into common stock upon the close of the IPO in February 2021 and there were no convertible notes outstanding as of March 31, 2021.

##### *Liability Classified Series C Convertible Preferred Stock Recorded at Fair Value*

Our Series C convertible preferred stock included settlement features that resulted in liability classification. 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 that was 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 outstanding convertible preferred stocks were converted into common stock upon the close of the IPO in February 2021 and there were no convertible preferred stocks outstanding as of March 31, 2021.

##### *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 that is accounted for under the equity method.

##### *Interest Income*

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

## Results of Operations

### Comparison For the Three Months Ended March 31, 2021 and 2020

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

	Three Months Ended March 31,		\$ Change	% Change
	2021	2020		
(In thousands, except percentages)				
<b>Revenue:</b>				
Contract revenue	\$ 371	\$ —	\$ 371	*
Grant revenue	—	865	(865)	(100)%
Total revenue	371	865	(494)	(57)%
<b>Operating expenses:</b>				
Cost of grant revenue	—	383	(383)	(100)%
Research and development	14,298	9,596	4,702	49 %
General and administrative	6,012	3,455	2,557	74 %
Total operating expenses	20,310	13,434	6,876	51 %
Loss from operations	(19,939)	(12,569)	(7,370)	59 %
Other income (expense),net	(16,748)	(653)	(16,095)	*
<b>Net loss</b>	<b>\$ (36,687)</b>	<b>\$ (13,222)</b>	<b>\$ (23,465)</b>	<b>*</b>

\* Not meaningful

#### Contract Revenue

Contract revenue increased by \$0.4 million from the three months ended March 31, 2020 to the three months ended March 31, 2021. The increase is attributable to revenue recognized related to the upfront payment from Vifor Pharma pursuant to the Vifor License Agreement entered into in November 2020.

#### Grant Revenue

Grant revenue decreased by \$0.9 million, or 100.0%, from the three months ended March 31, 2020 to the three months ended March 31, 2021. The decrease is primarily attributable to no submission for reimbursable costs relating to our grant from the DOD for the three months ended March 31, 2021.

#### Cost of Grant Revenue

Cost of grant revenue decreased by \$0.4 million, or 100.0%, from the three months ended March 31, 2020 to the three months ended March 31, 2021. The decrease is primarily attributable to no submission for reimbursable costs relating to our grant from the DOD for the three months ended March 31, 2021.

#### Research and Development Expenses

Research and development expenses increased by \$4.7 million, or 49.0%, from the three months ended March 31, 2020 to the three months ended March 31, 2021. The increase in research and development expenses was primarily due to an increase of \$3.2 million in personnel-related expenses, including salaries, benefits and stock-based compensation expenses, due to increases in headcount and an increase of \$1.5 million in fees paid to CROs and CMOs as a result of increased clinical and pre-clinical trial activities, primarily relating to the development of ANG-3777 and ANG-3070.

#### General and Administrative Expenses

General and administrative expenses increased by \$2.6 million, or 74.0%, from the three months ended March 31, 2020 to the three months ended March 31, 2021. The increase in general and administrative expenses was primarily due to an increase of \$2.0 million of personnel-related expenses, including salaries, benefits and stock-

based compensation expenses, due to higher headcount and an increase of \$0.6 million of professional fees for legal, consulting, accounting, tax and other services.

#### *Other Income (Expense)*

Other expenses increased by \$16.1 million from the three months ended March 31, 2020 to the three months ended March 31, 2021. This increase is primarily attributable to an increase of \$13.5 million in fair value related to our warrant liability, convertible notes, and Series C convertible preferred stock for which we have elected the fair value option and an increase of \$2.0 million in interest expense related to our convertible notes and Series C convertible preferred stock.

### **Liquidity and Capital Resources**

#### ***Sources and Uses of Liquidity***

We have incurred losses and negative cash flows from operations since inception, and we anticipate that 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. In February 2021, we generated aggregate net proceeds of approximately \$110.6 million from our IPO and Concurrent Private Placement, after deducting the underwriting discounts and commissions. As of March 31, 2021, we had \$130.5 million of cash and cash equivalents and an accumulated deficit of \$197.2 million.

Prior to our IPO, we have issued \$36.2 million in aggregate principal amount of convertible notes to various investors and we also issued 34,928 shares of Series C convertible preferred stock at \$642.75 per share for gross proceeds of approximately \$22.3 million. Upon the close of our IPO, all then outstanding convertible notes and shares of convertible preferred stock were converted into 5,870,829 shares of our common stock.

In April 2020, we were approved for and received a loan of approximately \$0.9 million from Hanmi Bank under the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act") and the Paycheck Protection Program ("PPP") offered by the U.S. Small Business Administration ("SBA"). The loan is evidenced by a promissory note and agreement, dated April 21, 2020 (the "PPP Note"). The PPP Note proceeds are available to be used to pay for payroll costs, including salaries, commissions, and similar compensation, group health care benefits, and paid leaves; rent; utilities; and interest on certain other outstanding debt, if any. The interest rate on the PPP Note is a fixed rate of 1% per annum. To the extent that the amounts owed under the PPP Note or a portion of them, are not forgiven, we will be required to make principal and interest payments in monthly installments beginning in August 2021. The SBA and U.S. Department of Treasury may continue to update guidance on the calculation of loan forgiveness, which updated guidance could affect the amount of the loan proceeds that could be forgiven. The PPP Note matures on the two year anniversary of the loan disbursement.

#### ***Future Funding Requirements***

Based on our current operating plan, we believe that 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. 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-3777, 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 3 registration trial of ANG-3777 for DGF, our Phase 2 clinical trial of ANG-3777 for CSA-AKI, our Phase 2 clinical trial in Brazil of ANG-3777 for the reduction of severity and progression of ALI in patients with COVID-19 associated pneumonia who are at high risk of progressing to acute respiratory distress syndrome (ARDS) and our Phase 1 clinical trial of ANG-3070 in healthy volunteers;

- whether we are able to take advantage of any FDA expedited development and approval programs for any of our product candidates;
- the clinical development of ANG-3777 for other potential indications in addition to DGF and CSA-AKI, including ALI and central nervous system (CNS) injuries;
- 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 Phase 3 registration trial, as well as our other completed and planned clinical trials and preclinical studies and other work, as the basis for review and approval of ANG-3777 for DGF and any other indication;
- 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-3777 or 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 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. This may be particularly true during the COVID-19 pandemic when the global capital markets are experiencing extreme volatility. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise 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, 2021 and 2020 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Net cash provided by (used in)		
Operating activities	\$ (12,551)	\$ (8,733)
Investing activities	(41)	(20)
Financing activities	108,444	3,936
Effect of foreign currency on cash	(3)	233
Net increase (decrease) in cash	<u>\$ 95,849</u>	<u>\$ (4,584)</u>

#### *Operating activities*

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 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.

For the three months ended March 31, 2020, net cash used in operating activities was \$8.7 million, which primarily consisted of a net loss of \$13.2 million, partially offset by a change in net operating assets and liabilities of \$2.6 million and net non-cash charges of \$1.9 million. The net non-cash charges were primarily related to a change in fair value of \$0.7 million in convertible notes and warrant liabilities and stock-based compensation expense of \$0.8 million. The change in net operating assets and liabilities was due to an increase of \$1.8 million in accrued expenses and \$1.4 million in accounts payable, due to our overall growth, increased research and development spending and timing of payments, partially offset by an increase of \$0.4 million in prepaid expenses and other current assets.

#### *Investing activities*

For the three months ended March 31, 2021 and 2020, net cash used in investing activities of \$41 thousand and \$20 thousand, respectively, was primarily related to purchases of fixed assets for research activities.

#### *Financing activities*

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.

For the three months ended March 31, 2020, net cash provided by financing activities was \$3.9 million, primarily due to net proceeds of \$3.1 million from the issuance of convertible notes and warrants and \$0.9 million in net proceeds from the issuance of our Series C convertible preferred stock.

### **Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements as defined under SEC rules.

## **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, or GAAP. The preparation of our condensed consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

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, 2020, which was filed with the SEC on March 30, 2021. During the three months ended March 31, 2021, except as described in Note 1 to the unaudited interim condensed 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 discussed.

## ***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) the last day of our fiscal year following the fifth anniversary of the completion of the IPO, (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 that is held by non-affiliates exceeds \$700 million as of the last business day of the issuer's 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" 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 of Sarbanes-Oxley, and reduced disclosure obligations regarding executive compensation in this Quarterly Report on Form 10-Q and 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 Interim 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, 2021.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our President and Chief Executive Officer and our Interim Chief Financial Officer, as appropriate 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 that our disclosure controls and procedures were not effective as of March 31, 2021 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, 2021, 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 for the years ended December 31, 2020 and 2019, we identified control deficiencies in the design and operation of our internal control over financial reporting that constituted material weaknesses, which remain unremediated as of March 31, 2021. 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. As of March 31, 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 the 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 that 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 that 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, 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 that 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 coronavirus disease 2019 (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 that cause an investment in the company to be speculative or risky:

#### ***Risks Relating to Our Financial Position and Need for Additional Capital***

- We are a late-stage biopharmaceutical company with no products approved for sale and we have not generated any product revenue to date. We have incurred significant losses since our inception, and we anticipate that we will continue to incur losses for the foreseeable future, 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-3777, 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.

#### ***Risks Relating to the Commercialization of Our Product Candidates***

- Our business currently depends substantially on the commercial success of ANG-3777, if approved. Our business will be materially harmed if we or our collaborators are unable to successfully commercialize ANG-3777.
- Our existing collaborations as well as additional collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our product candidates.

#### ***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.

#### ***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.

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

### **General Risk Factors**

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

### **Risks Relating to Our Financial Position and Need for Additional Capital**

***We are a late-stage biopharmaceutical company with no products approved for sale and we have not generated any product revenue to date. We have incurred significant losses since our inception, and we anticipate that we will continue to incur losses for the foreseeable future, which makes it difficult to assess our future viability.***

We are a late-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, including for ANG-3777, by regulatory authorities in any jurisdiction, including the United States Food and Drug Administration (FDA).

Since our inception, we have devoted substantially all of our efforts and financial resources to conducting research and development activities, including drug discovery and preclinical studies and clinical trials, establishing and maintaining our intellectual property portfolio, organizing and staffing our business, business planning, raising capital and providing general and administrative support for these operations. Prior to 2014, our efforts were primarily focused on researching a number of pathways related to serious organ diseases, applying our medicinal chemistry expertise towards creating potential therapeutics to address the unmet medical needs of patients and conducting preclinical and initial clinical development of ANG-3777. During this time period, our operations were funded primarily through the receipt of U.S. government grants and contracts. In 2014, we began raising capital through the sale of debt and equity securities as well as licenses, and since that time have significantly expanded our operations with a focus on advancing our lead product candidate, ANG-3777, into and through multiple clinical trials and accelerating our other development programs, including our second product candidate, ANG-3070. From our inception through March 31, 2021, we have received an aggregate of \$292.9 million in funding, which includes approximately net proceeds of \$110.6 million from the IPO and Concurrent Private Placement, approximately \$68.8 million from U.S. government grants, and contracts and aggregate gross proceeds of \$113.5 million through the issuance and sale of our debt and equity securities. As of March 31, 2021, we had cash and cash equivalents of \$130.5 million.

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. In addition, a significant portion of our future revenue and cash resources is expected to be derived from the our license agreement with Vifor Pharma and, to a lesser extent, our license agreement with Sinovant Sciences HK Limited. Our net losses were \$36.7 million and \$13.2 million for the three months ended March 31, 2021 and 2020, respectively. As of March 31, 2021, we had an accumulated deficit of \$197.2 million. 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-3777, ANG-3070 and our other product candidates through clinical trials and preclinical development, and as we seek regulatory approval for ANG-3777, ANG-3070 or any of our other product candidates. In addition, if we seek approval for any of our product candidates or indications for which we retain commercialization rights, we expect 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. Finally, we expect to incur increased expenses to protect our intellectual property and expand our general and administrative support functions, including hiring additional personnel, as well as incur additional costs associated with operating as a public company.

If ANG-3777, ANG-3070 or any of our other product candidates fail in ongoing clinical trials or do not gain regulatory approval, or if our product candidates, if approved, do not achieve market acceptance, we may never become profitable. These net losses and negative cash flows could have an adverse effect on our stockholders' equity and working capital.

In addition, while we have a license agreements with Vifor Pharma and Sinovant relating to ANG-3777 that contemplate upfront, regulatory and commercial milestone payments as well as royalties on sales of ANG-3777, there can be no assurance that we or Sinovant will be able to successfully advance ANG-3777 through approval, that Vifor Pharma or Sinovant will be able to successfully commercialize ANG-3777 for any indication following any approval or that any substantial revenue stream from milestone or royalty payments will be forthcoming under either license agreement.

***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.***

Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities. We are currently in the process of advancing ANG-3777 through clinical development for three indications, ANG-3070 through a Phase 1 clinical trial in 72 healthy volunteers in Australia, and other candidates through preclinical development. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We will require substantial additional future capital in order to complete clinical development and seek regulatory approval for ANG-3777 for any indication as well as to conduct the research, clinical and regulatory activities necessary to bring our other product candidates, including ANG-3070, to market. Regulatory authorities in the United States and elsewhere could also require that we perform additional preclinical studies or clinical trials to receive or maintain regulatory approval of our product candidates, including ANG-3777, and our expenses would further increase beyond what we currently expect and the anticipated timing of any potential regulatory approval could be delayed. 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 that our current cash and cash equivalents are sufficient for us to fund our operating expenses and capital expenditure requirements through at least the next 12 months. However, we will continue to require substantial additional capital to continue our clinical development activities as well as any commercialization activities we undertake with respect to our wholly-owned product candidates and those for which we retain the right to commercialize.

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-3777, 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 3 registration trial of ANG-3777 for DGF, our Phase 2 clinical trial of ANG-3777 for CSA-AKI, our Phase 2 clinical trial in Brazil of ANG-3777 for the reduction of severity and progression of ALI in patients with COVID-19 associated pneumonia who are at high risk of progressing to acute respiratory distress syndrome (ARDS) and our Phase 1 clinical trial of ANG-3070 in healthy volunteers;
- whether we are able to take advantage of any FDA expedited development and approval programs for any of our product candidates;
- the clinical development of ANG-3777 for other potential indications in addition to DGF and CSA-AKI, including ALI and central nervous system (CNS) injuries;
- 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 Phase 3 registration trial, as well as our other completed and planned clinical trials and preclinical



- studies and other work, as the basis for review and approval of ANG-3777 for DGF and any other indication;
- 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-3777 or 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 or 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 during the COVID-19 pandemic when the global capital markets are experiencing extreme volatility. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise 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.

***Our operations have historically been funded largely through government grants and contracts, and we may not seek or receive any additional funding under such mechanisms in the future.***

From our inception through March 31, 2021, we received approximately \$68.8 million from U.S. government grants and contracts, principally from the U.S. National Institutes of Health (NIH), and U.S. National Science Foundation (NSF), and the U.S. Department of Defense (DOD). These funds enabled us to progress our most advanced candidates into clinical development and preclinical development. These grants also provide fringe

benefits and indirect costs used to support our overhead expenses, as well as a negotiated fixed fee (*i.e.*, profit) equal to a percentage of total direct and indirect costs of the grant award, excluding subcontractor costs.

Since 2014, we have primarily funded our operations through the sale of debt and equity securities as well as licenses, and since that time have significantly expanded our operations, with a focus on advancing our lead product candidate, ANG-3777, into and through multiple clinical trials and accelerating our other development programs. However, we have several grant applications pending review by the NIH, NSF and DOD, and intend to continue to apply for grants to fund our discovery and development efforts. As of March 31, 2021, active grants and those for which we have received notification of the intent to fund are expected to provide approximately \$0.7 million in anticipated research cost reimbursements, which includes monies to be paid to university collaborators and other subcontractors named in the grant applications. If in the future we do not seek or receive any additional funding under government grants and contracts, or if we fail to remain eligible to receive grant funding, we may be required to significantly curtail one or more of our discovery or development programs, which could have a material adverse effect on our business, financial condition and results of 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.***

We are subject to risks related to public health crises such as the global pandemic associated with COVID-19. In December 2019, a novel strain of coronavirus, was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread to most countries and all 50 states within the United States, including countries and states in which we have planned or active clinical trial sites. As COVID-19 continues to spread around the globe, we have and/or will likely experience disruptions that could severely impact our business and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials;
- 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;
- 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.

Patient enrollment since February 2020 in each of our clinical trials has been impacted by public safety restrictions related to the COVID-19 pandemic. 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.

Numerous state and local jurisdictions have imposed, and others in the future may impose, "shelter-in-place" orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. Starting in mid-March 2020, the governor of California, where our corporate operations are based, issued "shelter-in-place" or "stay at home" orders restricting non-essential activities, travel and business operations for an indefinite period of time, subject to certain exceptions for necessary activities. Similar orders and restrictions have been imposed in New York and Massachusetts, and such orders or restrictions have resulted in our office closing, work stoppages, slowdowns and delays, travel restrictions and cancellation of events, among other effects, thereby negatively impacting our operations. In addition, even after the "shelter-in-place" orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19 are lifted, we may continue to experience disruptions to our business.

The global pandemic of COVID-19 continues to rapidly 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 ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, 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-3777, 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 that 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 that 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 that 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 that 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.

Our lead product candidate ANG-3777 is in late-stage clinical development and it is uncertain whether the results from our ongoing Phase 3 registration trial for DGF will lead to regulatory approval and, even if approved, will result in successful commercialization by our collaborators. For example, we have amended the protocol for our Phase 3 registration trial of ANG-3777 for DGF to change the primary endpoint from the difference in patient duration on dialysis between the treatment and placebo arms to the difference in patient estimated glomerular filtration rate (eGFR) between the treatment and placebo arms measured during a twelve month period following transplant. While we believe eGFR is a meaningful marker of the extent of recovery from the kidney dysfunction resulting from transplantation, there can be no assurance that the FDA will view the endpoint favorably during the review of any NDA we submit for such indication even if we are able to demonstrate a statistically significant improvement of eGFR in the ANG-3777 treatment group.

For example, in correspondence with the FDA regarding the amended protocol, the FDA has stated that, while we may submit our Phase 3 data demonstrating eGFR at 12 months post-transplant as part of our NDA, it does not agree with this change in the primary endpoint at this time in light of unresolved questions regarding data adequacy and justification of eGFR as a reasonable predictor of clinical benefit. Our belief that our amended Phase 3 protocol is appropriately designed to meet the FDA's requirements and to address the FDA's concerns may prove to be incorrect. If the totality of results of our Phase 3 clinical trial are not persuasive enough to support approval of an NDA for ANG-3777, additional evidence of efficacy may be required to substantiate the treatment benefit in DGF.

Prior to any submission of an NDA for ANG-3777, we will need to successfully complete our ongoing and planned clinical trials. However, we cannot be certain that ANG-3777 will be successful in clinical trials, and ANG-3777 may not receive regulatory approval even if it is successful in clinical trials or we may fail to maintain such regulatory approval if ANG-3777 is approved. For example, we have previously conducted several Phase 2 clinical trials of ANG-3777 in indications other than DGF and CSA-AKI that we subsequently terminated due to a number of reasons, including changes in treatment paradigms, lack of funds to support the trials, changes in principal investigators and changes in organ transplant allocation policies.

Of the large number of drugs in development in the pharmaceutical industry, only a small percentage result in approval by regulatory authorities such as the FDA. Furthermore, no regulatory authority has ever granted approval for a compound that mimics the activities of HGF in a manner similar to ANG-3777. As such, ANG-3777 for any indication we pursue may be subject to increased scrutiny by regulators or additional complexities.

Similar risks exist for the clinical development and potential regulatory approvals of ANG-3070 and could apply to any future product candidates.

We cannot predict whether our ongoing or future clinical trials of these 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 that we conduct in the future. Accordingly, we may never receive approval of ANG-3777, 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-3777, 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-3777 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 have completed enrolling patients in our Phase 2 clinical trial of ANG-3777 for CSA-AKI and for ALI in patients with COVID-19 associated pneumonia who are at high risk of progressing to ARDS and our Phase 1 clinical trial of ANG-3070 in healthy volunteers. 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 our clinical trials;
- the extent to which COVID-19 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 retain patients and the general willingness of patients to enroll, consent and complete participation in the trial;
- 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.

For example, while we completed enrollment in our Phase 3 registration trial of ANG-3777 for DGF, we began enrollment in 2016 and have experienced delays due to financial constraints. In addition, patient enrollment since February 2020 in each of our clinical trials was impacted by public safety restrictions related to the COVID-19 pandemic. In our fibrosis program, we are investigating ANG-3070 for the treatment of progressive fibrosis, beginning with a Phase 1 clinical trial in healthy volunteers in Australia. If successful, we intend to initiate a Phase 2 clinical trial in 2021 and are considering indications, such as primary proteinuric renal disease patients and potentially non-proteinuric renal diseases at high risk of progression, and there may be a significant competition for clinical trial subjects for such indications.

Changes in regulatory requirements and related guidance related to regulatory approval may also occur and we or any of our collaborators may need to amend clinical trial protocols to reflect these changes. Amendments may require us or any of our collaborators to resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. In addition, a clinical trial may be suspended or terminated at any time by us, our current or future collaborators, the FDA or other regulatory authorities due to a number of factors, including:

- our failure or the failure of our collaborators to conduct the clinical trial in accordance with regulatory requirements or adherence to our clinical protocols; and
- unforeseen safety issues or any determination a clinical trial presents unacceptable health risks.

For example, we have amended the protocol for our Phase 3 registration trial of ANG-3777 for DGF to change the primary endpoint from the difference in patient duration on dialysis between the treatment and placebo arms to the difference in patient eGFR between the treatment and placebo arms measured during a 12-month period following transplant, which we believe is a surrogate endpoint reasonably likely to predict clinical benefit in this population. The FDA has stated that, while we may submit our Phase 3 data demonstrating eGFR at 12 months post-transplant as part of our NDA, it does not agree with the proposed changes to the protocol at this time, including the change in the primary endpoint, because we have not yet provided information sufficient to justify eGFR as reasonably likely to predict clinical benefit. Based upon the totality of the Phase 3 results, including eGFR at 12 months and data from the key secondary endpoints (including duration on dialysis), we intend to submit the eGFR data to the FDA to support accelerated approval of ANG-3777 in DGF. However, we may have difficulty collecting sufficient data from patients to support an NDA submission on the basis of the revised primary endpoint or experience other complications, and our belief that our amended Phase 3 protocol is appropriately designed to meet the FDA's requirements and to address the FDA's concerns may prove to be incorrect.

In addition, certain of our Phase 1 clinical trials of ANG-3777 were conducted by a CRO that generated data that may not be sufficient for an NDA. As a result, we plan to repeat certain of such clinical trials in connection with the submission of an NDA, which will increase the overall costs associated with seeking approval of ANG-3777. The results of such Phase 1 clinical trials may also not replicate our earlier studies, which could result in further delays.

Furthermore, if we or any of our collaborators 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. If we are required to conduct one or more post-approval clinical trials, we may fail to demonstrate safety and efficacy in this context and our approval could be withdrawn or product labeling could be revised in a way that would make future commercialization difficult.

***Clinical failure can occur at any stage of clinical development, and we have never previously completed a Phase 3 registration trial or submitted an NDA to the FDA or a marketing application to any foreign regulatory authority. The results of earlier clinical trials are not necessarily predictive of future results, and any product candidate we advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval.***

Clinical failure can occur at any stage of our clinical development. 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.

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 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. For example, if the condition of the patients treated with ANG-3777 in our Phase 3 registration trial is unusually poor or the condition of the patients receiving placebo in that trial is unusually good, it could reduce the likelihood of there being a statistically significant difference in eGFR between the treatment and placebo arms of the trial. 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. In addition, while in our Phase 2 clinical trial for DGF ANG-3777 demonstrated statistically significant improvement in eGFR in a post-hoc analysis, it was not the primary endpoint and the trial only involved 28 patients, which is a relatively small study population with respect to diseases associated with transplantation given that there is a significant amount of heterogeneity among patients. As a result, the effect of ANG-3777 on eGFR may be less robust when measured among a patient cohort that is significantly larger in size than the cohort used in our Phase 2 clinical trial. 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-3777, 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.

***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.

For example, even if our Phase 3 registration trial of ANG-3777 for DGF is able to successfully demonstrate a statistically significant improvement in eGFR upon treatment with ANG-3777 as compared to placebo, there can be no assurance that the magnitude of benefit demonstrated will be sufficient to enable us to obtain accelerated approval of ANG-3777. 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.

***Even if we receive marketing approval of a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products, if approved.***

Any marketing approvals that we receive for any current or future product candidate may be subject to limitations on the approved indicated uses for which the product may be marketed or the conditions of approval, or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a Risk Evaluation and Mitigation Strategy (REMS) as a condition of approval of any product candidate, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import and export and record keeping for the product candidate will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current Good Manufacturing Practice (cGMP) and Good Clinical Practice (GCP) for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with any approved candidate, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or product recalls;
- fines, untitled and warning letters, or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications we filed or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of the product; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay marketing approval of a product. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

***Although we have received Fast Track designation for ANG-3777 for the prevention of DGF, there is no guarantee that ANG-3777 will experience a faster regulatory review or obtain regulatory approval. We may also seek to take advantage of other FDA expedited development and review programs, such as Breakthrough Therapy designation, Accelerated Approval, and Priority Review, but we may fail to qualify for such programs, which could substantially delay the approval of ANG-3777 and our other product***

***candidates. Even if we are successful in obtaining additional designations, our product candidates may still fail to obtain approval.***

If a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. We have received Fast Track designation for ANG-3777 for prevention of DGF, and we may receive Fast Track designation for other product candidates in the future; however, we may not experience a faster development process, review or approval compared to conventional FDA approval timelines, and the FDA may still decline to approve ANG-3777 or our other designated product candidates. The FDA may rescind the Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program or for any other reason.

We may also seek Breakthrough Therapy designation for any product candidate that we develop. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Like Fast Track designation, Breakthrough Therapy designation is within the discretion of the FDA. Accordingly, even if we believe a product candidate we develop meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if a product candidate we develop qualifies as a Breakthrough Therapy, the FDA may later decide that the drug no longer meets the conditions for qualification and rescind the designation.

Drugs designated as Fast Track products or Breakthrough Therapies by the FDA are also eligible for accelerated approval if the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. If we seek accelerated approval of ANG-3777 for DGF, we expect to be required to conduct one or more such a confirmatory trials post-approval, if obtained. In addition, the FDA requires pre-approval of promotional materials for accelerated approval products, once approved. We cannot guarantee that the FDA will agree that ANG-3777 or any other product candidate has met the criteria to receive accelerated approval, which would require us to conduct additional clinical testing prior to seeking FDA approval. Even if any of our product candidates received approval through this pathway, the product may fail required post-approval confirmatory clinical trials, and we may be required to remove the product from the market or amend the product label in a way that adversely impacts its marketing.

Once an NDA is submitted to FDA, the application may be eligible for Priority Review if the product candidate treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. Products with Fast Track or Breakthrough Therapy designation are generally eligible to be considered for Priority Review. If an NDA receives Priority Review, the FDA will aim to take action on the application within six months of confirming receipt, compared to ten months under standard review. We cannot guarantee that any NDA we submit will qualify for Priority Review, including our planned NDA for ANG-3777, which could significantly impact our timeline and plans for commercialization, if approved.

***Although we have received Orphan Drug designation for ANG-3777 to improve renal function and prevent DGF following renal transplantation, we may be unable to maintain the benefits associated with such designation, including the potential for market exclusivity.***

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as Orphan Drugs. Under the Orphan Drug Act, the FDA may designate a drug as an Orphan Drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the



United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, Orphan Drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax credits for certain clinical trial costs and user-fee waivers.

Similarly, in Europe, the European Commission grants Orphan Drug designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an Orphan Drug Designation application. Orphan Drug designation is intended to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in Europe and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug. In Europe, Orphan Drug designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor.

Generally, if a drug with an Orphan Drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the European Medicines Agency (EMA) or the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for Orphan Drug designation or if the drug is sufficiently profitable such that market exclusivity is no longer justified.

Although we have obtained Orphan Drug designation for ANG-3777 to improve renal function and prevent DGF following renal transplantation, we are pursuing development and approval for reducing the severity of DGF, and there is no guarantee that we will obtain approval or Orphan Drug exclusivity for this product. Since we expect to seek approval with a labeled indication of "reducing the severity" of DGF, and the language of this indication differs from the language of the Orphan Drug designation "to improve renal function and prevent" DGF, we may be required to seek an additional designation for "reducing the severity" of DGF in order to be eligible for Orphan Drug exclusivity for ANG-3777 for this indication. If we fail to receive approval of ANG-3777 for DGF, we may never be able to take advantage of Orphan Drug exclusivity. Without such exclusivity, we would only be able to rely on other regulatory exclusivities, such as for a new chemical entity, and our proprietary rights with respect to ANG-3777, some of which, including our issued claims to pharmaceutical compositions containing ANG-3777 and methods of use, will only remain in force in the United States until 2024 and in other jurisdictions until 2023, assuming the patents withstand any challenge and appropriate maintenance, renewal, annuity and other governmental fees are paid.

Even if we obtain Orphan Drug exclusivity for ANG-3777 or any other product candidates, that exclusivity may not effectively protect the product candidate from competition because different therapies can be approved for the same condition and the same therapy could be approved for different conditions. Even after an Orphan Drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated Orphan Drug may not receive Orphan Drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, Orphan Drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan Drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we may seek additional Orphan Drug designations for applicable indications for our current and any future product candidates, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations.

***Our product candidates may have undesirable side effects which may delay 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 that 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. This 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-3777 was designed to mimic the naturally occurring biological activities of hepatocyte growth factor (HGF), which is responsible for activating cellular repair pathways to prevent cell death and cellular dysfunction. However, such activation could result in unforeseen events, including by harming healthy cells or tissues and there are currently no approved HGF mimetic therapeutics available in the United States. Given the well-publicized effort to target c-Met for the treatment of cancer and safety concerns regarding tumorigenesis (initiation of cancer) or the enhancement and growth of existing tumors (promotion of cancer), we have excluded certain patients with a recent history of certain malignancies. While we have completed multiple animal studies demonstrating ANG-3777 had no enhancing effect in murine tumor models and researchers at the U.S. National Cancer Institute demonstrated that c-Met is actually a tumor suppressor in a liver cancer model, our ongoing and planned clinical trials could reveal a high and unacceptable severity and prevalence of side effects, and it is possible that patients enrolled in such clinical studies could respond in unexpected ways. In particular, in our Phase 3 registration trial of ANG-3777 for DGF, we have administered ANG-3777 in a significantly larger patient cohort than in our prior trials and will be conducting a follow-up period that is significantly longer than in our prior trials, which could result in an increase in the number of reported adverse events. In our Phase 2 clinical trial of ANG-3777 for CSA-AKI, we are administering ANG-3777 to cardiac surgery patients, which could exacerbate the risk of or increase the likelihood of adverse events. Additionally, in our Phase 2 clinical trial of ANG-3777 for ALI in patients with COVID-19 associated pneumonia who are at high risk of progressing to ARDS, we have administered ANG-3777 to patients with severe acute lung injury, including acute respiratory distress syndrome, which could also exacerbate the risk of or increase the likelihood of adverse events. Further, if we were to elect to conduct clinical trials of ANG-3777 in other forms of acute organ injuries, such patients could respond in unexpected ways, which could have an adverse effect on our other ANG-3777 programs. As a result, we cannot guarantee that ANG-3777 will continue to be generally well-tolerated as it has been in our clinical trials to date. Furthermore, although our ANG-3777 dosing regimen is based on short-term dosing soon after organ injury occurs, the long-term effects from exposure to this drug class are unknown. 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.

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 both nintedanib and pirfenidone 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 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 trial in Australia support the initiation of a Phase 2 clinical trial, there can be no assurance that similar or unforeseen side effects will not occur during such clinical trial. The range and potential severity of possible side effects from systemic therapies is 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 that patients may experience or be indicative of the effect of our product candidates 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 that 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 that 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. For instance, in our Phase 3 registration trial of ANG-3777 the percentage of enrolled patients that have received deceased-donor kidneys with donations after cardiac death is capped at 20% to match current epidemiological data regarding the rate of kidneys donated after cardiac death. However, if the actual percentage of patients that receive deceased-donor kidneys from donors after cardiac death in the general population is different or changes over time, our trial results may not be indicative. 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 that 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 that 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. Our initial focus is on AKI, which impairs kidney function, and when severe, can result in kidney failure and death. We are developing and plan to seek regulatory approval of ANG-3777 for DGF and CSA-AKI. We are also currently focused on advancing ANG-3070 from a Phase 1 healthy-volunteer study into Phase 2 development, and are considering indications such as primary proteinuric renal disease patients and potentially non-proteinuric renal diseases at high risk of progression.

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.

***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 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 by reducing the price we can charge and reducing our market share.

ANG-3777 is protected by a number of granted patents and pending patent applications as well as regulatory exclusivities. For example, the issued patent claiming pharmaceutical compositions and methods of use for ANG-3777 is eligible for patent term restoration, potentially for up to five years. In addition, ANG-3777 is protected by a United States patent claiming solid forms of ANG-3777 which will expire in 2040, and an international application filed under the Patent Cooperation Treaty is pending, and any patents issuing from this application would expire in 2040. Also, ANG-3777 may be eligible for five years of marketing exclusivity as a new chemical entity under the Hatch-Waxman Act, and its indication for DGF has been granted Orphan Drug designation, making it potentially eligible for seven years of orphan exclusivity for prevention of this indication upon approval. Should these regulatory exclusivities not be secured, and if other patent filings should not provide sufficient protection, then generic competitors may be able to enter the U.S. market upon expiration of the issued U.S. patent claiming pharmaceutical compositions and methods of treatment, which is expected to expire during 2024, assuming it withstands any challenge and all maintenance fees are paid.

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 that 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.

***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, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal civil and criminal false claims laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare providers starting in 2022, and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance

guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws that require the registration of pharmaceutical sales representatives; 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 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 or ACA), was signed into law, 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.

Among the provisions of the Affordable Care Act that are of importance to our potential product candidates are the following:

- an annual, nondeductible fee payable by any entity that manufactures, or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- an increase in the discount rate for the federal 340B program to eligible hospitals;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been judicial 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 December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseparable feature of the Affordable Care Act, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the Affordable Care Act are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unclear when the Supreme Court will make a decision. It is also unclear how other efforts to challenge, repeal or replace the Affordable Care Act will affect the law 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 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. 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 that 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 that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. 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 obtain regulatory approval or commercialize our product candidates may be harmed.***

We do not own facilities for clinical and commercial manufacturing of our product candidates, including ANG-3777, 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-3777 and to manufacture all clinical trial supplies of ANG-3777. Similarly, we rely on and have agreements

with a single third party manufacturer to supply drug substance for ANG-3070 and a separate single source third party manufacturer to supply clinical trial supplies of ANG-3070.

Additionally, the facilities at which ANG-3777 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 on 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 approval or commercialization of our product candidates, cause us to incur higher costs or prevent us from commercializing our product candidates successfully. Furthermore, if any of our product candidates are approved and contract manufacturers fail to deliver the required commercial quantities of finished product 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 would likely be unable to meet demand for our products and could lose potential revenue. It may take several years to establish an alternative source of supply for our product candidates and to have any such new source approved by the regulatory authorities that regulate our products. Further, such challenges could be compounded by the COVID-19 pandemic.

***Even if our product candidates receive regulatory approval, we may still face future development and regulatory difficulties.***

Our product candidates, if approved, will also be subject to ongoing regulatory requirements for labeling, packaging, storage, advertising, promotion, record-keeping, and submission of safety and other post-marketing information. In addition, approved products, manufacturers, and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory requirements and requirements of other similar agencies, including ensuring quality control and manufacturing procedures conform to cGMPs. As such, we and our contract manufacturers are subject to continual review and periodic inspections to assess compliance with cGMPs. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, quality control and quality assurance. We will also be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory and other similar agencies and to comply with certain requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. Accordingly, we may not promote our approved products, if any, for indications or uses for which they are not approved. We must also continue to comply with GCP requirements for any post-approval trials we are required to conduct or choose to undertake for additional indications in the future.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or disagrees with the promotion, marketing or labeling of a product, it may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If our product candidates fail to comply with applicable regulatory requirements, the FDA and other regulatory agencies may:

- issue Untitled or Warning letters;



- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us or our collaborators to enter into a corporate integrity agreement, consent decree or permanent injunction, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- impose other administrative or judicial civil or criminal penalties;
- withdraw regulatory approval;
- refuse to approve pending applications or supplements to approved applications filed by us or our potential future collaborators;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products.

***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 or commercialized 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.

Disruptions or reorganizations at the FDA and foreign regulatory authorities may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. FDA's Office of New Drugs recently underwent a reorganization, which could continue to affect staffing and priorities and cause delays with respect to the clinical development and regulatory approval process for ANG-3777 and potentially other product candidates. In addition, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Separately, in response to the global COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

***We have 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 have enrolled patients in Canada, Brazil and Georgia in our Phase 2 clinical trial of ANG-3777 for CSA-AKI under separate clinical trial applications in such jurisdictions and have enrolled healthy volunteers in Australia in our Phase 1 clinical trial of ANG-3070 under a separate clinical trial application. In addition, we are conducting our Phase 2 clinical trial of ANG-3777 for ALI in Brazil and we may conduct additional future clinical trials outside the United States. 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 that 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-3777 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-3777 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; and
- diminished protection of intellectual property in some countries.

#### **Risks Relating to the Commercialization of Our Product Candidates**

***Our business currently depends substantially on the commercial success of ANG-3777, if approved. Our business will be materially harmed if we or our collaborators are unable to successfully commercialize ANG-3777.***

Even if we receive regulatory approval of ANG-3777 for any indication, it is uncertain whether we or our collaborators will be able to successfully commercialize the product. In November 2020, we entered into the Vifor License, granting Vifor Pharma global rights (excluding Greater China) to develop, manufacture and commercialize ANG-3777 in all therapeutic, prophylactic and diagnostic uses for the Renal Indications. In addition, in August 2018 we granted Sinovant an exclusive, royalty-bearing license pursuant to the Sinovant License for the development and commercialization of ANG-3777 in Greater China for all indications.

Vifor Pharma's marketing of ANG-3777 for any Renal Indication, if approved, Sinovant's marketing of ANG-3777 for any indication, if approved, and our marketing of ANG-3777 for ALI or other non-Renal Indication outside Greater China, if approved, will be limited to ANG-3777's approved use and potentially subject to other limitations as set forth in its approved prescribing information and package insert. Accordingly, we cannot ensure that ANG-3777 will be successfully developed, approved or commercialized. If we or our collaborators are unable to successfully commercialize ANG-3777, if approved, we may not be able to generate sufficient revenue to operate our business.

In particular, the future commercial success of ANG-3777 for DGF is subject to a number of risks, including the following:

- potential side effects of ANG-3777 could emerge causing an approved drug to be taken off the market;
- even if approved, ANG-3777 may not receive market acceptance by physicians, hospitals, payers and patients; and
- we may not be able to obtain, maintain or enforce our patents and other intellectual property rights related to ANG-3777.

***Our existing collaborations as well as additional collaboration arrangements that 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 Sinovant 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.

Under the Vifor License, we retain responsibility at our own cost for a pre-specified clinical development plan designed to obtain regulatory approvals of ANG-3777 for DGF and CSA-AKI indications in the United States, the European Union, Switzerland and the United Kingdom, which includes the completion of the ongoing and currently planned clinical development activities and clinical trials in such indications. While we retain rights to develop and

commercialize ANG-3777 in non-Renal Indications (subject to certain protections for Vifor Pharma), we have granted Vifor Pharma global rights (excluding Greater China) to develop, manufacture and commercialize ANG-3777 in all therapeutic, prophylactic and diagnostic uses for all Renal Indications, including our most advanced product candidates, DGF and CSA-AKI. As a result, our ability to generate revenue from product sales in the near term is dependent on Vifor Pharma's ability to successfully commercialize ANG-3777 for Renal Indications, if approved.

To the extent that 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.

The success of our collaboration arrangements, including the Vifor License and the Sinovant License, will depend heavily on the efforts and activities of our collaborators and our dependence on collaborative arrangements subjects us to a number of risks, including the risk that:

- we may not be able to control the amount and timing of resources our collaborators may devote to the product candidates;
- collaborators may delay clinical studies, provide insufficient funding for a clinical study program, stop clinical studies, abandon product candidates, repeat or conduct new clinical studies or require a new formulation of a product candidate for clinical testing;
- collaborators, such as Sinovant, may independently be able to conduct preclinical studies and/or clinical trials of our product candidates, including ANG-3777 that result in negative outcomes that could harm our development, approval or commercialization of our product candidates;
- our collaborators may experience financial difficulties;
- we may be required to relinquish important rights, such as marketing and distribution rights, as is the case in the Vifor License;
- 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;
- a collaborator could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors;
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise with respect to the ownership of any intellectual property developed pursuant to our collaborations;
- our collaborators may experience security breaches, cyberattacks and other security incidents that result in compromises of personal information, clinical data and proprietary information, which could harm our reputation and expose us to potential liability; and
- collaborative arrangements are often terminated or allowed to expire, which would delay the development and may increase the cost of developing our product candidates.

If our collaborators are unable to successfully commercialize ANG-3777, if approved, we may not be able to generate sufficient revenue to operate our business. In addition, if any current or future collaborator were to delay or abandon development and commercialization of any product candidate we had licensed to them, we may be unable to reacquire such asset and may therefore never realize any revenue from milestone payments or royalties pursuant to our agreement with such collaborator.

***If our collaborators cease development and/or commercialization efforts under our existing or future collaboration agreements, or if any of those agreements are terminated, these collaborations may fail to***

***lead to commercial products and we may never receive milestone payments or future royalties under these agreements.***

A significant portion of our future revenue and cash resources is expected to be derived from the Vifor License and, to a lesser extent, the Sinovant License, as well as other similar agreements we may enter into in the future. Revenue from such collaboration arrangements depend upon continuation of the collaborations, the achievement of milestones and royalties, if any. For example, pursuant to the Vifor License, we are entitled to receive \$80 million in upfront and near-term clinical milestone payments, including \$30 million in upfront cash that we received in November 2020, and a \$30 million equity investment, and 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 up to 40%. However, if we are unable to successfully advance the development of ANG-3777 for DGF or CSA-AKI, our revenue and cash resources from sales-related milestone payments under the Vifor License will be substantially less than expected. In addition, even if we do obtain all necessary regulatory approvals for ANG-3777 for DGF or CSA-AKI, we may still never receive the revenue or cash resources from milestone payments we expect unless Vifor Pharma is able to successfully commercialize ANG-3777 for such indications. Pursuant to our Sinovant License, where Sinovant is responsible for the development and commercialization of ANG-3777 in Greater China for all indications, we are subject to further risks related to any development efforts undertaken by Sinovant.

To the extent that any of our existing or future collaborators were to terminate a collaboration agreement, we may be forced to assume further development costs, marketing and distribution costs and the costs of defending intellectual property rights. In certain instances, we may even be forced to abandon product candidates altogether. Any of the foregoing could result in a change to our business plan and a material and adverse effect on our business, financial condition, results of operations and prospects.

***Even if approved, our product candidates may not achieve broad market acceptance among physicians, patients, and healthcare payors and, as a result, our revenues generated from their sales may be limited.***

The commercial success of ANG-3777, ANG-3070 or our other product candidates, if approved, will depend upon their acceptance among the medical community including physicians, transplant centers, healthcare payors, and patients. There are currently no approved therapies for DGF or CSA-AKI and there are currently no pharmacologic therapies approved for use with ARDS. Nevertheless, in order for ANG-3777 to be commercially successful, we and our collaborators will need to demonstrate that it is safe and effective for patients with DGF, CSA-AKI or any other indications we pursue. In particular, even if our Phase 3 registration trial of ANG-3777 for DGF is able to successfully demonstrate a statistically significant improvement in eGFR upon treatment of ANG-3777 as compared to placebo and we receive approval of ANG-3777 for the reduction of severity of DGF, there can be no assurance that the magnitude of benefit demonstrated during our clinical trials will be sufficient to achieve market acceptance. The degree of market acceptance of our product candidates will depend on a number of factors, including:

- limitations in the approved clinical indications for our product candidates;
- demonstrated clinical safety and efficacy compared to other products;
- lack of significant adverse side effects;
- sales, marketing, and distribution support;
- the extent to which our product candidates are approved for inclusion on formularies of hospitals, integrated delivery networks, and managed care organizations;
- whether our product candidates are designated under physician treatment guidelines for the treatment of the indications for which we have received regulatory approval;
- availability of pricing and reimbursement from government entities and private and public third-party payors in and outside of the U.S.;
- timing of market introduction and perceived effectiveness of competitive products;
- the degree of cost-effectiveness as assessed by reimbursement-focused organizations, such as the "Institute for Clinical and Economic Review";
- availability of alternative therapies at similar or lower cost, including generics and over-the-counter products;
- adverse publicity about our product candidates or favorable publicity about competitive products;
- convenience and ease of administration of our product candidates; and
- potential product liability claims.

If our product candidates are approved, but do not achieve an adequate level of acceptance by hospitals, physicians, patients, the medical community, and healthcare payors, sufficient revenue from product sales may not be generated from these products either by us or our collaborators and we may not become or remain profitable. In addition, efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

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

There is significant uncertainty related to the insurance coverage and reimbursement of newly-approved and launched products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates including, for example, whether we will seek, and whether the Centers for Medicare and Medicaid (CMS) would approve a new technology add-on payment (NTAP) under the Medicare inpatient prospective payment system (IPPS) for our product candidates, once approved. Introduced in 2001, the NTAP program was created by Congress to support timely access to innovative therapies used to treat Medicare beneficiaries in the hospital inpatient setting. NTAP will only be available for our products if we submit a timely and complete application and CMS determines that our product candidates meet the eligibility requirements of NTAP, including, among other criteria, demonstrating a substantial clinical improvement relative to services or technologies previously available.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs and biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing third-party therapeutics may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. In addition, hospital and hospital systems are extremely cost-conscious and may require significant discounts on the list price of new medications before placing them on their formulary and in their treatment guidelines. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on our product candidates.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

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

States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially-reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

***Pricing and reimbursement decisions by government entities and third-party payors may have an adverse effect on the market acceptance of our approved candidates. If there is not sufficient reimbursement for our approved products, it is less likely they will be widely used.***

Market acceptance and sales of ANG-3777, ANG-3070 or any other product candidates, if approved, will depend on applicable pricing and reimbursement policies, health outcome and economic data we and our collaborators collect during clinical development and may be affected by future healthcare reform measures in the United States and elsewhere. Government authorities, specifically CMS, and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish payment levels. We cannot be certain reimbursement will be available for ANG-3777, ANG-3070 or any other product candidates we develop. Also, we cannot be certain pricing and reimbursement policies will not reduce the demand for, or the price paid for, our products. If reimbursement is not available or is available on a limited basis, we and our collaborators may not be able to successfully commercialize ANG-3777, ANG-3070 or any other product candidates.

The United States and several other jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect to experience pricing pressures in connection with the sale of products that we develop, due to the trend toward cost containment and additional legislative proposals.

***If we fail to develop ANG-3777 for additional indications or if the market opportunities for ANG-3777, ANG-3070 or any future products are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.***

To date, we have focused the majority of our development efforts on the development of ANG-3777 for DGF, an orphan or rare disease with a small numbers of potential patients, and ANG-3777 for CSA-AKI. 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. While Vifor Pharma is obligated to pay us tiered royalties on global net sales of ANG-3777 at royalty rates up to 40%, our ability to grow our revenue from product sales beyond the Vifor License will be dependent on our ability to successfully develop and commercialize ANG-3777 for the treatment of non-Renal Indications. Obtaining the approval and commercialization of ANG-3777 for future indications, including ALI or CNS indications, will require substantial additional funding and is prone to the risks of failure inherent in drug development. We cannot provide you any assurance we will be able to successfully advance any new indications through the development process. Even if we receive FDA approval to market ANG-3777 for the treatment of additional indications, we cannot assure you any such additional indications will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize ANG-3777 for additional indications, our commercial opportunity with ANG-3777 will be limited, and our business prospects will suffer.

In addition, the precise incidence and prevalence for all the conditions we currently or may intend to address with ANG-3777, ANG-3070 or any future product candidates are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment of ANG-3777, 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-3777, 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-3777, 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-3777, 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.

***We have no sales, marketing, market access or distribution experience and we will have to invest significant resources to develop those capabilities or enter into acceptable third-party sales and marketing arrangements.***

We have no sales, marketing, market access or distribution experience, nor have we commercialized a product. While we have granted commercialization rights for ANG-3777 to Vifor Pharma and Sinovant, we plan to independently commercialize ANG-3777 for any indications for which we retain commercialization rights as well as for ANG-3070 and any other product candidates for which we obtain approval in the United States. As a result, we expect that we will need to develop internal sales, distribution and marketing capabilities by investing significant amounts of financial and management resources, some of which will be committed prior to any confirmation that any such product candidates will be approved. We have no prior experience as a company in the marketing, sale and distribution of biopharmaceutical products and there are significant risks involved in building and managing a commercial organization, including our ability to hire, retain and incentivize qualified individuals, to generate sufficient sales leads, to provide adequate training to personnel and to effectively manage a geographically dispersed team. Any failure or delay in the development of our internal sales, marketing, market access, and distribution capabilities would adversely impact the commercialization of our products. We may in the future seek to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing, market access and distribution functions, but may fail to do so on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. For product candidates where we decide to perform sales, marketing, market access and distribution functions ourselves or through third parties, we could face a number of additional risks, including:

- we, or our third-party sales collaborators, may not be able to attract and build an effective marketing and sales force;
- the cost of securing or establishing a marketing or sales force may exceed the revenues generated by any products; and
- our direct sales and marketing efforts may not be successful.

We may have limited or no control over the sales, marketing and distribution activities of third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing any of our current or future product candidates, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue, we would incur significant additional losses and we may be unable to continue operations.

***If serious adverse events or other undesirable side effects are identified during the development of ANG-3777 for one indication, we may need to abandon our development or, if approved, commercial sales of ANG-3777 for other indications.***

Product candidates in clinical stages of development have a high risk of failure. We cannot predict if ANG-3777 will prove effective or safe in humans or will receive regulatory approval. Safety concerns could be identified as we expand our clinical trials for ANG-3777 for DGF and CSA-AKI and to other indications, including ALI and CNS indications. If new side effects are found during the development of ANG-3777 for any indication, we may need to abandon our development or, if approved, commercial sales of ANG-3777 for DGF and other potential indications. We cannot assure you that additional or severe adverse side effects with respect to ANG-3777 will not develop in future clinical trials, which could delay or preclude regulatory approval of ANG-3777 or limit its commercial use.

Under the Vifor License, we retain responsibility at our own cost for a pre-specified clinical development plan, which has been designed to obtain regulatory approvals of ANG-3777 of the DGF and CSA-AKI indications in the United States, the European Union, Switzerland and the United Kingdom. Such plan includes the completion of our ongoing and currently planned clinical development activities and clinical trials in such indications. However, we have granted Vifor Pharma the right to develop ANG-3777 for other Renal Indications beyond DGF and CSA-AKI, and will have very limited control with respect to any such development. Similarly, pursuant to the Sinovant License, we have very limited control over Sinovant, which has the right to develop and commercialize ANG-3777 in Greater China. If safety concerns are found during the development by Vifor Pharma or Sinovant of ANG-3777 for any indication, or if the results of future clinical trials of ANG-3777 conducted by Vifor Pharma or Sinovant generate negative results or results that conflict with the results of our clinical trials, the FDA or other regulatory authorities may delay, limit, or deny approval of ANG-3777, require us to conduct additional clinical trials as a condition to marketing approval, or withdraw their approval of ANG-3777 or otherwise restrict our ability to market and sell ANG-3777, if approved, and we may be forced to abandon our development of ANG-3777 for DGF, CSA-AKI or other potential indications in other territories around the world, including the United States and the European Union. In addition, treating physicians may be less willing to prescribe ANG-3777 due to concerns over such trial results or adverse events, which would limit our ability and the ability of our collaborators to commercialize ANG-3777.

## **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.

There is currently limited competition for ANG-3777 in the renal space. Quark Pharmaceuticals, Inc. has an anti-p53 siRNA molecule, QPI-1002. In December 2018, Quark's majority shareholder, SBI Holdings, announced QPI-1002 failed to meet its prespecified primary efficacy endpoint of a reduction in dialysis days in a Phase 3 registration trial for DGF prevention. Quark is also currently investigating QPI-1002 for CSA-AKI in a Phase 3 trial based on results observed in a pre-defined subgroup of patients in a Phase 2 trial. In addition, we are aware of Astellas Pharma Inc. and Alloksys Life Sciences B.V., which are advancing ASP1128 and bRESCAP respectively for AKI following coronary artery bypass graft and/or valve surgery. ASP1128 is currently in a Phase 2 clinical trial whilst bRESCAP is in a Phase 2/3 clinical trial.

In ALI, for COVID-19, there are a number of preventative vaccines in development with three having received an Emergency Use Authorization approval and others potentially nearing regulatory approval. Vaccine coverage and efficacy will be less than 100%, in our view, necessitating therapeutic intervention for these patients. There are hundreds of clinical trials examining various methods of treating COVID-19 related acute lung injury. To date, only a small number of these trials have resulted in data positive enough for regulators to approve therapeutics on either an emergency use or permanent basis. Therapeutics receiving an Emergency Use Authorization for the treatment of COVID-19 patients including but not limited to co-administration of casirivimab and imdevimab from Regeneron Pharmaceuticals, Inc., baricitinib (in combination with remdesivir) and bamlanivimab from Eli Lilly, and remdesivir from Gilead Sciences, Inc. In ARDS, there are no approved therapies but a number of companies have Phase 3 programs under way in the United States including brexanolone from Sage Therapeutics, ravulizumab from Alexion,



siltuximab from EusaPharma (UK) Limited, alteplase from Boehringer Ingelheim, MultiStem from Athersys, ruxolitinib from Incyte, and aviptadil from NeuroRX.

In an effort to expand ANG-3777's therapeutic area, we are currently exploring indications associated with the central nervous system. We are aware of Athira Pharma's ATH-1017, a small molecule that enhances HGF/c-Met activity and it is currently in two Phase 2 clinical trials for Alzheimer's Disease. Other programs targeting the HGF/c-Met pathway is Kringle Pharma's KP-100, a recombinant human HGF. KP-100 is currently being investigated in a Phase 2 clinical trials for amyotrophic lateral sclerosis and a Phase 3 clinical trial for acute spinal cord injury in Japan.

With respect to ANG-3070, in fibrosis-related primary renal diseases clinical programs in this space include bardoxolone methyl from Reata Pharmaceuticals, Lademirsen from Sanofi Genzyme, Sparsentan from Traverre Therapeutics, Bleselumab from Astellas Pharma, and Tesevatiniib from Kadmon Holdings. In IPF, there are two approved therapies, pirfenidone (Esbriet®, sold by Roche/Genentech) and nintedanib (OFEV®, sold by Boehringer-Ingelheim). There are several programs currently in development for IPF, including an anti-CTGF antibody from Fibrogen, Inc., a GPR84 inhibitor and an ENPP2 inhibitor from Galapagos NV, a Wnt-pathway inhibitor from United Therapeutics Corporation/Samumed, LLC.

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. We are also aware of other ROCK2 inhibitors in preclinical development.

Regarding competition for our CYP11B2 inhibitor, PhaseBio's CYP11B2 inhibitor PB6440 is preparing for Phase 1 trials in 2021 in treatment resistant hypertension. CinCor Pharma's RAAS pathway inhibitor CIN-107 is in Phase 2 trials for resistant hypertension and primary aldosteronism.

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 that our drug substance supplier will continue to provide us with sufficient quantities of drug substance, or that 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 that 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. While under the Vifor License we will not be responsible for securing the commercial supply of ANG-3777 for DGF or CSA-AKI, if approved, 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. 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 ANG-3777 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 on 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 expand our operations and increase the size of our company, and we may experience difficulties in managing growth. A deterioration in our relationships with our employees could have an adverse impact on our business.***

As of March 31, 2021, we had approximately 66 full-time employees and 24 consultants who provide part-time or full time support to the company. As we increase the number of ongoing product development programs and advance our product candidates through preclinical studies and clinical trials and, if approved, commercialization, we will need to increase our product development, scientific, commercial and administrative headcount to manage these programs. In addition, we currently operate out of three locations across the United States, which increases the overall complexity of the management of our operations. Furthermore, to meet our obligations as a public company, we will need to increase our general and administrative capabilities. Our management, personnel, and systems currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth, and various projects requires we:

- successfully attract and recruit new employees or consultants with the expertise and experience we will require;
- manage our clinical programs effectively, which we anticipate being conducted at numerous clinical sites;
- develop corporate infrastructure to support the commercialization of our products; and
- continue to improve our operational, financial, and management controls, reporting systems and procedures.

Maintaining good relationships with our employees is crucial to our operations. If we are unable to successfully maintain such relationships or manage any growth and increased complexity of operations, our business may be adversely affected. See "Our Business—Human Capital Resources."

***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 Executive Chairman and Chief Scientific Officer, Dr. Itzhak Goldberg, and 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 late-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-3777 and our ongoing clinical trial 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-3777;
- 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 product liability insurance coverage for clinical trials in the United States is currently limited to an aggregate of \$5.0 million and outside of the United States we have coverage for lesser amounts varying by country. As such, 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. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. 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.

### **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 that others have filed, and in the future may file, patent applications covering products and technologies that are similar, identical or competitive to ours, or that are otherwise important to our business. We cannot be certain that any patent filings owned by a third party will not have priority over patent applications filed or in-licensed by us, or that 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 that are 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 that 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 ANG-3777 and our other 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. If we are unable to obtain any patent term extensions, the issued pharmaceutical composition and method of treatment US patent for ANG-3777 is expected to expire during 2024, assuming it withstands any challenge. We expect that the other patents and patent applications, if issued, in our ANG-3777 portfolio, if the appropriate maintenance, renewal, annuity or other governmental fees are paid, would expire from 2023 to 2040.

***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 that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates, including ANG-3777 for DGF, and have not yet begun the process of applying to register trademarks for our current or any future 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 that 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 current or any other 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.

### **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-3777;
- 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 AKI;
- announcements of regulatory approval or disapproval of ANG-3777;
- 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-3777;
- announcements relating to future licensing, collaboration or development agreements;
- announcements relating to our existing collaborators;
- delays in the commercialization of ANG-3777;
- 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-3777;
- 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 that 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.

***Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.***

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline.

As of March 31, 2021, we had outstanding 29,660,458 shares of common stock, which includes the 5,750,000 shares sold as part of our IPO. The resale of 23,670,975 shares, or 79.8% of our outstanding shares of common stock is currently prohibited or otherwise restricted as a result of securities law provisions, market standoff agreements entered into by certain of our stockholders with us or lock-up agreements entered into by our stockholders with the underwriters in connection with our IPO.

The lock-up agreements in the IPO will expire at the close of business on August 4, 2021. After the lock-up agreements expire, the shares of common stock will be eligible for sale in the public market, approximately 28% of these shares are held by directors, executive officers and other affiliates and will be subject to Rule 144 under the Securities Act of 1933, as amended, or the Securities Act, and applicable vesting schedules. Cowen and Company, LLC and Stifel, Nicolaus & Company, Incorporated may, however, in their sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

In addition, as of March 31, 2021, approximately 1.9 million shares of common stock that are either subject to outstanding options or reserved for future issuance under our existing equity incentive plan will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

In addition, the holders of approximately 23.7 million shares of our common stock, or approximately 79.8% of our total outstanding common stock as of March 31, 2021, are entitled to rights with respect to the registration of their shares under the Securities Act, subject to vesting schedules and to the lock-up agreements described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

***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 weakness***

***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.***

In connection with the preparation of our consolidated financial statements for the years ended December 31, 2020 and 2019, we identified control deficiencies in the design and operation of our internal control over financial reporting that constituted material weaknesses, which remain unremediated as of March 31, 2021. 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. As of March 31, 2021 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 the 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.

Neither we nor our independent registered public accounting firm has performed an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act of 2002, as amended, (Sarbanes-Oxley). In light of the control deficiencies and the resulting material weaknesses that were previously identified as a result of the limited procedures performed, we believe that it is possible that, had we and our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley, additional material weaknesses and significant control deficiencies may have been identified. Material weaknesses may still exist when we report on the effectiveness of our internal control over financial reporting as required by reporting requirements under Section 404 of the Sarbanes-Oxley.

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 incur significant costs as a result of operating as a public company, and our management devotes substantial time to new compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404, which could result in sanctions or other penalties that would harm our business.***

We incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Exchange Act and regulations regarding corporate governance practices. The listing requirements of The Nasdaq Global Select Market and the rules of the Securities and Exchange Commission (SEC) require that we satisfy certain corporate governance requirements relating to director independence, filing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel need to devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations increase our legal and financial compliance costs and will make some activities more time-consuming and costly. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms and we may be

forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage.

We are subject to Section 404 and the related rules of the SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Beginning with the second annual report that we will be required to file with the SEC, Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company as defined in the JOBS Act or smaller reporting company, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to 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. Once we are no longer an emerging growth company or smaller reporting company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls over financial reporting. We will remain an emerging growth company until the earliest of (i) the last day of our fiscal year following the fifth anniversary of the completion of our IPO, (ii) the last day of our fiscal year in which we have total annual gross revenue of at least \$1.07 billion, (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 that is held by non-affiliates exceeds \$700.0 million as of the last business day of the issuer's 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.

To date, we have never conducted a review of our internal control for the purpose of providing the reports required by these rules. During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we will be required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. In order to report our results of operations and financial statements on an accurate and timely basis, we will depend on CROs to provide timely and accurate notice of their costs to us. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The Nasdaq Global Select Market or other adverse consequences that would materially harm to our business.

We are also subject to more stringent state law requirements. For example, in September 2018, California Governor Jerry Brown signed into law Senator Bill 826 (SB 826), which generally requires public companies with principal executive offices in California to have a minimum number of females on the company's board of directors. As of December 31, 2019, each public company with principal executive offices in California was required to have at least one female on its board of directors. By December 31, 2021, each public company will be required to have at least two females on its board of directors if the company has at least five directors, and at least three females on its board of directors if the company has at least six directors. The new law does not provide a transition period for newly listed companies. Similarly, in January 2020, New York enacted a new law that mandates a study on the number of female directors on the board of corporations doing business in New York.

Additionally, on September 30, 2020, California Governor Gavin Newsom signed into law Assembly Bill 979 (AB 979), which generally requires public companies with principal executive offices in California to include specified numbers of directors from "underrepresented communities." A director from an "underrepresented community" means a director who self-identifies as Black, African American, Hispanic, Latino, Asian, Pacific Islander, Native American, Native Hawaiian, Alaska Native, gay, lesbian, bisexual or transgender. By December 31, 2021, each public company with principal executive offices in California is required to have at least one director from an underrepresented community. By December 31, 2022, a public company with more than four but fewer than nine directors will be required to have a minimum of two directors from underrepresented communities, and a public company with nine or more directors will need to have a minimum of three directors from underrepresented communities. Similar to SB 826, AB 979 does not provide a transition period for newly listed companies.

If we fail to comply with either SB 826 or AB 979, we could be fined by the California Secretary of State, with a \$100,000 fine for the first violation and a \$300,000 fine for each subsequent violation of either law, and our reputation may be adversely affected.

***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 that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, 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 that are 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.

***Our principal stockholders and management own a significant percentage of our stock and are able to exert significant control over matters subject to stockholder approval.***

As of March 31, 2021, our executive officers, directors, holders of 5.0% or more of our capital stock and their respective affiliates held approximately 43.3% of our outstanding voting stock. Therefore, these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

Dr. Goldberg, our Executive Chairman and Chief Scientific Officer, beneficially owns a substantial percentage of our outstanding equity securities. As of March 31, 2021, Dr. Goldberg beneficially owned 1,881,968 shares of our common stock, or approximately 6.3% of our total outstanding common stock. In addition, as of March 31, 2021, Dr. Goldberg's family members beneficially owned 350,061 shares of our common stock, or approximately 1.2% of our total outstanding common stock. Accordingly, Dr. Goldberg will have significant influence over all business decisions, including with respect to such matters as amendments to our charter, other fundamental corporate transactions, such as mergers, asset sales, and the sale of the Company, and otherwise will be able to influence our business and affairs.

***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, our Executive Chairman and Chief Scientific Officer, 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 81.3%, 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 that 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 recorded rent expense for fixed lease payments of \$0.3 million and variable expenses related to the lease of \$0.1 million for each of the three months ended March 31, 2021 and 2020. Variable expenses include NovaPark management fees of \$15 thousand and \$18 thousand for each of the three months ended March 31, 2021 and 2020, respectively. We account for our investment in NovaPark under the equity method of accounting. We own, and Dr. Goldberg, and Rina Kurz, Dr. Goldberg's spouse, own 10%, 45% and 45%, respectively, of the membership interests in NovaPark.

Furthermore, we are party to a consulting agreement with Dr. Goldberg's spouse and Dr. Goldberg's son is a full-time employee.

We have adopted a written related-person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration and oversight of related-person transactions. However, as of March 31, 2021, Dr. Goldberg beneficially owned 1,881,968 shares of our common stock, or approximately 6.3% of our total outstanding common stock. Accordingly, he will have significant influence over all business decisions, including with respect to such matters as amendments to our charter, other fundamental corporate transactions, such as mergers, asset sales, and the sale of the Company, and otherwise will be able to influence our business and affairs.

***Provisions in our charter documents and under Delaware law could discourage a takeover that 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. For a description of our capital stock, see "Description of Capital Stock."

***Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.***

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case, to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

***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.

***We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.***

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your common stock for the foreseeable future. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

#### **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. 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 that 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.

***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.

***Our reported financial results may be adversely affected by changes in accounting principles generally accepted in the United States.***

Generally accepted accounting principles in the United States are subject to interpretation by the Financial Accounting Standards Board (FASB) or the SEC, and various bodies formed to promulgate and interpret appropriate accounting principles. A change in these principles or interpretations could have a significant effect on our reported financial results, may retroactively affect previously reported results, could cause unexpected financial reporting fluctuations and may require us to make costly changes to our operational processes and accounting systems.

***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 that 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 that violates (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 that require 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 that 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 that 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 of other incident, whether real or perceived, would cause us to lose product sales, 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 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.

***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 that we have obtained or licensed, or that 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 that enforce 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 that we have obtained or licensed or that 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 that 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 that the court will decide that such patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also a risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that 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 that 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 that our products or product candidates, or their manufacture or use, will not infringe third-party patents. Furthermore, a third party may claim that we or our manufacturing or commercialization collaborators are using inventions covered by the third party's patent rights. It is also possible that a third party might allege that 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 that a court would decide that 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 that 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 that our products or methods either do not infringe the claims of the relevant patent or that 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 that 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 that 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 that 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 that permit secrecy of patent applications and may be entitled to priority over our applications in such jurisdictions.

In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that 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.

***We may be subject to claims that 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 that 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 that 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 that 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.

***If securities or industry analysts do not publish research or reports about our business, or if an adverse or misleading opinion regarding our stock or business is published by anyone, our stock price and trading volume could decline.***

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. It may also be influenced by research, reports, and other opinions and statements published by others, including on social media. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us, or others, issues an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts or others, demand for our common stock could decrease.

and our stock price could decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

## 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.

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).

### Recent Sales of Unregistered Securities

The following list sets forth information as to all securities we have sold since January 1, 2021, which were not registered under the Securities Act.

#### Common Stock

On February 9, 2021, we closed the Concurrent Private Placement of 1,562,500 shares of common stock to Vifor Pharma for gross proceeds of \$25.0 million.

The Concurrent Private Placement is exempt from registration pursuant to Rule 4(a)(2) of the Securities Act of 1933, as amended (the Securities Act). Vifor Pharma acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends have been affixed to the securities issued in connection with the Concurrent Private Placement.

#### Preferred Series C

1. On February 9, 2021, upon the closing of our IPO all shares of our then-outstanding convertible preferred stocks including accrued dividend automatically converted into 2,234,640 shares of common stock.

#### Convertible Notes

2. In January 2021, the Company issued 33,978 shares of common stock upon the conversion of certain outstanding 2020 Notes.
3. On February 9, 2021, upon the closing of our IPO all of our then-outstanding redeemable convertible notes including accrued interest automatically converted into 3,636,189 shares of common stock.

#### Warrants

4. On February 9, 2021, upon the closing of our IPO all of our then-outstanding warrants with an exercise price of \$6.43 automatically converted into 844,335 shares of common stock.
5. Prior to the IPO, the Company issued 94,124 shares of common stock upon the exercise of certain warrants with an exercise price of \$6.43.

#### Stock Options

6. Prior to the IPO, we issued to certain of our employees and consultants, options to purchase an aggregate of 61,453 shares of our common stock with a weighted average exercise price of \$11.32 per share. We deemed these issuances to be exempt from registration under the Securities Act either in reliance on Rule 701 of the Securities Act as sales and offers under compensatory benefit.



The offers, sales and issuances of the securities described above were deemed to be exempt from registration under the Securities Act under (i) Rule 701 promulgated under the Securities Act as offers and sale of securities pursuant to certain compensatory benefit plans and contracts relating to compensation in compliance with Rule 701, (ii) Section 4(a)(2) of the Securities Act (and Regulation D promulgated thereunder) as transactions by an issuer not involving any public offering or (iii) transactions with a non-U.S. person (including Regulation S promulgated under the Securities Act).

**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	
1.1*	Form of Underwriting Agreement.				
3.1	<a href="#">Amended and Restated Certificate of Incorporation.</a>	8-K	2/9/2021	3.1	
3.2	<a href="#">Amended and Restated Bylaws.</a>	8-K	2/9/2021	3.2	
4.1	Reference is made to exhibits 3.1 through 3.2.				
4.2	<a href="#">Form of Common Stock Certificate.</a>	S-1/A	2/1/2021	4.2	
4.3	<a href="#">Form of Warrant to Purchase Common Stock.</a>	S-1	1/15/2021	4.3	
4.4	<a href="#">Form of Broker Warrant to Purchase Common Stock.</a>	S-1	1/15/2021	4.5	
4.5	<a href="#">Registration Rights Agreement, dated as of March 31, 2020, by and among Angion Biomedica Corp. and the investors party thereto.</a>	S-1	1/15/2021	4.6	
4.6	<a href="#">Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.</a>	10-K	3/30/2021	4.7	
10.1	<a href="#">Stock Purchase Agreement, dated February 4, 2021, by and among Angion Biomedica Corp. and the purchasers named therein.</a>	8-K	2/9/2021	10.1	
10.2#	<a href="#">2021 Incentive Award Plan.</a>	S-1/A	2/1/2021	10.6(a)	
10.3#	<a href="#">Form of Stock Option Grant Notice and Stock Option Agreement under the 2021 Incentive Award Plan.</a>	S-1/A	2/1/2021	10.6(b)	
10.4#	<a href="#">Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under the 2021 Incentive Award Plan.</a>	S-1/A	2/1/2021	10.6(c)	
10.5#	<a href="#">Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the 2021 Incentive Award Plan.</a>	S-1/A	2/1/2021	10.6(d)	
10.6#	<a href="#">2021 Employee Stock Purchase Plan.</a>	S-1/A	2/1/2021	10.7	
10.7#	<a href="#">Non-Employee Director Compensation Program.</a>	S-1/A	2/1/2021	10.13	
10.8	<a href="#">Form of Indemnification Agreement for directors and officers.</a>	S-1	1/15/2021	10.14	
21.1	<a href="#">Subsidiaries of the registrant.</a>	S-1	1/15/2021	21.1	
31.1	<a href="#">Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>				X
31.2	<a href="#">Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>				X
32.1^	<a href="#">Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>				X
32.2^	<a href="#">Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>				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

# Indicates management contract or compensatory plan.

^ 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.



**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.







